

Risk Factors Comparison 2024-03-14 to 2023-03-16 Form: 10-K

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Our business is subject to a number of risks and uncertainties. The following is a summary of the principal risk factors described in this section: Risks Related to our Financial Position and Need for Additional Capital • We have historically incurred net losses and anticipate that we will continue to incur net losses in the future. • If we fail to obtain additional financing, we will not be able to complete development and commercialization of our product candidates. • Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. • Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and its financial condition and results of operations. • **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 financial statements.** Risks Related to the Development of Our Product Candidates • Our business is highly dependent on the success of botensilimab and our combination therapy programs. • Preliminary or interim data that we report on our clinical trials could change materially by the time the data is finalized. • Our clinical trials or those of our current and future collaborators may reveal significant adverse events or lack of sufficient efficacy or durability of response. • If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. • We have limited resources, and the number of product candidates that we are attempting to simultaneously advance creates a significant strain on these resources and could prevent us from successfully advancing any candidates. Risks Related to the Commercialization of Our Product Candidates • We may not be able to commercialize, or may be delayed in commercializing, our product candidates. • **Our** ~~We expect the novel nature of our product candidates to create~~ **are new molecular entities that could face** challenges in obtaining regulatory approval. **As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted.** • Our product candidates may cause undesirable side effects. • Our competitors may have superior products, manufacturing capability, expertise and / or resources. • Even if our product candidates receive marketing approval, such products may not achieve market acceptance or coverage, or may become subject to unfavorable pricing regulations or third- party reimbursement practices. • The market opportunities for our product candidates may be small, and our estimates of the prevalence of our target patient populations may be inaccurate. • We have no **prior** experience **as a company** in marketing, selling and distributing products or performing commercial compliance. Risks Related to Manufacturing and Supply • Manufacturing challenges could result in having insufficient quantities of our drug candidates or drugs or such quantities at an acceptable cost. • We own and operate our own clinical scale manufacturing infrastructure, which is costly and time- consuming. • We have built and are in the process of qualifying our own commercial scale manufacturing ~~facility-~~ **facility**, which is costly and time- consuming and will require regulatory approvals before the facility can begin manufacturing. Risks Related to Our Reliance on Third Parties • We are dependent upon third parties to further develop and commercialize certain of our antibody programs. • Failure to enter into and / or maintain clinical trial, licensing, distribution and / or collaboration agreements may adversely affect our business. • If third parties do not carry out their contractual duties, we may not be able to obtain regulatory approval of or commercialize any potential product candidates. Risks Related to Government Regulation • The regulatory approval process for our product candidates is uncertain and will be lengthy, and may evolve even after we have engaged with relevant regulatory authorities and selected a regulatory pathway. • We may fail to obtain regulatory approval of our product candidates. • Our **business operations and** relationships with third parties are subject to extensive healthcare laws and regulations. • If we receive regulatory approval of any product candidates or therapies, we will be subject to ongoing regulatory obligations and continued regulatory review. • Healthcare ~~regulatory-reform~~ **measures initiatives** may have an adverse effect on our business. • Laws and regulations governing any international operations may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs. • Risks associated with doing business internationally could negatively affect our business. • Our ability to use net operating losses and tax credits to offset future income may be subject to limitations. Risks Related to Our Intellectual Property • We may be unable to obtain and enforce patent protection for our product candidates and related technology. • If we fail to comply with our intellectual property licenses, we could lose important license rights. • We may not be able to protect our intellectual property rights throughout the world. • Changes in U. S. patent law could diminish the value of patents. • We may be unable to protect the confidentiality of our proprietary information. • Our employees, consultants or independent contractors could wrongfully use or disclose confidential information. • We may infringe the patents and other proprietary rights of third parties. • We may become involved in lawsuits to protect or enforce our patents. Risks Related to Business Operations, Employee Matters and Managing Growth • We may encounter difficulties in managing our recent growth. • Legal claims against us may create distraction for our management team, adversely impact our ability to develop and gain approval for our products and / or result in substantial damages. • Information technology security breaches could result in a material disruption in our business and subject us to sanctions and penalties. • Our subsidiaries MiNK Therapeutics may be unsuccessful at advancing its cell therapy business, and SaponiQx, Inc. may be unsuccessful in advancing its vaccine adjuvant business. Our ~~subsidiaries~~ **subsidiary**, ~~ETC and~~ Atlant Clinical, may be unsuccessful in maintaining and growing ~~their~~ **its** clinical research organization ("CRO") businesses. Risks Related to Our Common Stock • **Our stock may be delisted from The Nasdaq Capital Market, which could affect its market price and liquidity.** • Our stock's trading volume and public trading price has been volatile. • We do not intend to pay cash dividends on our common stock. • Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control. Our future operating results could

differ materially from the results described in this Annual Report on Form 10- K due to the risks and uncertainties described herein. You should consider carefully all information about risks in evaluating our business. If any of the described risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline. We cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward- looking statements. See “ Note Regarding Forward- Looking Statements ” in this Annual Report on Form 10- K. Factors that could cause or contribute to such differences include those factors discussed below.

Risks Related to Our Financial Position and Need for Additional Capital We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future. Investment in I- O product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Our net losses for the years ended December 31, ~~2023, 2022, and 2021~~, ~~and 2020~~, were \$ ~~257.4 million, \$ 230.7 million, and \$ 28.7 million and \$ 182.9 million~~, respectively. We expect to incur significant losses for the foreseeable future as we continue our research and development efforts, seek regulatory approvals, and begin commercial readiness efforts for our product candidates. We anticipate that our expenses will increase substantially if, and as, we:

- conduct clinical trials for our pipeline of product candidates;
- further develop our antibody programs and platforms, MiNK' s cell therapy programs, and our saponin- based vaccine adjuvants (through SaponiQx);
- continue to discover and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific, manufacturing, commercial and related personnel;
- expand in- house clinical and commercial manufacturing capabilities;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- acquire or in- license other product candidates and technologies;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval; and
- add operational, regulatory, financial and management information systems and personnel, including personnel to support our product development and planned commercialization efforts.

To become profitable, we or any current or potential future licensees and collaboration partners must develop, gain approval and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. This will require us to be successful in a range of challenging activities, including completing clinical trials, obtaining marketing approval for product candidates, obtaining adequate reimbursement for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause our stockholders to lose all or part of their investment. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development costs and other expenditures to develop and market additional product candidates in our pipeline. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Furthermore, our ability to generate cash from operations is dependent in part on the success of our licensees and collaboration partners, as well as the likelihood and timing of new strategic licensing and partnering relationships and / or successful development, approval and commercialization of product candidates, including through our antibody programs and platforms, MiNK' s adoptive cell therapy programs, and our saponin- based vaccine adjuvants (through SaponiQx). We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we will not be able to complete the development and commercialization of our product candidates. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to conduct further research and development and preclinical or nonclinical testing and studies and clinical trials of our current and future programs, to build a supply chain, to seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval, including building our own commercial organization. To date, we have financed our operations primarily through the sale of equity, assets, notes, corporate partnerships and interest income. In order to finance future operations, we will be required to raise additional funds in the capital markets, through arrangements with collaboration partners or from other sources. As of December 31, ~~2022-2023~~, we had \$ ~~193.76.41~~ million of cash, cash equivalents and short- term investments. Based on our current plans and projections, we believe that our cash resources as of December 31, ~~2022-2023~~, **plus the milestone payment received in the first quarter of 2024, as well as additional funding we may receive from multiple sources, including out- licensing and / or partnering opportunities and the sale of non- strategic assets, and the repayment of our subordinated notes**, will be sufficient to satisfy our liquidity requirements ~~for more than one through the end of the year and into 2025~~ **for more than one through the end of the year and into 2025** from when the financial statements included in this Annual Report on Form 10- K were issued. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities.

Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical or nonclinical testing and studies and clinical trials for our product candidates;
- the clinical development plans we establish for our product candidates;
- the number and characteristics of future product candidates that we develop or may in-license;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such arrangements;
- the timing, receipt and amount of sales of, or royalties on, our future products and those of our partners, if any;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the ~~European Medicines Agency (the “EMA”)~~ and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the costs of establishing and maintaining a clinical and commercial supply chain for the development and manufacture of our product candidates;
- the cost and timing of establishing, expanding and scaling commercial manufacturing capabilities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements **and sale of non-strategic assets**. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives **as we did in August 2023 when we streamlined our operations to focus on our lead program**. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline and we may become insolvent. From time to time we have issued, and in the future may issue, projections regarding our future cash position. Such projections include the expectation that we will be able to raise additional funds from the aforementioned sources and our ability to do so is subject to the risks described herein. General economic conditions in the United States and abroad, including the impacts of public health crises, such as the COVID-19 pandemic, the policies of the Biden Administration or otherwise, and geopolitical disputes and wars such as the invasion of Ukraine by Russia **or conflicts in the Middle East**, may have a material adverse effect on the financial markets and our liquidity and financial condition, particularly if our ability to raise additional funds is impaired. We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements **and the sale of non-strategic assets**. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect their rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. The nature and length of our operating history may make it difficult to evaluate our technology and product development capabilities and predict our future performance. We have no products approved for commercial sale and have not generated any revenue from product sales. Our ability to generate product revenue or profits will depend on the successful development, regulatory approval and eventual commercialization of our product candidates, which may never occur. We may never be able to develop or commercialize a marketable product. All of our programs require additional pre-clinical or clinical research and development, clinical and commercial manufacturing supply, capacity and / or expertise, building of a commercial organization, substantial investment and / or significant marketing efforts before we generate any revenue from potential product sales. Other programs of ours require additional discovery research and then preclinical development. In addition, our product candidates must be approved for marketing by the FDA or certain other health regulatory agencies, including the EMA, before we may commercialize any product. Our operating history, particularly in light of the rapidly evolving and competitive I-O field, may make it difficult to evaluate our technology and industry and predict our future performance. We will encounter risks and difficulties frequently experienced by clinical stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our stockholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance. In addition, as a clinical stage company, we have encountered unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As we advance our product candidates, we will need to transition from a company with a research and clinical focus to a company capable of supporting commercial activities. We may not be successful in such a transition. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including increased inflation, severely diminished liquidity and credit availability, declines in consumer

confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, and the volatility of such market and economic conditions have increased as a result of the COVID- 19 pandemic and the Russian invasion of Ukraine. The scope, duration and long- term impact of the COVID- 19 pandemic and the Russian invasion are unknown at this time, so there can be no assurance how significant any deterioration in credit and financial markets and confidence in economic conditions will be and how long it may continue. Our general business strategy may be adversely affected by any such economic downturn, volatile geopolitical and business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, 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 or abandon clinical development plans for some or all of our pipeline candidates. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. As of December 31, 2022-2023, we had cash, cash equivalents and short- term investments of \$ 193-76. 4-1 million. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents and investments since December 31, 2022-2023, no assurance can be given that deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn. 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 financial statements, and it is possible that such report on our financial statements may include such an explanation again in the future. We believe we have sufficient capital, including funding anticipated from corporate events, to fund our operations through the end of the year and into 2025. Going forward, if we are unable to obtain sufficient funding to support our operations, we could be forced to delay, reduce or eliminate all of our research and development programs, product portfolio expansion or commercialization efforts, our financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. In the future, reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all. Our obligations to the holders of our promissory notes and certain finance leases could materially and adversely affect our liquidity and operations.** In February 2015, we issued subordinated promissory notes in the aggregate principal amount of \$ 14. 0 million, of which \$ 13. 0 million remains outstanding, with annual interest of 8 % (the “ 2015 Subordinated Notes ”). The 2015 Subordinated Notes have been amended to extend the maturity date to February 2025. The 2015 Subordinated Notes include default provisions that allow for the acceleration of the principal payment of the 2015 Subordinated Notes in the event we become involved in certain bankruptcy proceedings, become insolvent, fail to make a payment of principal or (after a grace period) interest on the 2015 Subordinated Notes, default on other indebtedness with an aggregate principal balance of \$ 13. 0 million or more if such default has the effect of accelerating the maturity of such indebtedness, or become subject to a legal judgment or similar order for the payment of money in an amount greater than \$ 13. 0 million if such amount will not be covered by third- party insurance. If we default on the 2015 Subordinated Notes and the repayment of such indebtedness is accelerated, our liquidity could be materially and adversely affected. **In 2021, we entered into a finance lease arrangement for the purchase of equipment installed in our Emeryville, CA facility. Under the terms of this agreement failure to maintain a minimum cash balance is an event of default as defined in the agreement. If the default is not cured or waived by the lessor, the lessor may take possession of the equipment which will significantly impact our manufacturing process.** If we do not have sufficient cash on hand to service or repay our 2015 Subordinated Notes, **or to maintain our required minimum cash balance**, we may be required to raise additional capital which entails the risks described herein. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non- performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations. We regularly maintain cash balances at third- party financial institutions, such as Silicon Valley Bank (“ SVB ”), in excess of the Federal Deposit Insurance Corporation (“ FDIC ”) insurance limit. ~~On In March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. If Although the Department of the Treasury, the Federal Reserve and the FDIC issued a joint statement on March 12, 2023 that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, if another depository institution is subject to other adverse conditions in the financial or credit markets, it could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. In addition, if any parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties’ ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. Our business is highly dependent on the success of our clinical stage programs, including botensilimab and related combination therapy programs, which still require significant additional clinical development. Our business and future success depends in large part on our ability to obtain regulatory approval of, and then successfully launch and commercialize, our product candidates. Our timelines are aggressive and subject to various factors outside of our control, including regulatory review and approval. Although we have engaged with the FDA on our regulatory programs and protocols, there is no guarantee that our BLA submissions, if any, will be approved, or that we will be able to successfully commercialize these assets. If the botensilimab programs (including combination therapies with botensilimab) encounter safety, efficacy, supply or manufacturing~~

