Risk Factors Comparison 2025-03-31 to 2024-03-29 Form: 10-K

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We are subject to a number of risks that if realized could affect our business, financial condition, results of operations and cash flows. As a clinical stage biopharmaceutical company, certain elements of risk are inherent to our business. Accordingly, we encounter risks as part of the normal course of our business. Some of the more significant challenges and risks include the following: • We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed, on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our research and development programs, commercialization efforts or cease operations. • We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited consolidated financial statements for the year ended December 31, ~~2023~~ **2024** included in this Annual Report on Form 10- K filed with the ~~Securities and Exchange Commission (“~~ SEC ~~”)~~. • We have incurred losses since inception, have never generated any revenue from product sales, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future. • We have identified material weaknesses in our internal control over financial reporting related to our control environment. If we do not remediate the material weaknesses in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock. • Our product candidates are at an early stage of development and, except for our ~~current~~ **AMPLIFY- 201 and AMPLIFY- 7P** clinical trials, we have not previously conducted clinical trials with our product candidates. We may not be able to effectively design and execute a clinical trial that supports marketing approval and may not successfully develop or commercialize our product candidates. • Our clinical trial results may not support approval by the ~~U. S. Food and Drug Administration (“~~ FDA ~~”)~~ or comparable foreign regulatory authorities and such failure to obtain regulatory approval of our product candidates would significantly harm our business, results of operations, and prospects. • We may be unable to use and expand our discovery engine to build a pipeline of product candidates and progress such product candidates through preclinical or clinical development, which may result in us abandoning our development efforts, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. • Due to our limited financial and managerial resources, we may focus on research programs and product candidates we identify for specific indications and may forego or delay other opportunities that may have greater commercial potential. • There are a number of factors that can impact the enrollment of patients in our clinical trials. If we experience difficulties in enrolling patients, we could experience significant delays and we may need to abandon one or more clinical trials, or we may need to increase development costs for our product candidates which could materially impair our ability to generate revenues. • Our product candidates may cause undesirable side effects, may not achieve the desired efficacy threshold, or have other properties or characteristics that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. • We may form or seek strategic partnerships or collaborations or enter into additional licensing arrangements with third parties and we may not realize the benefits of such transactions or arrangements. • We rely on contract manufacturing organizations (“ CMOs ”) to manufacture our product candidates and perform other manufacturing- related services. If these third parties do not successfully carry out their contractual duties, meet expected timelines, or otherwise conduct the trials as required or perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates when expected or at all, and our business could be substantially harmed. We face significant competition, and our competitors may achieve regulatory approval before us or develop safer, more advanced or effective therapies than we might develop. • Our AMP platform is novel and any current or future product candidates may be too complex to manufacture and such complexities could lead to regulatory delays or production problems that could harm our business. • Our success depends on our ability to obtain and maintain our intellectual property for our product candidates and their formulations. • We are substantially dependent on patents we license from ~~the Massachusetts Institute of Technology (“~~ MIT ~~”)~~ and if the licensed patent rights lack legal effect or if there is a dispute under the license agreement or changes to the scope of the agreement, it could lead to a material adverse effect on our business, financial condition, results of operations and prospects. • Even if we obtain regulatory approval for our product candidates, we will remain subject to ongoing regulatory requirements. Maintaining compliance with ongoing regulatory requirements may result in significant additional expense to us, and any failure to maintain such compliance could subject us to penalties and cause our business to suffer. • Healthcare and other legislative reform measures may have a materially negative impact on our business. • Cybersecurity incidents, loss of data and other disruptions, including from cyberattacks, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation. • The instability of the global credit and financial markets may adversely affect our business strategy, including our ability to secure necessary and timely financings, which may impact our financial performance, stock price and development of our product candidates. • We will continue to incur significant legal, accounting and other expenses in order to comply with the laws, rules, and regulations associated with being a public company. The above list is not exhaustive, and we face additional challenges and risks. Please carefully consider all of the information in this Annual Report on Form 10- K including matters set forth in this “ Risk Factors ” section. Risks Related to Our Operating History, Financial Position and Capital Requirements We will require

substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our research and development programs, commercialization efforts or cease operations. Our operations have consumed substantial amounts of cash. During the years ended December 31, **2024 and** 2023 ~~and 2022~~, we incurred research and development expenses of $ **33. 7 million and $** 23. 8 million **, respectively,** and **net losses of** $ ~~18~~ **51** . ~~1~~ **9 million and $ 35. 2** million, respectively. We will require substantial additional funds to support our continued research and development activities, including the anticipated costs of nonclinical studies and clinical trials, regulatory approvals and potential commercialization. Additionally, our estimates on future financial needs may be based on assumptions that prove to be wrong, and we may spend our available financial resources much faster than we expect. Until such time, if ever, that we can generate sufficient product revenue and achieve profitability, we expect to seek to finance future cash needs through the sale of common stock in public offerings and / or private placements, debt financings, or through other capital sources, including licensing arrangements, partnerships and collaborations with other companies or other strategic transactions. We currently have no other commitments or agreements relating to any of these types of transactions **, other than our Capital on DemandTM Sales Agreement with JonesTrading Institutional Services LLC and obligations related to the exercise of previously issued warrants,** and cannot be certain that additional funding will be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity, convertible debt or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect rights of our stockholders. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, completing acquisitions or declaring or paying dividends. Furthermore, the ~~ongoing~~ impact of ~~COVID- 19~~ **macroeconomic factors, including the current inflationary environment** and **the imposition of tariffs, in addition to** geopolitical instability ~~, including the military conflict between Russia~~ and ~~Ukraine, the conflicts in the Middle East, and geopolitical~~ tensions ~~between the United States and China~~, ~~as well as the impact of macroeconomic factors~~ could make the terms of any available financing less attractive to us and more dilutive to our existing stockholders. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs or cease operations. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day- to- day activities, which may adversely affect our management' s ability to oversee the development of our product candidates. Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern. We believe there is substantial doubt about our ability to continue as a going concern as of the date of this Annual Report on Form 10- K. Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited consolidated financial statements for the year ended December 31, ~~2023~~ **2024** included in this Annual Report on Form 10- K. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted a majority of our resources to developing ELI- 002, but this product candidate cannot be marketed **or commercialized** until regulatory approvals have been obtained. Meaningful revenues will likely not be available unless ELI- 002 or any of our current or future product candidates are approved by the FDA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner, an outcome which may not occur. We believe that our cash on hand will enable us to fund our operations into the ~~third~~ **fourth** quarter of ~~2024~~ **2025** based on our current plan. This period could be shortened if there are any significant increases in planned or actual spending on development programs or more rapid progress of development programs than anticipated. There is no assurance that financing will be available when needed to allow us to continue as a going concern. If we are unable to obtain additional capital and continue as a going concern, we might have to further scale back our operations or liquidate our assets and cease operations entirely, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. Our lack of capital resources and our conclusion that we may be unable to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties. We may be unsuccessful in raising the capital necessary to address our going concern issues, or if we are successful, it may be on terms that are highly dilutive to existing stockholders. Historically, we have funded our operations by raising capital from external sources and from the Merger **(as defined below)** . However, we are currently facing significant challenges to our ability to raise capital through the sale of common stock, including the following factors: • in general, it is difficult for development stage companies to raise capital under current market conditions, especially those with early- stage programs like ours; • the perception that we may be unable to continue as a going concern may impede our ability to attract further equity investment; and • our common stock has limited trading volume, which limits the demand for our common stock. Given these factors, there can be no assurances we will be successful at raising sufficient capital to address our going concern issues. Even if we are successful in raising capital, it may be on terms that are very highly dilutive to existing stockholders. In addition, if we are unable to raise additional capital, we may have to delay, curtail or eliminate one or more of our research and development programs or cease operations. We have a history of operating losses that are expected to continue for the foreseeable future, and we are unable to predict the extent of future losses, or whether we will generate significant revenues or achieve or sustain profitability. We are focused on product development and we have not generated any revenues to date. Additionally, we expect to continue to incur operating losses for the foreseeable future. These operating losses have adversely affected and are likely to continue to adversely affect our working capital, total assets and stockholders' deficit. Since we are ~~an early~~ **a clinical** - stage **biotechnology** company, our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. Specifically, we have

generated net losses each year since our inception, including $ **51. 9 million and $** 35 ~~. 2 million and $ 28 .~~ 2 million for the years ended December 31, **2024 and** 2023 ~~and 2022 ,~~ respectively. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit is expected to increase significantly as we expand development and clinical trial activities for our product candidates. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability. We believe that our cash on hand will enable us to fund our operations into the ~~third~~ **fourth** quarter of ~~2024~~ **2025** based on our current plan. We are dependent on obtaining, and are continuing to pursue, necessary funding from outside sources, including obtaining additional funding from the issuance of securities in order to continue our operations. Without adequate funding, we may not be able to meet our financial obligations. We have not demonstrated an ability to perform the functions necessary for the successful commercialization of any products. The successful commercialization of any of our products will require us to perform a variety of functions, including: • continuing to undertake preclinical and clinical development; • engaging in the development of product candidate formulations and manufacturing processes; • interacting with the applicable regulatory authorities and pursuing other required steps for regulatory approval; • engaging with payors and other pricing and reimbursement authorities; • submitting marketing applications to and receiving approval from the applicable regulatory authorities; and • manufacturing the applicable products and product candidates in accordance with regulatory requirements and, if ultimately approved, conducting sales and marketing activities in accordance with health care, FDA and similar foreign regulatory authority laws and regulations. We have never generated revenue from product sales and may never become profitable. We have no products approved for commercialization and have never generated any product revenue. Our ability to generate product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our current and future product candidates. We do not anticipate generating product sales for the next several years, if ever. Our product candidates will require additional clinical, manufacturing, and non- clinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before they generate any product sales. We cannot guarantee that we will meet our timelines for our development programs, which may be delayed or may not be completed for a number of reasons. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators', ability to successfully: • complete research and obtain favorable results from nonclinical and clinical development of our current and future product candidates, including addressing any clinical holds that may be placed on our development activities in the future by regulatory authorities; • seek and obtain regulatory and marketing approvals for any of our product candidates for which we complete clinical trials, as well as their manufacturing facilities; • **seek and maintain grants that may be necessary for continuing operations; •** launch and commercialize any of our product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing, and distribution infrastructure or, alternatively, collaborating with a commercialization partner; • qualify for coverage and establish adequate reimbursement by government and third- party payors for any of our product candidates for which we obtain regulatory and marketing approval; • develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop; • establish and maintain supply and manufacturing capabilities or capacities internally or with third parties that can provide adequate, in both amount and quality, products, and services to support clinical development and the market demand for any of our product candidates for which we obtain regulatory and marketing approval; • obtain market acceptance of current or any future product candidates as viable treatment options and effectively compete with other therapies to establish market share; • maintain a continued acceptable safety and efficacy profile of our product candidates following launch; • address competing technological and market developments; • implement internal systems and infrastructure, as needed; • negotiate favorable terms in any collaboration, licensing, or other arrangements into which we may enter and perform ~~its~~ **our** obligations in such collaborations; • maintain, protect, enforce, defend, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know- how; • avoid and defend against third- party interference, infringement, and other intellectual property claims; and • attract, hire, and retain qualified personnel. Even if one or more of our current and future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. If we are required to conduct additional clinical trials or other testing of our product candidates that we develop beyond those that we currently expect, if we are unable to successfully complete clinical trials of our product candidates or other testing, 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 our product candidates, not obtain marketing approval at all, or obtain more limited approvals. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations. 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 decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in our value also could cause our stockholders to lose all or part of their investment. We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance. We are a clinical stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited to organizing and staffing our company, acquiring, developing and securing our proprietary technology **,** and preclinical and clinical development of our product candidates. ~~We~~ **While we ended study visits for the Phase 1 trial of ELI- 002 in August 2024, we** have not yet successfully completed any **other** clinical trials for ~~any of~~ our product candidates, manufactured our product candidates at commercial scale or conducted sales and marketing activities that will be necessary to

successfully commercialize our product candidates, if approved. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter- to- quarter or year- to- year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere herein and also include, among other things: • our ability to obtain additional funding to develop our product candidates; • our ability to conduct and complete nonclinical studies and clinical trials; • delays in the commencement, enrollment and timing of clinical trials; • the success of our nonclinical studies and clinical trials through all phases of development; • any delays in regulatory review and approval of product candidates in clinical development; • our ability to obtain and maintain regulatory approval for our product candidates in the United States and foreign jurisdictions; • potential toxicity and / or side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved products, require the establishment of risk evaluation and mitigation strategies, cause an approved drug to be taken off the market or an inability to establish efficacy needed for approvals; • our ability to establish or maintain partnerships, collaborations, licensing or other arrangements; • market acceptance of our product candidates, if approved; • competition from existing products, new products or new therapeutic approaches that may emerge; • the ability of patients or health care providers to obtain coverage of or sufficient reimbursement for our products; • our ability to leverage our proprietary AMP technology platform to discover and develop additional product candidates; • our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business; and • potential product liability claims. Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Pursuant to Section 404 (" Section 404 ") of the Sarbanes- Oxley Act of 2002, as amended (the " Sarbanes- Oxley Act "), we are required to furnish a report by our management on our internal control over financial reporting in our periodic reports filed with the SEC. However, while we remain an emerging growth company, 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 achieve compliance with Section 404 within the prescribed period, we will be 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, 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 additional material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected and corrected on a timely basis. ~~We have~~ **In our 2023 Form 10- K, we** identified material weaknesses in our internal control over financial reporting related to our control environment. More specifically, we ~~have~~ determined that we **had** ~~have not maintained adequate formal accounting policies, processes and controls related to complex transactions as a result of a lack of finance and accounting staff with the appropriate U. S. generally accepted accounting principles (" U. S. GAAP ") technical expertise needed to identify, evaluate and account for complex and non- routine transactions. We have also determined that we have insufficient financial reporting and close controls to ensure that incurred expenses are accrued at period end. In addition, we have determined that we have~~ not ensured calculations used in financial reporting ~~are~~ **were** properly reviewed, including earnings per share (" EPS ") and weighted average shares outstanding (" WASO ") calculations as a result of a lack of finance and accounting staff with the appropriate U. S. GAAP technical expertise needed to identify, evaluate **,** and review such calculations. **This material weakness was remediated as of December 31, 2024. Additionally, in our 2023 Form 10- K, we determined that we had not maintained adequate formal accounting policies, processes and controls related to complex transactions as a result of a lack of finance and accounting staff with the appropriate U. S. generally accepted accounting principles (" U. S. GAAP ") technical expertise needed to identify, evaluate and account for complex and non- routine transactions. We also determined that we had insufficient financial reporting and close controls to ensure that incurred expenses are accrued at period end. Although we initiated efforts to remediate these material weaknesses, the material weaknesses have not been fully remediated as of December 31, 2024. Our remediation efforts are intended to address the identified material weaknesses. However, these material weaknesses will not be considered remediated until the applicable remedial actions operate effectively for a sufficient period of time.** We have implemented ~~, and over the next several months, we plan to implement~~ additional measures to address the **remaining** material weaknesses ~~we have~~ identified **, however, these material weaknesses will not be considered remediated until the applicable remedial actions operate effectively for a sufficient period of time. As part of these additional measures, we engaged SEC compliance and technical accounting consultants to assist in evaluating transactions for conformity with U. S. GAAP. Also, we hired additional finance and accounting personnel, including a Staff Accountant, to augment accounting staff and to provide more resources for complex accounting matters and financial reporting** . We ~~plan to design~~ **designed** additional controls around identification, documentation and application of technical accounting guidance with particular emphasis on complex and non- routine transactions. These controls ~~are expected to~~ include an additional review process to ensure that the correct conclusions are reached with respect to complex and non- routine transactions and avoid the potential for a material misstatement of our financial statements ~~. Additionally, we plan to engage SEC compliance and technical accounting consultants to assist in evaluating transactions for conformity with U. S. GAAP, as well as hire additional finance and accounting personnel~~

