

Risk Factors Comparison 2025-03-17 to 2024-03-15 Form: 10-K

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Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “ Risk Factors ” and should be carefully considered, together with other information in this Annual Report on Form 10- K, including our financial statements and related notes thereto, before making investment decisions regarding our common stock. • We have a limited history of profitability, which we have not maintained and may not achieve again, and only ~~three~~ two products that have been approved and marketed, one of which we have agreed to sell, and with multiple products that are not approved and still in development. • The commercial success of our existing products or any future products will depend upon the degree of market acceptance and adoption by prescribing physicians, healthcare providers and the patients to whom our medicines are prescribed. Additionally, obtaining placement on national and / or local clinical guidelines / pathways, as well as coverage on third- party payor formularies, can impact our short and long- term financial performance. • As we have in- licensed development and / or commercial rights to LOQTORZI, we rely on prior and ongoing preclinical, clinical, regulatory and manufacturing expertise of our collaborators in order to advance this product candidate through regulatory approvals in the United States and other licensed territories. • Our products and our product candidates, even if approved, will remain subject to regulatory scrutiny. • Disruptions at the FDA and other government agencies caused by funding shortages, government shut- downs or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, and conduct inspections of manufacturing facilities, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business. • Our biosimilar ~~products~~ product ~~face~~ faces significant competition from the reference ~~products~~ product and from other biosimilar products or pharmaceuticals approved for the same indication as the originator products. LOQTORZI faces significant competition from other immuno- oncology biologics. If we fail to compete effectively, we may not achieve significant market penetration and expansion. • We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates. • If an improved version of an originator product, such as Neulasta ~~or Humira~~, is developed or if the market for the originator product significantly declines, sales of our biosimilar ~~products~~ product may suffer. • Healthcare reform measures, including the IRA, may increase the difficulty and cost for us to obtain marketing approval for and commercialize our products, affect the prices we may set, and have a material adverse effect on our business and results of operations. • We are highly dependent on the services of our key executives and personnel, including our President and Chief Executive Officer, Dennis M. Lanfear, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer. • We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. • We are subject to a multitude of manufacturing risks and the risks of inaccurately forecasting sales of our products. We also need to make a determination of excess or obsolete inventory that requires ~~significant~~ judgment and may result in write- downs of inventory, charges related to firm purchase commitments, or both. Any adverse developments affecting the manufacturing operations of our products and product candidates could substantially increase our costs and limit supply for our products and product candidates. • The continuation of the war between Russia and Ukraine and conflicts in the Middle East may exacerbate certain risks we face. • Our products or our product candidates may cause undesirable side effects or have other properties that could, as applicable, delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted. • If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third- party claims of intellectual property infringement may prevent or delay our development and commercialization efforts. • We are heavily dependent on the development, clinical success, regulatory approval and commercial success of our product candidates. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized. Risk Factors Investing in the common stock of a biopharmaceutical company, including one with significant international partnerships and multiple products in development, is a highly speculative undertaking and involves a substantial degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10- K. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and / or prospects. Risks Related to Our Financial Condition and Capital Requirements We have a limited history of profitability, which we have not maintained and may not achieve again, and only ~~three~~ two products that have been approved and marketed, one of which we have agreed to sell, and with multiple products that are not approved and still in development. With the exception of generating net income of \$ 28.5 million, \$ 132.2 million and \$ 89.8 million in 2024, 2020 and 2019, respectively, we incurred net losses in each year from our inception in September 2010 through December 31, ~~2023~~ 2024, including net losses of \$ 237.9 million ~~and~~ \$ 291.8 million and \$ 287.1 million in ~~2023~~ and ~~2022~~ and ~~2021~~, respectively. It is uncertain that we will be profitable in future periods ,

particularly if the UDENYCA Sale is consummated, as research and development is expensive and risky. The amount of our future net losses or any future net income will depend, in part, on the amount of our future expenditures offset by the amount of future product sales, including sales of our current products or any other products that may receive regulatory approval. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. For example, as of December 31, ~~2023~~ **2024**, we had an accumulated deficit of \$ 1. 6 billion. The losses and accumulated deficit were primarily due to the substantial investments we made to identify, develop or license our product candidates, including conducting, among other things, analytical characterization, process development and manufacturing, formulation and clinical studies and providing general and administrative support for these operations. We have incurred and anticipate we will continue to incur certain development and commercial expenses for LOQTORZI, the anti- PD- 1 antibody we licensed from Junshi Biosciences in 2021, and have agreed to pay up to \$ 90. 0 million for the achievement of certain regulatory approvals and up to \$ 290. 0 million for the attainment of certain sales thresholds. The recent launch of this product and future work to advance our **other** product candidates through clinical development **in combination with toripalimab** will be expensive and could result in us continuing to experience future net losses. ~~For~~ **25For YUSIMRY, UDENYCA and LOQTORZI**, which are launched products, and if we obtain regulatory approval to market any other product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval and our ability to achieve sufficient market acceptance, pricing, reimbursement from third- party payers, and adequate market share for our product candidates which include all product candidates for which we obtained commercial rights, in those markets. However, even ~~26if~~ **if** additional product candidates in addition to our current products gain regulatory approval and are commercialized, we may not remain profitable. Our expenses will increase substantially if and as we: ~~• further develop our sales, marketing and distribution infrastructure for our current products and develop such infrastructure for new products once they are launched;~~ • establish a sales, marketing and distribution infrastructure to commercialize any of our product candidates for which we may obtain marketing approval; • make upfront, milestone, royalty or other payments under any license agreements; • continue our nonclinical and clinical development of our product candidates; • initiate additional nonclinical, clinical or other studies for our product candidates; • expand the scope of our current clinical studies for our product candidates; • advance our programs into more expensive clinical studies; • change or add contract manufacturers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers; • seek regulatory approvals for our product candidates that successfully complete clinical studies; • seek to identify, assess, acquire and / or develop other product candidates or products that may be complementary to our products; • seek to create, maintain, protect and expand our intellectual property portfolio; • engage legal counsel and technical experts to help us evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties; • engage in litigation, including patent litigation, and Inter Partes Review (“ IPR ”) proceedings with originator companies or others that may hold patents; • seek to attract and retain skilled personnel; • create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and • experience any delays or encounter issues with any of the above, including but not limited to failed studies, conflicting results, safety issues, manufacturing delays, litigation or regulatory challenges that may require longer follow- up of existing studies, additional major studies or additional supportive studies or analyses in order to pursue marketing approval. **In addition, the UDENYCA Sale may make it more difficult or make it take more time for us to become profitable at any point in the future. UDENYCA is our largest product that contributes significantly more revenue to our business than LOQTORZI currently. LOQTORZI may not increase its revenue contribution to our business as quickly as we project or at all and for our clinical trials for our product candidates may be delayed, may be unsuccessful or may take more time and expense to complete than we currently anticipate. The inherent risk involved in divesting a major business could make it difficult for us to replace the revenue lost by selling UDENYCA or by becoming profitable in the future.** Further, the net loss or net income we achieve may fluctuate significantly from quarter- to- quarter and year- to- year such that a period- to- period comparison of our results of operations may not be a good indication of our future performance quarter- to- quarter and year- to- year due to factors including the timing of clinical trials, any litigation that we may initiate or that may be initiated against us as well as any settlements or judgments from such litigation, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive thereunder. ~~We~~ **26We** continue to be dependent on the ability to raise funds. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development and commercialization efforts or other operations. As of December 31, ~~2023~~ **2024**, our cash, cash equivalents and marketable securities were \$ ~~117~~ **126. 7** million. We expect that our existing cash and cash equivalents, investments ~~and~~, cash collected from our product sales **and cash proceeds from the UDENYCA Sale (assuming it is consummated)** will be sufficient to fund our current operations for the foreseeable future. We have financed our operations primarily through the sale of equity securities, convertible notes, credit facilities, **divestitures**, license agreements and through recent product sales of our products. ~~27However~~ **27However**, our operating or investing plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to: • our ability to **consummate the UDENYCA Sale**; • **our ability to** continue to successfully commercialize **our products**; • **our ability to maintain continuity for the supply of** our products; • the scope, rate of progress, results and cost of any clinical studies, nonclinical testing and other related activities; • the cost of manufacturing clinical drug supplies and establishing commercial supplies, of our product candidates and any products that we may develop; • **prior to the consummation of the UDENYCA Sale, the timing for us to receive FDA authorization to produce UDENYCA product at our additional packaging and labeling CMO’ s facility and the timing for our additional packaging and labeling CMO to make UDENYCA products available in a sufficient quantity to meet the demand from our customers**; • the number and characteristics of product candidates that we pursue; • the cost, timing and outcomes of

regulatory approvals ; ~~• our ability to successfully integrate the business of Surface following consummation of the Surface Acquisition~~; • the cost and timing of establishing sales, marketing and distribution capabilities; • the terms and timing of any licensing or other arrangements to acquire intellectual property rights that we may establish, including any milestone and royalty payments thereunder; • **if not otherwise resolved with proceeds from the UDENYCA Sale**, the timing of conversion in common shares or repayment in cash of our convertible debt, or the timing of repayment in cash, whether due or not, of our long- term debt **and the payment of interest, principal and royalties related to our financial liabilities**; and • the cost, timing and outcomes of any litigation that we may file against third parties or that may be filed against us by third parties. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The sale of additional equity or convertible securities, such as the sales from time to time through our sales agreement dated November 8, 2022 (**the “ Sales Agreement ”**) with Cowen and Company, LLC (“ TD Cowen ”) pursuant to which we may issue and sell from time to time up to \$ 150. 0 million of our common stock **, including the common stock already sold**, through or to TD Cowen as our sales agent or principal in an at- the- market offering (“ ATM Offering ”), may dilute the share ownership of our existing stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as those contained in the loan agreement ~~we entered into in January 2022 (as amended to date, the “ 2029 Loan Agreement ”) with BioPharma Credit PLC, dated as of May 8, 2024 (the “ 2029 Term Loan Effective Date ”), by and among us, Ankura Trust Company, LLC, as administrative agent (in such capacity, the “ Collateral Agent ”), BPCR Limited Partnership, and the lenders signatory thereto (as a collectively, the “ 2029 Lender Lenders ”) governing the and BioPharma Credit Investments V (Master) LP, acting by its general partner, BioPharma Credit Investments V GP LLC (as a “ Lender ”) that provides for a senior secured term loan facility of up to \$ 300- 38. 0- 7 million (the “ 2029 Term Loan ”) we entered into on the 2029 Term Loan Effective Date~~, including limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business **such as a financial**. ~~For more information on our restrictive covenants- covenant which requires~~ please read the Loan Agreement, the First Amendment to Loan Agreement, the Second Amendment and Waiver to Loan Agreement, and Consent, Partial Release and Third Amendment dated February 5, 2024 (the “ Consent and Amendment ”) among us, the Collateral Agent and the Lenders filed as exhibits to our public filings **maintain certain levels of cash and cash equivalents**. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage or for a lower ~~price- 27~~**price** than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations. ~~We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage or for a lower price than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations.~~ If we are unable to obtain funding on a timely basis or at all, stay profitable or generate any net profits, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any products or product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our financial condition and results of operations. ~~28~~**Risks** ~~--~~ **Risks** Related to Launch and Commercialization of our Products and our Product Candidates We have a limited operating history in an emerging regulatory environment on which to assess our business. We are a biopharmaceutical company with a limited operating history in an emerging regulatory environment of biosimilar and immuno- oncology products. Although we have received upfront payments, milestone and other contingent payments and / or funding for development from some of our collaboration and license agreements, our only approved products ~~include are~~ **include are** UDENYCA, YUSIMRY and LOQTORZI which are approved for commercialization in the United States, and we have no products approved in any other territories. Our ability to generate meaningful revenue and remain profitable depends on our ability, alone or with strategic collaboration partners, to successfully market and sell our products, and to complete the development of, and obtain the regulatory approvals necessary to commercialize, one or more of our product pipeline candidates, which include: • CHS- 1000 • casdozokitug; ~~and~~ • CHS- 114 ; **and • toripalimab in non- NPC indications**. We may not be able to continue to generate meaningful revenue from product sales, as this depends heavily on our success in many areas, including but not limited to: • our ability to continue to successfully commercialize all three UDENYCA product presentations and LOQTORZI ; ~~• our ability to successfully commercialize YUSIMRY in a very competitive adalimumab market~~; • competing against numerous current and future pegfilgrastim, ranibizumab and adalimumab products with significant market share; • healthcare providers, payers, and patients adopting our products and product candidates once approved and launched; • our ability to procure and commercialize our ~~in- licensed~~ **in- licensed** biosimilar ~~candidates~~ **product**; • obtaining additional regulatory approvals for product candidates for which we complete clinical studies; • obtaining adequate third- party coverage and reimbursements for our products; • obtaining market acceptance of our products and product candidates as viable treatment options; • completing nonclinical and clinical development of our product candidates; • developing and testing of our product formulations; • attracting, hiring and retaining qualified personnel; • developing a sustainable and scalable manufacturing process for our products and any approved product candidates and establishing and maintaining supply and

manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) products to support clinical development and the market demand for our products and product candidates, if approved; • addressing any competing technological and market developments; • identifying, assessing and developing (or acquiring / licensing on favorable terms) new product candidates; **28** • negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter; • maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and • defending against any litigation including patent or trade secret infringement lawsuits, which may be filed against us, or achieving successful outcomes of IPR petitions that we have filed, or may in the future file, against third parties. ~~29~~ **Even** if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs to commercialize any such product. Our expenses could increase beyond our expectations if we are required by the FDA, the European Medical Agency (the “EMA”), other regulatory agencies, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, nonclinical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining additional regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the number of biosimilar or immuno-oncology competitors in such markets, the accepted price for the product, the ability to get reimbursement at any price, the nature and degree of competition from originators and other biosimilar or immuno-oncology companies (including competition from large pharmaceutical companies entering the biosimilar market or possessing large established positions in the immuno-oncology market that may be able to gain advantages in the sale of biosimilar or immuno-oncology products based on brand recognition ~~and~~ or existing relationships with customers and payers) and whether we own (or have partnered with companies owning) the commercial rights for that territory. If the market for our products and product candidates (or our share of that market) is not as significant as we expect, the price of our products is not what we project, the indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are unable to successfully complete development and obtain additional regulatory approval for our products, our business may suffer. The commercial success of our existing products or any future products will depend upon the degree of market acceptance and adoption by prescribing physicians, healthcare providers and the patients to whom our medicines are prescribed. Additionally, obtaining placement on national and / or local clinical guidelines / pathways, as well as coverage on third-party payor formularies, can impact our short and long-term financial performance. Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our products or product candidates, if approved, will depend in part on the medical community, patients and third-party payers accepting our products and product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. The degree of market acceptance of our ~~recently launched~~ product ~~LOQTORZI~~, or any of our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the safety and efficacy of the product, as demonstrated in clinical studies, and potential advantages over competing treatments; • the prevalence and severity of any side effects and any limitations or warnings contained in a product’s approved labeling; • the clinical indications for which approval is granted; • for our immuno-oncology product candidates, our ability to compete in a competitive immuno-oncology market that may differ from the biosimilar market; • inclusion, in either parity or better position, on commonly accepted clinical guidelines or pathways that influence prescribing patterns and / or affect reimbursement; • relative convenience, ease of administration and any real or perceived benefit from administration at home as opposed to in the clinic; • prevalence of the disease or condition for which the product is approved; • the cost of treatment, particularly in relation to competing treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the strength of marketing and distribution support and timing of market introduction of competitive products; • the extent to which the product is approved for inclusion on formularies of hospitals, integrated delivery networks and managed care organizations; **29** • publicity concerning our products or competing products and treatments; • the extent to which third-party payers (including government and national / regional commercial plans) provide adequate third-party coverage and reimbursement for our products and product candidates, if approved; • the price at which we sell our products; **30** • the potential impact of the IRA on the pharmaceutical industry and the market for ~~biosimilars~~ **our products**; • the actions taken by current and future competitors to delay, restrict or block customer usage of the product; and • our ability to maintain compliance with regulatory requirements. Market acceptance of any future product candidates, if approved, will not be fully known until after they are launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar and immuno-oncology products and product candidates. Further, continued market acceptance of ~~UDENYCA~~ **(prior to the UDENYCA Sale)** and ~~LOQTORZI~~ and ~~YUSIMRY~~, and any future product candidates that may be approved, depends on our efforts to educate the medical community and third-party payers on the benefits of our products and product candidates and will require significant resources from us and we have significantly less resources compared to large, well-funded pharmaceutical entities. Given the resource disparity, our outreach may have little success or may never be successful. If our products or any future product candidates that are approved fail to achieve an adequate level of acceptance by physicians, patients, third-party payers and others in the medical community, we will not be able to generate sufficient revenue to sustain profitability. The third-party coverage and reimbursement status of our products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue. Pricing, coverage and reimbursement of our products, or any of our product candidates, if approved, may not be adequate to support our commercial infrastructure. The prices required to successfully compete may not continue to be sufficient to recover our development and manufacturing costs,

and as a result, we may not be profitable in the future. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and commercial payers are essential to enable provider / patient access to our products and our patient support services must be sufficiently scaled to meet the needs of patients receiving our products. Sales will depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government authorities, private health insurers and other third- party payers. If coverage and reimbursement are not available, or are available only to limited levels, or become unavailable, we may not be able to successfully commercialize our products or any of our product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be adequate to allow us to establish or maintain pricing sufficient to realize a return on our investment. There is significant uncertainty related to third- party coverage and reimbursement of newly approved products. In the United States, third- party payers, including private and governmental payers such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older or those who are disabled or suffering from end- stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payers and other governmental payers develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict what third- party payers will decide with respect to the coverage and reimbursement for any newly approved product. In addition, in the United States, no uniform policy of coverage and reimbursement for biologics exists among third- party payers. Therefore, coverage and reimbursement for biologics can differ significantly from payer to payer. As a result, the process for obtaining favorable coverage determinations often is time-consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained. Effective January 2019, CMS assigned a product specific Q- Code to Udenyca, which is necessary to enable providers to separately bill for Udenyca to have its own reimbursement rate with Medicare or other third- party payers. However, reimbursement is not guaranteed, and rates may vary based on product life cycle, site of care, type of payer, coverage decisions, and provider contracts. Furthermore, while payers have adopted the Q- Code assigned by CMS for Udenyca, there remains uncertainty as to whether such payers will continue to cover and pay providers for the administration and use of the product with each patient or may favor competing products. If our products or any of our future product candidates, are not covered or adequately reimbursed by third- party payers, including Medicare, then the cost of the relevant product may be absorbed by healthcare providers or charged to patients. If this is the case, our expectations of the pricing we expect to achieve for such product and the related potential revenue may be significantly diminished. Outside of the United States, pharmaceutical businesses are generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Increasing efforts by governmental and third- party payers in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our products or any of our product candidates. While cost containment practices generally benefit biosimilars, severe cost containment practices may adversely affect our product sales. Furthermore, the impact of the IRA on our business and the pharmaceutical industry generally is currently unknown. We expect to experience pricing pressures in connection with the sale of our products and any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. Our products and our product candidates, even if approved, will remain subject to regulatory scrutiny. Our products and our product candidates, even if approved, will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to "current 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 NDA, original BLA submitted under Section 351 (a) of the Public Health Service Act- PHSA, Section 351 (k) BLA or marketing authorization application ("MAA"). Accordingly, we and others with whom we work must continue to spend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we or our collaboration partners receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to ensure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved

label. As such, we may not promote our products for indications or uses for which they do not have approval. If our product candidates are approved, we must submit new or supplemental applications and obtain approval for certain changes to the approved products, product labeling or manufacturing process. We or our collaboration partners could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval is obtained via an accelerated biosimilar approval pathway, we could be required to conduct a successful post-marketing clinical study to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other possibilities: • issue warning letters; • impose civil or criminal penalties; **31** • suspend or withdraw regulatory approval; • suspend any of our ongoing clinical studies; • refuse to approve pending applications or supplements to approved applications submitted by us; **32** • impose restrictions on our operations, including closing our contract manufacturers' facilities; or • seize or detain products or require a product recall. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. 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, China or other foreign countries. Disruptions at the FDA and other government agencies caused by funding shortages, **staffing limitations**, government shut-downs or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, and conduct inspections of manufacturing facilities, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, 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, government shut-downs, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies 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 and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States government has periodically shut down and certain regulatory agencies, such as the FDA, had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. **Even though the FDA has since resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to further administrative or inspectional delays.** If a prolonged government shutdown occurs **it, or if funding shortages, staffing limitations or further global health concerns emerge, such events** could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. **Risks Related to Competitive Activity** Our biosimilar products **product face faces** significant competition from the reference products **product** and from other biosimilar products or pharmaceuticals approved for the same indication as the originator products. Our product LOQTORZI and product candidate CHS-114, if approved, will face significant competition from other immuno-oncology biologics. If we fail to compete effectively, we may not achieve significant market penetration and expansion. We operate in highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical market have demonstrated the ability to effectively discover molecules, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced multinational pharmaceutical and biotechnology companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, legal, governmental affairs, manufacturing, personnel, and marketing resources, with additional benefits of mergers and acquisitions. **LOQTORZI 32LOQTORZI** recently entered a competitive market in the United States where a number of anti-PD-1 or PD-L1 antibody drugs have been approved by the FDA, **although not in NPC**, including the following marketed products from several competitors: Keytruda® (pembrolizumab) from Merck, Opdivo® (nivolumab) from BMS, Tecentriq® (atezolizumab) from Genentech, Imfinzi® (durvalumab) from AstraZeneca, Bavencio® **33** (avelumab) from EMD Serono Inc. and Pfizer, and Libtayo® (cemiplimab-rwlc) from Regeneron and Sanofi, and Jemperli (dostarlimab-gxly) from GlaxoSmithKline **and TEVIMBRA® (tislelizumab-jsgr) from BeiGene, Ltd.** In addition to LOQTORZI, multiple other competitors are seeking to develop and approve novel anti-PD-1 or PD-L1 antibody drugs in the United States in the coming years, including but not limited to **BeiGene camrelizumab from Elevar Therapeutics, Ltd Inc.** (in collaboration with **Novartis Jiangsu Hengrui Pharmaceuticals Co., Ltd.**). As the only immunotherapy approved by the

FDA for the treatment of NPC, we believe LOQTORZI addresses a potentially high unmet need. **UDENYCA faces competition in the United States from Amgen, Biocon, Sandoz, Pfizer, Spectrum, Amneal and Fresenius. Casdozokitug is in development and is the only antagonist antibody in development known to us that is targeting the immune regulatory cytokine IL- 27. CHS- 114 is in development and**, if approved, faces competition from programs in development specifically targeting CCR8, including those by Bristol- Myers Squibb Company, Gilead / Jounce, Shionogi, AbbVie, Bayer, **F. Hoffmann-La Roche Ltd, Amgen**, LaNova and Immunophage; **UDENYCA faces competition in the United States from Amgen, Viatrix, Sandoz, Pfizer, and Spectrum, and is expected to face competition from Amneal and Fresenius, each of which has announced the approval of a pegfilgrastim biosimilar and have launched their products for sale in the United States. YUSIMRY, following our launch in July 2023, faces competition in the United States from AbbVie (the holder of rights to Humira), Amgen (Amjevita™ (adalimumab- atto)), Sandoz (Hyrimoz™ (adalimumab- adaz)), Samsung Bioepis (Hadlima™ (adalimumab- bwwd)), Pfizer (Abrilada™ (adalimumab- afzb)), Boehringer Ingelheim (Cyltezo™ (adalimumab- adbm)) as well as Viatrix / Biocon (Hulio® (adalimumab- fljp)), Alvotect Holdings S. A. and Fresenius, each a company that has disclosed development plans for a Humira biosimilar candidate. As a result of continued expected competition from Humira and a large number of potential adalimumab (Humira) biosimilar competitors, we may not be able to achieve substantial topline sales for YUSIMRY in the United States.** These companies may also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates, obtaining FDA and other regulatory approvals of products and marketing and commercializing products once approved. Additionally, many manufacturers of originator products have increasingly used legislative, regulatory and other means, such as litigation, to delay regulatory approval and to seek to restrict competition from manufacturers of biosimilars. These efforts may include or have included: • settling, or refusing to settle, patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval; • submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted biosimilar applications; • appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of biosimilar applications; • restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans; • attempting to influence potential market share by conducting medical education with physicians, payers, regulators and patients claiming that biosimilar products are too complex for biosimilar approval or are too dissimilar from originator products to be trusted as safe and effective alternatives; • implementing payer market access tactics that benefit their brands at the expense of biosimilars; • seeking state law restrictions on the substitution of biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification; • seeking federal or state regulatory restrictions on the use of the same non- proprietary name as the reference brand product for a biosimilar or interchangeable biologic; • seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug and biologic standards; • obtaining new patents covering existing products or processes, which could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars; and • influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation. ~~34Our~~**33Our** products and our product candidates, if approved, could face price competition from other products or biosimilars of the same reference ~~products-~~ **product** for the same indication. This price competition could exceed our capacity to respond, detrimentally affecting our market share and revenue as well as adversely affecting the overall financial health and attractiveness of the market for the biosimilar. Competitors in the biosimilar market have the ability to compete on price through **PBMs pharmacy benefit managers**, payers and their third- party administrators, **IDNs integrated delivery networks** and hospitals who exert downward pricing pressure on our product offerings. It is possible our biosimilar competitors' compliance with price discounting demands in exchange for market share or volume requirements could exceed our capacity to respond in kind and reduce market prices beyond our expectations. There could be similar price competition in the immuno- oncology market that could adversely affect our results in the future. Such practices may limit our ability to increase market share and may also impact profitability. We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, less costly, easier to administer or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates. Many of our competitors have substantially greater financial, technical and other resources, **including such as** larger research and development **, staff and more experienced** marketing and manufacturing organizations. **Additional** **Additionally**, mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval, product commercialization and market penetration earlier than we do. Our competitors may have products that are easier to administer than our products, which could adversely affect our results ~~, such as due to the observed trend that a large number of patients demonstrate a preference to administer medication at home due to COVID- 19 or other factors~~. Biosimilar or immuno- oncology product candidates developed by our competitors may render our potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors. If other competitors to **LOQTORZI toripalimab** (in indications besides **NPC those approved for LOQTORZI**), casdozokitug **, CHS- 1000** and CHS- 114 are approved and successfully commercialized before **LOQTORZI toripalimab** (in indications besides **NPC those approved for LOQTORZI**), casdozokitug **, CHS- 1000** and CHS- 114, our business would suffer. There are a number of companies that currently commercialize PD- 1 / PD- L1 blocking antibodies or are developing such compounds for commercialization in the United States. If other competitors to **LOQTORZI toripalimab** (in indications besides **NPC those**

approved for LOQTORZI), casdozokitug, CHS- 1000 and CHS- 114 are successfully commercialized before LOQTORZI toripalimab (in indications besides NPC—those approved for LOQTORZI), casdozokitug, CHS- 1000 and CHS- 114, we may never achieve meaningful market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer. If an improved version of an originator product, such as Neulasta or Humira, is developed or if the market for the originator product significantly declines, sales of our biosimilar products—product may suffer. Originator companies may develop improved versions of a reference product as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a new or supplemental BLA submitted to the applicable regulatory authority. Should the originator company succeed in obtaining an approval of an improved biologic product, it may capture a significant share of the collective reference product market in the applicable jurisdiction and significantly reduce the market for the reference product and thereby the potential size of the market for our biosimilar products—product. In addition, the improved product may be protected by additional patent rights that may subject our follow- on biosimilar to claims of infringement. Biologic reference products may also face competition as technological advances are made that may offer patients a more convenient form of administration or increased efficacy or as new products are introduced. External developments can also result in changing preferences for convenient forms of administration of products that may impact our business. As new products are approved that compete with the reference product to our biosimilar products—product, sales of the reference originator product may be adversely impacted or rendered obsolete. If the market for the reference product is impacted, we may lose significant market share for our approved biosimilar products—product. As a result of the above factors, our business, prospects and financial condition could suffer. 35 Any 34 Any product candidates for which we intend to seek approval as original biologic products may face competition sooner than anticipated. Our development of novel biologic product candidates, such as casdozokitug, CHS- 1000 and CHS- 114, subjects us to additional risks relating to biosimilar competition. In particular, under the Biologics Price Competition and Innovation Act of 2009 (“ BPCIA ”), an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of its product. We believe that LOQTORZI does, and any of our future product candidates approved under an original BLA should, qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products will depend on a number of marketplace and regulatory factors that are still developing.