problems, developmental delays, regulatory or commercialization issues or other problems, our development plans and business may be significantly harmed. Even though we have observed positive results to date, they may not necessarily be predictive of the final results of the trials or future clinical trials or otherwise be sufficient to support an approval. Many companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results, and we cannot be certain that we will not face similar setbacks. All of our other product candidates are in earlier stages of development and will require additional nonclinical and / or clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing and commercial efforts before we can generate any revenue from product sales. **While we intend to submit our first botensilimab / balstilimab BLA in refractory MSS CRC in 2024 subject to feedback from the FDA. The FDA may disagree that our data and development program are sufficient to support BLA filing or approval. For example, prior to the availability of the Phase 2 data FDA noted that data from our development program do not appear to conclusively favor one dosage of botensilimab over the other. We believe that our Phase 2 data will inform dose selection and we intend to discuss those data with the FDA in an upcoming meeting to determine whether it may be appropriate to pursue BLA approval of both doses. The FDA may disagree with our assessment and recommend that additional clinical studies be undertaken in support of dose selection. Furthermore, because botensilimab and balstilimab are both novel agents, and are being used in combination, any BLA submission for the combination will require significant information on each agent as well as the combination.** The successful development of immune modulating antibodies, including botensilimab, alone and in combination with other therapeutic candidates, is highly uncertain. Successful development of immune modulating antibodies, such as botensilimab, is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Immune modulating antibodies that appear promising in the early phases of development may fail to reach, or remain in, the market for several reasons, including: • clinical trial results may show our candidates to be less effective than expected (e. g., a clinical trial could fail to meet its primary endpoint (s)) or to have unacceptable side effects, toxicities or other negative consequences; • failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical trials, patients dropping out of trials, length of time to achieve trial endpoints, additional time requirements for data analysis, or BLA preparation, discussions with the FDA, an FDA request for a diagnostic or additional nonclinical or clinical data that may be deemed necessary to meet evolving regulatory standards and pathways, or unexpected safety or manufacturing issues; • clinical and commercial manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the candidates uneconomical; • proprietary rights of others and their competing products and technologies that may prevent our candidates from being commercialized or profitable; • failure to initiate or successfully complete confirmation trials for candidates that receive accelerated approval; and • the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority may be difficult to predict for immune modulating antibodies, including for CTLA- 4 antibody and related combination therapies. Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of insurance coverage and adequate reimbursement from third- party payors, including government payors, such as the Medicare and Medicaid programs, and **managed care organizations private health insurers**, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third- party payors may limit **coverage to a** the definition of the target treatment population to one smaller than that implied in the label granted by regulatory authorities, and could require us to conduct additional studies, including post-marketing studies related to the cost- effectiveness or comparative benefit of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for any one of our products once approved, market acceptance and commercial success would be reduced. In addition, if any of our products are approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post- marketing information and reports and registration and will need to continue to comply (or ensure that our third- party providers comply) with cGMPs and good clinical practices (“GCPs”), for any clinical trials that we conduct post- approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post- approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly and any failure to comply or other issues with our product candidates’ post- approval could have a material adverse effect on our business, financial condition and results of operations. Interim top- line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim top- line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available and mature over time. Preliminary or top- line 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, interim and preliminary data should be viewed with caution until the final data are available. Multiple times last year ~~and earlier this year~~, we reported positive interim data from our lead trials of botensilimab (AGEN1181). For example, ~~in June 2022 at the ESMO World Congress on Gastrointestinal Cancer, and in November 2022 at the Society for Immunotherapy Cancer meeting and in January 2023~~ **ASCO GI Symposium, and in October 2023 at the ESMO Corporate Event** ~~American Society of Clinical Oncology—Gastrointestinal Cancers Symposium~~, we reported new clinical responses from a Phase 1 / 2 trial of botensilimab (as a monotherapy and combination with balstilimab). Each of these results may not be indicative of the final results from the relevant study, and the final results may not support a marketing approval for any of these candidates. There is no guarantee that botensilimab, balstilimab, zalifrelimab, or AGEN2373 (or any of our other earlier stage **or partnered** programs) will receive marketing approval in any jurisdiction, and failure to achieve

marketing approval for any of these programs as a monotherapy or combination could have a material adverse impact on our business. Any adverse differences between preliminary or interim data and final data could significantly harm our business and partnership prospects. Preclinical development is uncertain. Some of our antibody programs are in early stage development that may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, and which would have an adverse effect on our business. Several of our proprietary antibody programs are currently in early stage development, and many of our antibody programs are pre-clinical. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Our clinical trials or those of our current and future collaborators may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates. Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through potentially lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. 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 profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. ~~We intend to develop our existing antibody candidates, and may develop future product candidates, alone and in combination with one or more additional cancer therapies. The uncertainty resulting from the use of our product candidates in combination with other cancer therapies may make it difficult to accurately predict side effects in future clinical trials.~~ If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an institutional review board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of any approved product due to its tolerability versus other therapies. **Any of these developments could materially harm our business, financial condition and prospects. We intend to develop our existing antibody candidates, and may develop future product candidates, alone and in combination with one or more additional cancer therapies. The uncertainty resulting from the use of our product candidates in combination with other cancer therapies may make it difficult to accurately predict side effects in future clinical trials. The development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, we are currently developing botensilimab and balstilimab in combination for the treatment of certain cancers. The FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. Additionally, developments related to one product or product candidate may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include, among other things, changes to the other product's safety or efficacy profile, changes to the availability of the product, and quality, manufacturing and supply issues.** Any of these developments could materially harm our business, financial condition and prospects. Positive results from preclinical and clinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any future clinical trials of our product candidates. If we cannot replicate the positive results from our earlier studies of our product candidates in our later studies and future clinical trials, we may be unable to successfully develop, obtain regulatory for and commercialize our product candidates. Any positive results from our preclinical studies of our product candidates may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any future clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. Moreover, positive results observed in interim data may not necessarily be predictive of the results from final, more mature data. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval. If we encounter difficulties enrolling patients in our clinical trials or if our clinical trial sites encounter staffing shortages that impact their operations, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in patient enrollment and in and timely completion of 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, or the ability of our CROs to enroll a sufficient number of patients who remain in the study until its conclusion and the sites being able to operate as needed to adhere to the clinical requirements as set forth in the protocol. The enrollment of patients depends on many factors, including: • the severity of the disease under investigation; • the patient eligibility and exclusion criteria defined in the protocol; • the size of the patient population required for analysis of the trial's primary endpoints; • the proximity of patients to trial sites; • the design of the trial; • our ability, and that of our CROs, to recruit clinical trial investigators with the appropriate competencies and experience; • clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be in clinical development or approved for the indications we are investigating; • the efforts to facilitate timely enrollment in clinical trials; • the patient referral practices of physicians; • the ability of our CROs and our ability to oversee and / or the monitoring of patients adequately during and after treatment; • the ability of our CROs and our ability to oversee and / or to obtain and maintain patient consents; and • the risk that patients enrolled in clinical trials will drop out of the trials before completion. 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. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for our targeted therapeutic areas, potential patients and their doctors may be inclined to use conventional or newly launched competitive therapies, rather than enroll patients in any future clinical trial. Staffing shortages at clinical trial sites and delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. ~~The COVID-19 pandemic and staffing shortages impacted by the pandemic and disruptions in the broader labor market including at clinical trial sites may cause delays in the patient enrollment in our clinical trials and could prevent the completion and / or timely completion of such trials.~~ The number of product candidates that we are attempting to simultaneously advance creates a significant strain on our resources and may prevent us from successfully advancing any product candidates. If, due to our limited resources and access to capital, we prioritize development of certain product candidates, such decisions may prove to be wrong and may adversely affect our business. We or our affiliates are currently advancing multiple immune modulating antibodies, adoptive cell therapies (MiNK subsidiary) and vaccine adjuvants (SaponiQx subsidiary). Simultaneously advancing so many product candidates may create a significant strain on our limited human and financial resources. As a result, we may not be able to provide sufficient resources to any single product candidate to permit the successful development, approval and commercialization of such product candidate, causing material harm to our business. If, **as we announced in August 2023** due to our limited resources and access to capital, we prioritize development of certain product candidates **such as botensilimab / balstilimab in refractory MSS CRC** that ultimately ~~prove~~ **proves** to be unsuccessful, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired. Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Except for Prophage in Russia, we have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Although we successfully filed and had accepted the BLA for balstilimab in 2021, it was subsequently withdrawn, and we, as a company, have limited experience in filing and supporting the applications necessary to gain regulatory approvals and rely in part on third- party CROs and / or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved as well as evolving regulatory standards for products like ours. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, Premarket Approval, BLA or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or 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; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations; • 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 a product candidate's clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • **The FDA or comparable foreign regulatory authorities may disagree with our selected dosing regimen or regimens or determine that additional data are needed to support dose selection;** • the regulatory pathway being pursued is eliminated due to the unexpected or early full approval of a competing agent, as occurred with balstilimab; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an BLA or other submission or to obtain regulatory approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or those of our third- party manufacturers with which we contract for clinical and commercial supplies; 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. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial outcomes may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. **To** We expect the **extent that we seek** novel nature of our product candidates to create further challenges in obtaining regulatory approval **of**. As a result, our ability to **two novel** develop product candidates **at the same time on and an obtain accelerated basis, the risks and challenges associated with the regulatory review and approval process** may be **even more significantly** -- **significant impacted**. The general approach for FDA approval of a new biologic or drug is for sponsors to seek licensure or approval based on dispositive data from **adequate and** well- controlled, Phase 2 or 3 clinical trials of the relevant product candidate in the relevant patient population. Phase **2 or 3** clinical trials typically involve hundreds of patients dosed in well- controlled trials that have significant costs and **may** take years to complete. We may seek to utilize, among other strategies, FDA's accelerated approval program for our product candidates given the limited alternatives for treatments for certain rare diseases, cancer and autoimmune diseases, but the FDA may not agree with our plans. **Moreover** **The FDA may grant accelerated approval to a product for a serious or life- threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality , or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. For drugs granted accelerated approval, FDA generally requires sponsors to conduct, in a diligent manner, additional post- approval confirmatory studies to verify and describe the product's clinical benefit. The Food and Drug Omnibus Reform Act of 2022 gave FDA the authority to require, as appropriate, a post- approval study to be underway prior to granting accelerated approval. Failure to conduct required post- approval studies with due diligence, failure to confirm a clinical benefit during the post- approval studies, or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product approval on an expedited basis. even** **Even** if we do receive accelerated approval from the FDA for one or more of our product candidates, there is no guarantee that we will be able to successfully complete one or more confirmatory trials needed to obtain full approval. 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 approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials. Moreover, approval of genetic or biomarker diagnostic tests may be necessary in order to advance some of our product candidates to clinical trials or potential commercialization. In the future, regulatory agencies may require the development and approval of such tests, which can be expensive and time- consuming. Accordingly, the regulatory approval pathway for such product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, authorities may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could reduce the size of the potential market for our product candidates and materially harm the commercial prospects for our product candidates. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while 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 jurisdictions. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be deemed to have representative patients

enrolled or 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. We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. 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 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 product candidates may cause undesirable side effects 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. Undesirable side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. As is the case with many treatments for cancer and autoimmune diseases, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The treatment-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may delay and / or increase the costs of our development programs and harm our business, financial condition and prospects significantly. 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 our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates which could cause delay and / or increase costs;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy (“REMS”), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions which may cause delay and / or increase costs;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that 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 on our projected timelines and generate revenues. Our competitors may have superior products, manufacturing capability, selling and marketing expertise and / or financial and other resources. Our product candidates and the product candidates in development by our collaboration partners may fail because of competition from major pharmaceutical companies and specialized biotechnology companies that market products, or that are engaged in the development of product candidates and for the treatment cancer. Many of our competitors, including large pharmaceutical companies, have substantially greater financial, technical and other resources than we do, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Our competitors may:

- develop safer or more effective therapeutic drugs or vaccine adjuvants and other products;
- establish superior intellectual property positions;
- discover technologies that may result in medical insights or breakthroughs, which render our drugs or vaccine adjuvants obsolete, possibly before they generate any revenue, if ever;
- adversely affect our ability to recruit patients for our clinical trials;
- solidify partnerships or strategic acquisitions that may increase the competitive landscape;
- develop or commercialize their product candidates sooner than we commercialize our own, if ever; or
- implement more effective approaches to sales, marketing and patient assistance programs and capture some of our potential market share.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. There is no guarantee that our product candidates will be able to compete with potential future products being developed by our competitors including those described under “Item 1. Business – Competition.” Even if we obtain regulatory approval to market our product candidates, the availability and price of our competitors’ products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Even if our product candidates receive marketing approval, we, or others, may subsequently discover that such product is less effective than previously believed or causes undesirable side effects that were not previously identified and our

ability to market such product will be compromised. Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into such clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including: • withdrawal or limitation by regulatory authorities of approvals of such product; • seizure of the product by regulatory authorities; • recall of the product; • restrictions on the marketing of the product or the manufacturing process for any component thereof; • requirement by regulatory authorities of additional warnings on the label, such as a “ black box ” warning or contraindication; • requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients; • commitment to expensive additional safety studies prior to approval or post- marketing studies required by regulatory authorities of such product; • the product may become less competitive; • initiation of regulatory investigations and government enforcement actions; • initiation of legal action against us to hold us liable for harm caused to patients; and • harm to our reputation and resulting harm to physician or patient acceptance of our products. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition and results of operations. Even if our product candidates receive marketing approval, such products may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If any of our product candidates receive marketing approval, whether as single agents or in combination with other therapies, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and ~~doctors~~ **physicians** could continue to rely on these therapies. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any future products, if approved for commercial sale, will depend on a number of factors, including: • efficacy and potential advantages compared to alternative treatments; • the ability to offer our products, if approved, for sale at competitive prices; • convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the strength of marketing and distribution support; • sufficient third- party coverage or reimbursement, including of combination therapies; • adoption of a companion diagnostic and / or complementary diagnostic; and • the prevalence and severity of any side effects. Even if we are able to commercialize any product candidates, such products may not receive coverage or may become subject to unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives, all of which would harm our business. The legislation and regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or drug licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. In the United States, approval and reimbursement decisions are not linked directly, but there is increasing scrutiny from the Congress and regulatory authorities of the pricing of pharmaceutical products. 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 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, even if our product candidates obtain marketing approval. **The success** of our product candidates, if approved, depends on the availability of adequate coverage and reimbursement from third- party payors. In addition, because our product candidates represent new approaches to the treatment of the diseases they target, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates ~~or assure that coverage and reimbursement will be available for any product that we may develop~~. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, **private health insurers and other payors are critical to new product acceptance**. Significant uncertainty exists as to the coverage and reimbursement status of our product candidates for which we seek regulatory approval. ~~Our ability to commercialize any drugs successfully will depend, in part, on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.~~ Government authorities and **private** third- party payors, ~~such as private health insurers and health maintenance organizations,~~ decide which medications they will pay for and establish reimbursement levels. Obtaining and maintaining adequate reimbursement for our product candidates, if approved, may be difficult. Moreover, the process for determining whether a third- party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Further, one payor’s determination to provide coverage for a product **or decision regarding reimbursement** does not assure that other payors will also provide coverage and reimbursement for our products, if they are approved, ~~by third- party payors~~. A primary trend in the healthcare industry in the United States 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..... candidate for which we obtain marketing approval**. There may be significant delays in obtaining reimbursement for newly- approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable regulatory authorities outside ~~of~~ the United States. Moreover **Third- party payors may also seek, with** respect to an approved product, additional clinical evidence, including

comparative effectiveness evidence, that goes beyond the data required to obtain marketing approval **in order**. They may require **such evidence** to demonstrate clinical benefits and value **in specific patient populations or they may call for costly pharmaceutical studies to justify coverage and reimbursement or the level of reimbursement** relative to other therapies before covering our products. **If so, we may be required to conduct additional pharmacoeconomic studies beyond what is required for marketing approval.** Third party payors **providing coverage** may **nonetheless** manage utilization, **including** by implementing a drug formulary, establishing different copays for different drugs or requiring a prescriber to obtain prior authorization from the relevant third- party payor before a drug will be covered for a particular patient. We expect to experience pricing pressures in connection with the sale of our product candidates **due to eligibility**. **Eligibility** for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, regulatory approval, sale and distribution. **Interim reimbursement** **Reimbursement** levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used **;** may be based on reimbursement levels already set for lower cost drugs **and or** may be incorporated into existing payments for other services. **The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense and new products face increasing challenges in entering the market successfully.** Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or **requested by** private payors **in exchange for coverage** and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold **at lower prices**. **Our ability to commercialize our product candidates successfully may be adversely affected by discounts or rebates than that we are required to provide in order to ensure** the United States. Third- party payors often rely upon Medicare coverage policy of our products and **complete** payment limitations in setting their **the own marketplace.** **Accordingly, we cannot be sure that** reimbursement **will be available** policies. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for any approved drugs **drug** that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and **, if reimbursement is available, we cannot be sure as to the level of reimbursement and whether it will be adequate.** Coverage and reimbursement may impact the demand for, **our or overall financial condition the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.** The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our estimates of the prevalence of our target patient populations may be inaccurate. Cancer and autoimmune therapies are sometimes characterized as first- line, second- line, third- line and even fourth- line, and the FDA often approves new therapies initially only for last- line use. Initial approvals for new cancer and autoimmune therapies are often restricted to later lines of therapy, and in the case of cancer specifically, for patients with advanced or metastatic disease. Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases in a position to receive our therapies, if approved, are based on our current beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, input from key opinion leaders, patient foundations, or secondary market research databases, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Furthermore, regulators and payors may further narrow the therapy- accessible treatment population. Even if we obtain significant market share for our product candidates, because certain of the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. Prior to a product approval, we would need to build marketing, sales and commercial compliance functions, and as a company, we have no experience in marketing, selling and distributing products or adhering to commercial compliance standards and regulations. If we are unable to establish such capabilities or enter into agreements with third parties to perform such functions, we may not be able to generate product revenue. We currently have a small number of individuals who have capabilities to build our marketing, sales and commercial compliance functions, and we currently have no experience as a company performing such tasks. Developing an in- house marketing team, sales force and commercial compliance function will require significant capital expenditures, management resources and time and may ultimately prove to be unsuccessful. In the event we develop and deploy these capabilities, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain personnel qualified to perform these tasks. If we fail to market and sell our approved products in compliance with applicable laws and regulations, we may be subject to investigations and / or legal review and challenges which may result in fines or other penalties as well as causing distraction and reputational harm. In addition to establishing internal sales, marketing and distribution and commercial compliance capabilities, we may pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in- house sales and distribution capabilities or establish or maintain relationships with third- party collaborators to ensure compliance and support successful commercialization of any product in the United States or overseas. Our product candidates are uniquely manufactured. If we or any of our third- party manufacturers encounter difficulties in manufacturing our product candidates, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. The

manufacturing process used to produce certain of our product candidates is complex and novel and has not yet been validated for commercial production. As a result of these complexities, the cost to manufacture certain of our product candidates is potentially higher than traditional antibodies and the manufacturing process is less reliable and is more difficult to reproduce. Furthermore, our manufacturing process for certain of our product candidates has not been scaled up to commercial production. The actual cost to manufacture and process certain of our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of such product candidates. Our manufacturing process may be susceptible to logistical issues associated with the collection of materials sourced from various suppliers as well as shipment of the final product to clinical centers, manufacturing issues associated with interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in production batches, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in our manufacturing facilities in which our product candidates are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as we transition from late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. Although we continue to optimize our manufacturing process for our antibody product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of reagents and / or raw materials. We ultimately may not be successful in transferring our in-house clinical scale production system to any commercial scale manufacturing facilities that we establish ourselves or establish at a contract manufacturing organization (“ CMO ”). If we are unable to adequately validate or scale-up the manufacturing process for our product candidates with our contracted CMO, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us for all product candidates. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized. In November 2020, we entered into a long-term lease in Emeryville, CA for cGMP commercial manufacturing space. Construction of this end-to-end 83,000sqft. **000 square foot** GMP clinical and commercial biologics manufacturing facility in (from cell line development through Drug Product fill & finish, packaging and labeling) is **complete**. **It is** being commissioned for GMP manufacturing **but may take longer or be more costly than we anticipated**. We have never built, owned or operated a commercial manufacturing building, and there is no guarantee that we will be successful doing so. The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority **regulation and approval process**. **In complying with the manufacturing regulations of the FDA and 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, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements**. If we or our CMOs are unable to reliably produce products **in compliance with cGMPs and** to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product **in compliance with cGMPs and** to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. **Additionally, failure to comply with FDA or foreign regulatory authority requirements could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products**. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install unanticipated equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. We own and operate our own clinical scale manufacturing facility and infrastructure in addition to or in lieu of relying on CMOs for the manufacture of clinical supplies of our product candidates. This is costly and time-consuming. We own and operate the manufacturing pilot plant that supplies our antibody drug substance requirements for clinical proof-of-concept and other clinical studies. Any performance failure on the part of our existing facility could delay clinical development or marketing approval of our antibody programs. We have given our corporate QS- 21 STIMULON licensee, GSK, manufacturing rights for QS- 21 STIMULON for use in their product programs. We have retained the right to

manufacture QS- 21 for ourselves and third parties, although no other such programs are anticipated to bring us substantial revenues in the near future, if ever. **We Although we have the right to secure certain quantities of QS- 21 from GSK and we have some internal supply in- house and from a third- party supplier (s) and manufacturer (s), we currently do not have also contracted with a new third party to become an alternative long- term supply partner for some aspects of manufacturing this adjuvant.** In January 2019, we announced that the Bill & Melinda Gates Foundation awarded us a grant to develop an alternative, plant cell culture- based manufacturing process with the goal of ensuring the continuous future supply of QS- 21 STIMULON adjuvant. While we are pursuing this in partnership with Phyton Biotech and Ginkgo Bioworks, there is no guarantee that we will be successful in developing a scalable process. **In February 2024, SaponiQx and Ginkgo announced a 5- year contract totaling up to \$ 31 million from the DTRA to discover and develop next- generation vaccine adjuvants, but we cannot be certain that we will be successful with this contract in developing promising new adjuvants.** We also may encounter problems hiring and retaining the experienced scientific, quality- control and manufacturing personnel needed to operate our clinical and commercial manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. Any problems in our manufacturing process or facilities, or that of our licensees and suppliers, could 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. The FDA, the EMA and other foreign 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, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the relevant 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 product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet our clinical and regulatory timelines, and market demand for our products. We are dependent on suppliers for some of our components and materials used to manufacture our product candidates. We currently depend on suppliers for some of the components necessary for our product candidates. We cannot be sure that these suppliers will remain in business, that they will be able to meet our supply needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. There are, in general, relatively few alternative sources of supply for these components. These suppliers may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from a supplier or manufacturing location could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay and additional costs. While we seek to maintain adequate inventory of the materials used to manufacture our products, any interruption or delay in the supply of materials, or our inability to obtain materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders. In addition, as part of the FDA' s approval of our product candidates, we will also require FDA approval of the individual components of our process, which include the manufacturing processes and facilities of our suppliers. Our reliance on these suppliers subjects us to a number of risks that could harm our business, and financial condition, including, among other things: interruption of product candidate or commercial supply resulting from modifications to or discontinuation of a supplier' s operations; delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier' s variation in a component; a lack of long- term supply arrangements for key components with our suppliers; inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms; difficulty and cost associated with locating and qualifying alternative suppliers for our components and precursor cells in a timely manner; production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications; delay in delivery due to our suppliers prioritizing other customer orders over ours; and fluctuation in delivery by our suppliers due to changes in demand from us or their other customers. If any of these risks materialize, our manufacturing costs could significantly increase and our ability to meet clinical and commercial demand for our products could be impacted. We rely on third parties for the manufacture of clinical supplies of certain of our product candidates and expect to rely on third parties for commercial supplies of any approved product candidates until our new commercial manufacturing facility is completed and qualified. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We expect to rely on third- party manufacturers for the manufacture of commercial supplies of our drug candidates until our own commercial manufacturing facility is completed and qualified. At present, we do not have long- term supply agreements with all of the vendors needed to produce our product candidates for commercial sale and we may be unable to establish such agreements with third- party manufacturers or do so on acceptable terms. The agreements that we do have in place with our third- party manufacturers obligate us to make significant non- refundable deposits to reserve manufacturing slots prior to the receipt of marketing approval for our product candidates. Additionally, if our product candidates are approved, we will be required to make minimum purchases and will have limited ability to purchase product in excess of our forecasted needs. As a result, if product sales fall below our minimum purchase obligations, we will be obligated to purchase more product than we can successfully sell, and if product demand exceeds the amount that we can purchase from our manufacturers, we will have to forgo some product sales unless and until we are able to manufacture commercial supplies at our own facility. Either of these events may materially harm our financial prospects. Finally, reliance on third- party manufacturers entails additional risks, including: • reliance on the third