~~to augment accounting staff and to provide more resources for complex accounting matters and financial reporting~~ . However, we cannot assure you that we will be successful in remediating the material weaknesses we identified or that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future. Any failure to remediate the material weaknesses we identified or any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to remediate the material weaknesses we identified or any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock. Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes- Oxley Act could have a material adverse effect on our stock price. Section 404 of the Sarbanes- Oxley Act and the related rules and regulations of the SEC require annual management assessments of the effectiveness of our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act and the related rules and regulations of the SEC. If we cannot favorably assess the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price. We hold a portion of our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail. We hold a portion of our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts. The balance held in these accounts may exceed the Federal Deposit Insurance Corporation ~~(" FDIC ")~~ standard deposit insurance limit of $ 250, 000. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any loss or lack of access to these funds could adversely impact our short- term liquidity and ability to meet our operating expense obligations. Changes in interpretation or application of U. S. GAAP may adversely affect our operating results. We prepare our consolidated financial statements to conform to U. S. GAAP. These principles are subject to interpretation by the Financial Accounting Standards Board (" FASB "), **the** American Institute of Certified Public Accountants, the SEC and various other regulatory and accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. In addition, when we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period and make it more difficult to compare our financial results to prior periods. Risks Related to the Development of our Product Candidates Our product candidates are at an early stage of development and may not be successfully developed or commercialized. In April 2023, we completed enrollment of the AMPLIFY- 201 trial for ELI- 002, our 2- peptide formulation, targeting Kirsten rat sarcoma viral oncogene homolog (" KRAS ") gene mutations, which product candidate also includes ELI- 004, our universal AMP- modified CpG adjuvant. In October 2023, we completed enrollment of the AMPLIFY- 7P Phase 1 portion of the trial for ELI- 002, our 7- peptide formulation, and initiated enrollment of the AMPLIFY- 7P Phase 2 portion of the trial in January 2024. ~~We have not previously conducted clinical~~ **In November 2024, we completed enrollment in our AMPLIFY- 7P Phase 2 portion of the ELI- 002** ~~trials~~ **trial** ~~with our product candidates~~ . All of our other product candidates are in preclinical development and will require substantial further capital expenditures, development, testing, and regulatory approval prior to commercialization. With the limited data on ELI- 002, we may not be able to effectively design and execute clinical studies that ultimately support marketing approval. In addition, we have not initiated or submitted for any marketing authorization to any health authorities. The time required to obtain approval from the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. The outcome of studies is also inherently uncertain. Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval process and are commercialized. The results of nonclinical studies, interim or top- line study results, and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. Nonclinical and early clinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies have suffered significant setbacks in advanced clinical trials, notwithstanding promising results in earlier trials. In some instances, there can be significant variability in results between different clinical trials of the same product candidate due to numerous factors, including, among other things, differences in trial procedures set forth in protocols, differences in the type of the patient populations, changes in and adherence to the clinical trial protocols, the rate of dropout among clinical trial participants, and evolving standards of treatment from newly approved drugs. Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. Our failure to develop, manufacture or receive regulatory approval for or successfully commercialize any of our product candidates could result in the failure of our business and a loss of all of our stockholders' investment. Our product candidates are in various stages of development and we will not be able to commercialize our product candidates if our nonclinical and clinical studies do not produce successful results and / or our clinical trials do not demonstrate the safety and

efficacy of our product candidates; early results and early understanding of product candidate potential may not be predictive of later success. Any product candidates currently in clinical development or that we advance into clinical development are subject to extensive regulation, which can be costly and time- consuming, and we may experience unanticipated delays or be unable to receive the required approvals to commercialize our product candidates. Product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. The results of nonclinical studies, preliminary clinical trial results, and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Our product candidates may not perform as we expect, may ultimately have a different than expected impact or no impact at all, may have a different mechanism of action than we initially understand or than we expect in humans, and may not ultimately prove to be safe or effective. The nonclinical and clinical development, manufacturing, packaging, labeling, storage, record- keeping, advertising, promotion, post- approval monitoring and reporting, import, export, marketing and distribution, among other activities, of our product candidates are subject to extensive regulation by the FDA and by comparable health authorities in foreign markets. We are not permitted to market or promote our product candidates in the United States until we receive approval from the FDA of a ~~Biologics License Application (“~~ BLA ~~”)~~, or in any jurisdictions outside of the United States until we receive similar authorization from analogous foreign authorities, and we may never receive such regulatory approvals for any of our product candidates. Some of our product candidates have only been tested in a nonclinical setting and while those studies have been subject to certain regulatory requirements in order to support product development and regulatory progression, as such product candidates progress they will require clinical trials (which are subject to much more extensive requirements, including **GCP** ~~good clinical practice~~ standards), as well as additional manufacturing development, before we will be able to submit marketing applications to the applicable regulatory authorities. Even if our product candidates are approved, they may be subject to limitations on the indicated uses and populations for which they may be marketed. They may also be subject to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may ~~contain~~ **be subject to** requirements for costly post- market testing and surveillance, or other requirements, including the submission of a ~~risk evaluation and mitigation strategy (“~~ REMS ~~”)~~ to monitor the safety or efficacy of the products. If we do not receive regulatory authority approval for, and successfully commercialize our product candidates, we will not be able to generate revenue from these product candidates in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could have a material adverse impact on our business and financial condition. The process of product candidate development and obtaining marketing approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved and the conditions that they are intended to treat. The number and nature of nonclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. We have not previously submitted a marketing application to the FDA, or a similar marketing application to any comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. In addition to significant clinical testing requirements, our ability to obtain marketing approval for our product candidates depends on obtaining the final results of required nonclinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. Regulatory authorities may determine that our product manufacturing processes, testing procedures or facilities are insufficient to justify approval. Approval policies or regulations, or the type and amount of data necessary to gain approval, may change and may vary among jurisdictions. Moreover, regulatory authorities have substantial discretion in the biopharmaceutical approval process, including the ability to refuse to accept an application and to delay, limit or deny approval of a product candidate for many reasons, such as a determination that our data is insufficient for approval or that additional nonclinical studies, clinical trials or other data or development work is necessary. Despite the time and expense invested in the development of product candidates, regulatory approval is never guaranteed. Our product candidates may fail at any stage of preclinical or clinical development, and may also reveal unfavorable product candidate characteristics, including safety concerns or the failure to demonstrate efficacy in initial clinical trials. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. Although we have completed preclinical validation, including toxicology testing, **for our lead product candidate ELI- 002** and anticipate completing the preclinical development necessary to file additional ~~Investigational New Drug (“~~ IND ~~”)~~ applications for other product candidates in the future, we may experience numerous unforeseen events before, during, or as a result of clinical trials that could delay or prevent our ability to commence or complete development, commence or complete clinical trials, receive marketing approval or commercialize our product candidates, including: • we may be unable to generate sufficient nonclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials; • regulators or ~~institutional review boards (“ IRBs~~ **IRB** ~~”)~~ or Independent Ethics Committees (“ IECs ”) may not authorize us or our investigators to commence or continue a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols; • we, regulators, ~~independent data monitoring committees (“~~ IDMC ~~”)~~, IRBs, or IECs may recommend or require the suspension or termination of clinical research for various reasons, including non- compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks, undesirable side effects, or a failure of the product candidate to demonstrate any benefit to ~~subjects~~ **patients** , or other unexpected characteristics (alone or in combination with other products) of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate; • new information may emerge regarding our product candidates or technology platform that result in continued development of some or all of our product candidates being deemed undesirable; • we may have delays identifying,

recruiting and training suitable clinical investigators or investigators may withdraw from our studies; • we may experience delays in reaching, or ~~failing~~ **fail** to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or contract research organizations (" CROs "). Contractual terms can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites; • we may have delays in adding new clinical trial sites, or we may experience a withdrawal of clinical trial sites; • potential delays in patient enrollment for clinical trials due to public health emergencies pandemics, natural disasters, staffing shortages, or other events, which may affect our ability to initiate, conduct ongoing clinical trials, and delay initiation of planned and future clinical trials; • the number of patients required for clinical trials of our product candidates 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 or be lost to follow- up at a higher rate than we anticipate for a number of reasons, such as adverse events, lack of treatment effectiveness, fatigue with the clinical trial process or personal issues, electing to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates; • patients who enroll in our studies may misrepresent their eligibility or may otherwise not comply with clinical trial protocols, resulting in the need to increase the enrollment size for those studies, or extend the duration of those studies; • there may be flaws in our study design, which may not become apparent until a study is well advanced; • our contractors may fail to comply with regulatory requirements or clinical trial protocols, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring; • regulatory authorities or IRBs or IECs may disagree with the design, including endpoints, scope, or implementation of our clinical trials, or regulatory authorities may disagree with the study patient population against our intended indications or our interpretation of data from nonclinical studies or clinical trials; • regulatory authorities may disagree with the formulation for our product candidates, or our product candidate dose or dosing schedule; • we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe, pure, and potent for any indication; • regulatory authorities may not accept, or we or our clinical trials may not meet, the criteria required to submit ~~,~~ clinical data from trials which are conducted outside of their jurisdictions; • the results of clinical trials may be negative or inconclusive, may not meet the level of statistical significance required for, or may not otherwise be sufficient to support marketing approval, and we may decide, or regulatory authorities may require ~~it~~ **us** , to conduct additional clinical trials, analyses, reports ~~, data~~ , or nonclinical studies, or abandon product development programs; • our product candidates may have undesirable or unintended side effects, toxicities, or other properties or characteristics that preclude marketing approval or prevent or limit commercial use; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks or otherwise provide an advantage over current standard of care (" SOC ") or current or future competitive therapies in development; • the SOC for the indications we are investigating may change, which changes could impact the meaningfulness of our resulting study data or **require the initiation of new studies or** which may necessitate changes to our **ongoing or planned** studies ~~; • regulatory authorities may disagree with our scope, design, including endpoints, implementation, or our interpretation of data from nonclinical studies or clinical trials~~ ; • regulatory authorities may require us to amend our studies, perform additional or unanticipated clinical trials or nonclinical studies or manufacturing development work to obtain approval or initiate clinical trials, or we may decide to do so or abandon product development programs; • regulatory authorities may find that we or our third- party manufacturers do not satisfy regulatory requirements and standards for the facilities and operations used in the manufacture of our product candidates; • the cost of clinical trials of our product candidates may be greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA or other regulatory authorities upon the filing of a marketing application; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; • regulatory authorities may take longer than we anticipate to make a decision on our product candidates; • we may be unable to demonstrate the efficacy and safety of our product candidates to the FDA or other regulatory authorities, due to inaccurate or inconsistent potency assessments, potentially resulting in regulatory delays, additional testing requirements, or even rejection of our product candidates; • changes in regulatory guidelines of the FDA or other regulatory authorities may necessitate modifications to any future biological potency assays we may develop, requiring additional validation studies and potential delays in the development or commercialization of our product candidates; or • changes in or the enactment of the approval policies, statutes, or regulations of the applicable regulatory authorities may significantly change in a manner rendering our nonclinical or clinical data insufficient for approval. Additionally, our clinical trials, to date, have been open- label trials. Our Phase 2 study of AMPLIFY- 7P is an open- label, randomized study, where both the patient and investigator know whether the patient is receiving our product candidate or is under observation, which may introduce study bias. Most typically, open- label clinical trials test only the product candidate and sometimes do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when **or if** they are receiving treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received product candidate and may interpret the information of the treated group more favorably given this knowledge. Positive results observed in open- label trials may not be replicated in later clinical trials. Additionally, as patients become aware that they are not receiving our product candidate as part of the trial, they may elect to withdraw from our study and enroll in clinical trials sponsored by our competitors, which may extend our study timeline. **Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. While we take steps to assess for conflicts of interest, it remains possible that these relationships and any related compensation could result in perceived or actual conflicts of interest, or a regulatory authority may conclude that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could**

result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and ~~, while~~ **data analysis from such trials. Although** we expect to enter into agreements governing ~~their~~ **our CROs'** committed activities, we have limited influence over their actual performance. A clinical trial may be suspended or terminated by us, our partners, the IRBs of the institutions in which such trials are being conducted, the IDMC for such trial or by the FDA or other regulatory authorities 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 other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of any of our **current or** potential future product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenue, and we may not have the financial resources to continue development of the product candidate that is affected or any of our other product candidates. We may also lose, or be unable to enter into, collaborative arrangements for the affected product candidate and for other product candidates that we are developing. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our potential future product candidates. Preliminary results from our nonclinical studies and clinical trials that we announce or publish from time to time may change as more patient data becomes available and as the data undergoes audit and verification procedures. From time to time, we may publish interim, topline, or preliminary results from our nonclinical studies and clinical trials. Preliminary and interim results from our clinical trials are not necessarily predictive of final results and 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. Preliminary, interim and 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, preliminary, interim and topline data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the preliminary, interim or topline data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or therapeutic product, if any, and us in general. In addition, the information we choose to publicly disclose regarding a particular nonclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular therapeutic product, if any, product candidate or our business. If the preliminary, interim and topline data that we report differs from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates. The FDA standard for approval of a biologic generally requires two adequate, well- controlled clinical trials, each convincingly demonstrating the product candidate' s safety and effectiveness, or one large and robust, well- controlled trial providing substantial evidence that the product candidate is safe and effective for its proposed indication. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. Product candidates studied for their safety and effectiveness in treating serious or life- threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well- controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA usually requires a sponsor of a drug or biologic receiving accelerated approval to perform post- marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. Our clinical trial results may not support either accelerated or regular approval. The results of nonclinical studies and clinical trials may not be predictive of the results of later- stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks; • we may be unable to demonstrate that our product candidates' risk- benefit ratios for their proposed indications are acceptable; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical

trials; • the data collected from clinical trials of our product candidates may not be sufficient to satisfy the FDA or comparable foreign regulatory authorities or to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third- party manufacturer' s facilities with which we contract for clinical and commercial supplies; • the FDA or comparable foreign regulatory authorities may fail to approve our analytical testing methods, particularly with respect to bioassay potency testing; • we may fail to develop a potency assay for ELI- 002 that is satisfactory for the FDA or comparable foreign regulatory authorities; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects. We may not be successful in our efforts to use and expand our discovery engine to build a pipeline of product candidates. A key element of our strategy is to use and expand our discovery engine to build a pipeline of product candidates and progress these product candidates through preclinical and clinical development for the treatment of various diseases. Although our research efforts to date suggest that complex amphiphilic molecules can deliver conventional immunomodulatory payloads including peptides, proteins and nucleic acids directly and preferentially to lymph nodes, this hypothesis may prove incorrect, or we may not be able to identify a product candidate that is safe or effective as a treatment for various cancers or for other diseases. We also may not be able to identify an amphiphile product candidate that we can demonstrate to be safe or effective, and we may not be able to develop any other product candidates. Our scientific research that forms the basis of our efforts to discover product candidates based on our discovery engine is ongoing. Further, the scientific evidence to support the feasibility of developing viable product candidates based on our platform has not been established. Our discovery engine may not be proven to be superior to competing technologies. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following: • our platform may not be successful in identifying additional product candidates; • we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates; • our product candidates may not succeed in nonclinical or clinical testing; • a product candidate may upon further study demonstrate harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; • competitors may develop alternatives that render our product candidates obsolete or less attractive; • product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights; • the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and • a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Even if we receive FDA approval to market additional product candidates, whether for the treatment of cancers or other diseases, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Our ELI- 002 clinical trials are designed to require, as part of screening to determine whether ~~subjects~~ **patients** meet inclusion criteria, the use of an investigational in vitro diagnostic device. If we are not able to successfully collaborate or partner with a third- party company for the development and authorization of such a device, we may not be able to receive marketing authorization for ELI- 002. The clinical trials for ELI- 002 (AMPLIFY- 201 and AMPLIFY-7P) employ an investigational in vitro diagnostic device (" IVD "), that identifies gene mutations in KRAS and neuroblastoma rat sarcoma viral oncogene homolog (" NRAS ") genes and detects circulating tumor DNA (" ctDNA "), to identify patients who show signs of minimal residual disease in their blood, but before relapse is detected in traditional radiographic scans. Based on our Phase ~~1 and Phase~~ 2 study design, we must account for and address the investigational status of this device from a regulatory perspective through the course of clinical development (for example, through the compliance with any applicable investigational device exemption requirements). An IVD used to select patients who may be appropriate to receive our commercial product will be considered a companion diagnostic device. Companion diagnostic devices are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and we anticipate that separate regulatory marketing authorization will be required for the device prior to commercialization of ELI- 002. We plan to collaborate with appropriate companion diagnostic developers to seek marketing authorization from the FDA' s Center for Devices and Radiological Health ~~(" CDRH ")~~. If our companion diagnostic partner experiences any delays in development or is not able to successfully develop and obtain marketing authorization for its companion diagnostic, or does not comply with the FDA' s medical device regulations: • the development and commercialization of ELI- 002 may also be delayed because in most circumstances, FDA expects the companion diagnostic and its corresponding therapeutic product to be approved contemporaneously by the FDA; • ELI- 002 may not receive marketing approval if its safe and effective use depends on a companion diagnostic **,** and none is commercially available; and • ~~We~~ **we** may not realize the full commercial potential of ELI-002 if it receives marketing approval and, among other reasons, we are unable to appropriately identify patients or types of

tumors with the specific genetic alterations targeted by ELI- 002. Even if ELI- 002 and any associated companion diagnostics are approved for marketing, the need for companion diagnostics may slow or limit adoption of ELI- 002. Although we believe genetic testing is becoming more prevalent in the diagnosis and treatment of cancer, ELI- 002 may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic or the need to complete additional procedures to identify relevant biomarkers prior to administering our product candidates. If any of these events were to occur, our business and growth prospects would be harmed, possibly materially. We may seek designations under FDA programs designed to facilitate and potentially expedite product candidate development, such as fast track or breakthrough therapy designation. Our product candidates may not receive any such designations or if they do receive such designations it may not lead to faster development or regulatory review or approval and it does not increase the likelihood that ~~its~~ **our** product candidates will receive marketing approval. We may seek designations under the FDA' s expedited programs for serious conditions, such as fast track or breakthrough therapy designation, which are intended to facilitate and expedite the development or regulatory review or approval process for product candidates. Descriptions of the fast track and breakthrough therapy designations are included under " Description of Our Business — Government Regulation and Product Approval — Fast Track, Breakthrough Therapy and Priority Review Designations. " The granting of fast track or breakthrough therapy designation to an investigational product is entirely within the FDA' s discretion. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree and instead determine not to grant such designation. In any event, the receipt of a fast track or breakthrough therapy designation for a product candidate may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the product candidate no longer meets the designation conditions, in which case any granted designations may be revoked, or the agency may decide that the time period for review or approval of the product candidate will not be shortened. If we are unable to obtain approval via the accelerated approval pathway, we may be required to conduct additional nonclinical studies or clinical trials. Even if we receive accelerated approval from the FDA, the FDA may seek to withdraw accelerated approval. We may seek an accelerated approval development pathway for our product candidates. See " Description of Our Business — Government Regulation and Product Approval — Accelerated Approval " for a description of the accelerated approval pathway. If we choose to pursue accelerated approval, we intend to seek feedback from the FDA or will otherwise evaluate our ability to seek and receive such accelerated approval. After our evaluation of the feedback from the FDA or other factors, we may decide not to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. The FDA also could require us to conduct further studies or trials prior to considering our application or granting approval of any type, and may require us to have a confirmatory trial to verify the clinical benefit of the product underway and partially or fully enrolled before granting approval. We might not be able to fulfill the FDA' s requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. Even if we receive accelerated approval from the FDA, we will be subject to rigorous post- marketing requirements, including the completion of confirmatory post- market clinical trials, submission to the FDA of periodic progress reports on confirmatory trials, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post- market study with due diligence; a post- market study does not confirm the predicted clinical benefit; other evidence shows that the product is not safe or effective under the conditions of use; or we disseminate promotional materials that are found by the FDA to be false and misleading. Under the Consolidated Appropriations Act for 2023, the FDA may use expedited procedures to withdraw any product for which we receive accelerated approval if our confirmatory trials fail to verify the purported clinical benefits. A failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate that we may choose to develop would delay our commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. If we apply for orphan drug designation from the FDA, there is no guarantee that we will be able to obtain or maintain this designation, receive this designation for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation for a biologic must be requested before submitting a BLA. 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. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a biologic that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs or biologics that have a different active ingredient for use in treating the same indication or disease.

Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product. We may seek orphan drug designation for some or all of our product candidates in specific orphan indications for which there is a medically plausible basis for their use, but exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to 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 programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any future product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated. Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our product candidates may face competition from biosimilar products. In the United States, our amphiphile product candidates are expected to be regulated by the FDA as biological products, and we intend to seek approval for these product candidates pursuant to the BLA pathway. The enactment of the ~~Biologies Price Competition and Innovation Act of 2009 (“~~ BPCIA ~~”)~~ created an abbreviated pathway for the approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12- year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow- on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient- provider relationship and a patient’ s specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off- label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own nonclinical studies and clinical trials. In such a situation, any exclusivity for which our products candidates may be eligible under the BPCIA would not prevent the competitor from marketing a product similar or identical to our biological product as soon as it is approved. In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class- specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved. If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the trial until its conclusion. We may not be able to initiate or continue conducting clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials. The enrollment of patients depends on many factors, including: • the number of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for subjects and clinical trial sites; • the severity of the disease under investigation and the existence of current treatments; • the perceived risks and benefits of the product candidate, including the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies; • the subject eligibility criteria defined in the protocol, as well as our ability to compensate subjects **, as applicable,** for their time and effort; • the size and nature of the patient population; • the proximity and availability of clinical trial sites for prospective subjects; • the design of the trial, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements; • subjects’ and investigators’ ability to comply with the

specific instructions related to the trial protocol, proper documentation, and use of the product candidate; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • patient referral practices of physicians and the effectiveness of publicity created by clinical trials sites regarding the trial; • the ability to adequately monitor subjects during and after treatment and compensate them, as applicable, for their time and effort; • the ability of our clinical study sites, CROs, and other applicable third parties to facilitate timely enrollment; • the ability of clinical trial sites to enroll subjects that meet all inclusion criteria and any patient exclusion due to erroneous enrollment; • our ability to obtain and maintain subject informed consents; • the ability of clinical trial sites to enroll patients due to public health emergencies or pandemics, natural disasters, staffing shortages, or other events; and • the risk that subjects enrolled in clinical trials will drop out of the trials before completion of the study or not return for post- study follow- up, especially subjects in control groups, due to reasons such as, adverse events, lack of treatment effectiveness, fatigue with the clinical trial process or personal issues, electing to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in any of our future clinical trials. Our inability to enroll a sufficient number of subjects for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Moreover, a significant number of withdrawn subjects would compromise the quality of our data. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, or the inability to complete development of our product candidates, which could cause our value to decline, limit our ability to obtain additional financing, and materially impair our ability to generate revenues. Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent our regulatory approval or commercialization or limit our commercial potential. As with most biological products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects caused by any current or future product candidate could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. We initiated dosing of the AMPLIFY- 201 trial of our 2- peptide formulation of ELI- 002 in October 2021, **and** our 7- peptide formulation of ELI- 002, the AMPLIFY- 7P trial, began dosing in April 2023. We initiated enrollment of the Phase 2 of the AMPLIFY- 7P trial in January 2024 and we have not yet initiated clinical trials for any other product candidates. ELI- 002, through the course of the AMPLIFY- 201 **trial to August 2024, when we stopped the disease free survival follow up for this study,** and **the** AMPLIFY- 7P ~~trials~~ **trial** to date, has shown to induce mild to moderate side effects, such as fatigue, malaise, ~~injections~~ **injection** site reactions and myalgia. If we initiate future clinical trials for any other current or future product candidates or continue to advance the AMPLIFY- ~~201 or AMPLIFY-~~ 7P ~~studies~~ **study**, it is likely that there will be new or additional side effects associated with the use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. In such an event, our trials could be suspended or terminated, and the FDA or other regulatory authorities could place a clinical hold or order us to cease further development of or deny approval of a product candidate for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business and financial condition and impair our ability to generate revenues. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly larger number of patients are exposed to the product candidate or when patients are exposed for a longer period of time. If one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long- term follow- up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw or limit their approvals of such products; • regulatory authorities may require the addition of labeling statements, specific warnings or contraindications; • we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for health care providers, and / or other elements to assure safe use; • we may be required to change the way such products are distributed or administered, or change the labeling of the products; • the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post- marketing testing and surveillance to monitor the safety and efficacy of the products; • we may decide to recall such products from the marketplace after they are approved; • we could be sued and held liable for harm caused to individuals exposed to or taking our products; and • our reputation may suffer. In addition, adverse side effects caused by any therapeutics that may be similar in nature to our product candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product candidates following marketing approval. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues. We may form or seek strategic partnerships or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing

arrangements. From time to time, we may form or seek strategic partnerships or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any such 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. These relationships also may result in a delay in the development of our product candidates if we become dependent upon the other party and such other party does not prioritize the development of our product candidates relative to our other development activities. Additionally, any collaborations, or licensing arrangements would be subject to the same product candidate development and compliance risks and obligations as we would be if we were to develop the product candidate on our own. Should any third party with which we enter into any of these arrangements not comply with the applicable regulatory requirements, we or they may be subject to regulatory enforcement action and we or they may be delayed or prevented from obtaining marketing approval for the applicable product candidate. Any collaborations, or licensing arrangements may pose a number of risks, including the following: • any third party with which we enter into any of these arrangements often have significant discretion in determining the efforts and resources that they will apply to the arrangement and may not commit sufficient resources to the development, marketing or commercialization of the product or products that are subject to the arrangement; • third parties may not perform their obligations as expected or may breach or terminate their agreements with us or otherwise fail to conduct their collaborative or licensing activities successfully and in a timely manner; • any such collaboration, partnership, or licensing arrangement may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to us; • third parties may cease to devote resources to the development or commercialization of our product candidates if the partners view our product candidates as competitive with their own products or product candidates; • disagreements with third parties, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time consuming, distracting and expensive; • third parties may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the arrangement; • third parties may infringe the intellectual property rights of other third parties, which may expose us to litigation and potential liability; • the collaborations, partnerships, or licensing arrangements may not result in us achieving revenues sufficient to justify such transactions; • by entering into certain collaborations, partnerships, or licensing arrangements, we may forego opportunities to collaborate with other third parties who do not wish to be associated with our existing third- party strategic partners; and • such arrangements may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangement for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. Any licensed products or acquired businesses may also subject us to the risk of regulatory enforcement should the product or business not be compliant with applicable regulatory requirements. We cannot be certain that, following a strategic transaction or licensing arrangement, we will achieve the revenue or specific net income that justifies such a transaction. We rely on CMOs to manufacture our nonclinical and clinical pharmaceutical supplies and expect to continue to rely on CMOs to produce commercial supplies of any approved product candidate, and our dependence on CMOs could adversely impact ~~its~~ **our** business. We rely on CMOs for the manufacture of nonclinical and clinical supplies of our product candidates and plan to continue to do so for commercial supplies should we receive marketing approval for any of our product candidates. This reliance also results in our reduced control over the manufacture of our product candidates and the protection of our trade secrets and know- how from misappropriation or inadvertent disclosure, which may adversely affect our future business prospects. Nevertheless, as the developer of the product candidates and sponsor of clinical trials involving such product candidates, we continue to have regulatory obligations to maintain oversight of the CMOs to ensure compliance with, among other things, contractual obligations, specifications, and ~~current good manufacturing practices (" cGMP ")~~. In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third- party suppliers must spend significant time, money and effort in the areas of design and development, testing, including but not limited to, several complex release tests, including tests for biological potency, production, record- keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. Although our agreements with our CMOs require them to perform according to certain cGMP, such as those relating to quality control, quality assurance and qualified personnel, we cannot control the conduct of our CMOs to implement and maintain these standards. If our CMOs do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties, or if such parties are unable to support the commercialization of any of our product candidates for which we obtain marketing approval, we may not be able to produce, or may be delayed in producing sufficient product to meet our supply requirements. Any delays in obtaining adequate supplies on adequate terms with respect to our product candidates and components, due to manufacturing issues, global trade policies, or for other reasons, may delay the development, approval, or commercialization of our product candidates. We may not succeed in our efforts to establish manufacturing relationships on commercially reasonable terms. Our product candidates may compete with other products and product candidates for access to manufacturing facilities, of which there are a limited number that operate under cGMP conditions and that are both capable of manufacturing our product candidates and willing to do so. Even if

we do establish such collaborations or arrangements, our CMOs may breach, terminate, or not renew these agreements. These facilities may also be affected by general economic conditions, including but not limited to political unrest, global trade wars, natural disasters, such as floods or fires, acts of war, terrorism, or disease outbreaks, or such facilities could face manufacturing issues, such as contamination or adverse regulatory findings following a regulatory inspection. CMOs may also be subject to power failures and / or other utility failures or experience the breakdown, failure, substandard performance or improper installation or operation of equipment in the manufacturing process. Further, our CMOs may be temporarily unable to manufacture our product candidates due to government restrictions, requirements, or limitations. If our CMOs cease to manufacture our product candidates for any reason, we would experience delays in obtaining sufficient quantities of our product for us to meet commercial demand if we receive marketing approval or in advancing our development programs while we identify and qualify replacement suppliers. We could also incur added costs and delays in identifying and qualifying any such replacements and transferring any necessary technology and processes. The terms of a new arrangement may also be less favorable than any prior arrangements, if we are able to negotiate a new arrangement at all. The addition of a new or alternative CMO may also require FDA approval and may have a material adverse effect on our business. We or our CMOs may also encounter shortages in the raw materials or substances necessary to produce our product candidates in the quantities and at the quality needed for our nonclinical studies and clinical trials or, if any of our product candidates are approved for commercialization, to produce our products on a commercial scale, meet an increase in demand, or compete effectively. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by our competitors or others. Our or our third- party manufacturers' failure to obtain the raw materials or substances necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business. Moreover, any problems or delays we experience in preparing for commercial- scale manufacturing of a product candidate or component, including manufacturing validation, may result in a delay in a future marketing approval, if any, or commercial launch of any of our product candidates, should they receive regulatory approval, or may impair our ability to manufacture commercial quantities or manufacture such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of commercialization of our product candidates, if approved, and could adversely affect our business. Furthermore, if the future manufacturers of the commercial supplies of our products, if approved, fail to deliver the required commercial quantities of our product candidates on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we could lose potential revenues. The manufacture of biological products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, and foreign regulations. If our manufacturers were to encounter any of these difficulties and were unable to perform as agreed, our ability to provide our product candidates for use in nonclinical studies or our current and planned clinical trials, or, if any of our product candidates are approved, our ability to produce our product for commercial use, could be jeopardized. In addition, all manufacturers of our product candidates used in clinical trials and of our products for commercial supply, should any of our product candidates receive regulatory approval, must comply with cGMP regulations promulgated by the FDA and equivalent foreign regulatory authorities that are applicable to both finished products and their active components used both for clinical and commercial supply. Regulatory authorities enforce these requirements through facility inspections. CMO facilities must be satisfactory to the FDA and equivalent foreign regulatory authorities as determined by inspections that will be conducted after we submit our marketing applications to the appropriate agencies and prior to product approval and commercialization. Our CMOs will also be subject to continuing, periodic regulatory authority inspections should our product candidates receive marketing approval. Further, we, in cooperation with our CMOs, must supply all necessary chemistry, manufacturing, and control documentation to the FDA and equivalent foreign regulatory authorities in support of a marketing application on a timely basis. The cGMP include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with our specifications, cGMP or with other applicable regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our CMOs cannot successfully manufacture material that conforms to our specifications and the applicable regulatory requirements, they may not be able to secure or maintain regulatory acceptance of their manufacturing facilities for the purpose of producing our product candidates. Deviations from manufacturing requirements may also require reporting and remedial measures that may be costly and / or time- consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales, if any of our product candidates receives regulatory approval, or the temporary or permanent closure of a facility. Any such remedial measure could materially harm our business. Any delay in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to nonclinical studies and clinical trials, or potential product approvals or commercialization. Any such delay may also require that we conduct additional studies. While we are ultimately responsible for the manufacture and regulatory compliance of our products and product candidates, we have little control over our ~~manufacturers~~ **CMOs** ' compliance with these regulations and standards other than through our contractual arrangements. If the FDA or a comparable foreign regulatory authority does not find these facilities satisfactory for the manufacture of our products, if approved, or product candidates, or if such authorities find such facilities to be noncompliant in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain and maintain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive

FDA or other relevant comparable regulatory authority approval for the use of any new manufacturers for commercial supply. Our failure, or the failure of our **CMOs** ~~third- party manufacturers~~, to comply with applicable regulatory requirements may result in regulatory enforcement actions against our ~~manufacturers~~ **CMOs** or us, including fines and civil and criminal penalties, suspension of or restrictions on production, injunctions, delay, withdrawal or denial of product approval or supplements to approved products, clinical holds or termination of clinical studies, warning or untitled letters, regulatory authority communications warning the public about safety issues with a product, refusal to permit the import or export of a product, product seizure, detention, or recall, operating restrictions, civil penalties, criminal prosecution, corporate integrity agreements, or consent decrees and equivalent foreign sanctions. Depending on the severity of any potential regulatory action, supplies of our product candidates or products, if approved, could be interrupted or limited, which could have a material adverse effect on our business. A portion of the manufacturing for our product candidates takes place in China through third- party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China, or a change in the regulatory framework in the United States or China, could materially adversely affect our business, financial condition and results of operations. The recently proposed BIOSECURE Act ~~is~~ **was** aimed at discouraging federal contracting with certain Chinese biotechnology companies for biotechnology equipment or services ~~and~~ **. Although** the **proposed** ~~enactment and implementation of the~~ BIOSECURE Act **was not enacted before Congress adjourned at the end of December 2024, it or similar legislation if enacted with substantially similar provisions in the future** has the potential to impact supply of our product candidates. **If** ~~Additionally, if following the enactment and implementation of~~ the BIOSECURE ~~ACT~~ **Act, or any similar legislation, is enacted and implemented and** we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable **laws and** regulations ~~and guidelines~~. We anticipate that the complexity of the manufacturing process **for our biological product candidates** may impact the amount of time it may take to secure a replacement manufacturer and such delays could negatively affect our ability to develop product candidates in a timely manner or within budget, which could materially adversely affect our business, financial condition **and results of operations. Additionally, there may be increased competition to find CMOs in regions outside of China, which may cause us to face challenges finding available CMOs or CMOs that can manufacture our product candidates in a timely manner or within budget. The demand for glucagon- like peptide- 1 (" GLP- 1 ") agonists and other drugs or product candidates containing peptide active pharmaceutical ingredient (" API ") increased substantially in 2024. As ELI- 002 and our other product candidates use similar peptide API manufacturing methods to GLP- 1 drugs, the manufacturers that we utilize may face capacity challenges, which may impact the amount of time it takes to manufacture ELI- 002 and / or our other product candidates. Any scheduling delays or interruptions in manufacturing could negatively affect our ability to produce adequate supplies of our product candidates. Additionally, with the increased demand, manufacturers may increase the cost of their services. These potential delays and additional costs could materially affect our business, financial conditions** and results of operations. We rely on third parties to conduct some of our nonclinical studies and all of our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all. We do not have the ability to conduct all aspects of our clinical trials ourselves and do not currently plan to independently conduct clinical trials. We use third parties, such as CROs, to conduct, supervise, and monitor **our past trials, such as** the AMPLIFY- 201 **trial,** and **our current trials, such as the** AMPLIFY- 7P ~~trials~~ **trial,** and will rely upon such CROs, as well as medical institutions, investigators and consultants, to conduct ~~these~~ **current** trials and any future clinical trials that we may conduct in accordance with our protocols and applicable laws and regulations. In addition, we occasionally use third parties to conduct our nonclinical studies. Our CROs, investigators and other service providers play a significant role in the conduct of these trials and the subsequent collection and analysis of data from such trials. Our service providers are not our employees and, except for remedies available to us under our agreements with such third parties, we will have less control over the timing, quality and other aspects of such nonclinical studies and clinical trials than we would have if we were to conduct them on our own. If these third parties do not successfully carry out their contractual duties to us, meet our expected timelines or conduct our nonclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or applicable regulatory requirements or for other reasons, our trials may need to be repeated, extended, delayed, or terminated. Further, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, we may fail or be delayed in our efforts to successfully commercialize our product candidates, if approved. Such failures may also subject us or our third- party service providers to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of service providers in the future, our business may be materially and adversely affected. Our third- party service providers may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. Agreements with third parties conducting or otherwise assisting with our nonclinical studies or clinical trials might terminate for a variety of reasons, including a failure to perform by such parties. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with suitable alternative providers or do so on commercially reasonable terms. Switching or adding third parties involves additional cost and requires management time and focus. There is also a natural transition period when a new third party commences work. As a result, if we need to enter into alternative arrangements, we may need to delay our product development activities and our business could be adversely affected. Although we carefully manage our relationships with our third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our

business, financial condition and prospects, and results of operations. Our reliance on third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our oversight and regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for that trial. We must also ensure that our nonclinical studies are conducted in accordance with ~~good laboratory practice (“~~ GLP ~~”)~~ requirements, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with established ~~good clinical practice (“~~ GCP ~~”)~~ standards 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. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP conditions. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical and nonclinical investigators, manufacturers, and trial sites. If we or any of our third- party service providers fail to comply with applicable regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies, which may significantly delay our clinical development plans and the regulatory approval process. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that we, our third- party service providers, or clinical trial sites is in substantial compliance with the applicable regulatory requirements. In addition, we will be required to report certain financial interests of our third- party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest. We are also required to register certain clinical trials and post the results of certain completed clinical trials on a government- sponsored database, clinicaltrials. gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity. We rely on other third parties to store and distribute our product candidates for nonclinical studies and clinical trials that we conduct. We also rely on other third parties to store and distribute our product candidates for the nonclinical studies and clinical trials that we are conducting or plan to conduct. Any performance failure, or failure to comply with applicable regulations, on the part of our distributors could delay development, the regulatory approval process, or potential commercialization of our product candidates, producing additional losses and depriving us of potential product revenue. We may incur substantial product liability or indemnification claims relating to the clinical testing of our product candidates. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if the use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. We will face an even greater risk of product liability if we receive marketing approval for and commercialize any of our product candidates. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates and approved products, if any. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. There is a risk that our future product candidates may induce adverse events. Patients with the diseases targeted by our product candidates may already be in severe or advanced stages of disease and have both known and unknown significant preexisting and potentially life- threatening health risks. During the course of treatment, ~~subjects~~ **patients** may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured ~~subjects~~ **patients** , delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to our product candidates, the investigation into the circumstance may be time- consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. For instance, product liability claims may result in: • loss of revenue from decreased demand for our products and / or product candidates; • impairment of our business reputation or financial stability; • incurred costs and time of related litigation; • substantial monetary awards to patients or other claimants, and loss of revenue; • diversion of management attention; • withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs; • the inability to commercialize our product candidates; • significant negative media attention; • decrease in our stock price; • initiation of investigations, and enforcement actions by regulators; and / or • product recalls, withdrawals, revocation of approvals, or labeling, marketing or promotional restrictions. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit development or commercialization of our products or product candidates. Although we maintain product liability and clinical trial insurance coverage, it may be inadequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical development of our product candidates and if we successfully commercialize any medicine. 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. Risks Related to Our Business, Industry and Future Commercialization If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, health care payors and the medical community, the revenues that we generate from sales will be limited. Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians,

patients, health care payors and the medical community. Market acceptance of our products by the medical community, patients, and third- party payors will depend on a number of factors, some of which are beyond its control, including: • the efficacy of our products and the prevalence and severity of any adverse events; • any potential advantages or disadvantages when compared to alternative treatments; • interactions of our products with other medicines patients are taking and any restrictions on the use of our products together with other medications; • the clinical indications for which the products are approved and the approved claims that we may make for the products; • limitations or warnings contained in the product' s FDA- approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products; • changes in the standard of care for the targeted indications for such product candidates, which could reduce the marketing impact of any claims that we could make following approval, if obtained; • the safety, efficacy, and other potential advantages over alternative treatments, such as relative convenience and ease of administration of such products, and the availability of alternative treatments already used or that may later be approved; • cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies; • the availability of formulary coverage and adequate coverage or reimbursement by third parties, such as insurance companies and other health care payors, and by U. S. and international government health care programs, including Medicaid and Medicare; • the price concessions required by third- party payors and government health care programs to obtain coverage and payment; • the extent and strength of our marketing and distribution of such products; • distribution and use restrictions imposed by the FDA and equivalent foreign regulatory authorities with respect to such products or to which we agree, for instance, as part of a REMS or voluntary risk management plan; • the timing of market introduction of such products, as well as competitive products; • our ability to offer such products for sale at competitive prices; • our ability to offer programs to facilitate market acceptance and insurance coverage from public and private insurance companies, provide patient assistance, and transition patient coverage; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the extent and strength of our third- party manufacturer and supplier support; • the approval of other new products, including biosimilar products that may be priced at a substantially lower price than we expect to offer our product candidates for, if approved; • adverse publicity about the product or favorable publicity about competitive products; • support from patient advocacy groups; • the success of any efforts to educate the medical community and third- party payors regarding our products, which efforts may require significant resources and may not be successful; and If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, health care payors and patients, we may not generate sufficient revenue from these products and may not become or remain profitable. Our ability to negotiate, secure and maintain third- party coverage and reimbursement for our product candidates may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third- party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any drug or biologic candidate of ours that receives marketing approval in the future. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved. We do not have a sales or marketing infrastructure and we have limited experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved medicine for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our current and future product candidates if and when they are approved. There are risks involved with both establishing and managing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists 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 and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel. Factors that may inhibit our efforts to commercialize product candidates on our own include: • our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel; • the inability of sales personnel to obtain access to physicians to discuss our products; • the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors, and to secure adequate coverage; • reduced realization on government sales from mandatory discounts, rebates and fees, and from price concessions to private health plans and pharmacy benefit managers necessitated by competition for access to managed formularies; • the clinical indications for which the products are approved and the claims that we may make for the products, as well as any limitations on use or warnings; • the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions, and any liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements; • restricted or closed distribution channels that make it difficult to distribute our products to different segments of the patient population; • the lack of complementary medicines 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 commercialization organization. If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenues or the profitability of these product revenues to us may be lower than if we were to market and sell any product we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our products or may be unable to do so on terms that are favorable to us. We may 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 commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any products we may develop. We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop. The development and commercialization of new therapeutic biologics is highly competitive. Moreover, the immunotherapy field is characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. We will likely face competition with respect to any product candidates that we may seek to develop or commercialize in the future from numerous pharmaceutical and biotechnology organizations, as well as from academic institutions, government agencies and other public and private research organizations for our current and future product candidates. Our commercial success may be reduced or eliminated and our business, financial condition, results of operations, and prospects may be harmed if our competitors develop products that are safer, more effective or less costly than ours. A number of well- resourced pharmaceutical and biotechnology companies ~~with established relationships with patient organizations~~ are developing products to inhibit RAS mutated cancers. These products, as well as marketing campaigns by competitors and clinical trial results with competitive products, could significantly diminish our ability to market and sell ELI- 002 for RAS mutated cancers, if approved. For example, Amgen ~~Inc. (" Amgen ")~~, Mirati ~~Therapeuties, Inc. (" Mirati "), a wholly owned subsidiary of Bristol Myers Squibb Co.~~, and Revolution ~~Medicines, Inc.~~, among others, have developed small molecule therapies for the treatment of KRAS mutated cancer including G12C and other alleles. Other companies in the immunotherapy and cancer vaccine sector include **AstraZeneca,** BioNTech ~~SE~~ **, BridgeBio, Boehringer, Bristol Myers, Circio, Eli Lilly, Geneos** , Gilead ~~Sciences Inc.~~ **, Hookipa, Moderna, Merck** , Novartis ~~International AG, Gritstone Oncology, Inc. (" Gritstone "), Hookipa Pharma Inc., Circio Holding ASA, Moderna, Inc. (" Moderna ")~~, Roche ~~Holding Ltd.~~ / Genentech ~~, Inc., Merck & Co., Inc. (" Merck "), Bristol Myers Squibb Co., and AstraZeneca Plc~~. Closest in mechanism to ELI- 002 is the ~~Moderna mRNA~~ **Hookipa HB** - **700** ~~5671 cancer~~ vaccine **for KRAS mutated tumors** , which is currently ~~in~~ **anticipated for** Phase 1 clinical development **in mid- 2025** . While many of these programs are in preclinical stages or Phase 1 clinical trials, Amgen and Mirati have products that are approved by the FDA for the treatment of adult patients with KRAS G12C mutated locally advanced or metastatic ~~non- small cell lung cancer (" NSCLC ")~~, who have received at least one prior systemic therapy ~~. Additionally, Gritstone has product candidates in Phase 2 trials, including an " off the shelf " vaccine for solid tumors~~. Moderna and Merck are in a combined Phase 3 trial of their personalized cancer vaccine targeting melanoma (mRNA- 4157) and BioNTech and Roche **/ Genentech** are in ~~a combined~~ Phase 2 ~~trial~~ **trials** of their personalized cancer vaccine targeting pancreatic cancer **, colorectal cancer, and melanoma** (BNT122, RO7198457). Although ELI- 002 is being evaluated as an earlier line of therapy (before metastatic disease can be observed on radiographs), it may compete with existing and new therapies that may be approved in the future. Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical 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 or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than the product candidates we may develop or that would render any of our product candidates obsolete or non- competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. Our commercial opportunity may also be reduced or limited if ~~our~~ **we** or our partners are unable to scale up the manufacture of our product candidates to meet clinical or commercial requirements. ELI- 002 is comprised of eight ~~active pharmaceutical ingredients (" APIs ")~~ , ~~with~~ **including** peptides and nucleotides with a lipid modification. The compositions we seek to develop may exhibit poor pharmaceutical properties, and formulation, purification and stable storage could be challenging. In addition, we could face litigation with respect to the validity and / or scope of patents relating to our competitors' products. The availability of competitive products could limit the demand and the price we are able to charge for our products. Further, intellectual property protection for the amphiphile components of our product candidates is dynamic and rapidly evolving. The scope of intellectual property protection for our AMP platform may be limited, and its commercial opportunity may be reduced or limited if our competitors are able to acquire or develop the same or similar technologies. Corporate and academic collaborators may take actions to delay, prevent, or undermine the success of our products. Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of product candidates is heavily dependent on us entering into collaborations with corporations, academic institutions, licensors, licensees, and other parties and we may not be successful in establishing such collaborations. Some of our existing collaborations are, and future collaborations may be, terminable at the sole discretion of the collaborator. Replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and may not be within our power to influence. Any collaborators may not perform their obligations to our satisfaction, or at all, we may not derive any revenue or profits from such collaborations, and any collaborators may ultimately compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake development and marketing of our proposed products and may not be able to develop and market such products effectively, if at all. In addition, a lack of development and marketing collaborations may lead to significant delays in introducing proposed products into certain

