**Risk Factors Comparison 2024-03-29 to 2023-03-31 Form: 10-K**

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

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes, before making any decision to invest in shares of our common stock. This Annual Report on Form 10- K contains forward- looking statements. If any of the events discussed in the risk factors below occurs, our business, prospects, results of operations, financial condition and cash flows could be materially harmed. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. Following is a summary of our Risk Factors: • **Our business strategy depends substantially upon our ability to receive future contingent milestone and royalty payments from our partnered programs. •** We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We currently have no product revenues and no approved products and ~~will~~ **may** need to raise additional capital to operate our business ~~. • The failure of a financial institution counterparty could adversely affect our current and projected business operations and our financial condition and results of operations. • We are highly dependent on the success of clarekibep, our lead candidate in our respiratory pipeline. We are executing a broad development program for clarekibep and clinical and regulatory outcomes for clarekibep, which, if not successful, will significantly harm our business. • Our limited operating history as a clinical- stage company may hinder our ability to successfully meet our objectives. • Our global operations subject us to various risks, and our failure to manage these risks could adversely affect our results of operations. 46 • If we fail to comply with environmental, health and safety laws and regulations that apply to us, we could become subject to fines or penalties or incur costs that could harm our business. • Our current operations are largely concentrated in two locations and any adverse events affecting these locations may have material adverse consequences on our business. • Our failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and / or adverse publicity and could negatively affect our operating results and business. • Significant disruptions of information technology systems or security breaches could adversely affect our business. • We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively~~ . • We could be subject to product liability lawsuits based on the use of our drug candidates in clinical testing or, if obtained, following our products' marketing approval and commercialization. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to cease clinical testing or limit commercialization of our drug candidates. • ~~Our business has been and may continue to be adversely affected by the ongoing COVID- 19 pandemic. •~~ We are heavily dependent on the successful development of our **partnered** drug candidates ~~and programs~~ and we cannot be certain that ~~we~~ **our partners** will receive regulatory approvals or be able to successfully commercialize our ~~products~~ **partnered drug candidates** even if ~~we~~ **they** receive regulatory approvals. • Preclinical and clinical testing of our drug candidates that has been conducted to date or will be conducted in the future may not have been or may not be performed in compliance with applicable regulatory requirements, which could lead to increased costs or material delays for their further development. • **We** ~~Our research and development efforts are focused on a rapidly evolving area of science, and our approach to drug discovery and development is novel and~~ may **be treated as** ~~never lead to marketable products. • Clinical drug development involves~~ a **" public shell" company which** ~~lengthy and expensive process with uncertain outcomes, clinical trials are difficult to design and implement, and any of our clinical trials~~ could **have** ~~produce unsuccessful results or fail at any stage in the process. • If we experience delays or difficulties in the enrollment of research subjects in clinical trials, those clinical trials could take longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented. • The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities. • The review processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our drug candidates from applicable regulatory authorities, we will not be able to market and sell those drug candidates in those countries or regions and our business could be substantially harmed. • Our failure to obtain marketing approval in jurisdictions other than the United States and Europe would prevent our product candidates from being marketed in these other jurisdictions. Any approval that we are granted for our product candidates in the United States or Europe would not assure approval of product candidates in the other or in any other jurisdiction. • Our product candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit their commercial potential, or result in significant~~ negative consequences ~~following marketing approval, if marketing approval is obtained. • We may expend our limited resources to pursue a particular drug candidate or indication that does not produce any commercially viable products and may fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success. • We rely on third parties to conduct our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or otherwise conduct the trials as required or comply with regulatory requirements, we may not be able to obtain regulatory approval for our drug candidates, commercialize our product candidates when expected or at all, and our business could be substantially harmed. 47 • We rely and expect to continue to rely completely on third parties to formulate, manufacture, and transport our preclinical, clinical trial and commercial drug supplies. The development and commercialization of any of our drug candidates could be stopped, delayed or made less profitable if those third parties fail to provide us with~~