party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third party; • the possible failure of the third party to manufacture our drug candidate according to our schedule, or at all, including if the third-party manufacturer gives greater priority to the supply of other drugs over our drug candidates, or otherwise does not satisfactorily perform according to the terms of the manufacturing agreement; • staffing shortages, equipment malfunctions, power outages, natural or man-made calamities, geopolitical disputes, or other general disruptions experienced by our third-party manufacturers to their respective operations and other general problems with a multi-step manufacturing process; • the possible misappropriation or disclosure by the third party or others of our proprietary information, including our trade secrets and know-how; and • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. As is common in the industry, the agreements that we have in place with our third-party suppliers and manufacturers significantly limit the liability of such suppliers and manufacturers for failing to supply or manufacture, as applicable, our product candidates pursuant to the terms of our agreements, or as required by applicable regulation or law. As a result, if we suffer losses due to our suppliers or manufacturers failure to perform, we will have limited remedies available against such suppliers and manufacturers and are unlikely to be able to recover such losses from them. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Facilities used by our third-party manufacturers must be inspected by the FDA before potential approval of the drug candidate. Similar regulations apply to manufacturers of our drug candidates for use or sale in foreign countries. Until our own commercial manufacturing facility is completed and validated, we will not control the manufacturing process and will be completely dependent on our third-party manufacturers for compliance with the applicable regulatory requirements for the commercial manufacture of our drug candidates. If our manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays in obtaining approval for the applicable drug candidate as alternative qualified manufacturing facilities may not be available on a timely basis or at all. In addition, our manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs or other regulatory requirements could result in sanctions being imposed on us or the contract manufacturer, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of our drug candidates and have a material adverse impact on our business, financial condition and results of operations as well as cause reputational damage. Any drugs that we may develop may compete with other drug candidates and drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Our current and future dependence upon others for the commercial manufacture of our drug candidates or drugs until our own facility is completed and qualified may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis. We are dependent upon our collaborations with BMS, Gilead, Incyte and ~~Betta Pharmaceuticals Co., Ltd. (“Betta Pharmaceuticals”)~~ to further develop and commercialize certain of our antibody programs. If we or BMS, Gilead, Incyte or ~~Betta Pharmaceuticals~~ fail to perform as expected, the potential for us to generate future revenues under such collaborations could be significantly reduced, the development and / or commercialization of these antibodies may be terminated or substantially delayed, and our business could be adversely affected. In May 2021, we entered into a License, Development and Commercialization Agreement with BMS to collaborate on the development and commercialization of our anti-TIGIT bispecific antibody program AGEN1777. Pursuant to the license agreement, we received a non-refundable upfront cash payment of \$ 200. 0 million and are eligible to receive up to \$ 1. 36 billion in aggregate development, regulatory and commercial milestone payments plus tiered royalties. Additionally, we hold the option to co-fund a minority of the global development costs of products containing AGEN1777 or its derivatives, in exchange for increased tiered royalties on U. S. net sales of co-funded products. There can be no assurance that any of the development, regulatory or sales milestones will be achieved, or that we will receive any future milestone or royalty payments under the license agreement. BMS’ s activities will be influenced by, among other things, the efforts and allocation of resources by BMS, which we cannot control. If BMS does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval, and commercialization efforts related to the licensed antibodies could be delayed or terminated. In addition, our license with BMS may be unsuccessful due to other factors, including, without limitation, the following: • BMS may terminate the agreement or any individual program for convenience upon 180 days’ notice; • BMS may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to our licensed antibodies; and • BMS may choose not to develop and commercialize antibody products, if any, in all relevant markets or for one or more indications, if at all. In December 2018, we entered into a series of agreements with Gilead to collaborate on the development and commercialization of up to five novel I- O therapies. Pursuant to the collaboration agreements, Gilead received (i) worldwide exclusive rights to AGEN1423, a bispecific antibody, (ii) the exclusive option to license exclusively AGEN1223, a bispecific antibody, and AGEN2373, a monospecific antibody, and (iii) the right of first negotiation for two additional, undisclosed programs. Gilead had the exclusive right to develop and commercialize AGEN1423, and we were eligible to receive potential development and commercial milestones of up to \$ 552. 5 million in the aggregate. In November 2020, Gilead elected to return AGEN1423 to us and voluntarily terminated the license agreement effective as of February 4, 2021. In October of 2021, Gilead elected to terminate the option to license AGEN1223. The option agreement for AGEN2373 remains in place, and we are responsible for developing the program up to the option decision point, at which time Gilead may acquire exclusive rights to each program on option exercise. If Gilead exercises an option for AGEN2373, it would be required to pay an upfront option

exercise fee of \$ 50.0 million. Following any option exercise, we would be eligible to receive additional development and commercial milestones of up to \$ 520.0 million in the aggregate, as well as tiered royalty payments on aggregate net sales ranging from the high single digit to mid-teen percent, subject to certain reductions under certain circumstances. We will have the right to opt-in to share Gilead's development and commercialization costs in the United States for AGEN2373 in exchange for a profit (loss) share on a 50:50 basis and revised milestone payments. There is no guarantee that we will be able to successfully advance the AGEN2373 option program to the option decision point, and, even if we do, there is no guarantee that Gilead will exercise its option. If Gilead does not pursue a licensed or optioned program, there is no guarantee that we will be able to advance any such program ourselves or with another partner. In February 2017, we amended the terms of our collaboration agreement with Incyte to, among other things, convert the GTR and OX40 programs from profit-share programs, where we and Incyte shared all costs and profits on a 50:50 basis, to royalty-bearing programs, where Incyte funds 100% of the costs and we are eligible for potential milestones and royalties. In addition, the profit-share programs relating to TIGIT and one undisclosed target were removed from the collaboration, with TIGIT reverting to Agenus and the undisclosed target reverting to Incyte, each with a potential 15% royalty to the other party on any global net sales. The remaining three royalty-bearing programs in the collaboration targeting TIM-3, LAG-3 and one undisclosed target remain unchanged, and there are no more profit-share programs under the collaboration. For each program in the collaboration, Incyte has exclusive rights and all decision-making authority for manufacturing, clinical development and commercialization. Accordingly, the timely and successful completion by Incyte of clinical development and commercialization activities will significantly affect the timing and amount of any royalties or milestones we may receive under the collaboration agreement. In addition, in March 2017 we transferred manufacturing responsibilities to Incyte for antibodies under that collaboration. Any delays or weaknesses in the ability of Incyte to successfully manufacture could have an adverse impact on those programs. Incyte's activities will be influenced by, among other things, the efforts and allocation of resources by Incyte, which we cannot control. If Incyte does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval, and commercialization efforts related to antibodies under the collaboration could be delayed or terminated. There can be no assurance that any of the development, regulatory or sales milestones will be achieved, or that we will receive any future milestone or royalty payments under the collaboration agreement. In September 2018, we sold to XOMA a portion of the royalties and milestones we are entitled to receive from Incyte. **In October 2022, Incyte has provided notice of their intent to terminate terminated the OX40 program, effective October 2023, and has notified us of their intent to terminate both the GTR program and undisclosed program, effective May 2024. Upon termination, the rights to the OX40, GTR, and undisclosed programs revert back to us.** In addition, our collaboration with Incyte may be unsuccessful due to other factors, including, without limitation, the following: • Incyte may terminate the agreement or any individual program for convenience upon 12 months' notice; • Incyte has control over the development of assets in the collaboration; • Incyte may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to our collaboration; • Incyte may choose not to develop and commercialize antibody products, if any, in all relevant markets or for one or more indications, if at all; and • If Incyte is acquired during the term of our collaboration, the acquirer may have competing programs or different strategic priorities that could cause it to reduce its commitment to our collaboration. If Incyte terminates our collaboration agreement, we may need to raise additional capital and may need to identify and come to agreement with another collaboration partner to advance certain of our antibody programs. Even if we are able to find another partner, this effort could cause delays in our timelines and / or additional expenses, which could adversely affect our business prospects and the future of our antibody product candidates under the collaboration. In June 2020, we entered into a license and collaboration agreement with Betta Pharmaceuticals to collaborate on the development and commercialization of balstilimab and zalifrelimab in greater China. Pursuant to the license and collaboration agreement, Betta Pharmaceuticals received an exclusive license to develop, manufacture and commercialize zalifrelimab and balstilimab in all fields (other than intravesical delivery) in greater China. Under the agreement, Betta Pharmaceuticals is responsible for all of the development, regulatory approval, manufacturing and commercialization costs in greater China. As part of the collaboration, Betta Pharma made an upfront cash payment of \$ 15.0 million and agreed to make up to \$ 100.0 million in aggregate milestone payments plus tiered royalties on net sales of zalifrelimab and balstilimab. Royalties range from mid-single digit to low-twenties percent, subject to certain reductions under certain circumstances. Accordingly, the timely and successful completion by Betta Pharmaceuticals of development, regulatory approval, manufacturing and commercialization activities will significantly affect the timing and amount of any milestones or royalties we may receive from Betta Pharmaceuticals. Betta Pharmaceuticals' activities will be influenced by, among other things, the efforts and allocation of resources by Betta Pharmaceuticals, which we cannot control. In addition, our collaboration with Betta Pharmaceuticals may be unsuccessful due to other factors, including, without limitation, that Betta Pharmaceuticals: • may terminate any of the license and collaboration agreement for convenience upon 90 days' notice; • has control over the development, regulatory approval, manufacturing and commercialization of balstilimab and zalifrelimab in greater China; • may change the focus of its business efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to balstilimab and zalifrelimab; and • may choose not to develop and commercialize balstilimab and zalifrelimab in all markets within greater China or for one or more indications, if at all. Additionally, the US-China relationship has deteriorated in recent years and, further deterioration may impact the ability of Agenus and Betta Pharmaceuticals to successfully collaborate. Failure to enter into and / or maintain additional significant licensing, distribution and / or collaboration agreements in a timely manner and on favorable terms to us may hinder or cause us to cease our efforts to develop and commercialize our product candidates, increase our development timelines, and / or increase our need to rely on partnering or financing mechanisms, such as sales of debt or equity securities, to fund our operations and continue our current and anticipated programs. Even if we enter into and maintain such agreements, they may not prove successful, and / or we may not receive

significant payments from agreements. Part of our strategy is to develop and commercialize many of our product candidates by continuing or entering into arrangements with academic, government, or corporate collaborators and licensees. Our success depends on our ability to negotiate such agreements on favorable terms and on the success of the other parties in performing research, pre-clinical and clinical testing, completing regulatory applications, and commercializing product candidates. Our research, development, regulatory and commercialization efforts with respect to antibody candidates from our technology platforms are, in part, contingent upon the participation of institutional and corporate collaborators. For example, in February 2015, we began a broad collaboration with Incyte to pursue the discovery and development of antibodies, in December 2018 we entered into a partnership with Gilead relating to five of our antibody programs and in May 2021 we entered into a license agreement with BMS relating to our anti-TIGIT bispecific antibody program. Disagreements or the failure of either party to perform satisfactorily could have an adverse impact on these programs. In December 2022, we terminated our collaboration agreement with Recepta for the development of balstilimab and zalifrelimab antibodies in certain South American countries. As part of that termination, Agenus and Recepta settled lawsuits that had been pending in the United States and Brazil related to disputes arising from the companies' collaboration agreement and intellectual property rights granted under the collaboration agreement were returned to Agenus. Our ability to advance our antibody programs depends in part on such collaborations. In addition, from time to time we engage in efforts to enter into licensing, distribution and / or collaboration agreements with one or more pharmaceutical or biotechnology companies to assist us with development and / or commercialization of our other product candidates. Any licensing, distribution and / or collaborations agreements, we enter into, including those with BMS, Gilead and Incyte, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our current or future collaborations do not result in the successful discovery, development, approval and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product development, regulatory approval and commercialization described herein also apply to the activities of our therapeutic collaborators. Additionally, if one of our collaborators, such as BMS, Incyte or Gilead, terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected. Collaborations are complex and time-consuming to negotiate, document and execute. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate

revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates. We depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. Such reliance obligates us to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs. We rely heavily on third parties over the course of our clinical trials, and, as a result, have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials or at a particular site may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or sites, or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with biologic product produced under cGMP requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process and increase the costs of such trials. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. The persons engaged by third parties conducting our clinical trials are not our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not such persons devote sufficient time and resources to our ongoing pre-clinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs as we are required to do as part of our sponsor oversight, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Risks Related to Government Regulations The regulatory approval process for our product candidates in the United States, European Union and other jurisdictions is currently uncertain and will be 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, marketing and distribution of drug products, including biologics, are subject to extensive regulation by the FDA in the United States and regulatory authorities in other jurisdictions. We are not permitted to market any biological product in the United States for commercial use until we receive a biologics license from the FDA. Although we submitted and had accepted for filing the BLA for balsilimab, we subsequently voluntarily withdrew such application following a competitor's full approval. As a result, we have not submitted a BLA for any product candidate that was approved by the FDA. Even after submission of a BLA for one or more of our product candidates, we expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and we may never obtain regulatory approval for our product candidates. The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates. Although the regulatory framework for approving immunotherapy products is evolving, the general approach for FDA approval of a new biologic or drug has historically been to provide dispositive data from two well-controlled, Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We intend to utilize an accelerated approval approach for our product candidates given the limited alternatives for cancer treatments, but the FDA may not agree with our plans. In addition, our clinical trial results may also not support approval of our product candidates. Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the **FDA or comparable foreign regulatory**

authorities may disagree with our selected dosing regimen or regimens or determine that additional data are needed to support dose selection; • the data collected from clinical trials of our product candidates may be deemed by the FDA or comparable foreign regulatory authorities to be insufficient 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 or find deficiencies with the manufacturing processes and controls or facilities of third- party manufacturers with which we contract for clinical and commercial supplies or any facilities that we may operate in the future; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner that could render our clinical data insufficient for approval. The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, which may be difficult to predict. The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products, such as antibodies, adjuvants and adoptive cell therapies. Agencies at both the federal and state level in the United States, as well as the U. S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of antibodies, vaccine adjuvants or adoptive cell therapies products may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. Similarly, the EMA governs the development of antibodies, vaccine adjuvants and adoptive cell therapies in the European Union and may issue new guidelines concerning the development and marketing authorization for such products and require that we comply with these new guidelines. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post- approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all. Breakthrough Therapy Designation or Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States. We may seek a Breakthrough Therapy Designation (" BTD") for some of our product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a BTD for a product candidate may not result in a faster development process, review or approval compared to ~~therapies considered for approval under~~ conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, ~~even the FDA may withdraw Fast Track or Breakthrough Therapy designation if it believes~~ **one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates ~~the designation is~~ no longer supported by data from** ~~meet the conditions for qualification or our clinical development program~~ **decide that the time period for FDA review or approval will not be shortened.** If a therapy is intended for the treatment of a serious or life- threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation (" FTD"). The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure our stockholders that the FDA would decide to grant it. We may not experience a faster development process, review or approval compared to conventional FDA procedures for the product candidate for which we have received, or may receive in the future, FTD. The FDA may withdraw FTD if it believes that the designation is no longer supported by data from our clinical development program. FTD alone does not guarantee qualification for the FDA' s priority review procedures. ~~We~~ **Neither FTD nor BTD changes the scientific or medical standards for approval or the quality of evidence necessary to support approval. In April 2023, we** received FTD for investigation of ~~balstilimab- botensilimab~~ in combination with ~~zalifrelimab- balstilimab~~ for the treatment of patients with relapsed or refractory metastatic **MSS CRC** ~~cervical cancer and balstilimab alone for the treatment of cervical cancer, and we intend to apply for such designation for our other product candidates in~~ **patients** the future. The FDA subsequently determined it was no longer appropriate to review the BLA for balstilimab (alone) for accelerated approval in view of its grant of full approval to pembrolizumab and recommended that we withdraw our BLA. We subsequently made a strategic decision to withdraw our BLA for balstilimab (alone). The decision to withdraw the BLA does not change the development plans for balstilimab combinations, including plans for ~~balstilimab in combination with~~ **non** ~~botensilimab, our Fe-~~ **active liver metastases enhanced CTLA- 4 antibody.** We may seek priority review designation for one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process. If the FDA

determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness **over available therapies**, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA **is to review an take action on the marketing application is within six months of the 60- day filing date**, rather than the standard review period of ten months **from filing**. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. **A. Moreover, a priority review designation does not necessarily result in expedited development change the scientific or medical standards, or for regulatory review or approval process or the quality of evidence necessarily -- necessary confer any advantage with respect to support approval compared to conventional FDA procedures.** Receiving priority review from the FDA does not guarantee approval within the six- month review cycle or at all. We may not be able to obtain or maintain orphan drug designations from the FDA for our current and future product candidates, as applicable. Our strategy includes filing for orphan drug designation where available for our product candidates, but thus far, our applications for orphan drug designation with respect to balstilimab and zalifrelimab have been rejected. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user- fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application, or NDA, or BLA, to market the same drug or 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 where the original manufacturer is unable to assure sufficient product quantity. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan- designated disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan- designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may again seek orphan drug designation for our product candidates, we may never receive such designations. Our **relationships business operations and current and future arrangements with contractors, investigators, healthcare providers and physicians and professionals, consultants, third- party payors will be subject to applicable anti- kickback, fraud patient organizations and customers may abuse and other healthcare laws and regulations, which could expose us to investigations, litigation, criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Our business operations and current and future arrangements with contractors, investigators, Healthcare healthcare providers professionals, physicians and consultants, third- party payors, patient organizations, in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third- party payors and customers can may expose us pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market without limitation, sell, and distribute our product candidates, if approved. Such laws, some of which may apply only after our products are approved for marketing, include:**

- **the federal healthcare Anti-anti- Kickback kickback Statute statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, either the referral of and- an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made, under federal and state healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the anti- kickback statute or specific intent to violate it in order to have committed a violation;**
- **the federal False Claims Act (the-“ FCA ”), which may constrain the business imposes criminal and civil penalties on individuals or entities or for knowingly presenting financial arrangements and relationships through which such companies sell, or causing to be presented market and distribute pharmaceutical products. In particular, to the promotion federal government, sales and claims for payment that are false or fraudulent or marketing- -- making of healthcare items a false statement to avoid, decrease, or conceal and- an services- obligation to pay money to the federal government and actions under the FCA may be brought by private whistleblowers as well as certain business arrangements in the healthcare industry government. In addition, are subject to extensive the government may assert that a claim including items and services resulting from a violation of the federal anti- kickback statute constitutes a false or fraudulent claim for the purposes of the FCA;**
- **the federal civil monetary penalties laws designed to prevent fraud- , which impose civil fines kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare**

laws and regulations laws that may affect our ability to operate include, but are not limited to: • the federal Anti-Kickback Statute, which prohibits, among other things, **the knowingly and willfully soliciting, receiving, offering or paying any transfer of remuneration** (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal **Medicare state** healthcare program **beneficiary**; such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; • federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery; • the federal anti-inducement law, prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know **it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of items or services reimbursable by a federal Medicare or a state governmental healthcare program**; • federal laws, including the Medicaid Drug Rebate Program, 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 government healthcare programs; • the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), **as amended**, which **imposes** created new federal criminal statutes that prohibit knowingly and willfully **civil liability for** executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain **and also establishes requirements related to the privacy security**, by means of **and transmission or individually identifiable health information which apply to many healthcare providers, physicians and third-party payors with whom we interact**; • **the federal false statement statute prohibits** or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements- **statement** in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it; • HIPAA, **the federal anti-kickback prohibition known as amended-Eliminating Kickbacks in Recovery Act, or EKRA, which prohibits certain payments related to referrals of patients to certain providers (recovery homes, clinical treatment facilities, and laboratories) and applies to services reimbursed by the private Health health plans as well as government Information Technology for Economic and Clinical Health health care programs**; • Act of 2009 (“HITECH”), and their- **the FDCA** respective implementing regulations, which impose, among other things, **strictly regulates drug product requirements on certain covered healthcare providers, health plans, and medical device marketing, prohibits manufacturers from marketing such products** healthcare clearinghouses as well as their respective business associates that perform services for **off-label** them that involve the use or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions; • the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act, and its implementing regulations **regulates**, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services (“HHS”), information related to payments or other- **the distribution** “transfers of **samples value**” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and other categories of healthcare providers, as well as ownership and investment interests held by physicians and their immediate family members; • the U. S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; • federal laws, such as the Medicaid Drug Rebate Program, 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 governmental healthcare programs**; • federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • the so-called federal “sunshine law” or **Open Payments which requires manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare & Medicaid Services information related to payments and other “transfers of value” to teaching hospitals, physicians and other healthcare practitioners, as well as ownership and investment interests held by physicians and their**

immediate family members; and • analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that **which regulate interaction between pharmaceutical companies and healthcare providers,** require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, **or otherwise restrict payments that may be made to healthcare providers;** state and foreign laws that require drug manufacturers **pharmaceutical companies** to report information **on** related to payments and other transfers of value to physicians and other healthcare providers or, marketing expenditures; **or pricing information** and **/or require licensing of sales representatives.** state **State** and foreign laws **also governing**--- **govern** the privacy and security of health information in **certain some** circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. **The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's financial resources and management's attention away from the business. On January 31, 2019, the HHS and HHS Office of Inspector General proposed an amendment to one of the existing Anti-Kickback Statute safe harbors (42 C. F. R. 1001.952 (h)) which would prohibit certain pharmaceutical manufacturers from offering rebates to pharmacy benefit managers ("PBMs"), in the Medicare Part D and Medicaid managed care programs. The proposed amendment would remove protection for "discounts" from Anti-Kickback enforcement action and would include criminal and civil penalties for knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward the referral of business reimbursable under federal health care programs. At the same time, HHS also proposed to create a new safe harbor to protect point-of-sale discounts that drug manufacturers provide directly to patients and adds another safe harbor to protect certain administrative fees paid by manufacturers to PBMs. The revisions to the federal Anti-Kickback regulations referenced above were initially scheduled to take effect in 2022 but have now been delayed to 2027 certain Congressional actions signed into law by President Biden. The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. We have adopted and revised our code of business conduct and ethics which we review and update on a periodic basis, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If 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, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, **among amount** other foreign laws. **We have adopted and revised our code of business conduct and ethics which we review and update on a periodic basis, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare and other laws and regulations will involve substantial costs. Given the breadth of the laws and regulations and narrowness of any exceptions, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, regulatory authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations, including our consulting agreements and other relationships with healthcare providers. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to actions including the imposition of civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, individual imprisonment, contractual****

damages, reputational harm, diminished profits and future earnings, additional reporting requirements, or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Even if we receive regulatory approval of any product candidates or therapies, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, **limit how we market and manufacture our products,** and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, export, import, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. **Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.** Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved 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 risk evaluation and mitigation strategies, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration. The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; • fines, warning letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; • product seizure or detention or refusal to permit the import or export of our product candidates; and • injunctions or the imposition of civil or criminal penalties. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are in development, as well as those placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. 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. 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 which would adversely affect our business, prospects and ability to achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. ~~For example, policy changes by the new presidential administration may impact our business and industry. The previous administration took several executive actions imposing burdens on, or otherwise materially delaying, the FDA's ability to engage in routine regulatory and oversight activities, such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. While the new administration has revoked a number of the executive orders imposing these burdens or delays, it is difficult to predict what executive actions the new administration may implement, and the extent to which such action may impact the FDA's ability to exercise its regulatory authority.~~ If any executive **such** actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. **Healthcare insurance coverage and reimbursement may be..... containment initiatives and additional legislative changes.** Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations. Changes in **statutes,** regulations, ~~statutes~~ or the interpretation of **existing regulations the same** could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the United States, there have been and continue to be a number of ~~legislative~~ initiatives to **contain reform**

delivery of, or payment for healthcare, which include initiatives to reduce the costs— cost of healthcare generally and drugs specifically. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (“ACA”), which substantially expanded healthcare coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the way coverage and reimbursement of drug products under government healthcare programs as well as is financed by both governmental and private insurers, and significantly impacts the U. S. pharmaceutical industry. The ACA, among other things, subjects biological products, a number of which have focused on regulation of prices or payment for drug products. Drug pricing and payment reform has been to potential competition by lower-cost biosimilars, addresses a focus of new methodology by which rebates owed by manufacturers under the Biden Administration. For example, federal legislation enacted in 2021 eliminates a statutory cap on Medicaid Drug Rebate Program are calculated for drugs— drug that are inhaled, infused, instilled, implanted or injected; increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program rebates effective January 1, 2024. As another example, the Inflation Reduction Act (“IRA”) of 2022 includes a number of changes intended to individuals enrolled address rising prescription drug prices in Medicaid Medicare Parts B managed care organizations, establishes annual fees and taxes—D, with varying implementation dates. These changes include caps on manufacturers Medicare Part D out-of-pocket costs, Medicare Part B and Part D drugs— drug, and price inflation creates— rebates, a new Medicare Part D manufacturer discount drug program (replacing the ACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with the first list of drugs announced in 2023). As another example, in 2022, subsequent to the enactment of the IRA, the Biden administration released an executive order directing the HHS to report on how the Center for Medicare and Medicaid Innovation (“CMMI”) could be leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. The report was issued in 2023 and proposed various models that CMMI is currently developing which seek manufacturers must agree to lower offer 50% (increased to 70% pursuant to the cost Bipartisan Budget Act of 2018— drugs, effective— promote accessibility and improve quality of care. Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the ACA, tax reform legislation as was of enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019) point and, in 2021, the U. S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection of sale discounts off-negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for traditional the manufacturer’s outpatient drugs to be covered under Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Beyond Pursuant to court order, the ACA removal was delayed and recent legislation imposed a moratorium on implementation of the rule until January 2032. As another example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups. Recently, there it puts further pressure on has been considerable public and government scrutiny of pharmaceutical pricing and proposals manufacturers in setting prices. Oregon has passed a similar law, requiring pharmaceutical manufacturers to disclose address the perceived high cost of pharmaceuticals components, and other states are likely to follow. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect to experience pricing pressures in connection with the sale of any of our product candidates, if and when approved for marketing, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes. In addition, other legislative changes have been ongoing adopted that could have an adverse effect upon, and could prevent, our product candidates’ commercial success. For example, the Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through 2032. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health care programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenues. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. We cannot predict the ultimate content, timing or effect of any federal and state reform efforts, including a number of recent actions. Some recent healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare, accelerated or advanced Medicare payments to healthcare providers and payments to providers for COVID-19-related expenses and lost revenues. Other reform efforts affect pricing or payment for drug products, which was a focus of the Trump Administration. For example, in May of 2018, President Trump and the Secretary of HHS released a “blueprint” for lowering prescription drug prices and out-of-pocket costs, which contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of product candidates paid by consumers. Subsequent to the ACA, the Medicaid Drug Rebate Program was subject to statutory and regulatory changes and the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap increased from 50% to 70%. A number of regulations were issued in late 2020 and early 2021, some of which

have been and may continue to be subject to scrutiny and legal challenge. For example, courts temporarily enjoined a new “most favored nation” payment model for select drugs covered under Medicare Part B that was to take effect on January 1, 2021 and would have limited payment based on international drug price and CMS subsequently indicated that the rule would not be implemented without further rulemaking. The nature and scope of health care reform remains uncertain. The Department of Justice under the Biden administration informed the Supreme Court in connection with case *Texas v. Azar*, that the government no longer takes the position that the individual mandate is unconstitutional and cannot be severed from the rest of the ACA. President Biden temporarily halted implementation of new rules issued immediately prior to the transition that had not yet taken effect (which included a number of health care reforms) to allow for review by the new administration. By Executive Order, President Biden directed federal agencies to reconsider rules and other policies that limit Americans’ access to health care and consider actions that will protect and strengthen that access. With respect to prescription drugs specifically, President Biden supported reforms to lower drug prices during his campaign for the presidency. The American Rescue Plan Act of 2021, comprehensive COVID-19 relief legislation recently enacted under the Biden administration, includes a number of healthcare-related provisions, such as support to rural health care providers, increased tax subsidies for health insurance purchased through insurance exchange marketplaces, financial incentives to states to expand Medicaid programs and elimination of the Medicaid drug rebate cap effective in 2024. Moreover, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no **assurance** obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy. We expect that additional foreign, federal and **or** state healthcare reform measures will be adopted in the **not adversely affect our** future **business**, any of which could limit the amounts that federal and **financial** state governments will pay for healthcare products and services, which could result **results** in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states. We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of pharmaceutical products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures. Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician’s employer, his or her competent professional organization and / or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. In addition, in most foreign countries, including the European Economic Area, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected. European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information. The collection and use of personal health data in the European Union (“EU”), was