Risks Related to Our Ability to Hire and Retain Highly Qualified Personnel We are highly dependent on the services of our key executives and personnel, including our President and Chief Executive Officer, Dennis M. Lanfear, and if we are not able to retain these members of our management or recruit additional management, product development and scientific personnel, our business will suffer. We are highly dependent on the principal members of our management and scientific and technical staff. The loss of service of any of our management or key scientific and technical staff could harm our business. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, product development and scientific personnel. If we are not able to retain our management, particularly our President and Chief Executive Officer, Mr. Lanfear, and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow. Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain “ key person ” life insurance on the lives of our executives or any of our employees. We will need to expand and effectively manage our managerial, scientific, operational, financial, commercial and other resources in order to successfully pursue our product development and commercialization efforts. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and technical personnel. We may not be able to attract or retain qualified management and scientific and product development personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly those located in the San Francisco Bay Area. We also use equity compensation as a part of a comprehensive compensation package for our personnel. The majority of our outstanding options have exercise prices that are above our current stock price. **See the tables describing our outstanding stock options in Note 12. Stock- Based Compensation and Employee Benefits to our financial statements included in our Annual Report for the Fiscal Year ended December 31, 2024.** If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. We may need to expand **experience difficulties in managing changes in our organization—number of employees**, particularly due to **employee—employees turnover—departing due to divestitures, reductions** and we may experience difficulties in **managing this force and** turnover, which could disrupt our operations. As of December 31, 2023–2024, we had 306–228 full- time and part- time employees, **which represented a decrease of 78 full- time and part- time employees since December 31, 2023**. As our development and commercialization plans and strategies develop and evolve from time to 35to time, and as we **face difficulty**

experience turnover, we may need to hire additional people in the future. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these hiring activities changes as we experience changes in our number of employees, including due to divestitures, like the potential employee transfers to Accord in the UDENYCA Sale, reductions in force and turnover. We may not be able to effectively manage during a period of significant change in our number of employee-employees turnover, which 36may-- may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity and morale among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage the changes in our turnover-number of employees, our expenses may increase more than expected, and our ability to generate and/or grow revenue could be reduced. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth changes in our number of employees. Risks Related to Reliance on Third Parties We rely on third parties, and in some cases a single third party, to manufacture nonclinical, clinical and commercial drug supplies of our products and product candidates and to store critical components of our products and product candidates for us. Our business could be harmed if those third parties fail to provide us with sufficient quantities of products and product candidates or fail to do so at acceptable quality levels or prices. We do not currently have the infrastructure or capability internally to manufacture supplies of our products and product candidates for use in our nonclinical and clinical studies, and we lack the resources and the capability to manufacture any of our products and product candidates on a clinical or commercial scale. We rely on third-party manufacturers to manufacture and supply us with our products and product candidates for our preclinical and clinical studies as well as to maintain-establish commercial supplies of our products- product candidates. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and we may 37may not be able to achieve such transfer or do so in a timely manner. Moreover, the availability of contract manufacturing services for protein-based therapeutics is highly variable and there are periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Although we will plan accordingly and generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete such study, any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations. 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 and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the United States. Our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates or products that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant. On September 13, 2024, we announced that we engage our third-party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to increase manufacturing over-commitments and capacity constraints. If we are unable to build and stock our product candidates in sufficient quantities to meet the requirements for the launch of These these delays caused a temporary UDENYCA candidates or to meet future demand, our revenue and gross margins could be adversely affected. Although we believe that we will not have any material supply interruption issues, we cannot be certain that quickly took away we will be able to obtain long-term supply arrangements for our product candidates our- or ability-materials used to sell our product produce UDENYCA them on acceptable terms, if at that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024. The Company announced in January 2025 that due to strong demand in Q4 2024 and into Q1 2025, all three presentations of UDENYCA were being temporarily allocated. If we are unable Based on individual distributor historical purchasing patterns, supply allocations to wholesalers arrange for third-party manufacturing, for- or all three presentations to do so on commercially reasonable terms, we may not be able to complete development of UDENYCA were removed between our product candidates or market the them end of January 2025 and the end of February 2025. We The temporary UDENYCA supply interruption had a significant impact on our rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We have relied upon and plan to continue to rely upon third-party clinical-contract research organizations ("CROs") to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical and clinical studies and

control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, GCP, and **good laboratory practices** (“GLP”), which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections or remote regulatory assessments (“RRAs”) of study sponsors, principal investigators, study sites and other contractors. If we, any of our CROs, service providers or investigators fail to comply with applicable regulations or GCPs, the data generated in our nonclinical and clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional nonclinical and clinical studies before approving our marketing applications. There can be no assurance that upon inspection or conclusion of an RRA by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with GCP regulations. In addition, our clinical studies must be conducted with product generated under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process. Moreover, our business may be implicated if our ~~CRO~~ **CROs** or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare **or data** privacy and security laws. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on- going nonclinical and clinical programs. If CROs 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 data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, a transition period is necessary when a new CRO commences work, which can materially impact our ability to meet our desired clinical development timelines. Though we strive to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects and financial condition. We **rely on third parties, and in..... product candidates or market them.** We are dependent on Junshi Biosciences and Orox / **Gador** for the commercialization of our product candidates in certain markets and we intend to seek additional commercialization partners for major markets, and the failure to commercialize in those markets could have a material adverse effect on our business and operating results. We have **an** exclusive ~~licenses~~ **license** from Junshi Biosciences to develop and commercialize LOQTORZI in the United States and Canada. Our licensors are responsible for supplying us with drug substance and final drug products. Our exclusive licensee, Orox / **Laboratorio Gador S. A.**, is responsible for commercialization of certain of our products and product candidates, including UDENYCA, ~~and YUSIMRY~~ in certain Caribbean and Latin American countries (excluding Brazil, and in the case of UDENYCA, also excluding Argentina). ~~Our~~ **37Our** licenses with Junshi Biosciences, ~~Bioeq~~, Orox / **Laboratorio Gador S. A.**, or other future license or collaboration agreements, may not result in positive outcomes. Factors that may affect the success of our licenses and collaborations include, but are not limited to, the following: • our existing and potential collaboration partners may fail to provide sufficient amounts of commercial products, including because of import restrictions, or they may be ineffective in doing so; • our existing and potential collaboration partners may fail regulatory inspections or RRAs which may preclude or delay the delivery of commercial products; • our existing and potential collaboration partners may fail to exercise commercially reasonable efforts to market and sell our products in their respective licensed jurisdictions or they may be ineffective in doing so; • our existing and potential licensees and collaboration partners may incur financial, legal or other difficulties that force them to limit or reduce their participation in our joint projects; ~~38~~ • our existing and potential licensees and collaboration partners may terminate their licenses or collaborations with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities; and • our existing and potential licensees and collaboration partners may choose to pursue alternative, higher priority programs, which could affect their commitment to us. Moreover, any disputes with our licensees and collaboration partners ~~will could~~ substantially divert the attention of our senior management from other business activities and ~~will may~~ require us to incur substantial costs associated with litigation or arbitration proceedings. If we cannot maintain successful license and collaboration arrangements, our business, financial condition and operating results may be adversely affected. Risks Related to **the UDENYCA Sale and our future operations following the UDENYCA Sale****The announcement and pendency of the UDENYCA Sale, whether or not consummated, may adversely affect our business. The announcement and pendency of the UDENYCA Sale, whether or not consummated, may adversely affect the trading price of our common stock, our business or our relationships with customers, suppliers and employees. In addition, pending the completion of the UDENYCA Sale, we may be unable to attract and retain key personnel and the focus and attention of our management and employee resources may be diverted from operational matters during the pendency of the UDENYCA Sale. The closing of the UDENYCA Sale is subject to multiple conditions beyond our control. Failure to complete the UDENYCA Sale could materially and adversely affect our future business, results of operations, financial condition and stock price. The closing of the UDENYCA Sale is subject to the satisfaction or waiver of various conditions, including FDA authorization of commercial supply from our additional packaging and labeling CMO for UDENYCA. We cannot predict whether and when the conditions will be satisfied. If one or more of these conditions is not satisfied, and as a**

result, we do not complete the UDENYCA Sale, or in the event the UDENYCA Sale is not completed or is delayed for any other reason, we and investors in our common stock may be harmed. If we are unable to satisfy the closing conditions in Intas' favor or if other mutual closing conditions are not satisfied, Intas will not be obligated to complete the UDENYCA Sale. In the event that the UDENYCA Sale is not completed, the announcement of the termination of the UDENYCA Purchase Agreement may adversely affect the trading price of our common stock, our business and operations or our relationships with our employees. Any delay in completing the UDENYCA Sale may significantly reduce the benefits that we expect to achieve if we successfully complete the UDENYCA Sale within the expected timeframe. The UDENYCA Purchase Agreement limits our ability to pursue alternatives to the UDENYCA Sale. The UDENYCA Purchase Agreement contains customary "no-shop" restrictions on our ability to solicit alternative acquisition proposals from third parties for the UDENYCA Business and to provide information to, and participate and engage in discussions or negotiations with, third parties regarding any alternative acquisition proposals. These restrictions are subject to a customary "fiduciary out" provision that allows us, under certain specified circumstances, to provide information to, and participate or engage in discussions or negotiations with and afford access to, third parties with respect to an acquisition proposal if our Board determines in good faith (after consultation with its financial advisor and outside legal counsel) that such alternative acquisition proposal either constitutes a superior proposal or would be reasonably likely to result in a superior proposal, and our Board determines in good faith (after consultation with its outside legal counsel) that the failure to take such actions would be inconsistent with its fiduciary duties pursuant to applicable law. There is no guarantee that we will receive either of the Earnout Payments under the UDENYCA Purchase Agreement. A portion of the Consideration potentially payable to us under the UDENYCA Purchase Agreement is in the form of two Earnout Payments of \$ 37.5 million each. The first such payment is payable by Intas to us if Net Sales of UDENYCA for four consecutive fiscal quarters within the first five full fiscal quarters following the consummation of the UDENYCA Sale are equal to or greater than \$ 300 million, and the second such payment is payable by Intas to us if Net Sales of UDENYCA for four consecutive fiscal quarters within the first seven full fiscal quarters following the consummation of the UDENYCA Sale are equal to or greater than \$ 350 million. However, there is no guarantee that we will receive either of the Earnout Payments, and we may not receive more than the Closing Consideration for selling the UDENYCA Business. If we do not receive the Earnout Payments the total consideration paid to us for the sale of UDENYCA will be significantly lower, which could be harmful to our future financial position. Our stockholders should not assume that they will receive any of the proceeds of the UDENYCA Sale. The proceeds from the UDENYCA Sale will be paid directly to us and not to our stockholders. We intend to use substantially all of the proceeds to pay off certain financial liabilities and for working capital and general corporate purposes in connection with its continued business which is focused on the research, development and commercialization of innovative immunotherapies to treat cancer and the development of an innovative immuno-oncology pipeline. We have never declared or paid any cash dividends on our common stock and the Board does not currently expect to declare a special dividend of any UDENYCA Sale proceeds to our stockholders. We have incurred and will continue to incur significant expenses in connection with the UDENYCA Sale, regardless of whether the UDENYCA Sale is completed. We have incurred and expect to continue to incur significant expenses related to the UDENYCA Sale. These expenses are substantial and include, but are not limited to, financial advisory and opinion fees and expenses, legal fees and expenses, accounting fees and expenses, certain employee expenses, filing fees, printing expenses and other related fees and expenses. Many of these expenses have already been incurred by us and will be payable by us regardless of whether the UDENYCA Sale is completed. Immediately following the UDENYCA Sale, we will be a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Upon the closing of the UDENYCA Sale, we will no longer operate the UDENYCA Business, other than certain transition activities for a temporary period of time to transition the UDENYCA Business to Intas pursuant to the UDENYCA TSA, and will be focused on the research, development and commercialization of innovative immunotherapies to treat cancer and the commercialization of LOQTORZI for the treatment of NPC patients in the U. S. We expect to continue to generate revenue by sales of our commercial product LOQTORZI and otherwise expect to devote substantial resources to our research, development and commercialization efforts for our pipeline product candidates. However, there is no guarantee that these efforts will ever result in any meaningful revenue for us, and revenue generated from these immunotherapies alone or in combination with revenue generated by LOQTORZI may never equal or surpass revenue generated by the UDENYCA Business. If our stock price decreases after the closing of the UDENYCA Sale because our revenue is lower than when we operated the UDENYCA Business or for other reasons it could result in the delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business and prospects. We have discretion in the use of the proceeds from the UDENYCA Sale and our choices about the use of proceeds may not be effective. If the UDENYCA Sale is consummated, we will receive the Closing Consideration proceeds from the UDENYCA Sale. We announced that we plan to use a portion of the proceeds of the UDENYCA Sale to pay off the \$ 230 million in aggregate principal amount of convertible notes due April 2026 and to buy out the right to receive royalties on net sales of UDENYCA, which is expected to be \$ 47.7 million, assuming a close late in the first quarter or early in the second quarter of 2025, in accordance with the Revenue Purchase and Sale Agreement. We plan to use the remainder for working capital and general corporate purposes, in connection with our continued business, which is focused on the research, development and commercialization of innovative immunotherapies to treat cancer and the development of an innovative immuno-oncology pipeline and the commercialization of LOQTORZI for the treatment of NPC patients in the U. S. We will have broad discretion in the application of the proceeds from the UDENYCA Sale and our planned use of proceeds described above may not improve our results of operations or enhance the value of our common stock. If our planned use of