~~sufficient quantities of such drug supplies or fail to do so at acceptable quality levels~~, including **potential Nasdaq delisting of** ~~in accordance with applicable regulatory requirements or~~ **our common stock** ~~contractual obligations, and our operations could be harmed as a result~~. • Disagreements with respect to the commercial terms of our sales, licensing, purchase or manufacturing agreements may limit our commercial success. • We depend on third parties and intend to continue to license or collaborate with third parties, and events involving these strategic partners or any future collaboration could delay or prevent us from developing or commercializing products. • Our success depends ~~in part~~ on the efforts of our current ~~and possible future~~ collaborators, who will likely have substantial control and discretion over the continued development and commercialization of drug candidates that are the subject of our collaborations. • We may not receive any further milestone, royalty or license payments under our current collaborations ~~. • Our commercial success depends upon attaining significant market acceptance of our drug candidates, if approved, among physicians, patients, third- party payors and other members of the medical community. • Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations. • Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop~~. • If we breach any of the agreements under which we license from third parties the intellectual property rights or commercialization rights to our drug candidates, particularly our license agreements with TUM and Kelun, we could lose license rights that are important to our business and our operations could be materially harmed. • ~~If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively and our business could be harmed. • Claims that we infringe the intellectual property rights of others may prevent or delay our drug discovery and development efforts. • We may desire to, or be forced to, seek additional licenses to use intellectual property owned by third parties, and such licenses may not be available on commercially reasonable terms, or at all. • Certain technologies and patents have been developed with partners and we may face restrictions on this jointly developed intellectual property. • If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy. •~~ We have broad discretion in how we use our cash, cash equivalents and investments, including the net proceeds from our collaborations, public and private securities offerings, and may not use these financial resources effectively, which could affect our results of operations and cause our stock price to decline. • We have had and have previously reported material weaknesses in our internal controls over financial reporting. If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us. • **Our shares of common stock could be delisted from the Nasdaq Capital Market, which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock. •** Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or otherwise, could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall. A detailed discussion of the above Risk Factors follows below. Risks Related to **our Corporate Strategy Our business strategy depends substantially upon our ability to receive future contingent milestone and royalty payments. Our business strategy depends substantially upon our ability to receive future milestone and royalty payments from Pfizer (formerly Seagen), Boston Pharmaceuticals, and Servier. On March 27, 2024, we announced a strategy to maximize our ability to capture the potential milestones from licensing and collaboration agreements with our partners, including Pfizer, Boston Pharmaceuticals, and Servier, while maintaining the capability to consider other strategic options. Our Board of Directors implemented a series of measures designed to extend our cash runway into at least 2027 and maximize our ability to capture the potential milestone payments. These measures include discontinuing research and development activities, which is expected to be completed in the middle of 2024, conducting further workforce reduction that affect additional employees and the executive leadership team, which is expected to be implemented in the second quarter of 2024, and reducing the size of our Board of Directors, which is also expected to be implemented in the second quarter of 2024. We do not have any ongoing research or development activities. Any failure to achieve such milestones or a perception that the milestones may not be achieved will materially and adversely affect the company and the value of the common stock. 28Even if some or all of the milestones or royalties set forth in the Pfizer Agreement, Boston Pharmaceuticals Agreement, or Servier Agreement are achieved, it may take significantly longer than we anticipate and could require us to raise additional funding in order to maintain our ability to receive payment for such milestones. Achievement of the milestones set forth in the Pfizer Agreement, the Boston Pharmaceuticals Agreement, and the Servier Agreement are not guaranteed and there is significant risk that some or all of such milestones will not be achieved when anticipated, if at all. If achievement of the milestones is delayed beyond what we currently anticipate, it could require us to raise additional funds in order to maintain our ability to receive payment for the potential future achievement of such milestones. Sources of funds may not be available or, if available, may not be available on terms satisfactory to us. Raising additional funds could be dilutive or otherwise disadvantageous to our stockholders. Any delay in receipt of the potential benefit to the company or our stockholders resulting from achievement of such milestones, in addition to any additional uncertainty as to whether such milestones will be achieved at all, would materially and adversely affect the company and the value of the common stock. Time and costs associated with winding down our research and development activities and any return of cash to stockholders may be significant. There are significant costs associated with winding down our normal historic operations, such as separation of employees, termination of contracts and engagement of external consultants, all of which have and may in the future reduce our cash resources. Additionally, if our Board of Directors decide to issue any cash dividends to our stockholders in the future, we may incur third party costs associated with the distribution of such dividends, all of which would reduce our cash resources. If some or all of our partners terminate our partnerships for which we may be entitled to milestone payments, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the**