previously governed by the provisions of the Data Protection Directive, which has been replaced by the General Data Protection Regulation 2016 / 679 (“ GDPR ”) as of May 2018. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area, (“ EEA ”), including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals’ requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record- keeping. The GDPR substantially increases the penalties to which we could be subject in the event of any non- compliance, including fines of up to 10 million Euros or up to 2 % of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20 million Euros or up to 4 % of our total worldwide annual turnover for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. In particular, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EU. Also, in the field of handling genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. With respect to our clinical trials in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States in compliance with European data protection laws including the GDPR. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi- national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations. Because we have operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The 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. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. We, directly or through our CROs, are conducting clinical trials in countries that Transparency International has identified as “ perceived as more corrupt ”, including, Brazil, Chile, Georgia, Russia and Ukraine. 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. As we expand our presence outside of the United States, we must 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 civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA’ s accounting provisions. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions **(including sanctions against Russia following their invasion of Ukraine)**, and other trade laws and regulations. We can face serious consequences for violations. Among other matters, U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We also expect our non- U. S. activities to increase in time. We engage third parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities

of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. The Russian invasion of Ukraine has resulted in new and expanded U. S. and EU sanctions against Russia which have impacted the conduct of business with Russian entities, **has** and may **continue to** impact existing sales of services within Russia by our wholly- owned, independently- operated subsidiary, Atlant Clinical, a CRO based in Moscow, Russia, which we acquired in 2020. Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes and the impact of crises that hinder its operations, such as COVID- 19. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently from December 22, 2018 to January 25, 2019, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If we do not comply with environmental laws and regulations, we may incur significant costs and potential disruption to our business. We use or may use hazardous, infectious, and radioactive materials, and recombinant DNA in our operations, which have the potential of being harmful to human health and safety or the environment. We store these hazardous (flammable, corrosive, toxic), infectious, and radioactive materials, and various wastes resulting from their use, at our facilities pending use and ultimate disposal. We are subject to a variety of federal, state, and local laws and regulations governing use, generation, storage, handling, and disposal of these materials. We may incur significant costs complying with both current and future environmental health and safety laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration, the Environmental Protection Agency, the Drug Enforcement Agency, the Department of Transportation, the Centers for Disease Control and Prevention, the National Institutes of Health, the International Air Transportation Association, and various state and local agencies. At any time, one or more of the aforementioned agencies could adopt regulations that may affect our operations. We are also subject to regulation under the Toxic Substances Control Act and the Resource Conservation Development programs. Although we believe that our current procedures and programs for handling, storage, and disposal of these materials comply with federal, state, and local laws and regulations, we cannot eliminate the risk of accidents involving contamination from these materials. Although we have a workers' compensation liability policy, we could be held liable for resulting damages in the event of an accident or accidental release, and such damages could be substantially in excess of any available insurance coverage and could substantially disrupt our business. If we or our employees, independent contractors, consultants, commercial partners and vendors fail to comply with laws or regulations, it could adversely impact our reputation, business and stock price. We are exposed to the risk of employee fraud or other misconduct our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by employees could include intentional and / or negligent failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health care fraud and abuse, transparency, and / or data privacy laws and regulations (including the California Consumer Privacy Act) and security laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices; to promote transparency; and to protect the privacy and security of patient data. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. While we have adopted a corporate compliance program, we may not be able to protect against all potential issues of noncompliance. Efforts to ensure that our business complies with all applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable laws and regulations. Employee misconduct could also involve the improper use or disclosure of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. We may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert the attention of our management team. We currently have research and development operations in the United Kingdom (" UK ") and clinical operations in ~~western and~~ eastern Europe, and we expect to pursue pathways to develop and commercialize our product candidates in both U. S. and ex- U. S. jurisdictions. Various risks associated with foreign operations may impact our success.

Possible risks of foreign operations include fluctuations in the value of foreign and domestic currencies, requirements to comply with various jurisdictional requirements such as data privacy regulations, disruptions in the import, export, and transportation of patient tumors and our products or product candidates, the product and service needs of foreign customers, difficulties in building and managing foreign relationships, the performance of our licensees or collaborators, geopolitical instability, unexpected regulatory, economic, or political changes in foreign and domestic markets, including without limitation any resulting from the UK's withdrawal from the EU or our current political regime, and limitations on the flexibility of our operations and costs imposed by local labor laws. Although we do not anticipate a material impact to our global business operations, our subsidiary Atlant Clinical has employees in Russia who could be adversely affected by the impact of the Russian invasion of Ukraine. The war may impact staffing and adversely impact existing business, new business development, the completion of projects and adherence to timelines by affected employees. The exit of the UK from the European Union may materially affect the regulatory regime that governs our handling of EU personal data and expose us to legal and business risks under European data privacy and protection law. As a result of the UK exiting the EU, commonly known as Brexit, since January 1, 2021, any transfers of personal data to the UK are subject to the requirements of Chapter V of the GDPR and of the Law Enforcement Directive and absent an adequacy finding under GDPR, transfers of personal data from the EU to the UK, including to our facility in Cambridge, UK, would be illegal without adequate safeguards provided for under EC- approved mechanisms, such as current standard contractual clauses or, if approved in the future, an EU- UK privacy shield similar to the current framework in place between the EU and the United States. The extensive authority of UK intelligence and law enforcement agencies, including to conduct surveillance on personal data flows, could reduce the likelihood that the EC would give the UK an adequacy finding and reduce the likelihood that the EC would approve an EU- UK privacy shield. Accordingly, we may be exposed to legal risk for any of our EU- UK personal data transfers, including those that involve sensitive data such as patient and genetic data. Given the uncertainties surrounding the UK's departure from the EU, it is difficult to precisely identify or quantify the risks described above. Additionally, it is possible that, over time, the UK Data Protection Act could become less aligned with the GDPR, which could require us to implement different compliance measures for the UK and the European Union and result in potentially enhanced compliance obligations for EU personal data. As a result, Brexit adds legal risk, uncertainty, complexity and cost to our handling of EU personal information and our privacy and data security compliance programs. If we do not successfully manage such risk, our prospects may be materially harmed. Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations. As of December 31, 2022-2023, we had U. S. federal and state net operating loss, or Net Operating Losses ("NOLs"), carryforwards of \$ 690-814.1 million and \$ 263-390.6-7 million, respectively, which may be available to offset future taxable income. The federal NOLs include \$ 549-505.3-7 million which expire at various dates through 2042-2037 and \$ 140-308.8-4 million which carryforward indefinitely. The state NOLs expire at various dates through 2042-2043, with the exception of \$ 1.7 million of these net operating loss carryforwards which do not expire. As of December 31, 2022-2023, we also had U. S. federal and state research and development tax credit carryforwards of \$ 8-7.4-5 million and \$ 1.9-8 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2023-2024. In addition, in general, under Sections 382 and 383 of the Code and corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre- change net operating loss carryforwards or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5 % of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, including in connection with our recent private placements, IPO and other transactions. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code and our ability to utilize NOLs or credits may be impaired. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under "Risk factors — Risks Related to Our Financial Position and Need for Additional Capital," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U. S. federal or state taxable income necessary to utilize our NOLs or credits that are subject to limitation by Sections 382 and 383 of the Code. The reduction of the corporate tax rate under the TCJA caused a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, net operating loss carryforwards generated after December 31, 2017 will not be subject to expiration. If we are unable to obtain and enforce patent protection for our product candidates and related technology, our business could be materially harmed. We rely upon a combination of patents, trade secrets and confidentiality agreements to protect the intellectual property related to our product candidates and technology. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to duplicate or surpass our technological achievements, eroding our competitive position in the market. Our patent applications may not result in issued patents, and, even if issued, the patents may be challenged and invalidated. Moreover, our patents and patent applications may not be sufficiently broad to prevent others from practicing our technologies or developing competing products. We also face the risk that others may independently develop similar or alternative technologies or may design around our proprietary property. Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18

months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own, or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from biosimilar or generic versions of our product candidates. Furthermore, the product development timeline for biotechnology products is lengthy and it is possible that our issued patents covering our product candidates in the United States and other jurisdictions may expire prior to commercial launch. For example, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection could be reduced. Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we and our current or future licensors or licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our current licensors or licensees, or any future licensors or licensees, may not identify patentable aspects of inventions made in the course of development and commercialization activities in time to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc. If we or our current licensors or licensees, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current licensors or licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. The patent landscapes in the fields of antibody, adjuvant and adoptive cell therapy development, manufacture and commercialization are crowded. For example, we are aware of third- party patents directed to methods for identifying and producing therapeutic products such as antibodies, adjuvants and adoptive cell therapies. We are also aware of third- party patents directed to products targeting numerous antigens for which we also seek to identify, develop, and commercialize products. For example, some patents claim products based on competitive binding with existing products, some claim products based on specifying sequence or other structural information, and some claim various methods of discovery, production, or use of such products. These or other third- party patents could impact our freedom to operate in relation to our technology platforms, as well as in relation to development and commercialization of products identified by us as therapeutic candidates. As we discover and develop our candidates, we will continue to conduct analyses of these third- party patents to determine whether we believe we might infringe them, and if so, whether they would be likely to be deemed valid and enforceable if challenged. If we determine that a license for a given patent or family of patents is necessary or desirable, there can be no guarantee that a license would be available on favorable terms, or at all. Inability to obtain a license on favorable terms, should such a license be determined to be necessary or desirable, could, without limitation, result in increased costs to design around the third- party patents, delay product launch, or result in cancellation of the affected program or cessation of use of the affected technology. Third parties may also seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and / or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid and / or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. ~~Through our acquisitions of 4- AB, PhosImmune and certain assets of Celxion, we own, co-own, or have exclusive rights to a number of patents and patent applications directed to various methods and compositions, including methods for identifying therapeutic antibodies and product candidates arising out of such entities' technology platforms. In particular, we own patents and patent applications relating to our Retrocyte Display™ technology platform, a high throughput antibody expression platform for the identification of fully- human and humanized monoclonal antibodies. This patent family is projected to expire between 2029 and 2031. Through our acquisition of PhosImmune, we own, co-own, or have exclusive rights to patents and patent applications directed to various methods and compositions, including a patent directed to methods for identifying phosphorylated proteins using mass spectrometry. This patent is projected to expire in 2023.~~ In addition, as we advance our research and development efforts with our institutional and corporate collaborators, we are seeking patent protection for newly identified therapeutic antibodies and product candidates. We can provide no assurance that any of our

patents, including the patents that we acquired or in- licensed in connection with our ~~acquisitions~~ **acquisition** of 4- AB ; ~~PhosImmune and certain assets of Celexion~~, will have commercial value, or that any of our existing or future patent applications, including the patent applications that we acquired or in- licensed in connection with our ~~acquisitions~~ **acquisition** of 4- AB ; ~~PhosImmune and certain assets of Celexion~~, will result in the issuance of valid and enforceable patents. The patent position of biopharmaceutical, pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in biopharmaceutical, pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in foreign jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide competitive advantage. Moreover, we cannot predict whether third parties will be able to successfully obtain claims or the breadth of such claims. The allowance of broader claims may increase the incidence and cost of patent interference proceedings, opposition proceedings, post- grant review, inter partes review, and / or reexamination proceedings, the risk of infringement litigation, and the vulnerability of the claims to challenge. On the other hand, the allowance of narrower claims does not eliminate the potential for adversarial proceedings and may fail to provide a competitive advantage. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage. If any of our owned or in- licensed patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents . ~~With respect to our patent portfolio, as of the date of this filing, we own, co- own or have exclusive rights to approximately 37 issued United States patents and approximately 124 issued foreign patents. We also own, co- own or have exclusive rights to approximately 38 pending United States patent applications and approximately 317 pending foreign patent applications.~~ Our patent positions, and those of other biopharmaceutical, pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific, and factual questions. The standards which the United States Patent and Trademark Office (“ USPTO ”) uses to grant patents, and the standards which courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be provided by our patents if we attempt to enforce them and they are challenged, is uncertain. In addition, the type and extent of patent claims that will be issued to us in the future is uncertain. Any patents that are issued may not contain claims that permit us to stop competitors from using similar technology. With respect to both in- licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time- consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our ~~approximately 40 pending United States patent applications and approximately 260 pending foreign~~ patent applications may not result in patents being issued which protect our product candidates or patents which effectively prevent others from commercializing competitive technologies and product candidates. No consistent policy regarding the scope of claims allowable in patents in the biotechnology field has emerged in the United States. The patent situation outside of the United States is even more uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. With respect to both licensed and company- owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications

or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our products and the methods used to manufacture those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented product candidates and practicing our proprietary technology. Our issued patent and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and patents that we own or license may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may be subject to a third party preissuance submission of prior art to the USPTO or to foreign patent authorities or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize our product candidates, and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We may in the future co-own patent rights relating to future product candidates with third parties. Some of our in-licensed patent rights are, and may in the future be, co-owned with third parties. In addition, our licensors may co-own the patent rights we in-license with other third parties with whom we do not have a direct relationship. Our exclusive rights to certain of these patent rights are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patent rights, who are not parties to our license agreements. If our licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patent rights or we are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business. We are currently party to various intellectual property license agreements. These license agreements impose, and we expect that future license agreements may impose, various diligence, milestone payment, royalty, insurance, prosecution, enforcement and other obligations on us. These licenses typically include an obligation to pay an upfront payment, yearly maintenance payments and royalties on sales. If we fail to comply with our obligations under the licenses, the licensors or licensees may have the right to terminate their respective license agreements, in which event we might not be able to market or obtain royalties or other revenue from any product that is covered by the agreements. Termination of the license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our competitive business position and harm our business. In addition, court decisions may introduce uncertainty with respect to terms of a license agreement such as the impact of a challenge to the validity of a licensed patent on the payment obligations or termination rights of the license. Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a