markets and / or reduced sales of proposed products in such markets. **In addition, we expect that changing policies of and actions by the U. S. government may adversely affect the ability of certain of our current, or potential, collaborators to maintain or retain our product candidates. In particular, upon taking office in January 2025, the Trump Administration implemented a freeze that prevented the NIH from reviewing and awarding grants, or paying out funds under already awarded grants, including for research or other projects. If this hold on government grants continues, or if the U. S. government takes any other actions to limit funds available for life science or healthcare research or other projects, it may affect certain of our current, or potential, collaborators and may have a material and adverse impact on our business, financial condition and results of operations.** Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete. We rely on third- party vendors, scientists and collaborators to provide us with significant data and other information related to our projects, clinical trials and our business. If such third parties provide inaccurate, misleading or incomplete data, our business, prospects and results of operations could be materially adversely affected. Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, reimbursement practices, or health care reform initiatives, which would harm our business. The regulations that govern pricing and reimbursement for new medicines vary widely from country to country, and current and future legislation may change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Outside the United States, some countries require approval of the sale price of a medicine 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 candidate in a particular country, but then be subject to price regulations that delay or might even prevent our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates we may develop, even if any such product candidates obtain marketing approval. Our ability to commercialize any product candidates successfully also will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from government authorities or health care programs, private health plans, and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary and / or cost- effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis **. In addition, reduction in Medicaid or other healthcare reimbursements may impact our future potential domestic customers which may eventually have an adverse impact on us** . At this time, we are unable to determine their cost effectiveness or the likely level or method of reimbursement for our product candidates. Government authorities and third- party payors, such as private health plans, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U. S. health care industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are challenging the prices charged for medical products and requiring that biopharmaceutical companies provide them with predetermined discounts from list prices. Novel medical products, if covered at all, may be subject to enhanced utilization management controls designed to ensure that the products are used only when medically necessary. Such utilization management controls may discourage the prescription or use of a medical product by increasing the administrative burden associated with its prescription or creating coverage uncertainties for prescribers and patients. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. We currently expect that any drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U. S. law, certain therapeutic products that are not usually self- administered (such as most injectable drugs and biologics) may be eligible for coverage under the Medicare Part B program if: • they are incident to a physician' s services; • they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and • they have been approved by the FDA and meet other requirements of the statute. There may be significant delays in obtaining reimbursement for newly approved product candidates, and coverage may be more limited than the purposes for which the product candidate is approved by the FDA or other regulatory authorities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third- party payors to pay all or part of the costs associated with their prescription medications. Patients are unlikely to use our products unless coverage is provided and payment is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate payment is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Moreover, eligibility for reimbursement does not imply that any product candidate will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new product candidates, 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 product candidate and reimbursement in the clinical setting in which it is used may be based on reimbursement levels already set for lower cost therapies or medicines and may be incorporated into existing payments for other services. Net prices for product candidates may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third- party payors often rely upon Medicare coverage policy

and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for coverage and reimbursement for drug products exists among third- party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for any approved product candidates we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines, and our overall financial condition. We believe that the efforts of governments and third- party payors to contain or reduce the cost of health care and legislative and regulatory proposals to broaden the availability of health care will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory changes in the health care system in the United States and other major health care markets have been proposed and / or adopted in recent years, and such efforts have expanded substantially in recent years. In particular, in March 2010, the ~~Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the "~~ACA ~~")~~ was signed into law. This legislation changed the system of health care insurance and benefits and was intended to broaden access to health care coverage, enhance remedies against fraud and abuse, add transparency requirements for the health care and health insurance industries, impose taxes and fees on the health care industry, impose health policy reforms, and control costs. This law also contains provisions that ~~would~~ affect companies in the pharmaceutical industry and other health care related industries by imposing additional costs and changes to business practices. Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. We continue to evaluate the effect that the ACA has or any potential changes to the ACA could have on our business. Additional federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug and biologic pricing and reimbursement. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. If the market opportunities for any of our product candidates are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer. We focus certain research and product development pipelines and our product candidates on lymph node- directed immunotherapies for cancer ~~and infectious diseases~~. ELI- 002 is a KRAS therapeutic vaccine in clinical development for the potential treatment of several cancer types with KRAS mutations. ELI- 002 targets six position 12 and one position 13 KRAS mutations, representing approximately 25 % of solid tumors. While we believe that the cancer types to be included in our early- stage clinical trials have a large KRAS mutation positive patient population in the United States, our understanding of both the number of patients who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, is based on estimates. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. By example, because some of the cancer indications that we are targeting are rare, certain estimates are based upon studies with small patient populations. Moreover, because our product candidates, such as ELI-002 **,** target specific positions on a mutation, not all patients with the mutation will be treatment candidates. As a result, the number of patients in the United States may turn out to be lower than expected, may not be otherwise eligible for treatment with ELI- 002, or patients may become increasingly difficult to identify and access for clinical trials, all of which could adversely affect our business, financial condition, results of operations and prospects. If we or any CMOs and suppliers we engage 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 and any CMOs and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. Although we believe that the safety procedures utilized by us and such third parties for handling and disposing of these materials and wastes generally comply with the standards prescribed by applicable laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental 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. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third- party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies (which provide for adequate and reasonable amounts of coverage for a company in our industry and at our size and stage) specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have

a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruptions, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Any CMOs and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our technologies are novel, and any product candidates we develop may be complex and difficult to manufacture on a clinical or commercial scale. We could experience delays in satisfying regulatory authorities or production problems that result in delays in our development or commercialization programs, limit the supply of our product candidates we may develop, or otherwise harm our business. Our AMP platform is novel, and the manufacture of products on the basis of our platform is untested at a large scale. Any current and future product candidates will likely require processing steps that are more complex than those required for most chemical pharmaceuticals. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory, or potentially delay progression of our regulatory filings. Even if we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality of clinical- grade materials that meet FDA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. If we or our CMOs are unable to scale our manufacturing at the same levels of quality and efficiency, we may not be able to supply the required number of doses for our current or planned clinical trials or for commercial supply, if any of our product candidates receive regulatory approval, and our business could be harmed. As product candidates proceed through nonclinical studies to clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are tested and then altered along the way in an effort to optimize processes and results. We have updated ELI-002, with two peptides (ELI- 002- 2P), to a new version of ELI- 002, with seven peptides (ELI- 002- 7P), as part of our product development activities, and, may continue to update ELI- 002 in the future if needed and subject to receipt of additional funding. Any such changes could cause any product candidates we may develop to perform differently and affect the results of clinical trials conducted with the materials manufactured using altered processes. Such changes may also require a new IND to be filed, additional testing, FDA notification, and FDA authorization. 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 product candidates and jeopardize our ability to commence sales and generate revenue. For instance, the FDA may require that we conduct a comparability study that evaluates the potential differences in the product candidate resulting from the change. Delays in designing and completing such a study to the satisfaction of the FDA could delay or preclude our development and commercialization plans, and the regulatory approval of our product candidates. Any of the foregoing could limit our future revenues and growth. Any changes would also require that we devote time and resources to manufacturing development and would also likely require additional testing and regulatory actions on our part, which may delay the development of our product candidates. In addition, the FDA and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, a regulatory authority may require that we do not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations, and prospects. We also may encounter problems hiring and retaining the experienced scientific, quality control, and manufacturing personnel needed to manage our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. For example, given the aseptic controls required for the manufacture of our product candidates, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any such contamination could materially harm our ability to produce product candidates on schedule and could delay our development programs and results of operations and cause reputational damage. We cannot assure that any such issues relating to the manufacture of ELI- 002 or any other product candidate will not occur in the future or that significant delays would not occur as a result of any such issue. ELI- 002 drug substances and drug products are supplied by multiple manufacturers at present. Any problems in our manufacturing process or the facilities with which we contract to make, store **, test, release,** or ship our product candidates or any problems caused by it, our vendors or other factors not in our control could result in the loss of usable product or prevent or delay the delivery of product candidates to patients in our clinical trials, including the AMPLIFY- ~~201 and the AMPLIFY-~~ 7P ~~trials~~ **trial**. Any such loss or delay could materially delay our development timelines and harm our business, financial condition and results of operations. Such losses or delays could also make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Problems with third- party manufacturing processes or facilities also could restrict our ability to ensure sufficient clinical material for any clinical trials we may be conducting or plan to conduct and meet market demand for any product candidates we may develop, obtain regulatory approval for, and commercialize. Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities. We carry insurance for

most categories of risk that our business may encounter; however, we may not have adequate levels of coverage. ~~We~~ **The insurance policies that we** currently maintain **include** general liability, property, workers' compensation, products liability and directors' and officers' insurance, along with an umbrella policy. We may not be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations **. Business interruptions could adversely affect future operations, revenues, and financial conditions, and may increase our costs and expenses. Our operations, and those of our directors, advisors, contractors, consultants, CROs, and collaborators, could be adversely affected by earthquakes, floods, hurricanes, typhoons, extreme weather conditions, fires, water shortages, power failures, business systems failures, medical epidemics and other natural and man- made disaster or business interruptions. Our phones, electronic devices and computer systems and those of our directors, advisors, contractors, consultants, CROs, and collaborators are vulnerable to damages, theft and accidental loss, negligence, unauthorized access, terrorism, war, electronic and telecommunications failures, and other natural and man- made disasters. Operating as a company where a portion of our employees have worked and are working remotely, results in our employees conducting business outside of our headquarters. These locations may be subject to additional security risks and other risk factors. If such an event as described above were to occur in the future, it may cause interruptions in our operations, delay research and development programs, clinical trials, regulatory activities, manufacturing and quality assurance activities, future sales and marketing activities, hiring, training of employees and persons within associated third parties, and other business activities. For example, the loss of clinical trial data from current or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we will rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events as those described in the prior paragraph relating to their business systems, equipment and facilities could also have a material adverse effect on our business. 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 and the further development and commercialization of our product candidates could be delayed or altogether terminated. Indemnity provisions in various agreements potentially expose us to substantial liability for intellectual property infringement, data protection, and other losses. Our agreements with third parties may include indemnification provisions under which we agree to indemnify them for losses suffered or incurred as a result of claims of intellectual property infringement or other liabilities relating to or arising from our contractual obligations. Large indemnity payments could harm our business, financial condition, results of operations and growth prospects. Although we normally contractually limit our liability with respect to such obligations, we may still incur substantial liability. Any dispute with a third party with respect to such obligations could have adverse effects on our relationship with that third party and relationships with other existing or new partners, harming our business** . Risks Related to Our Intellectual Property Our success will depend upon intellectual property and proprietary technologies, and we may be unable to protect our intellectual property. Our success will depend, in large part, on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third- party challenges. If we or our licensors fail to appropriately prosecute and maintain patent protection for our product candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations. We have sought patent protection in the United States and internationally related to the AMP platform technology as well as the mKRAS ~~and~~ **,** universal adjuvant **, mutant serine / threonine- protein kinase BRAF and mutant TP53** programs. We have issued patents in **Australia, China, Hong Kong, Israel,** Japan, Nigeria, Russia, ~~and~~ **Saudi Arabia,** Singapore **, Ukraine, and the United States,** covering clinical product candidates but the patent portfolio owned by us currently largely comprises pending applications. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following: • pending patent applications may not result in any patents being issued; • patents that may be issued or in- licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide barriers to entry or any competitive advantage; • because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing or eliminating any advantage of the patent; • our competitors, many of which have substantially greater resources than us or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have sought or obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products; • others may design around our patent claims to produce competitive technologies, products or uses which fall outside of the scope of our patents or other intellectual property rights; • others may identify prior art or other bases which could render unpatentable our patent applications or invalidate our patents; • there may be significant pressure on the U. S. government and other 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; • 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 products; and **/ or** • we may be involved in lawsuits to protect or enforce ~~its~~ **our** patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful **. The pending application directed to the mutant BRAF program is co- owned by Cornell University. Cornell University has the right to make decisions, including decisions on patent prosecution and licensing, independent of us. These**

decisions may be detrimental to us, including to our ability to commercialize a mutant BRAF product . In addition to patents, we also rely on trade secrets and proprietary know- how. Although we have taken steps to protect our trade secrets and unpatented know- how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or come upon this same or similar information independently. We may become subject to claims that ~~us~~ **we,** ~~or~~ **our employees,** consultants, advisors or independent contractors that we may engage to assist us in developing our product candidates have wrongfully or inadvertently disclosed to us or used trade secrets or other proprietary information of their former employers or their other clients. We may be forced to litigate to enforce or defend our intellectual property rights, and / or the intellectual property rights of our licensors. We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets against unauthorized use. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable, or limited or narrowed in scope such that we may no longer be used to adequately prevent the manufacture and sale of competitive products. Further, an adverse result in any litigation or other proceedings before government agencies such as the ~~United States Patent and Trademark Office (“~~ USPTO ~~”)~~, may place pending applications at risk of non- issuance. Further, interference proceedings, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes reexamination, inter partes review, post- grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge the inventorship, ownership, claim scope, or validity of our **patents or** patent applications. Additionally, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information or trade secrets could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. We have rights in some intellectual property that have been discovered through **United States** government funded programs and thus are subject to federal regulations such as “ march- in ” rights, certain reporting requirements, and a preference for U. S. industry. We have rights in some intellectual property that have been discovered through **U. S.** government funded programs and thus are subject to federal regulations such as “ march- in ” rights, certain reporting requirements, and a preference for U. S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non- U. S. manufacturers. Some of the intellectual property rights in- licensed to us have been generated through the use of U. S. government funding and are therefore subject to certain federal regulations. For example, all of the intellectual property rights licensed to us under our license agreement with MIT have been generated using U. S. government funds. As a result, the U. S. government has certain rights to intellectual property embodied in our current or future products pursuant to the Bayh- Dole Act of 1980. These U. S. government rights in certain inventions developed under government- funded programs include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as “ march- in rights ”). The U. S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U. S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under **U. S.** government funded programs is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U. S. This requirement can be waived if the owner 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 U. S. manufacturing may limit our ability to license the applicable patent rights on an exclusive basis under certain circumstances. If we enter into future arrangements involving government funding, and we make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh- Dole Act. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects. We are substantially dependent on patents we license from MIT, and if such licensed patent rights lack legal effect or if a dispute arises under such license agreement and our licensed rights are narrowed or this license is terminated, that could cause significant impairment to our ability to develop and commercialize certain of our product candidates. Our business is substantially dependent upon technology licensed from MIT. Pursuant to our license agreement with MIT, we were granted an exclusive, worldwide license, including the right to sublicense, ~~under~~ patents and patent applications owned by MIT related to the “ Amphiphile ” technology for the diagnosis, treatment or prevention of diseases. The patent rights licensed from MIT cover products in development by us for all