proceeds is not effective it could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest the proceeds in a manner that does not produce income or that loses value. Although our Board will evaluate various alternatives regarding the use of the proceeds from the UDENYCA Sale, it has made no decision with respect to the specific use of 39 proceeds other than as described above and has not committed to making any such decision by a particular date. This uncertainty may negatively impact the value and liquidity of our common stock. There are risks and uncertainties associated with the transition services agreement that will be entered into between us and Intas at or before the date of the closing of the UDENYCA Sale, one or more of which could have a material adverse effect on our business, financial condition, results of operations, cash flows or stock price. In connection with the UDENYCA Sale, we are required to enter into the UDENYCA TSA pursuant to which we expect to be required to provide certain business support services to Intas for a defined transition period of time. There are a number of risks and uncertainties associated with the UDENYCA TSA, which could have a material adverse effect on our business, financial condition, results of operations, cash flows or stock price, including, among other things: • the need to expend our management and employee time and attention on the UDENYCA TSA that could be spent on other areas of our business; • the need to provide significant support services under the UDENYCA TSA on behalf of Intas, such as logistics, payments, accounting, finance, commercial, regulatory and manufacturing support; • the exposure to the financial status of Intas for any payments due to us under the UDENYCA TSA, which may be significant; and • potential unanticipated costs to us under the UDENYCA TSA. **Risks Related to Manufacturing and Supply Chain** We are subject to a multitude of manufacturing risks and the risks of inaccurately forecasting sales of our products. We also need to make a determination of excess or obsolete inventory that requires significant judgment and may result in write-downs of inventory, charges related to firm purchase commitments, or both. Any adverse developments affecting the manufacturing operations of our products and product candidates could substantially increase our costs and limit supply for our products and product candidates. The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including but not limited to: • product loss due to contamination, equipment failure or improper installation or operation of equipment or vendor or operator error; • equipment failures, labor shortages, natural disasters, power failures and numerous other factors associated with the manufacturing facilities in which our product candidates are produced, and potentially exacerbated by climate change; and • disruption of supply chains for critical and specialized raw materials, delays in regulatory inspections of manufacturing and testing facilities, and reduced manufacturing capacities created by global events such as the COVID- 19 pandemic and the ongoing conflict-conflicts in Ukraine and the Middle East. We have experienced reduced production yields, product defects and other supply disruptions. For example, we have experienced failures with respect to the manufacturing of certain lots of each of our products and product candidates resulting in delays prior to our taking corrective action. Additionally, if microbial, viral or other contaminations are discovered in our products or product candidates or in the manufacturing facilities in which our products or product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any adverse developments affecting manufacturing operations for our products and product candidates, including due to sudden or long-term changes in weather patterns or conflicts in particular geographic areas, may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our products and product candidates. We also need to make a determination of excess or obsolete inventory that requires significant judgment and includes consideration of many factors, such as estimates of future product demand, current and future market conditions, product expiration information and potential product obsolescence, among others. Although we believe that the assumptions we use in estimating potential inventory write-downs are reasonable, if actual market conditions are less favorable than projected by us, write-downs of inventory, charges related to firm purchase commitments, or both may be required which would be recorded as cost of goods sold in our consolidated statements of operations. Adverse developments affecting our assumptions of the level and timing of demand for our products include those that are outside of our control such as the actions taken by competitors and customers, the direct or indirect effects of the COVID- 19 pandemic, and other factors. We 40 We may have to take inventory write-downs and incur other charges and expenses, such as charges related to firm purchase commitments, for products that are manufactured in reliance on a forecast that proves to be inaccurate because we do not sell as many units as forecasted. For example, during the third quarter of 2022, we recorded a \$ 26. 0 million write-down of UDENYCA inventory that was at risk of expiration and during the fourth quarter of 2023, we recorded a \$ 47. 0 million charge for the write-down of slow moving YUSIMRY inventory and the related partial recognition of certain firm purchase commitments. Although we believe that the assumptions that we use in estimating inventory write-downs are reasonable, additional write-downs of inventory may be required in the future if actual market conditions are less favorable than our projections, which could materially and adversely impact our financial results. In addition to such write-downs, we may also have to incur charges and expenses related to firm purchase commitments or for product candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives. 39 We On September 13, 2024, we announced that our third-party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to over-commitments and capacity constraints. These delays caused a temporary UDENYCA supply interruption that quickly took away our ability to sell our product UDENYCA, that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024. The Company announced in January 2025 that due to strong demand in Q4 2024 and into Q1 2025, all three presentations of UDENYCA were being temporarily allocated. Based on individual distributor historical purchasing patterns, supply allocations to wholesalers for all three presentations of UDENYCA were removed between the end of January 2025 and the end of February 2025. The temporary UDENYCA supply interruption had a significant impact on our business, relationships with customers and affected the negotiations with potential counterparties in the UDENYCA Sale. Similar circumstances to the temporary UDENYCA supply interruption could arise in the future,

which would have an adverse impact on our financial statements and reputation. We currently engage single suppliers for manufacture, clinical trial services, formulation development and product testing of our **products and** product candidates. The loss of any of these suppliers or vendors could materially and adversely affect our business. For our products and our product candidates, we currently engage a distinct vendor or service provider for each of the principal activities supporting our manufacture and development of these products, such as manufacture of the biological substance present in each of the products, manufacture of the final filled and finished presentation of these products, as well as laboratory testing, formulation development and clinical testing of these products. Because we currently have engaged a limited number of back- up suppliers or vendors for these single- sourced services, and although we believe that there are alternate sources that could fulfill these activities, we cannot **make any assure assurances you** that identifying and establishing relationships with alternate suppliers and vendors would not result in significant delay in the development of our product candidates. Additional delays or cost increases could occur due to the direct or indirect effects of the COVID- 19 pandemic and the ongoing conflict in Ukraine. Additionally, we may not be able to enter into arrangements with alternative service providers on commercially reasonable terms or at all. A delay in the development of our **products and** product candidates, or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers, could have a material adverse impact on our business. **For example, on September 13, 2024, we announced that our third- party labeling and packaging CMO for UDENYCA delayed production of UDENYCA due to over- commitments and capacity constraints. These delays caused a temporary UDENYCA supply interruption that quickly took away our ability to sell our product UDENYCA, that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024. The Company announced in January 2025 that due to strong demand in Q4 2024 and into Q1 2025, all three presentations of UDENYCA were being temporarily allocated. 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All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the **quality-41quality** of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners, or our contract manufacturers must supply all necessary documentation in support of a Section 351 (k) BLA, original BLA, NDA or MAA on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaboration partners and third- party contractors must **pass successfully complete** a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not **pass successfully complete** a pre- approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. The regulatory authorities also may, at any time following approval of a product for sale, inspect, audit or initiate an RRA of the manufacturing facilities of our collaboration partners and third- party contractors. If any such inspection, audit or RRA identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection, audit or RRA, we or the relevant regulatory authority may require remedial measures that may be costly **and/or** time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we, our collaboration partners or any of our third- party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be materially harmed. Additionally, if **a manufacturer cannot meet the supply demand,** supply from **one approved manufacturer is interrupted,** an alternative manufacturer would **require the submission of need to be qualified through a PAS, BLA / NDA supplement or MAA variation Variation (** or equivalent foreign regulatory filing **)** which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. **For example, on September 13, 2024, we announced that our third- party labeling and packaging CMO for**

UDENYCA delayed production of UDENYCA due to over- commitments and capacity constraints. 40These-- These delays caused a temporary UDENYCA supply interruption that quickly took away our ability to sell our product UDENYCA, that makes up a large percentage of our total revenue, for a significant period of time. Production resumed in November 2024. The Company announced in January 2025 that due to strong demand in Q4 2024 and into Q1 2025, all three presentations of UDENYCA were being temporarily allocated. Based on individual distributor historical purchasing patterns, supply allocations to wholesalers for all three presentations of UDENYCA were removed between the end of January 2025 and the end of February 2025. These factors could cause us to incur additional costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue. The structure of complex proteins used in protein- based therapeutics is inherently variable and highly dependent on the processes and conditions used to manufacture them. If we are unable to develop manufacturing processes that achieve a requisite degree of biosimilarity to the originator drug, and within a range of variability considered acceptable by regulatory authorities, we may not be able to ~~obtain~~ **maintain** regulatory approval for our biosimilar ~~products--~~ **product** . Protein- based therapeutics are inherently heterogeneous and their structures are highly dependent on the production process and conditions. Products from one production facility can differ within an acceptable range from those produced in another facility. Similarly, physicochemical differences can also exist among different lots produced within a single facility. The physicochemical complexity and size of biologic therapeutics create significant technical and scientific challenges in the context of their replication as biosimilar products. ~~The~~ **42The** inherent variability in protein structure from one production lot to another is a fundamental consideration with respect to establishing biosimilarity to an originator product to support regulatory approval requirements. For example, the glycosylation of the protein, meaning the manner in which sugar molecules are attached to the protein backbone of a therapeutic protein when it is produced in a living cell, is critical to therapeutic efficacy, half- life, efficacy and even safety of the therapeutic and is therefore a key consideration for biosimilarity. Defining and understanding the variability of an originator molecule in order to match its glycosylation profile requires significant skill in cell biology, protein purification and analytical protein chemistry. Furthermore, manufacturing proteins with reliable and consistent glycosylation profiles at scale is challenging and highly dependent on the skill of the cell biologist and process scientist. There are extraordinary technical challenges in developing complex protein- based therapeutics that not only must achieve an acceptable degree of similarity to the originator molecule in terms of characteristics such as the unique glycosylation pattern, but also the ability to develop manufacturing processes that can replicate the necessary structural characteristics within an acceptable range of variability sufficient to satisfy regulatory authorities. Given the challenges caused by the inherent variability in protein production, we may not be successful in ~~continuing to developing~~ **develop** our biosimilar ~~products--~~ **product** if regulators conclude that we have not achieved a sufficient level of biosimilarity to the originator product, or that the processes we use are unable to generate our products **are** within an acceptable range of variability. Risks Related to Adverse Events Our products or our product candidates may cause undesirable side effects or have other properties that could, as applicable, delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted. As with most pharmaceutical products, use of our products or our product candidates could be associated with side effects or adverse events, which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects such as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which will harm our business. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product- related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, prospects and financial condition. Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other such related considerations, hence any manufacturing process changes we implement prior to or after regulatory approval could impact product safety and efficacy. ~~41Drug-- Drug -~~ related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance and we are required to maintain product liability insurance pursuant to certain of our license agreements. We ~~believe our~~ **cannot assure that out** product liability ~~insurance~~ coverage ~~is sufficient~~ **will cover** in **full claims to which** ~~light of our current clinical programs; however, we~~ **are exposed. We** may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management' s attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale. Additionally, if one or more of our product candidates receives marketing approval,

and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to: ● regulatory authorities may withdraw approvals of such product; ● regulatory authorities may require additional warnings on the label; **43** ● we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and / or other elements to assure safe use; ● we could be sued and held liable for harm caused to patients; and ● our reputation may suffer. 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, results of operations and prospects. **For our products and** If we receive approval for our product candidates, regulatory agencies including the FDA and foreign regulatory agencies, regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or extended delay in approval or clearance of future products. Adverse events involving an originator product, ~~or other biosimilars of such originator product~~, **or other anti- PD- 1 or PD- L1 antibody product** may negatively affect our business. In the event that use of an originator product, ~~or other biosimilar for such originator product~~, **or anti- PD- 1 or PD- L1 antibody product** results in unanticipated side effects or other adverse events, it is likely that our ~~biosimilar~~ product will be viewed comparably and may become subject to the same scrutiny and regulatory sanctions as the originator product ~~or other biosimilar~~, **or other anti- PD- 1 or PD- L1 antibody product**, as applicable. Accordingly, we may become subject to regulatory supervisions, clinical holds, product recalls or other regulatory actions for matters outside of our control that affect the originator product, ~~or other biosimilar~~, **or other anti- PD- 1 or PD- L1 antibody product**, as applicable, if and until we are able to demonstrate to the satisfaction of our regulators that our ~~biosimilar~~ product is not subject to the same issues leading to the regulatory action as the originator product or other biosimilar ~~or other biosimilar~~, **or other anti- PD- 1 or PD- L1 antibody product**, as applicable. Risks Related to Intellectual Property If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third- party claims of intellectual property infringement may prevent or delay our development and commercialization efforts. Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. ~~42~~**Our** research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. The ~~companies~~ **company** that originated the ~~products~~ **product** for which we introduced a ~~biosimilar~~ ~~versions~~ **version**, such as Amgen, ~~AbbVie and Genentech~~, as well as other competitors (including other companies developing biosimilars) have developed, and are continuing to develop, worldwide patent portfolios of varying sizes and breadth, many of which are in fields relating to our business, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. Third parties may assert that we are employing their proprietary technology without authorization. We are aware of third- party patents or patent applications with claims, for example, to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. While we have conducted freedom to operate analyses with respect to our products and our product candidates, including our in-licensed biosimilar candidates, as well as our pipeline candidates, we cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. With respect to products we are evaluating for inclusion in our future product pipeline, our freedom to operate analyses, including our research on the timing of potentially relevant patent expirations, are ongoing. ~~There~~ **44****There** may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions, which do not require publication of patent applications until 18 months after filing. Moreover, some United States patents may issue without any prior publication in cases where the patent applicant does not also make a foreign filing. We may also face claims from non- practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid ~~and~~ or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable 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. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have

sufficient resources to bring these actions to a successful conclusion. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial monetary damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or are required to seek licenses from third parties, these licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license may obligate us to pay substantial license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would likely involve substantial litigation expense and would likely be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may, in addition to being blocked from the market, have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. ~~On May 10, 2017, Amgen Inc. and Amgen Manufacturing Inc. filed an action against us in the United States District Court for the District of Delaware alleging infringement of one or more claims of Amgen's US patent 8, 273, 707 (the "707 patent") under 35 U. S. C. § 271. The complaint seeks injunctive relief, monetary damages and attorney fees. On December 7, 2017, the United States Magistrate Judge issued under seal a Report and Recommendation to the District Court recommending that the District Court grant, with prejudice, our pending motion to dismiss Amgen's complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12 (b) (6). On March 26, 2018, Judge Stark of the District Court adopted the United States Magistrate Judge's Report and Recommendation to grant our motion pursuant to Federal Rule of Civil Procedure 12 (b) (6) to dismiss with prejudice the patent infringement complaint alleging infringement of the '707 patent on the grounds that such complaint failed to state a claim upon which relief may be granted. In May 2018, Amgen filed a Notice of Appeal in the United States Court of Appeals for the Federal Circuit. We and Amgen filed briefs in this matter and oral argument was held on May 8, 2019. On July 29, 2019, the Federal Circuit issued a precedential opinion affirming the District Court's judgment in our favor. The Federal Circuit held that the doctrine of prosecution history estoppel barred Amgen from succeeding on its infringement claim and affirmed the District Court's dismissal. In a Joint Status Report, dated September 20, 2019, Amgen stated that it does not intend to further appeal the Federal Circuit's decision. On October 11, 2019, we filed a Motion for Attorneys' Fees with the District Court. Amgen filed its Answering Brief in Opposition on November 8, 2019. On November 22, 2019, we filed our Reply Brief with the District Court. On November 30, 2020, the District Court issued an order denying our motion. On January 24, 2019, we entered into settlement and license agreements with AbbVie, which grant us global, royalty-bearing, non-exclusive license rights under AbbVie's intellectual property to commercialize YUSIMRY. The global settlements resolved all the pending disputes between the parties related to YUSIMRY. Under the United States settlement, our license period in the United States commenced on July 1, 2023.~~ In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, IPR, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. An unfavorable outcome in any such proceeding could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights. Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the E. U. states and Switzerland seeking to extend certain patent protection, which, if approved, may interfere with or delay the launch of one or more of our products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. The companies that originated the products for which we intend to introduce biosimilar versions, as well as other competitors (including other biosimilar companies) may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. We do not know whether any of our pending patent applications will result in the issuance of any patents or whether the rights granted under any patents issuing from these applications will prevent any of our competitors from marketing similar products that may be competitive with our own. Moreover, even if we do obtain issued patents, they will not guarantee us the right to use our patented ~~technology~~ **technology 45** for commercialization of our product candidates. Third parties may have blocking patents that could prevent us from commercializing our own products, even if our products use or embody our own, patented inventions. The validity and enforceability of patents are generally uncertain and involve complex legal and factual questions. Any patents that may be issued on our pending applications may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing products similar to ours. Furthermore, our competitors may develop similar or alternative technologies not covered by any patents that may issue to us. For technologies for which we do