claimed drug. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and / or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel or service providers to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. In addition, we are responsible for the payment of patent fees for patent rights that we have licensed from other parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the United States has enacted and implemented wide-ranging patent reform legislation. Further, recent U. S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or 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 value of patents, once obtained. If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected. In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. Depending upon the nature of the

product and the specifics of the related FDA marketing approval, data exclusivity under the Biologics Price Competition and Innovation Act (“ BPCIA ”) or related laws in the U. S. or certain foreign countries and territories may be available for our products. The BPCIA provides that FDA shall not approve certain biosimilars from the date of first licensure of a reference product for 12 years, subject to certain restrictions. However, we may not obtain or be eligible for data exclusivity because of, for example, the nature of the product with respect to other products on the market, our relationships with our partners (including our licensors and licensees), failing to claim the exclusivity at the appropriate time or otherwise failing to satisfy applicable requirements. If we are unable to obtain data exclusivity, our competitors may obtain earlier approval of competing products, and our business, financial condition, results of operations and prospects could be materially harmed. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We may have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biopharmaceutical, biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees’ former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. In particular, the patent landscapes around the discovery, development, manufacture and commercial use of our product candidates are crowded. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition, and results of operations. Furthermore, we would be exposed to a threat of litigation. In the biopharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include: • we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties’ patents; • if our competitors file patent applications that claim technology also claimed by us or our licensors or licensees, we or our licensors or licensees may be required to participate in interference, derivation or other proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position; • if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and • if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and / or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings. These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third party’ s patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business. The biopharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management’ s time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates. The cost of any patent litigation or other proceeding, even if resolved in

our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. 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. Patent litigation and other proceedings may also absorb significant management time. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent which might adversely affect our ability to develop and market our product candidates. We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U. S. patent applications filed before November 29, 2000 and certain U. S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects. We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Third parties may infringe or misappropriate our intellectual property, including our existing patents, patents that may issue to us in the future, or the patents of our licensors or licensees to which we have a license. As a result, we may be required to file infringement claims to stop third- party infringement or unauthorized use. Further, we may not be able to prevent, alone or with our licensors or licensees, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. If we or one of our licensors or licensees were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In addition, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the biopharmaceutical industry. Notably, the AIA, introduced new procedures, including inter partes review and post grant review. These procedures may be used by competitors to challenge the scope and / or validity of our patents, including those patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges. Even after they have been issued, our patents and any patents which we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. The following are non- exclusive examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us: • we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights; • third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us; • third parties may initiate opposition proceedings, post- grant review, inter partes review, or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and / or licensors or licensees to participate in such proceedings to defend the validity and scope of our patents; • there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us; • the USPTO may initiate an interference or derivation proceeding between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and / or licensors or licensees to participate in an interference or derivation proceeding to determine the priority of invention, which could jeopardize our patent rights; or • third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement. These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. There is a risk that a court or

administrative body could decide that our patents are invalid or not infringed by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents could limit our ability to assert our patents against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. An adverse outcome may also put our pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administrative panel to affect the validity or enforceability of a claim, for example, if a priority claim is found to be improper. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our relevant product candidates. Such a loss of patent protection could have a material adverse impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed. Any of these occurrences could adversely affect our competitive business position, business prospects, and financial condition. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: • others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents; • others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents; • we might not have been the first to make the inventions covered by patents or pending patent applications; • we might not have been the first to file patent applications for these inventions; • any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or • we may not develop additional proprietary technologies that are patentable. If we do not obtain patent term extension and / or data exclusivity for any product candidates we may develop, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in- licensed U. S. patents may be eligible for limited patent term extension under the Hatch- Waxman Act. The Hatch- Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and / or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in- licensed patent rights, trade secrets, or other intellectual property as an inventor or co- inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our licensors' ownership of our owned or in- licensed patent rights, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered 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. We also have partners who may market or refer to our trademarks or trade names and may use the trademarks or trade names in ways that impair our branding strategy. For example, Betta Pharmaceuticals has rights to our antibody, zalifrelimab, in greater China and may adopt a marketing strategy in their territories, including use or registration of trademarks and tradenames for our antibody, that could impair our brand identity or strategy and possibly cause market confusion. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior

rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. 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 diversion of resources and could adversely affect our business, financial condition, results of operations and prospects. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects. We have ~~undergone significant growth across multiple locations over the past several years and are focusing on further enhancing core areas and capabilities.~~ In addition, we have consolidated certain sites while expanding others to focus on our core priorities and future needs. We may encounter difficulties in managing these growth and / or consolidation efforts, either of which could disrupt our operations. Over the past several years, we have expanded our headcount through various acquisitions and the expansion of our research, development and manufacturing infrastructure and activities both nationally and internationally, while at the same time, in May 2022, we announced that we had reduced expenses by approximately 20 % to improve efficiency and focus on our most promising development candidates, such as botensilimab . **Further, in August 2023, we announced that we had further realigned our personnel and resources to focus on progression of our lead program, botensilimab, in metastatic MSS CRC, including a 25 % overall reduction in employees** . To manage these organizational changes, we must continue to implement and improve our managerial, operational, and financial systems and continue to recruit, train and retain qualified personnel. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our timelines may be delayed, our ability to generate revenue could be reduced, and we may not be able to implement our business strategy. As part of our efforts to optimize efficiency across our organization, we previously closed offices in Germany and Switzerland and consolidated these operations in the UK. In January 2020, our subsidiary MiNK closed its Waterloo, Belgium office and consolidated those operations in our Lexington, MA facility. In March 2020, as a result of the COVID- 19 pandemic, we completed a company- wide reduction in force. If as a result of these or similar future efforts we identify management or operational gaps in connection with our changes, it could cause delays in discovery timelines and increased costs for certain of our internal and partnered programs, which also could have an adverse effect on our business, financial condition and results of operations. We ~~are still in~~ **believe that we have completed** the process of liquidating Agenus Switzerland. Certain intellectual property rights were transferred from Switzerland to the United States or elsewhere to support licensing transactions with third parties. Following those transfers, tax authorities in Canton Basel notified Agenus Switzerland of tax outstanding tax obligations of approximately CHF 4. 0 million for tax years 2018 – 2020 combined and sought and obtained court orders to collect such sums from Agenus Switzerland (formerly 4- AB), or in the alternative liquidate the business. As part of its wind down, Agenus Switzerland transferred all remaining intellectual property rights to Agenus Inc. effective December 2022. There could be additional adverse tax consequences in Switzerland resulting from the migration of those remaining intellectual property rights as part of the final wind down of the business, which could have an adverse effect on our business and operations. Product liability and other claims against us may reduce demand for our products and / or result in substantial damages. We face an inherent risk of product liability exposure related to testing our product candidates in human clinical trials and manufacturing antibodies in our Berkeley, CA facility and may face even greater risks if we ever sell products commercially. An individual may bring a product liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. Product liability claims may result in:

- regulatory investigations;
- injury to our reputation;
- withdrawal of clinical trial volunteers;
- costs of and distraction related to litigation;
- substantial monetary awards to plaintiffs; and
- decreased demand for any future products.

We have limited product liability coverage for use of our product candidates. Our product liability policy provides \$ 10. 0 million aggregate coverage and \$ 10. 0 million per occurrence coverage. This limited insurance coverage may be insufficient to fully cover us for future claims. We are also subject to domestic and international laws generally applicable to businesses, including but not limited to, federal, state and local wage and hour, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistleblowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle- blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects. We are highly reliant on certain members of our management team. In

addition, we have limited internal resources and if we fail to recruit and / or retain the services of key employees and external consultants as needed, we may not be able to achieve our strategic and operational objectives. Garo H. Armen, Ph. D., the Chairman of our Board of Directors and our Chief Executive Officer who co- founded the Company in 1994 is integral to building our company and developing our technology. Jennifer Buell, Ph. D., Chair of Agenus' Executive Council, also provides key strategic advice. If either Dr. Armen or Dr. Buell is unable or unwilling to continue his or her relationship with Agenus, our business may be adversely impacted. We have an employment agreement with Dr. Armen. Dr. Armen plays an important role in our day- to- day activities, and we do not carry key employee insurance policies for Dr. Armen or any other employee. The loss of the services of Dr. Armen or Dr. Buell, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. Dr. Buell also serves as Chief Executive Officer for MiNK Therapeutics, and Dr. Armen is Chairman of the Board of Directors of MiNK Therapeutics. The bulk of our operations are conducted at our facilities in Cambridge, UK, Lexington, MA and Berkeley, CA. The Cambridge, UK, greater Boston area, and Northern California regions are headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Our future growth success depends to a significant extent on the skills, experience and efforts of our executive officers and key members of our clinical and scientific staff. We face intense competition for qualified individuals from other pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions, particularly in the historically tight labor market prevailing currently. To attract and retain employees at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Employment of our key employees is at- will, which means that any of our employees could leave our employment at any time, with or without notice. We may be unable to retain our current personnel or attract or assimilate other highly qualified management and clinical personnel in the future on acceptable terms. The loss of any or all of these individuals could harm our business and could impair our ability to support our collaboration partners or our growth generally. Our internal computer systems, or those of our third- party CROs, CMOs, licensees, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption in our business and operations or could subject us to sanctions and penalties that could have a material adverse effect on our reputation or financial condition. Despite the implementation of security measures, our internal computer systems and those of our current and future CROs, CMOs, licensees, collaborators and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Potential vulnerabilities can also be exploited from inadvertent or intentional actions of our employees, third- party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In July 2020, the United States Government charged a pair of Chinese hackers working on behalf of China’ s intelligence service in relation to the hacking of U. S. based biotechnology companies researching COVID- 19 vaccines. We anticipate that U. S. companies may also be targeted by Russia and / or its supporters as the result of the U. S.’ s support of Ukraine. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, on- going or future clinical trials could result in delays in our regulatory approval efforts and significant costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture certain of our drug candidates and conduct clinical trials, and similar events relating to their computer systems 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 liabilities and the further development and commercialization of our product candidates could be delayed. We do not maintain cyber liability insurance and would therefore have no coverage for any losses resulting from any data security incident. We use and store customer, vendor, employee and business partner and, in certain instances patient, personally identifiable information in the ordinary course of our business. We are subject to various domestic and international privacy and security regulations, including but not limited to the HIPAA, which mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with these standards, or a computer security breach or cyber- attack that affects our systems or results in the unauthorized release of proprietary or personally identifiable information, could subject us to criminal penalties and civil sanctions, and our reputation could be materially damaged, and our operations could be impaired. We may also be exposed to a risk of loss or litigation and potential liability, which could have a material adverse effect on our business, results of operations and financial condition. Natural or man- made calamities, or public health crises, could disrupt our business and materially adversely affect our operations and those of our strategic partners. Our operations, and those of our CROs, CMOs, and other contractors and consultants together