of our current lead programs in tumor indications where mutant KRAS, **mutant BRAF** ~~rearranged anaplastic lymphoma kinase (" ALK ")~~, or **mutant TP53** ~~expression of human papillomavirus proteins~~ are a driver of disease, as well as programs using CpG as an adjuvant for immune activation. Therefore, our ability to develop and commercialize several of our product candidates, including ELI- 002, are substantially dependent on the legal effectiveness of the MIT patent rights licensed under this agreement and continuation of this agreement. MIT has the right to control the preparation, filing and prosecution of the patent applications, and to maintain the patents, covering the patent rights we licensed from MIT under this license agreement. Therefore, we cannot be certain that these patents and patent applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If MIT fails to maintain such patents, or loses rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and its right to develop and commercialize any of our products that are the subject of such licensed patent rights could be adversely affected, and we may not be able to prevent competitors from making, using or selling competing products. MIT also has the right to control defense of any claims asserting the invalidity of these licensed patent rights and, even if we are permitted to pursue such defense, we cannot ensure the cooperation of MIT. We cannot be certain that MIT will allocate sufficient resources or prioritize their or our enforcement of such patent rights or their defense of such claims to protect our interests in the licensed patent rights. Even if we are not a party to these legal actions, an adverse outcome could harm ~~its~~ **our** business because it might prevent us from continuing to license intellectual property that ~~it~~ **we** may need to operate ~~its~~ **our** business. In addition, although we have the right to control enforcement of the licensed patents, we may be adversely affected or prejudiced by actions or inactions of MIT and their counsel that took place prior to or after us assuming control. The license agreement with MIT is complex, and certain provisions in this license agreement may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow or eliminate what we believe to be the scope of our rights to the licensed patent rights or increase what we believe to be our financial or other obligations under the license agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. If we or our partners are sued for infringing on the intellectual property rights of third parties, it could be costly and time- consuming, and an unfavorable outcome in any such litigation could have a material adverse effect on our business. Our success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing on the proprietary rights of third parties. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may ~~be directed at~~ **have issued or pending** claims that overlap with the subject matter of our intellectual property **or our product candidates**. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe upon. Similarly, there may be issued patents relevant to our product candidates of which we are not aware. In addition, third parties may sue us for infringing on their patents. Even if we are successful in defending any claims of infringement, the defense of such claims may be costly and present a time-consuming distraction. In the event of a successful claim of infringement against us, we may be required to: • pay substantial damages; • stop using ~~its~~ **certain** technologies and methods; • stop certain research and development efforts; • develop non-infringing products or methods; and / or • obtain one or more licenses from third parties. If required, we cannot assure you that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in the development, manufacture and commercialization of our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we infringed ~~on~~ third- party rights, could be costly, time-consuming, and may distract management from other important tasks. As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent **that** our employees are involved in ~~research~~ endeavors which are similar to those ~~which~~ **that** they were involved in at their former employers, we may be subject to claims that such employees ~~and / or we~~ have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of such former employers **and / or that we have inadvertently or otherwise used the alleged trade secrets or other proprietary information**. Litigation may be necessary to defend against such claims, which could result in substantial costs, be a distraction to management and ultimately have a material adverse effect on us, even if we are successful in defending such claims. The biotechnology and pharmaceutical industries have experienced substantial litigation and other proceedings concerning intellectual property rights, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which could be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts. Our commercial success depends upon our ability and the ability of our collaborators and licensors to develop, manufacture, market, and sell ELI- 002 and other Amphiphile immunotherapies. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be subject to and may in the future become party to, or threatened with, adversarial proceedings or litigation concerning intellectual property rights with respect to our Amphiphile platform and any product candidates we may develop, including interference proceedings, post- grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office (" EPO "). Numerous U. S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates and infringement claims may be asserted against us or our partners based on existing patents or patents that may be granted in the future, regardless of their merit. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our AMP platform and product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always

clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. As with many technology- based products, there may be third- party patent applications that, if issued, may be construed to cover components of our AMP platform and product candidates. There may also be third- party patents **or pending patents** of which we are currently unaware with claims ~~to~~ **covering** our technologies, compositions, methods of manufacture **,** or methods of use. Because of the large number of patents issued and patent applications filed in our fields, third parties may allege they have patent rights encompassing our product candidates, technologies or methods. Third parties may assert that we are employing their proprietary technology without authorization and may file patent infringement claims or lawsuits against us, and if we are found to be infringing on any such third- party patents, we may be required to pay damages, cease commercialization of the infringing technology, or obtain a license from such third party, which may not be available on commercially reasonable terms or at all. Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot successfully defend infringement claims, or obtain a license on commercially reasonable terms to relevant third- party patents that cover our product candidates. Even if we believe third- party intellectual property claims are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third- party patents are valid and enforceable and have been infringed ~~upon~~ **by us** , which could materially and adversely affect our ability to commercialize ELI- 002 or any other product candidates and any other product candidates or technologies covered by the asserted third- party patents. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claims, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. If we are found to be infringing on a third party' s intellectual property rights, and ~~it is~~ **we are** unsuccessful in demonstrating that any such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing ELI- 002 or any other product candidates and ~~its~~ **our** technologies. 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 such a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies **as us. The** ~~licensed~~ **license** ~~to it~~ , ~~and it~~ **if available,** could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, we may be unable to commercialize our AMP platform or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the **allegedly** infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed on a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects. The defense of third- party claims of infringement, misappropriation, or violation of intellectual property rights often involves substantial litigation expense and could be a substantial diversion of management and employee time and resources from our business. Some third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations **,** and prospects. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of our common stock. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and **patent** applications are due to be paid to the USPTO and foreign patent agencies outside of the United States over the lifetime of our owned or licensed patents and **patent** applications. For our in- licensed patents and patent applications, we generally rely on our ~~licensors~~ **licensor, MIT,** to pay these fees due to **USPTO** ~~U. S.~~ and non- U. S. patent agencies; however, we reimburse MIT for these fees as required by our license agreement with MIT. For our owned patent applications, we rely on our outside patent counsel in the United States and foreign countries to monitor these deadlines and to pay these fees when so instructed. The USPTO and foreign patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions, such as the requirement to disclose known prior art, during the patent application process. We depend on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property, and for our owned patent applications, we engage counsel and other professionals to help us comply with these requirements. While certain inadvertent lapses can 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 a partial or complete loss of patent rights in the relevant jurisdiction. Were a non- compliance event to occur, our competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on its business, financial condition, results of operations, and prospects. Changes in patent law in the United States and in non- U. S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our technologies and product candidates. As is the case with other biotech and pharmaceutical companies, our success is heavily dependent on intellectual property, **and** particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and are therefore costly, time- consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents. In addition, 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the 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 weaken our ability to obtain new patents or to enforce our existing patents and patents that we ~~might~~ obtain in the future. Under the Leahy- Smith America Invents Act (" AIA "), the United States adopted a " first- inventor- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that filed or files a patent application with the USPTO after March 16, 2013 but before we ~~file~~ **filed** an application could therefore have been granted a patent covering an invention of ours even if we had made the invention before it was made by the third party. Since patent applications in the United States and most other countries are confidential at least 18 months after filing, we cannot be certain that we were the first to file any patent application related to our **product** ~~drug or biologic~~ candidates. The AIA also provides a process known as inter partes review (" IPR "), which has been used by many third parties to challenge and invalidate patents. The IPR process is not limited to patents filed after the AIA was enacted and would therefore be available to a third party seeking to invalidate any of our U. S. patents, even those issued or filed before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings **, where IPRs are conducted,** compared to the evidentiary standard in U. S. federal ~~court~~ **courts** necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a ~~district~~ **U. S. federal** court action. Accordingly, a third party may attempt to use the USPTO procedures, e. g., an IPR, to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a ~~district~~ **U. S. federal** court action. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non- provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory- related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions including patent term extension (" PTE ") and patent term adjustment (" PTA ") may be available, but the lives of such extensions, and the protections they afford, are limited. Although we will likely seek patent term extensions in the U. S. and in one or more foreign jurisdictions where available, we cannot provide any assurances that any such patent term extensions will be granted and, if so, for how long. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars and generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient **future** rights to exclude others from commercializing products similar or identical to ours. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed. In addition to seeking patents for ~~or~~ **our** technologies and product candidates, we also rely on trade secret protection, as well as confidentiality agreements, non- disclosure agreements and invention assignment agreements with our employees, consultants and third parties ~~,~~ to protect our know- how and other confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, **CMOs** ~~contract manufacturers~~, consultants, advisors, and other third parties to execute confidentiality agreements upon the commencement of employment ~~or~~ **,** consulting **, or service** relationships with us. These agreements generally provide that all confidential information concerning our business or financial affairs developed by or made known to an individual or entity during the course of that party' s relationship with us is to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third- party service providers, the agreements provide us with certain rights to all inventions arising from the services provided to us by those individuals or entities. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technologies and processes. Additionally, the assignment of intellectual property rights may not be self- executing, or assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against ~~it~~ **us**, to determine the ownership of what we regard as our intellectual property. We may not be able to obtain adequate remedies for any breaches of such agreements. Ultimately, enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know- how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. In addition, our trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a

competitor, our competitive position could be harmed. In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. If we chose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume significant amounts of our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Third parties may assert that our employees, consultants, or advisors have wrongfully used or disclosed confidential information or misappropriated trade secrets. As is common in the biotechnology and pharmaceutical industries, we employ individuals that are currently or were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer. We may then be involved in litigation proceedings to defend against these claims. If we fail in defending against any such claims, in addition to potentially paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. Ultimately, any such litigation could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately engage in such litigation. For example, some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business. We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. However, 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. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered 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 diversions of resources and could adversely affect our business, financial condition, results of operations and growth prospects. In addition, any proprietary name we propose to use with any product candidate in the United States must be approved by the FDA, regardless of whether we have registered it ~~,~~ or applied to register it ~~,~~ as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify ~~a suitable~~ **an alternate** proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. 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: • any of our current and future product candidates, if approved, may eventually become commercially available in generic or biosimilar product forms; • others may be able to make immunotherapies that are similar to any of our current and future product candidates or utilize lymph node targeting technology but that are not covered by the claims of the patents that we license or may own in the future; • we, or our licensors or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent ~~application~~ **applications** that we license or may own in the future, potentially resulting in the invalidation of such patents or refusal of such applications; • we, or our licensors or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions; • we, or our licensors or current or future collaborators, may fail to meet ~~our~~ **the** obligations to the U. S. government regarding any in- licensed patents and patent applications funded by U. S. government grants, leading to the loss or unenforceability of patent rights; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing on our owned or licensed intellectual property rights; • it is possible that our pending, owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents; • it is possible that there are prior public disclosures that could invalidate our owned or in- licensed patents, or parts of our owned or in- licensed patents; • it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours; • it is possible that our owned or in- licensed patents or patent applications omit individual (s) that should be listed as inventor (s) or include individual (s) that should not be listed as inventor (s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable; • issued patents that we hold rights to may be held invalid, unenforceable, or narrowed in scope, including as a result of legal challenges by our competitors; • the claims of our owned or in- licensed issued patents or patent applications, if and when issued, may not cover our product candidates; • the laws of foreign countries may not protect our proprietary rights or the proprietary rights of our licensors or current or future collaborators to the same extent as the laws of the United States; • the

inventors of our owned or in- licensed patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; • our competitors might conduct research and development activities in countries where ~~it does~~ **we do** not have patent rights and then use the information learned from such activities to develop competitive products for sale in ~~its~~ major commercial markets; • we have engaged in scientific collaborations in the past and we intend to continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents; • we may not develop additional proprietary technologies that are patentable; • any product candidates we develop may be covered by third-party patents or other exclusive rights; • the patents of others may prohibit or otherwise harm our business; **and /** or • we may choose not to file a patent **, or we may choose not to extend patent coverage in a particular region,** 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, they could have a material adverse effect on our business, financial condition, results of operations, and prospects. Risks Related to Regulatory and Compliance Matters The FDA regulatory approval process is lengthy, time-consuming, and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates. The research, testing, manufacturing, labeling, approval, selling, import, export, adverse event reporting, record keeping, advertising, promotion, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological product in the United States until we receive a biologics license from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe, pure, potent, and effective for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre- license inspection. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained. Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements. If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities must comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing applications, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long- term patient follow- up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post- approval. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant liability. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements may result in revisions to the approved labeling to add new safety information; imposition of post- market studies; clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls; • fines, restitution, disgorgement of profits or revenues, warning letters or other enforcement- related letters or clinical holds on post- approval clinical trials; • refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product approvals or suspension of any ongoing clinical trials; • product seizure or detention, recalls or refusal to permit the import or export of products; • injunctions or the imposition of civil or criminal penalties; and • consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to

changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Additional regulatory burdens and other risks and uncertainties in foreign markets may limit our growth. Our future growth may depend, in part, on our ability to develop and commercialize product candidates in foreign markets for which we may rely on strategic partnership with third parties. We will not be permitted to market or promote any product candidate before we receive regulatory approval from the applicable regulatory authority in a foreign market, and we may never receive such regulatory approval. To obtain separate regulatory approval in foreign countries, we generally must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of a product candidate, and we cannot predict success in these jurisdictions. In particular, the European Commission issued a proposal in April 2023 for a new Directive and a new Regulation, which will revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU. If we obtain approval of any of our potential future product candidates and ultimately commercialize any such product candidate in foreign markets, we would be subject to risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries. In addition, 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, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies ~~,~~ or clinical trials as 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 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 fail to comply with the regulatory requirements in international markets and / or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Our relationships with health care providers, physicians, and third- party payors will be subject to applicable anti- kickback, fraud and abuse, anti- bribery and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings. Physicians, other health care providers and third- party payors will play a primary role in the recommendation and prescription of ELI- 002 or any other product candidates for which we obtain marketing approval. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, including Medicare and Medicaid. Restrictions under applicable domestic and foreign health care laws and regulations include but are not limited to the following: • the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase order or recommendation of a good or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which impose criminal and civil penalties 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; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal health care programs for items and services which results from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • the ~~Health Insurance Portability and Accountability Act of 1996 (“~~ HIPAA ~~”)~~ which imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or 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 health care benefits, items or services; similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the federal transparency requirements, sometimes referred to as the “ Sunshine Act, ” enacted as part of the ~~Patient Protection and Affordable Care Act (the “~~ ACA ~~”)~~, which ~~requires~~ - **require**, among other things, manufacturers of drugs, devices, biologics and medical supplies that are reimbursed under Medicare, Medicaid, or the Children’ s Health Insurance Program to report annually to the ~~Centers for Medicare & Medicaid Services (“~~ CMS ~~”)~~ information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain advanced non- physician health care practitioners (such as physician assistants and nurse practitioners) and teaching hospitals, as well as physician ownership and investment interests, including such ownership and investment interests held by a physician’ s immediate family members; • analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti- kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care