not seek patent protection, we may rely on trade secrets to protect our proprietary position. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, consultants, advisors, contractors or collaborators. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. ~~44~~**We** may be involved in lawsuits or IPR proceedings to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. We may discover that competitors are infringing our issued patents. Expensive and time-consuming litigation may be required to abate such infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid ~~and/or~~ unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity ~~and/or~~ unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if we cannot obtain a license from the prevailing party on commercially reasonable terms. Third parties may request an IPR of our patents in the USPTO. An unfavorable decision may result in the revocation of our patent or a limitation to the scope of the claims of our patents. Our defense of litigation, interference or IPR proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during any litigation we initiate to enforce our patents. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. We employ individuals, retain independent contractors and consultants and members on our board of directors or scientific advisory board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chief Executive Officer, Dennis M. Lanfear, is a former employee of Amgen. Mr. Lanfear was employed at Amgen during periods when Amgen's operations included the development and commercialization of Neulasta. Senior members of our commercial team and medical affairs team who were responsible for the launch of additional presentations of UDENYCA formerly held positions at Amgen. Our board of directors and scientific advisory board include members who were former employees of Genentech, Amgen and ~~Abbott~~ **46Abbott** Laboratories. Although we have procedures in place to try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. 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. On March 3, 2017, Amgen filed an action against us, KBI Biopharma, our employee Howard S. Weiser and Does 1-20 in the Superior Court of the State of California, County of Ventura. The complaint, which was amended, alleged that we engaged in unfair competition and improperly solicited and hired certain former Amgen employees in order to acquire and access trade secrets and other confidential information belonging to Amgen. The complaint, as amended, sought injunctive relief and monetary damages. On May 2, 2019, we and Amgen settled the trade secret action brought by Amgen. The details of the settlement are confidential, but we will continue to market UDENYCA, **until the closing of the UDENYCA Sale, and began paying from July 1, 2019 to July 1, 2024 we paid** a mid-single digit royalty to Amgen ~~for five years starting on July 1, 2019~~. If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. ~~45~~**We** are a party to certain non-exclusive intellectual property license agreements with certain vendors ~~(pertaining to mammalian cell lines) and with AbbVie (pertaining to AbbVie's intellectual property related to YUSIMRY)~~ that are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and

other obligations on us. If we fail to comply with our obligations under these agreements or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates. In the event we breach any of our obligations related to such agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to: ● the scope of rights granted under the license agreement and other interpretation- related issues; ● the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; ● the sublicensing of patents and other rights; ● our diligence obligations under the license agreement and what activities satisfy those diligence obligations; ● the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and ● the priority of invention of patented technology. If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could have a material adverse effect on our business. We may not be successful in obtaining or maintaining necessary rights to our products and product candidates through acquisitions and in- licenses. We currently have rights to certain intellectual property, through licenses from third parties and under patent applications that we own, to develop and commercialize our products and product candidates. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license or use these proprietary rights. We may be unable to acquire or in- license compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, **companies 47 companies** that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment. We may also get into disputes or litigation with third parties from whom we license intellectual property rights necessary for the sale of our products. ~~For example, on June 6, 2023 we received a notice letter from AbbVie alleging that we breached our settlement and license agreement with AbbVie (the “AbbVie Agreement”), which grants us a royalty- bearing, non- exclusive license under AbbVie’s intellectual property rights to commercialize YUSIMRY in the United States commencing on July 1, 2023, because of our announcement on June 1, 2023 of our pricing agreement with Mark Cuban Cost Plus Drug Company, PBC and its plans to offer YUSIMRY to its customers beginning in July 2023. The parties engaged in discussions to resolve the dispute and on June 14, 2023 entered into a stipulation resolving our motion for temporary restraining order, whereby AbbVie agreed that it will not seek to terminate the AbbVie Agreement based on its June 6, 2023 notice and that it will not terminate the AbbVie Agreement unless it first serves a new notice of breach and affords us an opportunity to cure any alleged breach. While we remain in discussion with AbbVie, the litigation is ongoing and there can be no guarantee we will reach resolution. If we are unable to successfully obtain required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer. 46~~Our ability to market our biosimilar products in the United States may be significantly delayed or prevented by the BPCIA patent dispute resolution mechanism. The BPCIA created an elaborate and complex patent dispute resolution mechanism for biosimilars that, if we choose to implement it, could prevent us from launching our product candidates in the United States or could substantially delay such launches. However, even if we elect not to implement this mechanism, the launch of our products in the United States could still be prevented or substantially delayed by intellectual property disputes with originator companies that market the reference products on which our biosimilar products are based. The BPCIA establishes a patent disclosure and briefing process between the biosimilar applicant and the originator that is demanding and time- sensitive. While certain aspects of this process are still being tested in the federal courts, the United States Supreme Court, as discussed further below, ruled in 2017 that this process is not mandatory, such that a biosimilar applicant may elect to engage in this process, but is not required to do so. The following is an overview of the patent exchange and patent briefing procedures established by the BPCIA for biosimilar applicants that elect to employ them: 1. Disclosure of the Biosimilar Application. Within 20 days after the FDA publishes a notice that its application has been accepted for review, a Section 351 (k) biosimilar applicant may elect to provide a copy of its application to the originator if it chooses to engage in the BPCIA patent exchange mechanism. 2. Identification of Pertinent Patents. Within 60 days of the date of receipt of the application the originator must identify patents owned or controlled by the originator, which it believes could be asserted against the biosimilar applicant. 3. Statement by the Biosimilar Applicant. Following the receipt of the originator’s patent list, the biosimilar applicant must state either that it will not market its product until the relevant patents have expired or alternatively provide its arguments that the patents are invalid, unenforceable or would not be infringed by the proposed biosimilar product candidate. The biosimilar applicant may also provide the originator with a list of patents it believes the brand- name firm could assert against the reference product. 4. Statement by the Originator. In the event the biosimilar applicant has asserted that the patents are invalid, unenforceable or would not be infringed by the proposed follow- on product, the originator must provide the biosimilar applicant with a response within 60 days. The response must provide the legal and factual basis of the opinion that such patent will be infringed by the commercial marketing of the proposed biosimilar. 5. Patent Resolution Negotiations. If the originator provides its detailed views that the proposed biosimilar would infringe valid and enforceable patents, then the parties are required to engage in good faith negotiations to identify which of the discussed patents will be the subject of a patent infringement action. If the parties agree on the patents to be litigated, the brand- name firm must

bring an action for patent infringement within 30 days. 6. Simultaneous Exchange of Patents. If those negotiations do not result in an agreement within 15 days, then the biosimilar applicant must notify the originator of how many patents (but not the identity of those patents) that it wishes to litigate. Within five days, the parties are then required to exchange lists identifying the patents to be litigated. The number of patents identified by the originator may not exceed the number provided by the biosimilar applicant. However, if the biosimilar applicant previously indicated that no patents should be litigated, then the originator may identify one patent. 7. Commencement of Patent Litigation. The originator must then commence patent infringement litigation within 30 days. That litigation will involve all of the patents on the originator's list and all of the patents on the follow-on applicant's list. The follow-on applicant must then notify the FDA of the litigation. The FDA must then publish a notice of the litigation in the Federal Register. 8. Notice of Commercial Marketing. The BPCIA requires the biosimilar applicant to provide notice to the originator 180 days in advance of its first commercial marketing of its proposed follow-on biologic. The originator is allowed to seek a preliminary injunction blocking such marketing based upon any patents that either party had preliminarily identified but were not subject to the initial phase of patent litigation. The litigants are required to "reasonably cooperate to expedite such further discovery as is needed" with respect to the preliminary injunction motion. The federal courts have not yet settled the issue as to when, or under what circumstances, the biosimilar applicant must provide the 180-day notice of commercial marketing provided in the BPCIA. On June 12, 2017, the Supreme Court issued its decision in *Amgen v. Sandoz*, holding that (i) the "patent dance" is optional; and (ii) the 180-day pre-marketing notification may be given either before or after receiving FDA approval of the biosimilar product. The Supreme Court declined to rule whether a state injunctive remedy may be available to the originator and remanded that question to the Federal 47th Circuit for further consideration. On December 14, 2017, the Federal Circuit decided that state law claims are preempted by the BPCIA on both field and conflict grounds. A significant legal risk for a biosimilar applicant that pursues regulatory approval under the Section 351(k) regulatory approval route and also elects to engage in the above-described BPCIA patent exchange mechanism, is that the process could result in the initiation of patent infringement litigation prior to FDA approval of a Section 351(k) application, and such litigation could result in blocking the market entry of the biosimilar product. However, even if biosimilar applicants opt out of the BPCIA patent exchange process, originators will still have the right to assert patent infringement as a basis to enjoin a biosimilar product launch. Thus, whether or not we engage in the BPCIA patent exchange process, there is risk that patent infringement litigation initiated by originators could prevent us indefinitely from launching our biosimilar products. The legal and strategic considerations weighing for or against a decision to voluntarily engage in the BPCIA patent exchange process are complex and will differ on a product-by-product basis. If we decide to engage in the BPCIA patent exchange process, preparing for and conducting the patent exchange, briefing and negotiation process outlined above will require extraordinarily sophisticated legal counseling and extensive planning, all under extremely tight deadlines. Moreover, it may be difficult for us to secure or retain such legal support if large, well-funded originators have already entered into engagements with highly qualified law firms or if the most highly qualified law firms choose not to represent biosimilar applicants due to their long-standing relationships with originators. Under the complex, and uncertain rules of the BPCIA patent provisions, coupled with the inherent uncertainty surrounding the legal interpretation of any originator patents that might be asserted against us in this new process, we see substantial risk that the BPCIA process may significantly delay or defeat our ability to market our biosimilar products in the United States, or may result in us incurring substantial legal settlement costs.

Risks Related to the Discovery and Development of Our Product Candidates We are heavily dependent on the development, clinical success, regulatory approval and commercial success of our product candidates. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized. We ~~invested~~ **invest substantially** ~~substantial~~ **all** of our efforts and financial resources to identify, acquire and develop our product candidates. Our future success is dependent on our ability to develop, obtain regulatory approval for, and then commercialize and obtain adequate third-party coverage and reimbursement for one or more of our product candidates. We currently have ~~three~~ **two** approved products: UDENYCA ; YUSIMRY and LOQTORZI. Our product candidates are in varying stages of development and will require additional clinical development, management of nonclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supplies, commercial organization and significant marketing efforts before we generate any revenue from product sales. Other than certain pharmacokinetic bridging studies, we have not initiated ~~phase~~ **Phase** 3 clinical trials for other product candidates in our pipeline. It may be some time before we file for market approval with the relevant regulatory agencies for these product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we and our existing or future collaboration partners do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. We, together with our collaboration partners, generally plan to seek regulatory approval to commercialize our product candidates in the United States, the E. U., and additional foreign countries where we or our partners have commercial rights. To obtain regulatory approval, we and our collaboration partners must comply with numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales, and pricing and distribution of our product candidates. Even if we and our collaboration partners are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we and our collaboration partners are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected. ~~48~~ **The** ~~The~~ regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and the regulatory approval requirements for biosimilars are evolving. If we and our collaboration partners are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting and export and import of biologic and biosimilar products are subject to extensive regulation by the