with regulatory agencies such as the FDA or EMA, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could prevent us, or our collaborators and business partners or regulators, from using all or a significant portion of our, or their, facilities or disrupt our supply chain, and, it may be difficult or, in certain cases, impossible for us to continue certain activities, such as for example our manufacturing capabilities, for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses and delays as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. We rely in part on third-party manufacturers to produce and process some of our product candidates. Our ability to obtain some of our clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. We own an antibody pilot plant manufacturing facility and in November 2020, entered into a long-term lease in Emeryville, CA for cGMP commercial manufacturing space. Construction of this end-to-end 83,000-sq-ft **000 square foot**, GMP clinical & commercial biologics manufacturing facility (from cell line development through Drug Product fill & finish, packaging and labeling) is being commissioned. These locations are in an area of seismic activity near active earthquake faults and active wildfire activity. We do not maintain earthquake insurance coverage for our owned and leased properties in Berkeley, CA or Emeryville, CA. In March 2020, we put in place a number of protective measures in response to the COVID-19 pandemic that have since been lifted. We revisited the various health and safety measures on a regular basis as the pandemic evolved, and we could take additional action if instructed by national, state and local governmental agencies or as we deem necessary to protect our employees. These measures resulted, and any future actions may result, in potential disruption to our business. Our employees are also impacted by the local government regulations that impact schools and other public services for lengthy periods of time. Not all of our employees are able to perform their duties or function remotely. The operations of our strategic partners could also be impacted by calamities or public health crises, which could materially and adversely affect our cash resources and operations. For instance, at the beginning of 2020, we projected receipt of approximately \$ 60.0 million of cash milestone payments from existing partners in 2020. Although we did receive \$ 25.1 million of this in 2020, as a result of the impact of COVID-19 on our partner's programs and trials, the remaining \$ 35.0 million was delayed and not received in 2020, which **impacts impacted** our cash runway and ability to fund our operations. Additional delays resulting from ~~COVID-19 or~~ other crises are likely to materially adversely affect our business. Although we do not expect Russia's invasion of Ukraine to materially impact our global operations, the war may impact our business, and that of our wholly-owned, independently-operated subsidiary Atlant Clinical based in Moscow, Russia. We have employees in Russia that may be adversely affected by the war. The war may make it difficult for these employees to work, travel and may result in disruption to certain programs and timelines as well as future business opportunities. The Russian invasion of Ukraine may also adversely impact the ability of our existing strategic partners to conduct business in the Ukraine and Russia. Failure to realize the anticipated benefits of our strategic acquisitions and licensing transactions could adversely affect our business, operations and financial condition. An important part of our business strategy has been to identify and advance a pipeline of product candidates by acquiring and in-licensing product candidates, technologies and businesses that we believe are a strategic fit with our existing business. Since we acquired 4-AB in 2014, we have completed numerous additional strategic acquisitions and licensing transactions. The ultimate success of these strategic transactions entails numerous operational and financial risks, including: • higher than expected development and integration costs; • difficulty in combining the technologies, operations and personnel of acquired businesses with our technologies, operations and personnel; • exposure to unknown liabilities; • difficulty or inability to form a unified corporate culture across multiple office sites both nationally and internationally; • inability to retain key employees of acquired businesses; • disruption of our business and diversion of our management's time and attention; and • difficulty or inability to secure financing to fund development activities for such acquired or in-licensed product candidates, technologies or businesses. We have limited resources to integrate acquired and in-licensed product candidates, technologies and businesses into our current infrastructure, and we may fail to realize the anticipated benefits of our strategic transactions. Any such failure could have an adverse effect on our business, operations and financial condition. Our subsidiary, MiNK, successfully closed an IPO in October 2021. We have made substantial investments in MiNK. There is no guarantee that it will be able to continue to attract funding from other sources, and, even if the business receives such funding, there is no guarantee that it will be successful. MiNK closed an IPO in October 2021. **We As of December 31, 2023, we own-owned 26-21, 332-772, 958-863** shares, representing approximately ~~78-63~~ % of MiNK's common stock. There is no guarantee that MiNK will be able to attract external funding in the future. If **external** funding is available, there is no guarantee that it will be on attractive or acceptable terms, or that it will be adequate to advance the business to an inflection point for additional funding. Similarly, there is no guarantee that partnership opportunities will be available on attractive terms, if at all. Even if adequate funding and partnership opportunities are available, there is no guarantee that MiNK will be successful in advancing one or more product candidates through clinical development. **In February 2024, we acquired from MiNK We have previously disclosed our interest in potentially issuing a dividend-convertible promissory note in the principal amount of \$ 5 million and if external funding is not available, we may need to Agenus-provide additional funding. On February 23, 2024, MiNK was notified by the Nasdaq Staff that MiNK was not in compliance with Nasdaq's stockholders in-s Minimum Value of Listed Securities requirement of \$ 35 million and that Nasdaq has provided MiNK with 180 calendar days, or until August 21, 2024, to regain compliance. On February 26, 2024, MiNK was notified by the Nasdaq Staff that MiNK was not in compliance with the Bid Price Requirement because Nasdaq's bid price form-for of its common stock of had closed below the minimum \$ 1.00 per share requirement for 30 consecutive business days. Nasdaq provided MiNK 180 calendar days, or otherwise distributing until August 26, 2024, to regain compliance with the Bid Price Requirement. As of March 14, 2024, MiNK shares to**

Agenu stockholders **was still not in compliance with these requirements**. There is no assurance MiNK guarantee that any such dividend or distribution will **maintain** be tax-free or that it **its listing on The Nasdaq Capital Market** will be issued at all, or the timing thereof. If we issue a dividend or distribution in the form of stock, there could be adverse tax consequences for certain of our stockholders. Risks Related to our Common Stock **Our common stock is currently listed on The Nasdaq Capital Market under the symbol “AGEN.” In the event that we fail to maintain compliance with the applicable listing requirements, our common stock could become subject to delisting from The Nasdaq Capital Market. On December 4, 2023, we were notified by the Nasdaq Staff that we are not in compliance with the Bid Price Requirement because the bid price for our common stock had closed below the minimum \$ 1. 00 per share requirement for 30 consecutive business days. Nasdaq provided us 180 calendar days, or until June 3, 2024, to regain compliance with the Bid Price Requirement. Compliance can be achieved by maintaining a closing bid price of at least \$ 1. 00 per share for at least 10 consecutive business days prior to the expiration of our 180 calendar day grace period. However, the Nasdaq Staff has the discretion to monitor the closing bid price for up to 20 business days, in certain circumstances, before deeming a company back in compliance. As of March 14, 2024, we have not achieved compliance with the Bid Price Requirement. In the event that compliance is not achieved by June 3, 2024, we could be eligible for an additional 180- day period to meet the requirement. Eligibility for this extension includes meeting the continued listing requirement of market value and all other initial listing standards for the Nasdaq Capital Market, except for the minimum bid price. We would also need to indicate our commitment to resolving this deficiency. Should we not meet the minimum bid price requirement within the given periods and any granted extensions, Nasdaq will issue a delisting notice. However, we retain the right to request a review of this decision by a Nasdaq hearing panel and can further appeal any panel decision to the Nasdaq Listing and Hearing Review Council. There can be no assurance that we will regain compliance with the Bid Price Requirement prior to our June 4, 2024 compliance deadline, that an extension will be granted, or that an appeal would be successful, thereby allowing us to remain listed on The Nasdaq Capital Market beyond the hearing date. On February 15, 2024 we announced a Special Meeting of Stockholders to be held on April 3, 2024, at which our stockholders will vote on an amendment to our Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of our issued and outstanding common stock at a ratio of 1- for- 20. If approved, the Certificate of Amendment will be filed with the Secretary of State of the State of Delaware to effect the amendment to our Certificate of Incorporation as soon as practicable after the Special Meeting. However, the Board reserves the right to abandon the amendment to our Certificate of Incorporation without further action by our stockholders at any time before the effectiveness of the filing with the Secretary of State of Delaware of the Certificate of Amendment to the Company’ s Certificate of Incorporation, even if the proposed amendment has been authorized by our stockholders at the special meeting. Although the Board expects that a reduction in outstanding shares of common stock resulting from a reverse stock split will result in an increase in the per share price of the Company’ s common stock and the ability to regain compliance with the Minimum Bid Rule, there is no assurance that such a result will occur or that a reverse stock split alone will guarantee our continued listing on The Nasdaq Capital Market. Further, the liquidity of our publicly traded common stock could be adversely affected by the reduced number of shares that would be outstanding after a reverse stock split, and the reverse- split adjusted stock price and our market capitalization may decline following a reverse stock split.** The trading volume and public trading price of our common stock has been volatile. During the period from our initial public offering on February 4, 2000 to December 31, 2022-2023, and the twelve- months ended December 31, 2022-2023, the closing price of our common stock has fluctuated between \$ 1-0. 30 (or 63 and \$ 315. 78 per share and \$ 0. 63 22 pre- reverse stock split) and \$ 2. 315- 31. 78 (or \$ 52. 63 pre- reverse stock split) per share and \$ 1. 30 and \$ 3. 47 per share, respectively. The average daily trading volume for the twelve- months ended December 31, 2022-2023 was approximately 4-5, 538-979, 552-632 shares. The market in general, and biotechnology companies in particular, may experience significant price and volume fluctuations that are often unrelated to the operating performance of individual companies. In addition to general market volatility, many factors may have a significant adverse effect on the market price of our stock, including: • continuing operating losses, which we expect over the next several years if we are able to transition to a commercial organization; • announcements of decisions made by public officials or delays in any such announcements; • results of our pre- clinical studies and clinical trials or delays in anticipated timing; • delays in our regulatory filings or those of our partners; • announcements of new collaboration agreements with strategic partners or developments by our existing collaboration partners; • announcements of acquisitions; • announcements of technological innovations, new commercial products, failures of products, or progress toward commercialization by our competitors or peers; • failure to realize the anticipated benefits of acquisitions; • developments concerning proprietary rights, including patent and litigation matters; • publicity regarding actual or potential results with respect to product candidates under development; • quarterly fluctuations in our financial results, including our average monthly cash used in operating activities; • variations in the level of expenses related to any of our product candidates or clinical development programs; • additions or departures of key management or scientific personnel; • conditions or trends in the biopharmaceutical, biotechnology and pharmaceutical industries generally; • other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; • changes in accounting principles; • general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and • sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock. In the past, securities class action litigation has often been brought against a company following a significant decline in the market price of its securities. This risk is especially relevant for us because many biopharmaceutical, biotechnology and pharmaceutical companies experience significant stock price volatility. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock, or publishes inaccurate or unfavorable

research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline. The invasion of Ukraine by Russia has caused worldwide market volatility to markets. Until there is a resolution to the conflict, we anticipate that the war may continue to cause market volatility. We do not intend to pay cash dividends on our common stock and, consequently your ability to obtain a return on your investment will depend on appreciation in the price of our common stock. We have never declared or paid any cash dividend on our common stock and do not intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or maintain their current value. Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes- Oxley Act of 2002 and to comply with changing regulation of corporate governance and public disclosure could have a material adverse effect on our operating results and the price of our common stock. The Sarbanes- Oxley Act of 2002 and rules adopted by the SEC and Nasdaq have resulted in significant costs to us. In particular, our efforts to comply with Section 404 of the Sarbanes- Oxley Act of 2002 and related regulations regarding the required assessment of our internal control over financial reporting, and our independent registered public accounting firm' s audit of internal control over financial reporting, have required commitments of significant management time. We expect these commitments to continue. Our internal control over financial reporting (as defined in Rules 13a- 15 of the Exchange Act) is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external purposes in accordance with U. S. GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all deficiencies or weaknesses in our financial reporting. While our management has concluded that there were no material weaknesses in our internal control over financial reporting as of December 31, 2022, our procedures are subject to the risk that our controls may become inadequate because of changes in conditions or as a result of a deterioration in compliance with such procedures. No assurance is given that our procedures and processes for detecting weaknesses in our internal control over financial reporting will be effective. Changing laws, regulations and standards relating to corporate governance and public disclosure, are creating uncertainty for companies. Laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided, which could result in continuing uncertainty regarding compliance matters and higher costs caused by ongoing revisions to disclosure and governance practices. If we fail to comply with these laws, regulations and standards, our reputation may be harmed, and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our operating results and the market price of our common stock. The sale of a significant number of shares could cause the market price of our stock to decline. The sale by us or the resale by stockholders of a significant number of shares of our common stock could cause the market price of our common stock to decline. As of March 15, 2023, we had 332,418,513,920,275,071, shares of common stock outstanding. Certain of these shares are subject to sales volume and other limitations. We have filed registration statements to permit the sale of approximately 70,200,000 shares of common stock under our equity incentive plans, and to permit the sale of 1,500,000 shares of common stock under our 2015 Inducement Equity Plan. We have also filed registration statements to permit the sale of approximately 1,167,000 shares of common stock under our Employee Stock Purchase Plan, to permit the sale of 775,000 shares of common stock under our Directors' Deferred Compensation Plan, to permit the sale of approximately 31,100,319 shares of common stock pursuant to various private placement agreements and to permit the sale of up to 200,350,000,000 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of December 31, 2022, an aggregate of approximately 213.5 million 152,251,882 of these shares remained available for sale. As part of our collaboration with Betta Pharmaceuticals, we completed a private placement of 4,962,779 shares of common stock in July 2020. As part of our collaboration with Gilead, we completed a private placement of 11,111,111 shares of common stock in January 2019, and on October 25, 2019, we filed a Registration Statement on Form S- 3 to register the resale of these shares by Gilead, as required under our agreement. In addition, we may be obligated in the future to pay certain contingent milestones payments, payable at our election in cash or shares of our common stock of up to \$ 30.0 million in the aggregate. If we elect to pay any of these contingent milestones in shares, we are obligated to file registration statements covering any such shares. The market price of our common stock may decrease based on the expectation of such sales. As of December 31, 2022, warrants to purchase approximately 1,980,000 shares of our common stock with a weighted average exercise price per share of \$ 2.87 were outstanding. As of December 31, 2022, options to purchase 354,984,827,967,211 shares of our common stock with a weighted average exercise price per share of \$ 3.51 were outstanding. These options are subject to vesting that occurs over a period of up to four years following the date of grant. As of December 31, 2022, we had 21,29,575,002,514,299 vested options and 355,543,802,278 non- vested shares outstanding. As of December 31, 2022, our outstanding shares of Series A- 1 Convertible Preferred Stock were convertible into 333,333 shares of our common stock. We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options or warrants are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options or warrants would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors. Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management. Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. Our

certificate of incorporation provides for a staggered board and removal of directors only for cause. Accordingly, stockholders may elect only a minority of our Board at any annual meeting, which may have the effect of delaying or preventing changes in management. In addition, under our certificate of incorporation, our Board of Directors may issue additional shares of preferred stock and determine the terms of those shares of stock without any further action by our stockholders. Our issuance of additional preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock and thereby effect a change in the composition of our Board of Directors. Our certificate of incorporation also provides that our stockholders may not take action by written consent. Our bylaws require advance notice of stockholder proposals and director nominations and permit only our president or a majority of the Board of Directors to call a special stockholder meeting. These provisions may have the effect of preventing or hindering attempts by our stockholders to replace our current management. In addition, Delaware law prohibits a corporation from engaging in a business combination with any holder of 15 % or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our Board of Directors may use this provision to prevent changes in our management. Also, under applicable Delaware law, our Board of Directors may adopt additional anti- takeover measures in the future. These anti- takeover provisions and other provisions in our certificate of incorporation and bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for our stockholders and other stockholders to elect directors of their choosing or cause us to take other corporate actions they desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. We have broad discretion in the use of our existing cash, cash equivalents and investments and may not use them effectively. Our management has broad discretion in the application of our cash, cash equivalents and investments. Because of the number and variability of factors that will determine our use of our cash, cash equivalents and investments, their ultimate use may vary substantially from their currently intended use. Our management might not apply our cash, cash equivalents and investments in ways that ultimately increase the value of our stockholders investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest our cash in short- term, investment- grade, interest- bearing securities. These investments may not yield a favorable return to our stockholders. If we do not use our resources in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline. If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.