items or services reimbursed by non- governmental third- party payors, including private insurers; • analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and / or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other health care providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the health care industry; • the U. S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal health care programs; • HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of **protected** ~~individually identifiable~~ health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of **protected** ~~individually identifiable~~ health information; and • state and foreign laws which govern the privacy and security of health information **and personal data** in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways or conflict with each other and often are not preempted by HIPAA, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti- Kickback and criminal health care fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a health care company may run afoul of one or more of the requirements. If our operations are found to be in violation of any applicable laws or any other government regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, individual imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government health care programs, integrity obligations, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre- marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, additional reporting requirements and oversight if subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We intend to develop and implement a comprehensive corporate compliance program prior to the commercialization of our product candidates. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management' s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. Moreover, federal, state or foreign laws or regulations are subject to change, and while we, our collaborators, manufacturers and / or service providers currently may be compliant, that could change due to changes in interpretation, prevailing industry standards or other reasons. Health care and other reform legislation may increase the difficulty and cost for us and any collaborators we may have to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain. All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable U. S. federal and state laws and agency regulation, as well as foreign laws and regulations, could have a materially negative impact on our business. In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates or any of our potential future product candidates, restrict or regulate post- approval activities, or affect our ability to profitably sell any product candidates for which we obtain marketing approval. Increased scrutiny by the U. S. 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. **We cannot be sure whether additional legislative changes will be enacted, or whether any of the FDA' s regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be.** Congress also must reauthorize the FDA' s user fee programs every five years and often makes changes to those programs in addition to policy or procedural changes that may be negotiated between the FDA and industry stakeholders as part of this periodic reauthorization process. **The next FDA** ~~Congress most recently reauthorized the~~ user fee **reauthorization package is expected to enter stakeholder negotiations beginning in mid- 2025, with any agreement sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee** ~~programs~~ **program** ~~in~~ **would need to be finalized by Congress by the end of** September ~~2022~~ **2027** ~~without any substantive policy changes~~ **in order to avoid a disruption in FDA' s review goals for BLAs and other activities supported by user fees assessed against industry** . Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and / or expanding access. In the United States,

the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, Congress passed the ACA, which substantially changed the way health care is financed by both the government and private insurers, and significantly impacts the U. S. pharmaceutical industry. ~~There remain~~ **Aspects of the ACA have been the subject of** judicial and Congressional challenges ~~to certain aspects of the ACA~~ , and as a result certain sections of the ACA have not been fully implemented or **have been** effectively repealed. ~~However, following~~ **Following** several years of litigation ~~in the federal courts, in June 2021~~ , the U. S. Supreme Court upheld the ACA **in June 2021** when it dismissed a legal challenge to the law' s constitutionality. Further legislative and regulatory changes under the ACA remain possible, although it is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States. In addition, the ~~Drug Supply Chain Security Act (the "~~ DSCSA ~~")~~ enacted in 2013 imposed obligations on manufacturers of pharmaceutical products related to product tracking and tracing, and ~~in February~~ **the applicable requirements under the law became fully enforceable as of November 27,** ~~2022~~ **2024** ~~, FDA released proposed regulations to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third- party logistics providers; and create a federal system for licensure for use in the absence of a State program, each of which is mandated by the DSCSA~~ . As another example, on December 20, 2019, ~~President Trump~~ **a piece of bipartisan legislation called the CREATES Act, which establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on " commercially reasonable, market- based terms, " was** signed **into law as part of** the Further Consolidated Appropriations Act for 2020 ~~into law~~ (P. L. 116- 94) **. Although lawsuits have been filed under** ~~that includes a piece of bipartisan legislation called~~ the CREATES Act **since its enactment,** ~~. The CREATES Act aims to address the~~ **those lawsuits** ~~concern articulated by both the FDA and others in the industry that some brand manufacturers~~ have **settled** ~~improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private~~ **privately ; therefore** ~~cause of action that permits a generic or biosimilar product developer~~ to **date no federal court has reviewed or opined** ~~sue the brand manufacturer to compel it to furnish the necessary samples~~ on **the statutory language** ~~" commercially reasonable, market- based terms. " Whether~~ and ~~how generic and biosimilar product developments will use this new pathway, as well as the~~ **there continues** ~~likely outcome of any legal challenges~~ to **be** ~~provisions of the CREATES Act, remain highly uncertain~~ **uncertainty regarding the scope** and **application of the law** ~~its potential effects on our future commercial products are unknown~~ . Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are unsure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or whether such changes will have any impact on our business. Additionally, there ~~have~~ **has** been heightened governmental scrutiny in the United States of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several ~~recent~~ 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 products. For example, state legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical 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 December 2020, the U. S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate ~~pharmaceutical benefit managers (~~ " PBMs ~~")~~ and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The U. S. Federal Trade Commission (" FTC ") in mid- 2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Both the U. S. Congress and state legislatures are increasingly scrutinizing the industry and proposing novel regulatory approaches to address various perceived public policy concerns. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical product developers like us. Further, in September 2023, the FTC issued a policy statement articulating its view that certain " improper " patent listings by drug developers in FDA' s Orange Book represent an unfair trade practice and indicated that industry should be prepared for potential enforcement actions based on its analysis. The FTC followed that action in November 2023 by publicly calling out over 100 " improper " patent listings made by ten large pharmaceutical companies and initiating an FDA administrative process with respect to those patents. ~~It~~ **Initial federal court decisions appear to support the FTC' s policy challenging such patent listing practices, but it** remains to be seen whether the FTC, other governmental agencies, pharmaceutical manufacturers, or other stakeholders continue to prioritize the policy issue of " improper " patent listings and whether **additional** significant litigation will develop in this area. Accordingly, regulatory and government interest in biopharmaceutical industry business practices continues to expand and pose a risk of uncertainty. ~~At the federal level, there have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.~~ In ~~addition, the Department of Health and Human Services (" HHS ") has solicited feedback on various measures intended to lower drug prices and reduce the out- of- pocket costs of drugs and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare~~

~~Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS' s policy change that was effective January 1, 2019. Most recently, in~~ August 2022, ~~President Biden~~ **the IRA was** signed into ~~the~~ law **. The** ~~the Inflation Reduction Act of 2022 (" IRA~~ **includes** ~~"). Among other things, the IRA has~~ multiple provisions that may impact the prices of drug products ~~that are both sold into the Medicare program and~~ throughout the United States. ~~Starting in 2023~~ **Under the IRA** , a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the product' s price increases faster than the rate of inflation. This calculation is made on a ~~drug~~ product ~~-~~ by ~~drug -~~ product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug **or biological** product that is paid for by Medicare Parts B or D. ~~Additionally, starting~~ **Starting** in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition ~~.~~ **, and starting in payment year 2028,** CMS will ~~also~~ **begin** ~~negotiate~~ **negotiating** drug prices for a select number of Part B drugs ~~starting for payment year 2028~~ . If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with ~~pharmaceutical~~ **drug and biological product** manufacturers ~~to conduct~~ **for negotiated** ~~price~~ **prices** ~~negotiations in October~~ **of 10 products, which will become applicable for payment year** ~~2023~~ **2026** . ~~However~~ **Ultimately** , the IRA' s impact on the biopharmaceutical industry in the United States remains uncertain, in part because **of** multiple **ongoing lawsuits against CMS brought by** large pharmaceutical companies and other stakeholders (e. g., the U. S. Chamber of Commerce) ~~have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing~~ . Any additional federal or state health care reform measures could limit the amounts that third- party payers will pay for future health care products and services, and, in turn, could significantly reduce the projected value of certain development projects and reduce our profitability. Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, consultants, and commercial partners, and, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA or other regulatory authorities, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, and prospects, including the imposition of significant fines or other sanctions. Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs. We will be subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate in the future. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. The ~~Foreign Corrupt Practices Act (" FCPA ")~~ prohibits any U. S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti- bribery provisions of the FCPA are enforced primarily by the **DOJ** ~~U. S. Department of Justice~~ . The SEC is involved with enforcement of the books and records provisions of the FCPA **. However, in February 2025, President Trump issued an executive order directing the DOJ to pause enforcement of the FCPA and to issue new enforcement guidelines that take into consideration U. S. national security and the competitiveness of U. S. companies abroad. It is unclear how this presidential directive may affect the biopharmaceutical industry as a whole or our business in particular** . Similarly, the U. K. Bribery Act 2010 has extra- territorial effect for companies and individuals having a connection with the United Kingdom. The U. K. Bribery Act prohibits inducements both to public officials and private individuals and organizations. Compliance with the FCPA and the U. K. Bribery Act 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. 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 business outside of the United States, we will be required 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. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violations of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U. S. government until the pending claims are resolved. A conviction under the FCPA can result in long- term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices could have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. We are subject to, and may in the future become subject to, U. S. federal and state, and foreign, stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy **, artificial intelligence,** and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business. We and our current and potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i. e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws (e. g., HIPAA as amended by the **HITECH** ~~Health Information Technology for Economic and Clinical Health~~ Act ~~(" HITECH ")~~), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose protected health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. However, determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. If we are unable to properly protect the privacy and security of protected health information or other personal, sensitive, or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal and outside resources. Furthermore, state ~~attorney~~ **attorneys** ~~generals~~ **general** are authorized **to enforce HIPAA and** to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving **privacy and data security** laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Many state laws govern the privacy and security of **health information and** personal ~~information and~~ data in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts. For example, the California Confidentiality of Medical Information Act (" CMIA ") imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California' s patient privacy laws, for example, provide for penalties of up to $ 250, 000 and permit injured parties to sue for damages. In addition to the CMIA, in 2018, California 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 and security obligations on **certain** entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt- out of certain sales or transfers of personal information, and provide consumers with additional causes of action. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. In addition, the ~~California Privacy Rights Act (" CPRA ")~~ was recently enacted to strengthen elements of the CCPA and became effective on January 1, 2023. A number of other states ~~have considered~~ **continue to introduce** similar privacy proposals, with states like Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Montana, Oregon, Tennessee, Texas, Utah and Virginia enacting their own **omnibus** privacy laws. These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data. **Numerous other federal and state laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of patient health information. For example, Washington state recently enacted the " My Health My Data " Act which regulates a broad category called " consumer health data, " defined as " personal information that is linked or reasonably linkable to a consumer and that identifies a consumer' s past, present, or future physical or mental health. " Notably, the " My Health My Data " Act contains a private right of action, which is expected to increase litigation. In addition, Congress and some states are considering new laws and regulations that further protect the privacy and security of medical records or medical information. With the recent increase in publicity regarding data breaches resulting in improper dissemination of consumer information, all 50 states have passed laws regulating the actions that a business must take if it experiences a data breach, as defined by state law, including prompt disclosure within a specified amount of time to affected individuals. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data**

security requirements for personal information. Congress has also been considering similar federal legislation relating to data privacy and data protection. In the European Union, we may be subject to the ~~General Data Protection Regulation (“~~ GDPR ~~”)~~ which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross- border transfer of such data. The GDPR applies to any company established in the ~~European Economic Area (“~~ EEA ~~”)~~ (which includes the European Union Member States plus Iceland, Liechtenstein, and Norway) and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR establishes stringent requirements applicable to the processing of personal data, including strict requirements relating to the validity of consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for “ high risk ” processing, limitations on retention of personal data, special provisions affording greater protection to and requiring additional compliance measures for “ special categories of personal data ” including health and genetic information of data subjects, mandatory data breach notification (in certain circumstances), “ privacy by design ” requirements, and direct obligations on service providers acting as processors. The GDPR also prohibits the international transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. If we or our partners’ or service providers’ privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and / or fines of up to 20 million Euros or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. The GDPR may also impose additional compliance obligations relating to the transfer of data between us and our affiliates, collaborators, or other business partners. For example, on July 16, 2020, the Court of Justice of the European Union (“ CJEU ”), issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C- 311 / 18), called Schrems II. This decision (a) ~~calls~~ **called** into question commonly relied upon data transfer mechanisms as between the European Union Member States and the United States (such as the Standard Contractual Clauses) and (b) ~~invalidates~~ **invalidated** the European Union- U. S. Privacy Shield on which many companies had relied as an acceptable mechanism for transferring such data from the European Union to the United States. On July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU- US Data Privacy Framework (the “ Framework ”). The Framework provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the Schrems II decision. Notably, the new obligations were geared to ensure that data can be accessed by US intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The Commission will continually review developments in the US along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Some patients or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data- related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective patients or other business relationships. Relatedly, following the United Kingdom’ s withdrawal from the European Union (i. e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the European Union GDPR has been implemented in the United Kingdom (as the “ UK GDPR ”). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the European Union GDPR into United Kingdom law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £ 17. 5 million or 4 % of global turnover. Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent our product candidates 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 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 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. **Future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes or executive orders will be enacted, or whether any of the FDA’ s regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, the next FDA user fee reauthorization package is expected to enter stakeholder negotiations beginning in mid- 2025, with any agreement sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program would need to be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA’ s review goals for BLAs and other activities supported by user fees assessed against industry. In addition,** ~~Disruptions~~ **disruptions** at the FDA and other agencies may ~~also~~ slow the time necessary for new drugs and biologic products to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, ~~over the last several years,~~ **political disputes in Congress may result in a shutdown of** the U. S.

government ~~has shut down several times~~ , ~~including from December 22, 2018 through January 25, 2019,~~ and **in such** ~~congressional impasses periodically threaten to cause~~ - **cases** ~~future government shutdowns. When a shutdown occurs,~~ certain regulatory agencies, such as the FDA and the SEC, **would** have ~~had~~ to furlough ~~critical FDA, SEC and other government~~ employees and ~~stop~~ **cease** critical activities ~~. Moreover, government shutdowns or slowdowns can increase the time needed for an agency to complete its review or make final approvals or other administrative decisions~~ . If a prolonged government shutdown or slowdown occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, 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. Risks Related to Employee and Operations Matters, Managing Growth and Information Technology Our business, operations and clinical development timelines and plans are subject to risks arising from epidemic or pandemic diseases. The COVID- 19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, **CMOs,** communities and business operations, as well as the U. S. and global economies and financial markets ~~. International and U. S. governmental authorities in impacted regions took multiple and diverse actions in an effort to slow the spread of COVID- 19 and variants of the virus, including issuing varying forms of " stay- at- home " orders~~ . To date we have not experienced material disruptions in our business operations due to COVID- 19. ~~Such measures~~ **Measures** taken by the governmental authorities to respond to any future epidemic or pandemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for clinical products for use in our clinical trials and research and nonclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including due to measures taken that may limit social interaction or prevent reopening of high- transmission settings, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our nonclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future epidemic or pandemic disease outbreak could also potentially further affect the business of the FDA, the ~~European Medical Association (~~ EMA ~~)~~ or other regulatory authorities, which could result in delays in meetings related to our planned clinical trials. Any future epidemic disease outbreak may have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. Our future success depends on our ability to retain our key executives and to attract, retain, and motivate qualified personnel. We are highly dependent on the principal members of our senior management and scientific teams. Such principal members are employed " at will, " meaning we or they may terminate the employment relationship at any time. The loss of the services of any of these persons could impede the achievement of our research, development, and commercialization objectives. Recruiting and retaining qualified scientific, clinical, manufacturing, business development, general and administrative and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors, including our scientific co- founder, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. In addition, inflation has had, and we expect that it will continue to have, an impact on the costs that ~~it~~ **we** ~~incurs~~ - **incur** to attract and retain qualified personnel, and may make it more difficult for us to attract and retain such personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants, or advisors, may impede the progress of our research, development, and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations, and prospects. If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed. Over time we will need to hire additional qualified personnel with expertise in drug development, product registration, clinical, preclinical and nonclinical research, quality compliance, government regulation, formulation and manufacturing, financial matters and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. As a result, competition for personnel is intense and the turnover rate can be high. Attracting and retaining qualified personnel will be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel may impede the progress of our research, development and commercialization objectives and would negatively impact our ability to succeed in our product development strategy. We expect to expand our development, regulatory, and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of December 31, ~~2023~~ **2024** , we had 32 full- time employees and, in connection with the growth and advancement of our pipeline and becoming a public company, we expect **to continue** to increase the number of our employees and the scope of our operations, particularly in the areas of product development, regulatory affairs, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and