FDA and other regulatory authorities in the United States, by the EMA and EEA Competent Authorities in the European Economic Area (“ EEA ”), and by other regulatory authorities in other countries, where regulations differ from country to country. Neither we nor any existing or future collaboration partners are permitted to market our product candidates in the United States until we and our collaboration partners receive approval from the FDA, or in the EEA until we and our collaboration partners receive EC or EEA Competent Authority approvals. The time required to develop new products or obtain approval for new products by the FDA and comparable foreign authorities is unpredictable, may take many years following the completion of clinical studies and depends upon numerous factors. Further, applications to the Human Genetic Resources Administration of China (HGRAC) required for any activities, including development activities and data sharing with our partners in China, may result in product development delays. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’ s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Neither we nor any collaboration partner has obtained regulatory approval for any of our products and product candidates, other than UDENYCA, which has received 48 received approval from the FDA and EMA, YUSIMRY, which has received approval from the FDA, and LOQTORZI, which has received approval from the FDA and is also approved for use in China, and it is possible that none of our other current or future product candidates will ever obtain additional regulatory approvals. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following: ● the data collected from clinical studies of our product candidates may not be sufficient to support the submission of an original BLA, an NDA, a Section 351 (k) BLA, a biosimilar marketing authorization under Article 6 of Regulation (EC) No. 726 / 2004 and / or Article 10 (4) of Directive 2001 / 83 / EC in the EEA or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere; ● the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies; ● the FDA may determine that the population studied in the clinical program may not be sufficiently broad or representative to assure safety and efficacy in the full population for which we seek approval, or that conclusions of clinical trials conducted in a single country or region outside the United States may not be generalizable to the patient population in the United States; ● the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies; ● we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate’ s risk- benefit ratio for its proposed indication is acceptable; ● the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of our collaborators or 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. This approval process, as well as the unpredictability of the results of clinical studies, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business. Any delays in the commencement or completion of clinical testing could significantly impact our product development costs and could result in the need for additional financing, which may be unavailable to us on acceptable terms or at all. 49 Clinical -- Clinical drug development involves a lengthy and expensive process and we may encounter substantial delays in our clinical studies or may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we or our collaboration partners, or both, as the case may be, must conduct clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of later- stage clinical studies. Product candidates that have shown promising results in early- stage clinical studies may still suffer significant setbacks in subsequent registration clinical studies. There is a high failure rate for product candidates proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Nonclinical and clinical data are also often susceptible to varying interpretations and analyses. We do not know whether any clinical studies we may conduct for our product candidates will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval. Furthermore, biosimilar clinical studies must use originator products as comparators, and such supplies may not be available on a timely basis to support such trials. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to: 49 ● inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical studies; ● delays in reaching a consensus with regulatory agencies on study design; ● delays in reaching agreement on acceptable terms with prospective CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites; ● delays in obtaining required IRB approval at each clinical study site; ● imposition of a clinical hold by regulatory agencies, after review of an IND or amendment or equivalent application or amendment, or an inspection of our clinical study operations or study sites or as a result of adverse events reported during a clinical trial; ● delays in recruiting suitable patients to participate in our clinical studies sponsored by us or our partners; ● difficulty collaborating with patient groups and investigators; ● failure by our CROs, other third parties or us to adhere to clinical study requirements; ● failure to perform in accordance with the FDA’ s good clinical practices requirements or applicable regulatory guidelines in other countries; ● delays in patients completing participation in a study or return for post- treatment follow- up, or patients dropping out of a study; ● occurrence of adverse events associated with the product candidate

that are viewed to outweigh its potential benefits; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • the cost of clinical studies of our product candidates being greater than we anticipate; • clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical studies or abandon product development programs; and • delays in manufacturing, testing, releasing, validating or importing / exporting and / or distributing sufficient stable quantities of our product candidates and originator products for use in clinical studies or the inability to do any of the foregoing. ~~50~~Any-- Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to continue to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials will depend, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable regulatory authorities. Some of the conditions for which we may plan to evaluate our product candidates are rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. Patient enrollment in clinical trials may be affected by other factors, including: • size and nature of the targeted patient population; • severity of the disease or condition under investigation; • availability and efficacy of approved therapies for the disease or condition under investigation; • patient eligibility criteria for the trial in question as defined in the protocol; • perceived risks and benefits of the product candidate under study; ~~50~~ • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating; • efforts to facilitate timely enrollment in clinical trials; • patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • proximity and availability of clinical trial sites for prospective patients; • continued enrollment of prospective patients by clinical trial sites; and • the risk that patients enrolled in clinical trials will drop out of such trials before completion. Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll any clinical trials. We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates. The development, manufacture and commercialization of biosimilar products under various global regulatory pathways pose unique risks. We and our collaboration partners intend to pursue market authorization globally. In the United States, an abbreviated pathway for approval of biosimilar products was established by the BPCIA, enacted on March 23, 2010, as part of the ACA. The BPCIA established this abbreviated pathway under Section 351 (k) of the PHSA. Subsequent to the enactment of the BPCIA, the FDA issued guidance documents regarding the demonstration of biosimilarity and interchangeability as well as the submission and review of biosimilar applications. Moreover, market acceptance of biosimilar products in the United States is unclear. Numerous states are considering or have already enacted laws that regulate or restrict the substitution by state pharmacies of biosimilars for originator products already licensed by the FDA. Market success of biosimilar products will depend on demonstrating to patients, physicians, payers and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product. ~~51~~We We will continue to analyze and incorporate into our biosimilar development plans any final regulations issued by the FDA, pharmacy substitution policies enacted by state governments and other applicable requirements established by relevant authorities. The costs of development and approval will be dependent upon the application of any laws and regulations issued by the relevant regulatory authorities. Biosimilar products may also be subject to extensive originator- controlled patent portfolios and patent infringement litigation, which may delay and could prevent the commercial launch of a product. Moreover, the BPCIA prohibits the FDA from accepting an application for a biosimilar candidate to a reference product within four years of the reference product's licensure by the FDA. In addition, the BPCIA provides innovative biologics with 12 years of exclusivity from the date of their licensure, during which time the FDA cannot approve any application for a biosimilar candidate to the reference product. Under current E. U. regulations, an application for regulatory approval of a biosimilar drug cannot be submitted in the E. U. until expiration of an eight- year data exclusivity period for the reference (originator) product, measured from the date of the reference product's initial marketing authorization. Furthermore, once approved, the biosimilar cannot be marketed until expiration of a ten- year period following the initial marketing authorization of the reference product, such ten- year period being extendible to 11 years if the reference product received approval of an additional therapeutic indication, within the first eight years following its initial marketing authorization, representing a significant clinical benefit in comparison with existing therapies. In Europe, the approval of a biosimilar for marketing is based on an opinion issued by the EMA and a decision issued by the EC. Therefore, the marketing approval will cover the entire EEA. However, substitution of a biosimilar for the originator is a decision that is made at the national level. Additionally, a number of countries do not permit the automatic substitution of biosimilars for the originator product. Therefore, even if we obtain marketing approval for the entire EEA, we may not receive substitution in one or more European nations, thereby restricting our ability to market our products in those jurisdictions. ~~Other~~51Other regions, including Canada, Japan and South Korea, also have their own legislation outlining a regulatory pathway for the approval of biosimilars. In some cases, other countries have either adopted European guidance (Singapore and Malaysia) or are following

guidance issued by the World Health Organization (Cuba and Brazil). While there is overlap in the regulatory requirements across regions, there are also some areas of non- overlap. Additionally, we cannot predict whether countries that we may wish to market in which do not yet have an established or tested regulatory framework could decide to issue regulations or guidance and/or adopt a more conservative viewpoint than other regions. Therefore, it is possible that even if we obtain agreement from one health authority to an accelerated or optimized development plan, we will need to defer to the most conservative view to ensure global harmonization of the development plan. Also, for regions where regulatory authorities do not yet have sufficient experience in the review and approval of a biosimilar product, these authorities may rely on the approval from another region (e. g., the United States or the E. U.), which could delay our approval in that region. Finally, it is possible that some countries will not approve a biosimilar without clinical data from their population or may require that the biosimilar product be manufactured within their region, or some countries may require both. If other biosimilars of pegfilgrastim (Neulasta) or adalimumab (Humira) are determined to be interchangeable and our biosimilar products ~~product are is~~ not, our business could suffer. The FDA or other relevant regulatory authorities may determine that a proposed biosimilar product is “ interchangeable ” with a reference product, meaning that the biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, if the application includes sufficient information to show that the product is biosimilar to the reference product and that it can be expected to produce the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar product and the reference product is not greater than the risk of using the reference product without such alternation or switch. To make a final determination of interchangeability, regulatory authorities may require additional confirmatory information beyond what we plan to initially submit in our applications for approval, such as more in- depth analytical characterization, animal testing or further clinical studies. Provision of sufficient information for approval may prove difficult and expensive. We cannot predict whether any of our biosimilar products and product candidates will meet regulatory authority requirements for approval not only as a biosimilar product but also as an interchangeable product in any jurisdiction. Furthermore, legislation governing interchangeability could differ by jurisdiction on a state or national level worldwide. **For example, recent U. S. legislative proposals have sought to reduce or altogether eliminate the statutory and regulatory distinctions between interchangeable products and conventional biosimilars. Such efforts, if successful, could reduce or eliminate any competitive or regulatory advantages currently afforded to interchangeable products.** The labelling of “ interchangeable ” is important because, in the United States for example, the first biosimilar determined to be interchangeable with a particular reference, or originator, product for any condition of use is eligible for a period of market exclusivity that ~~52delays--~~ **delays** an FDA determination that a second or subsequent biosimilar product is interchangeable with that originator product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U. S. C. § 262 (l) (6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U. S. C. § 262 (l) (6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U. S. C. § 262 (l) (6). Thus, a determination that another company’ s product is interchangeable with the originator biologic before we obtain approval of our corresponding biosimilar product candidates may delay the potential determination that our products are interchangeable with the originator product, which could materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue. Failure to obtain regulatory approval in any targeted regulatory jurisdiction would prevent us from marketing our products to a larger patient population and reduce our commercial opportunities. We are marketing LOQTORZI ~~and~~ **UDENYCA** and **YUSIMRY** in the United States, and subject to product approvals and relevant patent and settlement agreement expirations, we intend to market our other biosimilar products in the United States and outside the United States on our own or with future collaboration partners. We entered into a distribution agreement with our licensee Orox / **Gador** for the commercialization of ~~a biosimilar versions--~~ **version** of etanercept (Enbrel) ~~(for which we discontinued development), rituximab (Rituxan) (for which we discontinued development), adalimumab (Humira) and~~ pegfilgrastim (Neulasta) in certain Caribbean and Latin American countries. We intend to market our products in the United States and may seek to partner commercially all products outside the United States **, such as our Canada License Agreement with Apotex in Canada for LOQTORZI.** ~~In~~ **52In** order to market our products in the E. U., the United States and other jurisdictions, we and our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The EMA is responsible for the centralized procedure for the regulation and approval of human medicines. This procedure results in a single marketing authorization that is valid in all E. U. countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We or our collaboration partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. Failure to obtain these approvals would materially and adversely affect our business, financial condition and results of operations. We may not be successful in our efforts to identify, develop or commercialize additional product candidates. Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends upon our ability to identify, develop and commercialize additional product candidates. Research programs to identify

new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for clinical development and commercialization for a number of reasons, including but not limited to the following: • we may not be successful in identifying potential product candidates that pass our strict screening criteria; • we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost or at all; • we may not be able to assemble sufficient resources to acquire or discover additional product candidates; • our product candidates may not succeed in nonclinical or clinical testing; • ~~our potential product candidates may fail to show sufficient biosimilarity to originator molecules;~~ and • competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development. ~~53~~**If** any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Risks Related to Our Compliance with Applicable Laws Healthcare reform measures, including the IRA, may increase the difficulty and cost for us to obtain marketing approval for and commercialize our products, affect the prices we may set, and have a material adverse effect on our business and results of operations. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA, was passed, which substantially changed the way health care is financed by both governmental and private insurers and has impacted and continues to impact the United States pharmaceutical industry. The ACA, among other things, modified the **average manufacturer price (“AMP”)** definition under the **Medicaid Drug Rebate Program (“MDRP”)** for drugs that are inhaled, infused, instilled, implanted or injected and not generally distributed through the retail channel; expanded rebate payments under the MDRP to include utilization by individuals enrolled in Medicaid managed care organizations; added a provision to increase the Medicaid rebate for line extension drugs; established annual fees and taxes on manufacturers of certain branded prescription drugs; expanded the entities eligible for discounts under the Public Health Service 340B drug pricing program; and established the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’ s outpatient drugs to be covered under Medicare Part D. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the United States Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. ~~In~~**53****In** addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include the American Rescue Plan Act of 2021, which eliminated the statutory cap on the Medicaid drug rebate beginning January 1, 2024. The rebate was previously capped at 100 % of a drug’ s AMP. Most significantly, on August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined. If a product becomes subject to the IRA negotiation provision and related price cap, that may significantly alter the economic rationale for developing and commercializing a biosimilar. Additionally, in response to the Biden administration’ s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. The cost of prescription pharmaceuticals in the United States is likely to remain the subject of considerable discussion. There have been several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. The likelihood of implementation of these and other reform initiatives is uncertain. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. Individual states in the United States have also proposed and enacted legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, **drug price reporting** and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. **Some states have enacted legislation creating so- called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states**. We expect that additional state and federal healthcare reform measures will be adopted in the future, any ~~54~~**of** which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures, such as a single reimbursement code for biosimilar products. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, new payment

methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. In the E. U., similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the E. U. or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the E. U., including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than E. U., law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most E. U. member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing E. U. and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and E. U., reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We may be subject, directly or indirectly, to federal and state healthcare laws, including fraud and abuse, false claims and physician payment transparency laws. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties. Our operations are directly or indirectly through our customers subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws impact, among other things, sales, marketing and education programs. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or in return for the purchase, recommendation, order or furnishing of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;
- **federal civil and criminal false claims laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;**
- federal civil and criminal false claims laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal physician "sunshine" requirements under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors, and certain non-physician practitioners (physician assistants, nurse practitioners, ~~55clinical~~ **clinical** nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives)), and teaching hospitals and ownership and investment interests held by physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. Efforts to ensure that our operations and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, 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 and the curtailment or restructuring of our

operations, any of which could adversely affect our ability to operate our business and our ~~55~~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. If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We participate in governmental programs that impose drug price reporting, payment, and other compliance obligations on pharmaceutical manufacturers. Medicaid is a joint federal and state program for low-income and disabled beneficiaries. Medicare is a federal program that is administered by the federal government covering individuals age 65 and over as well as those with certain disabilities. Medicare Part B reimburses physicians who administer our products. Under the MDRP, as a condition of having federal funds available for our covered outpatient drugs under Medicaid and under Medicare Part B, we must enter into, and have entered into, an agreement with the Secretary of Health and Human Services to pay a rebate to state Medicaid programs for each unit of our covered outpatient drugs dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid rebates are based on pricing data that we are required to report on a monthly and quarterly basis to CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the AMP for each drug and, in the case of innovator products, the Best Price, which represents the lowest price available from us to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. In connection with Medicare Part B, we must provide CMS with ASP information on a quarterly basis. CMS uses this information to compute Medicare Part B payment rates, which consist of ASP plus a specified percentage. If we become aware that our MDRP submissions for a prior period were incorrect or have changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. Pursuant to the IRA, the AMP and ASP figures we report will also be used to compute rebates under Medicare Part D and Medicare Part B triggered by price increases that outpace inflation. If we fail to provide information timely or are found to have knowingly submitted false information to CMS, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP. Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program is administered by the HRSA and requires us to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered drugs when used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil ~~56~~monetary -- **monetary** penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges. In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, a pharmaceutical manufacturer must also participate in VA FSS pricing program. Under the VA FSS program, we must report the Non- **Federal Average Manufacturer Price ("Non-FAMP")** for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non FAMP using a statutory formula. These four agencies are the VA, the U. S. Department of Defense, the U. S. Coast Guard, and the U. S. Public Health Service (including the Indian Health Service). We must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If a manufacturer participating in the FSS program fails to provide timely information or is found to have knowingly submitted false information, the manufacturer may be subject to civil monetary penalties. Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements. If we are found to have violated ~~state 56~~state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or underage in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of ASP, if we fail to submit the required price data on a timely

basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot **make any assure assurances you** that our submissions will not be found by CMS or other governmental agencies to be incomplete or incorrect. Risks Related to Ownership of Our Common ~~Stock~~ **Stock** The market price of our common stock may be highly volatile, and purchasers of our common stock could incur substantial losses. The market price of our common stock has been highly volatile since our Initial Public Offering (“ IPO ”) and the intraday sales price per share has ranged from \$ ~~10.43-66~~ to \$ 38.10 per share during the period from November 6, 2014 through December 31, ~~2023-2024~~ and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in the “ Risk Factors ” section of this Annual Report on Form 10-K and others such as: • adverse results or delays in preclinical or clinical studies; • the risk of deterioration in our financial conditions, such as reduced collection of cash and increased costs in the future; • any inability to obtain additional funding; • any delay **or inability to satisfy the conditions to closing of the UDENYCA Sale or failure to receive either of the Earnout Payments after the closing**; • any delay in filing an IND, NDA, BLA, Section 351 (k) BLA or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency’ s review of that IND, NDA, BLA, Section 351 (k) BLA or other regulatory submission; • the perception of limited market sizes or pricing for our products and product candidates; • failure to successfully develop and commercialize our product candidates; ~~57~~ • post- marketing safety issues relating to our product candidates or **products biosimilars generally**; • failure to maintain our existing strategic collaborations or enter into new collaborations; • failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights; • changes in laws or regulations applicable to our products; • future outbreaks of COVID- 19 and other viral pandemics; • any inability to obtain adequate product supply for our **products and** product candidates or the inability to do so at acceptable prices; • adverse regulatory decisions; • introduction of new products, services or technologies by our competitors; • failure to meet or exceed financial projections we may provide to the public; • failure to meet or exceed the financial projections of the investment community; • the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; ~~57~~ • announcements of significant acquisitions, dispositions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • additions or departures of key scientific or management personnel; • lawsuits, including but not limited to complaints initiated by stockholders, customers and collaboration partners, and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights; • the outcomes of any citizen petitions filed by parties seeking to restrict or limit the approval of **our biosimilar products- product**; • if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our **company or our** stock; • changes in the market valuations of similar companies; • general market or macroeconomic conditions, including rising interest rates and inflation; • sales of our common stock by us or our stockholders in the future; • trading volume of our common stock; • issuance of patents to third parties that could prevent our ability to commercialize our product candidates; • reductions in the prices of originator products that could reduce the overall market opportunity for our product ~~candidates~~ intended as **a biosimilars- biosimilar** to such originator products; and • changes in ~~biosimilar~~ regulatory requirements that could make it more difficult for us to develop our product candidates. In addition, biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. **We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, which may result in a material misstatement of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations. Effective internal controls are necessary to provide reliable financial reports and to assist in the effective prevention of fraud. Any inability to provide reliable financial reports or prevent fraud could harm our business. We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes- Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. As discussed below in Item 9A, “ Controls and Procedures, ” of this Annual Report on Form 10- K, we have identified a material weakness in the operating effectiveness of our procedures related to documentation and review of certain inventory account reconciliations. The lack of sufficient evidence of the review performed over these accounting records did not allow for the testing and validation that the relevant internal controls operated, and thus it resulted in the material weakness. This material weakness related to documentation and did not result in a misstatement with respect to our financial statements included in this Form 10- K. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of December 31, 2024. Notwithstanding this material weakness, our management concluded the consolidated financial statements included in this Annual Report on Form 10- K present fairly, in all material respects, our financial condition, results of operations and cash flows for the periods covered by this report and our external auditors have issued an unqualified opinion on our consolidated financial statements as of and for the year ended December 31, 2024. Following identification of this material weakness, and as part of our commitment to strengthen our internal control over financial reporting, we are implementing remedial actions to address this deficiency. The remediation measures include additional training and enhancement of our documentation and retention procedures, particularly as they relate to our inventory**

account reconciliations. This remediation is in progress and will require validation and testing of operating effectiveness of internal controls over multiple financial reporting cycles. We will continue to monitor the design and operating effectiveness of these and other processes, procedures and controls and make any further changes management determines are appropriate. While we are undertaking efforts to remediate this material weakness, the material weakness will not be considered remediated until our remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time, and we have concluded, through testing, that the newly implemented and enhanced controls are operating effectively. At this time, we cannot predict the success of such efforts or the outcome of our assessment of the remediation efforts. We can give no assurance that our efforts will remediate this material weakness in our internal control over financial reporting, or that additional material weaknesses will not be identified in the future. The effectiveness of our internal control over financial reporting is subject to various inherent limitations, including judgments used in decision making, assumptions about the likelihood of future events, the possibility of human error and the risk of fraud. If we are unable to remediate the material weakness, our ability to maintain compliance with the covenants contained in our 2029 Loan Agreement, record, process and report financial information accurately, and to prepare the consolidated financial statements within the time periods specified by the rules and regulations of the SEC, could be adversely affected which, in turn, may adversely affect our reputation and business and the trading price of our common stock. Any failure to implement new or improved controls, or difficulties encountered in their implementation, could result in errors in our consolidated financial statements and could cause us to fail to meet our reporting obligations, any of which could diminish investor confidence in us and cause a decline in the price of our common stock. In addition, any such failures could result in litigation or regulatory actions by the SEC or other regulatory authorities, loss of investor confidence, delisting of our common stock, harm to our reputation or diversion of management resources from the operation of our business.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of December 31, 2023-2024, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 30-32.6-3% of our voting stock (assuming no exercise of outstanding options or conversion of our outstanding convertible notes). These stockholders have the ability to influence us through their ownership positions, which may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Our indebtedness could adversely affect our financial condition, our ability to raise additional capital to fund our operations, our ability to operate our business, our ability to react to changes in the economy or our industry and our ability to pay our debts and could divert our cash flow from operations for debt payments. Our leverage and debt service obligations could adversely impact our business, including by:

- impairing our ability to generate cash sufficient to pay interest or principal, including periodic principal payments;
- increasing our vulnerability to general adverse economic and industry conditions;
- increasing our need to meet minimum net sales requirements when our future sales are uncertain;
- requiring the dedication of a portion of our cash flow from operations to service our debt, thereby reducing the amount of our cash flow available for other purposes, including funds for clinical development or to pursue future business opportunities;
- requiring us to sell debt or equity securities or to sell some of our core assets, possibly on unfavorable terms, to meet payment obligations;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industries in which we compete; and
- placing us at a possible competitive disadvantage with less leveraged competitors and competitors that may have better access to capital resources.

Any of the foregoing factors could have negative consequences on our financial condition and results of operations. This indebtedness could be due sooner upon the triggering of certain covenants in our debt agreements and or upon the occurrence of an event of default. If and when our indebtedness becomes due, if we do not have sufficient cash or access to capital to pay such indebtedness, we will default on our obligations which will adversely harm our business. We entered into a the 2029 Loan Agreement that contains affirmative and negative covenants that restrict our operations, including, among other restrictions, the requirement to maintain 59certain levels of cash minimum trailing twelve-month net sales in an and cash equivalents amount that began at \$ 200.0 million in the first quarter of 2022 and increases to \$ 210.0 million for the quarter ended March 31, 2024. Beginning in the second quarter of 2024 and continuing through the quarter ended December 31, 2026, the requirement is to maintain minimum trailing twelve-month net sales of \$ 125.0 million. In addition, there is a requirement to maintain a minimum trailing twelve-month net sales for LOQFORZI tested quarterly at the end of each quarter commencing with the quarter ended December 31, 2024. Further, the 2029 Loan Agreement includes certain other affirmative covenants and negative covenants, including, covenants and restrictions that among other things, restrict our ability to incur liens, incur additional indebtedness, make investments, engage in certain mergers and acquisitions or asset sales, and declare dividends or redeem or repurchase capital stock. We may need to request additional-waivers from time to time with respect to the 2029 Loan Agreement and if we are unable to obtain a waiver that we need it could materially impact our business and financial results. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. If our existing stockholders sell or indicate an intention to sell substantial amounts of our common stock in the public market the market price of our common stock could decline. In addition, we may authorize our sales agent to sell our common stock from time to time as part of the ATM Offering. As of December 31, 2023-2024, there were 112.2 million-115,614,548 shares of our common stock outstanding. In addition, as of December 31, 2023-2024, approximately 30-37.6-2 million shares of common stock that are either subject to outstanding options and restricted stock units or reserved for future issuance under our equity incentive plans were eligible or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act -Certain of our outstanding options have exercise prices that are above our current stock price. See the tables describing our outstanding stock options in Note 12- Stock-Based Compensation and Employee Benefits to our financial statements included in this report. If these additional shares of common stock are sold or if it is perceived that they will be sold in the public market, the market price of our common stock

could decline. ~~59~~~~Future~~ **Future** sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans and convertible notes, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We have needed and anticipate we will need additional capital in the future to continue our planned operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. Similar to prior or ongoing financing transactions like the ATM Offering or the exchange of our shares for shares of outstanding stock of Surface as part of the acquisition of Surface, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. In addition, if we raise additional funds through licensing arrangements, it may be necessary to grant potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Pursuant to our **Amended and Restated** 2014 Equity Incentive Award Plan (the “2014 Plan”), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. ~~The~~ **Any increase in the** number of shares available for future grant under the 2014 Plan ~~will must~~ **be increased approved** by (i) ~~the number of shares pursuant to outstanding awards under the 2010 Plan that are forfeited or~~ **our stockholders** ~~lapse unexercised and which following the effective date are not issued under the 2010 Plan and~~ (ii) ~~an annual increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 4 % of the shares of stock outstanding as of the last day of the preceding fiscal year, or such smaller number of shares as determined by our board of directors.~~ Pursuant to our 2014 Employee Stock Purchase Plan (“ESPP”), eligible employees are able to acquire shares of our common stock at a discount to the prevailing market price, and an aggregate of 320,000 shares are initially available for issuance under the ESPP. The number of shares available for issuance under the ESPP ~~will were~~ **automatically increase increased** on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year or such smaller number of shares as determined by our board of directors. ~~If our board of directors elects to increase the number of shares available for future grant under the 2014 Plan or the ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall.~~ Pursuant to our 2016 Employment Commencement Incentive Plan (the “2016 Plan”), our management ~~is was~~ **authorized** to grant stock options and other equity-based awards to our new employees. ~~The~~, **however in connection with the approval of the 2014 Plan in 2024, we agreed that we would not make any new awards under the** 2016 Plan ~~after~~ **is designed to comply with the effective date** inducement exemption contained in Nasdaq’s Rule 5635 (c) (4), which provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, performance awards, dividend equivalents, deferred stock awards, deferred stock units, stock payment and stock appreciation rights to a person not previously an employee or director, or following a bona fide period of non-employment, as an inducement material to the individual’s entering into employment with us. As of December 31, 2023, we reserved for future issuance under the 2016 ~~2014~~ **Plan** a total of 1.8 million shares of common stock for new employees. The 2016 Plan does not provide for any annual increases in the number of shares available. In April 2020, we issued and sold \$ 230.0 million aggregate principal amount of our 1.5% senior convertible notes due April 2026 (the “2026 Convertible Notes”). The holders may convert their 2026 Convertible Notes at their option at any time prior to the close of business on the second scheduled trading day immediately before April 15, 2026. Upon conversion of the 2026 Convertible Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. Since inception, the conversion price has been 51.9224 shares of common stock per \$ 1,000 principal amount of the 2026 Convertible Notes, which represents a conversion price of approximately \$ 19.26 per share of common stock. **We plan to use a portion of the proceeds of the Udenyca Sale to fully repay the entirety of the 2026 Convertible Notes.** 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 business operations, financial condition, results of operations and prospects. Our cash and cash equivalents are deposited or invested with several banks and other financial institutions. Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank was closed and taken over by the Federal Deposit Insurance Corporation (“FDIC”) and subsequently had all of its customer deposits and other liabilities and ~~substantially~~ **60substantially** all loans and other assets acquired by First-Citizens Bank & Trust Company. We had approximately \$ ~~117~~ **126** . ~~70~~ million of cash, cash equivalents and marketable securities as of December 31, ~~2023~~ **2024** with the majority held by custodians or in money market mutual funds that are not bank deposits. Our bank deposits are primarily held in accounts at three large banks that we believe to be stable at this time. Actual and perceived stability of banks can change from time to time and adverse perceptions by customers or investors about the banks where we deposit money could result in a material and adverse effect on our ability to access necessary cash. Investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including ~~60higher~~ **higher** interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources, could, among other risks, adversely impact our ability to access funds for our basic operating expenses, financial obligations, payroll or fulfill our other important obligations. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity, business operations, financial condition, results of operations and prospects. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividends on our common stock.