business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. As a growing biotechnology company, we are actively pursuing new platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our product candidates, if approved, will depend in part on our ability to effectively manage our future development and expansion. Our internal information technology systems, or those of our vendors, collaborators or other contractors or consultants, may fail or suffer cybersecurity incidents, loss of data, and other disruptions, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business. In the ordinary course of our business, we collect and store sensitive data, intellectual property, and proprietary business information. This data encompasses a wide variety of business- critical information including research and development information, clinical trial information, personal information, commercial information, and business and financial information. We face risks relative to protecting this critical information, including loss of access, unauthorized access or disclosure, unauthorized modification, and inadequate monitoring of our controls over these risks. Despite the implementation of security measures, our internal information technology (“ IT ”) systems and those of our current and any future third- party vendors, collaborators and other contractors or consultants are vulnerable to risks and damages from a variety of sources, including, interruption, failure, damage, cybersecurity incidents, or data theft from computer viruses, computer hackers, malicious code, employee theft or misuse, malware, including ransomware, social engineering (including phishing attacks), denial- of- service attacks, sophisticated nation- state and nation- state- supported actors, unauthorized access, cyber- attacks, phishing schemes, breaches, interruptions due to employee error or malfeasance, damage from natural disasters, terrorism, war and telecommunication, network, and electrical failures. As use of digital technologies has increased, cybersecurity incidents, including deliberate attacks and attempts to gain unauthorized access to IT systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our IT systems and networks and the confidentiality, availability, and integrity of our data. There can be no assurance that we will be successful in detecting or preventing cybersecurity incidents, or successfully mitigating their effects. Any such disruption or security incident could cause interruptions in our operations, and result in a disruption of our development programs and our business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we were to experience a significant cybersecurity incident that impacts our IT systems or data, the costs associated with the investigation, remediation and potential notification of the cybersecurity incident to counterparties, regulatory authorities, and data subjects could be material. In addition, our remediation efforts may not be successful. Cybersecurity incidents could also lead to significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. In addition, our remote workforce could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruption. To the extent that any disruption or cybersecurity incident were to result in a loss of, or damage to, our or our third- party vendors’, collaborators’ or other contractors’ or consultants’ data or applications, or inappropriate disclosure of confidential, proprietary, or other critical or sensitive information or data, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory actions or investigations, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients, to the extent we have such information, or our employees, could harm our reputation, require us to comply with federal and / or state data breach notification laws and foreign law equivalents, and potential contractual obligations, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Despite our implementation of security and other protective measures, sustained or repeated IT system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business. Any of the above could have a material adverse effect on our business, financial condition, reputation, competitive advantage, results of operations or prospects. While we maintain cyber- liability insurance (covering security and privacy matters), such insurance may not be adequate to cover any losses experienced as a result of a cybersecurity incident. General Risk Factors Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. The global credit and financial markets have ~~recently~~ **periodically** experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflicts in the Middle East and between Russia and Ukraine, geopolitical tensions with China, terrorism or other geopolitical events **, including the imposition of tariffs** . Sanctions imposed by the United States and other countries in response to such conflicts, including the ones in the Middle East and in Ukraine, may also adversely impact the financial markets and the global

economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability **. Additionally, the imposition of substantial tariffs by the United States on imports from various countries, including China, Canada, and Mexico, and the possible countermeasures by these countries could increase costs, disrupt the global supply chain, and create additional operational challenges. The uncertainty surrounding future trade relationships and the potential for increased market volatility and currency exchange rate fluctuations along with tariffs and trade regulations could have an adverse effect on our business** . There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves, or on less favorable terms than we would otherwise choose. In addition, one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our clinical development goals on schedule and on budget. Uncertainty about global economic conditions could result in increased costs related to the manufacture of our product candidates and, if our product candidates are approved and made available for sale, customers may postpone purchases of our product candidates in response to tighter credit, unemployment, negative financial news and / or declines in income or asset values and other macroeconomic factors, which could have a material adverse effect on demand for our product candidates. Inflation could adversely affect our business and results of operations. While inflation in the United States has **reduced** ~~been relatively low in recent~~ **recently** ~~years~~ , during 2021 and 2022, the economy in the United States encountered a material level of inflation. The impact of COVID- 19, geopolitical developments such as the Russia- Ukraine and Middle East conflicts, geopolitical tensions with China, and global supply chain disruptions continue to increase uncertainty in the outlook of near- term and long- term economic activity ~~, including whether inflation will continue and how long, and at what rate~~ . Increases in inflation raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, ~~along with the uncertainties surrounding COVID- 19,~~ geopolitical **and macroeconomic** developments **,** and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment, which may make it more difficult, costly or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows **. We have broad discretion in the use of our financial resources and may not use them effectively. Our management has broad discretion in the application of our financial resources. Because of the number and variability of factors that determine our use of our financial resources, their ultimate use may vary substantially from their currently intended use. Our management may not apply our financial resources in ways that ultimately increase the value of any investment in our securities or enhance stockholder value. The failure by our management to apply these funds effectively could harm our business. We have invested and may in the future invest our cash in interest- bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which may result in a decline in the price of our shares of common stock, and, therefore, may negatively impact our ability to raise capital, invest in or expand our business, acquire additional licenses, commercialize our product candidates, or continue our operations** . U. S. federal income tax reform could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, ~~former~~ President Trump signed into law the CARES Act which included certain changes in tax law intended to stimulate the U. S. economy in light of the COVID- 19 ~~coronavirus~~ outbreak, including temporary beneficial changes to the treatment of net operating losses (" NOLs "), interest deductibility limitations and payroll tax matters. Additionally, on December 22, 2017, ~~former~~ President Trump signed into law the Tax Cuts and Jobs Act of 2017 (" TCJA "), which significantly reformed the Internal Revenue Code. The TCJA included significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. Under the TCJA, in general, NOLs generated in taxable years beginning after December 31, 2017 may offset no more than 80 percent of such year' s taxable income and there is no ability for such NOLs to be carried back to a prior taxable year. The CARES Act modifies the TCJA with respect to the TCJA' s limitation on the deduction of NOLs and provides that NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021, may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80 percent of current year taxable income for taxable years beginning before January 1, 2021. As a result of such limitation, we may be required to pay federal income tax in some future year notwithstanding that we had a net loss for all years in the aggregate. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock. The market price of our common stock is expected to be volatile, and the market price of our common stock may drop. The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early- stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some

of the factors that may cause the market price of our common stock to fluctuate include: • our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals; • failure of any of our product candidates, if approved, to achieve commercial success; • failure by us to maintain our existing third- party license and supply agreements; • failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights; • changes in laws or regulations applicable to our product candidates; • any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices; • adverse regulatory authority decisions; • adverse results, clinical holds, or delays in the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates; • introduction of new products, services or technologies by our competitors; • failure to meet or exceed financial and development projections we may provide to the public; • failure to meet or exceed the financial and development projections of the investment community; • the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; • announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors; • disputes or other developments relating to proprietary rights, 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 an adverse or misleading opinion regarding our business and stock; • changes in the market valuations of similar companies; • general market or macroeconomic conditions; • sales of ~~its~~ **our** common stock by us or our stockholders in the future; • trading volume of our common stock; • failure to maintain compliance with the listing requirements of ~~The~~ **the** Nasdaq **Stock** ~~Global Select~~ Market **LLC (“ Nasdaq ”)** ; • announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments; • adverse publicity generally, including with respect to other products and potential products in such markets; • the introduction of technological innovations or new therapies that compete with our potential products; • changes in the structure of health care payment systems; • disruptions in the financial markets; • the impact of political instability and military conflict ~~, such as geopolitical tensions between the United States and China, the conflicts in the Middle East, and the conflict in Ukraine~~ , which has resulted in instability in the global financial markets and export control; and • period- to- period fluctuations in our financial results. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of 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 those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock. We will continue to incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies. We will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We will also incur costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC as well as the Nasdaq rules. These laws, rules and regulations are expected to increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, some members of our management team have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These laws, rules and regulations also may make it difficult and expensive for us to maintain directors’ and officers’ liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence and could cause our business or stock price to suffer. We may become involved in securities litigation that could divert management’ s attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages. We may be exposed to securities litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management’ s attention and resources, which could adversely affect our business and cash resources. We may become involved in such litigation, and our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development efforts or the development efforts of current or future collaboration partners or competitors, the addition or departure of our key personnel, ~~the announcement of the strategic restructuring,~~ variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, it could result in substantial costs for defending the lawsuit and diversion of the time, attention and resources of our board of directors and management, which could significantly harm our profitability and reputation. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management. Provisions in our **amended and restated** certificate of incorporation and **amended and restated** bylaws may delay or prevent an acquisition or a change in management. In addition, because we **are** ~~will be~~ incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (“ DGCL ”), which prohibits stockholders owning in excess of 15 % of ~~or~~ **our** outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer

may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees, and could make it more costly for stockholders to bring a claim against us. Our amended and restated certificate of incorporation and amended and restated bylaws, provide, among other things, that that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) generally will be the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and the amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities ~~Exchange~~ Act of ~~1934~~ **1933 , as amended** (the " Securities Act "). However, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims, and investors cannot waive compliance with the federal laws and rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation and amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there is uncertainty that the provision would be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects. This exclusive forum 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 a stockholder' s ability to bring a claim in a judicial forum that it 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 provision contained in our amended and restated certificate of incorporation or amended and restated bylaws 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. 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 development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain, if any, for the foreseeable future. **Our stockholders may experience future dilution as a result of future equity offerings. In addition to the (i) " at- the- market " offering program entered into in June 2024 under which we may offer and sell, from time to time, up to $ 40 million of shares of common stock through JonesTrading Institutional Services LLC, as agent, (ii) March 2024 private placement of pre- funded warrants to purchase up to 1, 032, 702 shares of our common stock, (iii) July 2024 underwritten offering of 500, 000 shares of our common stock, pre- funded warrants to purchase up to 1, 800, 000 shares of our common stock and common warrants to purchase up to 2, 300, 000 shares of our common stock, and (iv) January 2025 underwritten offering of 1, 261, 830 shares of our common stock and common warrants to purchase up to 1, 261, 830 shares of our common stock, we may offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock in order to raise additional capital in the future. We cannot assure our stockholders that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share our stockholders paid for our shares. Investors purchasing shares or other securities in the future could have rights, preferences or privileges senior to those of our stockholders and our stockholders may experience dilution. Our stockholders may incur additional dilution upon the exercise of any outstanding stock options or warrants, the issuance of shares of restricted stock, the vesting of restricted stock units, or the issuance, vesting or exercise of other equity awards.** An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all. An active trading market for our shares of common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all. Future sales of a substantial number of shares by existing stockholders, or the perception that such sales could occur, could cause our stock price to decline. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We are unable to predict the effect that sales may have on the prevailing

market price of our common stock. In addition, shares of our common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plan will be eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline **. Our largest stockholder has significant influence over us, including influence over decisions that require the approval of stockholders, which could limit our stockholders' ability to influence the outcome of key transactions, including a change of control. Yekaterina (Katie) Chudnovsky, a member of our board of directors, and GKCC, LLC (" GKCC "), an entity controlled by Ms. Chudnovsky, together beneficially own 34. 1 % of our outstanding common stock. Additionally, GKCC holds common warrants to purchase approximately 1. 6 million shares of common stock and pre- funded warrants to purchase approximately 2. 6 million shares of common stock, which could result in GKCC owning an even greater percentage of our outstanding common stock if exercised. Although we are not a " controlled company " within the meaning of the corporate governance standards of Nasdaq, Ms. Chudnovsky, through her control of GKCC, is able to significantly influence our decisions, including the election of directors, the approval of significant corporate transactions, such as mergers and related party transactions. Ms. Chudnovsky, through her control of GKCC, has the ability to delay or perhaps even block, by ownership of our stock, an unsolicited tender offer. This concentration of ownership could have the effect of delaying, deterring or preventing a change in control of our company that stockholders might view favorably. Additionally, our largest stockholder' s interests may not align with the interests of our other stockholders. Our largest stockholder may make investments in companies and may acquire and hold interests in businesses that compete directly or indirectly with us and our largest stockholder may also pursue acquisition opportunities that may be complementary to our business, and, as a result, those acquisition opportunities may not be available to us. Although we do not expect to rely on the " controlled company " exemption, we may soon become a " controlled company " within the meaning of the Nasdaq listing standards, and we would qualify for exemptions from certain corporate governance requirements. A " controlled company, " as defined in the Nasdaq listing standards, is a company of which more than 50 % of the voting power for the election of directors is held by an individual, a group or another company. Controlled companies are not required to comply with certain Nasdaq listing standards relating to corporate governance, including: • the requirement that a majority of a company' s board of directors consist of independent directors; • the requirement that a company' s nominating and corporate governance committee be composed entirely of independent directors with a written charter addressing the committee' s purpose and responsibilities; and • the requirement that a company' s compensation committee be composed entirely of independent directors with a written charter addressing the committee' s purpose and responsibilities. If our largest stockholder were to obtain a majority of the voting power for the election of our directors, we would meet the definition of a " controlled company. " As a result, these requirements would not apply to us as long as we remain a " controlled company. " Although we may soon qualify as a " controlled company, " we currently do not, and we do not expect to, rely on this exemption and we currently comply with, and we expect to continue to comply with, all relevant corporate governance requirements under the Nasdaq listing standards. However, if we were to utilize some or all of these exemptions, our stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq listing standards that relate to corporate governance** . 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 is 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 are expected to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies and emerging growth companies, which could result in our common stock being less attractive to investors. We have a public float of less than $ 250 million and therefore qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, we are able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if 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. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $ 250 million. In that event, we could still be a smaller reporting company if our annual revenues were below $ 100 million and we have a public float of less than $ 700 million. We are an emerging growth company (" EGC "), as defined in the Jumpstart Our Business Startups Act of 2012, as amended. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may remain an EGC or until the earlier of (a) December 31, 2026, (b) the last day of the fiscal year in which we have total

annual gross revenue of at least $ 1. 235 billion or more, (c) the date we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non- affiliates to exceed $ 700. 0 million as of the prior June 30th, and (d) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. Changes in tax laws may materially adversely affect our business, prospects, financial condition and operating results. New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business, prospects, financial condition and operating results. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act, the CARES Act, and the IRA enacted many significant changes to the U. S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Such tax law changes could have a material adverse impact on us. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. While it is too early to assess the overall impact of these changes, as these and other tax laws and related regulations are revised, enacted, and implemented, our financial condition, results of operations, and cash flows could be materially adversely impacted. Our ability to use NOL carryforwards and other tax attributes may be limited. We have incurred losses during our history, and we do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all. As of December 31, ~~2023~~ **2024**, we had U. S. federal NOL carryforwards and state NOL carryforwards of approximately $ ~~237~~ **261**. 8 million and $ ~~170~~ **145**. ~~4~~ **2** million, respectively. Under current law, U. S. federal NOL carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Code, federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An “ ownership change ” pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5 % of a company’ s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes or other transactions. Similar rules may apply under state tax laws. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.