We currently anticipate that we will retain any future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any **potential** return to stockholders will therefore be limited to **any the** appreciation of their stock **, if any**. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and bylaws include provisions that: • authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock; • create a classified board of directors whose members serve staggered three- year terms; • specify that special meetings of our stockholders can be called only by our corporate secretary pursuant to a resolution adopted by a majority of our board of directors; • prohibit stockholder action by written consent; • establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors other than nominations made by or at the direction of the board of directors or a committee of the board of directors; • provide that our directors may be removed only for cause or without cause by the holders of 66 2 / 3 % of the voting power of all then outstanding shares of voting stock; • provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; • specify that no stockholder is permitted to cumulate votes at any election of directors; • expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and • require holders of 66 2 / 3 % of the voting power of all then outstanding shares of voting stock to amend specified provisions of our amended and restated certificate of incorporation except for the provision making it possible for our board of directors to issue “blank check” preferred stock, and amended and restated bylaws. These provisions, alone or together, could delay, deter or prevent hostile takeovers and changes in control or changes in our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15 % of our outstanding voting stock to merge or combine with us. ~~Any~~ **61 Any** provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. ~~61 General~~ **General Risk Factors** ~~The Factors We~~

depend on a limited number of wholesalers for a significant amount of our total revenue, and if we lose any of our significant wholesalers, our business could be harmed. We sell our products to wholesalers and distributors and the wholesalers and distributors then resell to hospitals and clinics pursuant to contracts with us. The majority of our revenue comes from a limited number of wholesalers. In 2024, three wholesalers individually comprised approximately 42 %, 38 %, and 18 %, respectively, of our total gross product revenue. We expect that revenue from a limited number of wholesalers will continue to account for a large portion of our revenue in the future. The loss by us of any of these wholesalers, or a material reduction in their purchases or their market pricing, could harm our business, results of operations, financial condition and prospects. In addition, if any of these wholesalers were to fail to pay us in a timely manner, it could harm our cash flow. The international aspects of our business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States. We currently have limited international operations of our own and have and may have in the future a number of international collaborations, including our significant collaboration with Junshi Biosciences in China. Doing business internationally involves a number of risks, including but not limited to: • multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses, including those that affect our work with a collaboration partner in China; • failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries; • additional potentially relevant third- party patent rights; • **foreign CMOs may be subject to U. S. legislation, sanctions, trade restrictions, new or increasing tariffs, retaliatory trade actions due to recent or future trade tension and other regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure commitments from governments to purchase our products;** • complexities and difficulties in obtaining protection and enforcing our intellectual property; • difficulties in staffing and managing foreign operations by us or our collaboration partners; • complexities associated with managing multiple payer reimbursement regimes, government payers or patient self- pay systems by our collaboration partners; • limits in our or our collaboration partners’ ability to penetrate international markets; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; • natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; • certain expenses including, among others, expenses for travel, translation and insurance; **62** • expose us to sanctions, such as the sanctions levied by United States, E. U. and Russian regulatory bodies in connection with **the war between Russia and** ~~’s invasion of Ukraine in February 2022~~; and • regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the United States Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions. Investors’ expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks. **Although the degree of focus on these factors may change in the future,** ~~There~~ **there** is **continued scrutiny** ~~an increasing focus~~ from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance (or “ESG”) factors. Some

investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake ~~62costly~~ **costly** initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies. We also face significant costs from complying with **any** new ESG regulations, for example, the SEC's proposed climate disclosure ~~rule~~ **rules** would result in significant costs of compliance if it is approved as proposed in the future. We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchange or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaboration partners, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. So called "submarine" patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether. The term "submarine" patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from an application that was not published, publicly known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may issue to our competitors covering our pipeline candidates and thereby cause ~~significant~~ **significant** market entry delay, defeat our ability to market our products or cause us to abandon development ~~and/~~ or commercialization of a molecule. ~~Examples of submarine patents include Brockhaus, et al., United States patents 8,063,182 and 8,163,522 (controlled by Amgen), which are directed to the fusion protein in Enbrel. On July 1, 2020, the United States Court of Appeals for the Federal Circuit issued a decision that affirmed the lower court's decision upholding the validity of these patents. As a result, we discontinued the development of CHS-0214 (our etanercept (Enbrel) biosimilar candidate).~~ The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a biosimilar candidate into the United States market. We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. 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 products or pipeline molecules. We may incorrectly determine that our products are not covered by a third-party patent. ~~63Many~~ **Many** patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of an originator product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. 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 products. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. If we are unable to obtain and maintain effective patent rights for our ~~product~~ **products and candidates or any future** product candidates, we may not be able to prevent competitors from using technologies we consider important in our successful development and commercialization of our product candidates, resulting in loss of any potential competitive advantage our patents may have

otherwise afforded us. While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. Our ability to enjoy any competitive advantages afforded by our own intellectual property depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business. We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications. The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions. As a result, the patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patent claims being narrowed, found unenforceable or invalidated. Our patents and patent applications, even if they are unchallenged, may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business. In addition, changes to United States patent laws provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products using our proprietary technology. Further, because patent applications in the United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before we do, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates. **In June 2023, the European Unitary Patent system and the European Unified Patent Court (“UPC”) were launched. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system began and granted thereafter, are subject to the jurisdiction of the UPC, unless actively opted out. This was a significant change in European patent practice, and deciding whether to opt-in or opt-out of Unitary Patent practice entails strategic and cost considerations. The UPC provides third parties with a new forum to centrally revoke our European patents and makes it possible for a third party to obtain pan-European injunctions against us. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court’s existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.** We have issued patents and have filed patent applications, which are currently pending, covering various aspects of our **products and** product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened or infringed by third parties. Any successful actions by third parties to challenge the validity or enforceability of any

patents, which may issue to us could deprive us of the ability to prevent others from using the technologies claimed in such issued patents. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. While our biosimilar business is based primarily on the timing of our biosimilar product launches to occur after the expiration of relevant patents and on avoiding infringing valid and enforceable rights of third parties, we have filed a number of patent applications seeking patents that cover various proprietary elements of our product candidates when we have believed securing such patents may afford a competitive advantage. Our patent portfolio includes pending patent applications and issued patents, in the United States and globally, covering our biosimilar ~~products-- product~~ and methods of making ~~them it~~. We cannot guarantee that our proprietary technologies will avoid infringement of third- party patents. Moreover, because competitors may be able to develop their own proprietary technologies, it is uncertain whether any of our issued patents or pending patent applications ~~directed to etanercept and adalimumab~~ would cover the ~~etanercept and adalimumab~~ products of any competitors. The product and patent landscape is highly uncertain and we cannot predict whether our patent filings will afford us a competitive advantage against third parties or if our ~~etanercept and adalimumab~~ products will avoid infringement of third- party patents. ~~We 65~~ We do not consider it necessary for us or our competitors to obtain or maintain a proprietary patent position in order to engage in the business of biosimilar development and commercialization. Hence, while our ability to secure patent coverage on our own proprietary developments may improve our competitive position with respect to the product candidates we intend to commercialize, we do not view our own patent filings as a necessary or essential requirement for conducting our business nor do we rely on our own patent filings or the potential for any commercial advantage they may provide us as a basis for our success. Obtaining and maintaining our patent protection depends on compliance with various procedural requirements, document submissions, fee payment and other requirements imposed by governmental patent agencies. Our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. ~~65 Many~~ Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, 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, whether or not successful, 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. Governments of foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. 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 develop or license. If we are unable to maintain effective (non- patent) proprietary rights for our ~~product products and candidates or any future~~ product candidates, we may not be able to compete effectively in our markets. While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know- how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, for example, our employees, consultants, scientific advisors, board members, contractors, potential collaborators and investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have ~~adequate 66adequate~~ adequate remedies for any breach. Our confidential information and trade secrets thus may become known by

our competitors in ways we cannot prove or remedy. Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “first-to-file” laws in the United States and the EU, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions. We may be subject to claims challenging the inventorship of our patent filings and other intellectual property. Although we are not currently aware of any claims challenging the inventorship of our patent applications or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of 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 ownership. If we 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 valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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. ~~We~~ **We** or the third parties upon whom we depend on may be adversely affected by earthquakes, **wildfires** or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our corporate headquarters and laboratory are located in the San Francisco Bay Area and in Southern California (Camarillo), respectively. These locations have in the past experienced severe earthquakes, floods, **wildfires** and other natural disasters. **Wildfires have been increasing in intensity and frequency in recent years**. We do not carry earthquake insurance. Earthquakes, **wildfires** or other natural disasters could severely disrupt our operations or those of our collaboration partners and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure (such as the manufacturing facilities of our third-party contract manufacturers) or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business 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 as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. The continuation of the war in Ukraine and conflicts in the Middle East may exacerbate certain risks we face. The war between Russia and Ukraine and the global response, including the imposition of sanctions by the United States and other countries, could create or exacerbate risks facing our business. Conflicts in the Middle East may also increase the risks facing our business. We have evaluated our operations and partner contracts, and we currently do not expect either conflict to directly have a significant effect on our financial condition or results of operations. However, if the war between Russia and Ukraine or conflicts in the Middle East escalate or expand, risks that we have identified in this Annual Report on Form 10-K may be materially increased. For example, if our supply arrangements or clinical operations are disrupted due to expanded sanctions or involvement of, and adverse impacts on, countries where we have operations or relationships, our business could be materially disrupted. Further, the use of cyberattacks could expand as part of the ongoing conflicts, which could adversely affect our ability to maintain or enhance our ~~cyber security~~ **cybersecurity** measures. These and other risks are described more fully in this “Risk Factors” section. ~~We~~ **We** incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business. We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act, and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel must devote a substantial amount of time to ensure that we maintain compliance with all of these requirements. Moreover, the reporting requirements, rules and regulations have increased our legal and financial compliance costs and make some activities more time consuming and costly. Any changes we have made, and may make in the future to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, may also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors’ and officers’ insurance, on acceptable terms. We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 (“Section 404”), and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. During the course of our review and testing, we may

identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. **For example, as described elsewhere in this Annual Report on Form 10-K, our management concluded that our internal control over financial reporting was not effective as of December 31, 2024 due to a material weakness in the operating effectiveness of our procedures related to our documentation and review of certain inventory account reconciliations. We are taking steps to remediate this material weakness and to strengthen our internal control over financial reporting, which include additional training and enhancement of our documentation and retention procedures, particularly as they relate to our inventory account reconciliations. However, this remediation is in progress and will require validation and testing of operating effectiveness of internal controls over multiple financial reporting cycles and we cannot make any assurances as to when or whether the material weakness will be remediated.** In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the ~~67manner~~ **manner** in which we operate our business in ways we cannot currently anticipate. For example, the SEC's proposed climate disclosure rule would result in significant costs of compliance if final rules that are similar to the proposed rules are approved in the future. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage. Our information technology systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches and geopolitical tensions or conflicts, such as the ongoing war in Ukraine or conflicts in the Middle East, may create a heightened risk of cyberattacks. We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data, and personal information (collectively, "Confidential Information") of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information. ~~Despite 68~~ **Despite** the implementation of security measures, our information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers, may be vulnerable to damage from physical or electronic break-ins, computer viruses, misconfigurations, "bugs" or other vulnerabilities, "phishing" attacks, malware, ransomware, denial of service and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of Confidential Information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. In addition, geopolitical tensions or conflicts, such as the war between Russia and Ukraine or **the** conflicts in the Middle East, may create a heightened risk of cyberattacks. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our Confidential Information. If we or any of our third-party collaborators or service providers were to experience any material failure or security breach, it could result in a material disruption of our development programs, reputation, and business operations. For example, the loss of clinical study data from completed or ongoing clinical studies could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of Confidential Information, we may have to notify individuals, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on our third-party CROs and other third parties to conduct clinical studies, and similar events relating to their computer systems could also have a material adverse effect on our business. There can also be no assurance that our and our service providers' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Further, the continued hybrid working environment has generally increased the attack surface available to criminals, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such ~~an incident~~ **incidents**, is increasing. Because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection,

and to remove or obfuscate forensic evidence. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of Confidential Information, we could incur liability and suffer reputational harm, and the development and commercialization of our products could be delayed. Federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. We may also be exposed to a risk of loss or litigation and potential liability, which could materially and adversely affect our business, results of operations or financial condition. Our insurance policies may not be ~~adequate~~ **adequate** to compensate us for the potential losses arising from such disruptions, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly, divert management attention, and harm our reputation. We are subject to governmental regulation and other legal obligations related to privacy, data protection and information security. Compliance with these requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations. The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U. S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Compliance with these privacy and data ~~security~~ **security** requirements is rigorous and time- intensive and may increase our cost of doing business. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations. In the United States, we and our partners may be subject to numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, that govern the collection, use, disclosure, and protection of health- related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under ~~the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA.~~ **the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA.** Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. Even when HIPAA does not apply, according to the Federal Trade Commission (“ FTC ”), failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act. The FTC expects a company’ s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. The FTC has authority to initiate enforcement actions against entities that make deceptive statements about privacy and data sharing in privacy policies, fail to limit third- party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5 (a) of the FTC Act. Additionally, federal and state consumer protection laws are increasingly being applied by the FTC and states’ attorneys general to regulate the collection, use, storage, and disclosure of personal ~~or personally identifiable~~ information, through websites or otherwise, and to regulate the presentation of website content. In addition, state laws govern the privacy and security of ~~health~~ **personal** information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. By way of example, California enacted the California Consumer Privacy Act (~~the “ CCPA ”~~) **on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as amended by** well as a private right of action for data breaches that has increased the likelihood of, and risks associated with, data breach litigation. Further, the California Privacy Rights Act (~~collectively, the “ CPRA- CCPA ”~~) **generally went into effect on January 1, which requires 2023, and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses that, including additional consumer rights processes-- process the personal information of California residents to, limitations among other things: (i) provide certain disclosures to California residents regarding the business’ s collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business’ s behalf process changes may also be required.** Similar laws have passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, ~~the CPRA~~ or other domestic privacy and data protection laws, any liability from failure to

comply with the requirements of these laws could adversely affect our **business and** financial condition. **69****In** addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal **and confidential** data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the General Data Protection Regulation (“GDPR”) took effect. The GDPR is applicable in each EEA member state and applies to companies established in the EEA as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EEA, including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data. Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. The GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union (“CJEU”) states that reliance on the standard contractual clauses- a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism- alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case- by- case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU- US Data Privacy Framework (“DPF”) rendering the DPF effective as a GDPR transfer mechanism to U. S. entities self- certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain **operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames. Penalties and fines for failure to comply with GDPR are significant, including fines of up to € 20 million or 4 % of total worldwide annual turnover, whichever is higher. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease / change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and / or civil claims (including class actions). Further, since the beginning of 2021, we have also been subject to the United Kingdom General Data Protection Regulation and Data Protection Act 2018, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £ 17. 5 million or 4 % of a noncompliant company’s global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK government), as a UK GDPR data transfer mechanism from the U. K. to U. S. entities self- certified under the DPF. Other foreign jurisdictions are increasingly implementing or developing their own privacy regimes with complex and onerous compliance obligations and robust regulatory enforcement powers. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and have a material adverse effect on our business, financial condition and results of operations. We may be negatively impacted by continued inflation. We may be adversely impacted by continued increases in inflation. Current and future inflation may be driven by the following factors: supply chain disruptions, increased costs of transportation, increased input costs such as the cost of fuel, shortages, and governmental stimulus or fiscal policies. Continuing increases in inflation could impact the overall demand for our products, our costs for labor and materials and the size of any margins we are able to realize on our revenues. This would have a material and adverse impact on our business, financial position, results of operations and cash flows. Inflation may also result in higher interest rates, which in turn would result in higher interest expense related to our variable rate indebtedness. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. Our research and development activities and our third- party manufacturers’ and suppliers’ activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds.**-70