**amount of cash that will need to be reserved for commitments and contingent liabilities. There can be no assurance or guarantee that we will realize all or some of the milestone payments in connection with our licensing and collaboration agreements, and in the event our partners terminate their respective licensing and collaboration agreements, our board of directors may decide to pursue a dissolution and liquidate. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Nevada corporate law to pay our outstanding debts and other obligations prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up. We may rely on external consultants for the execution of our business strategy. In connection with our March 27, 2024 announcement, we disclosed an additional reduction in force impacting additional employees and our executive leadership team, which is expected to be implemented in the second quarter of 2024. We expect that as the number of employees is reduced, we may become reliant on a limited number of external consultants for the operation of our company, any of whom may terminate their consultancy with us at any time. The loss of some or all of our consultants could delay or inhibit our ability to run our operations or consummate any divestitures of our remaining assets or could interfere with our ability to receive and distribute any potential milestones from Pfizer, Boston Pharmaceuticals, Servier, or any other future partner. While we have announced that we remain open to considering other strategic opportunities that might arise, there is no assurance that we would be successful in pursuing any such strategic opportunities. Since we announced in July 2023 that we intend to explore engaging in one or more strategic transactions, our strategic review process has focused on maximizing stockholder value, which includes the maximization of potential milestone payments we are eligible to receive. Management and the Board of Directors evaluated a broad spectrum of potential options, including asset in- licensing, out- licensing, royalty monetization, strategic transactions (including reverse mergers, strategic mergers, and sale), and liquidation. With the assistance of our retained strategic advisor, Stifel, Nicolaus & Company, more than 500 companies were contacted regarding a strategic transaction, and we underwent a robust process to identify and negotiate with a select number of final candidates. We entered into extended exclusivity with one party contemplating a strategic merger, which centered on that party' s interest in developing our clinical- stage asset cinrebafusp alfa, but after extensive diligence and negotiations, that counterparty was unable to secure adequate capitalization and offer acceptable terms. On March 27, 2024, we announced a strategy that would maximize our ability to capture potential milestones from our licensing and collaboration agreements while maintaining the capability to consider other strategic opportunities, which we believe offers the best opportunity to maximize stockholder value. Despite remaining open to considering other strategic opportunities that might arise, there can be no assurance that we will be successful in pursuing any opportunity or that any opportunity, if pursued, will be completed on attractive terms or at all. we may rely on the support of consultants and external advisors to assist in the review of strategic opportunities which may be costly. Additionally, there can be no assurance that any particular course of action, strategy to capture potential milestones or other strategy, business arrangement or transaction, or series of transactions, will be successfully pursued, consummated or lead to increased stockholder value. Such other strategies, business arrangement or transaction, or series of transactions could lead to increased costs, dilution to our existing stockholders' percentage of ownership, or assumption of debt and liabilities. 29Our common stock is currently listed on the Nasdaq Capital Market, or Nasdaq. We have no current plans to delist our common stock from Nasdaq. However, following the discontinuation of historical research and development efforts, we may be treated as a " public shell " company under the Nasdaq rules and the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act. Although Nasdaq evaluates whether a listed company is a public shell company based on a facts and circumstances determination, a Nasdaq- listed company with no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets is generally considered to be a public shell company. Listed companies determined to be public shell companies by Nasdaq may be subject to delisting proceedings or additional and more stringent listing criteria. In addition, among other requirements, a minimum $ 1. 00 per share bid price requirement for continued inclusion on the Nasdaq pursuant to Nasdaq Listing Rule 5550 (a) (2), or the Bid Price Requirement. The closing bid price for our common stock must remain at or above $ 1. 00 per share to comply with the Bid Price Requirement for continued listing. As previously disclosed, on May 15, 2023, we received a deficiency letter, or the Notice, from the Nasdaq Listing Qualifications Department, or the Staff, notifying us that because the closing bid price of our common stock had fallen below $ 1. 00 per share for 30 consecutive business days, we no longer met the Bid Price Requirement. Pursuant to Nasdaq Listing Rule 5810 (c) (3) (A), or the Compliance Period Rule, we had an initial period of 180 calendar days, or until November 13, 2023, or the Compliance Date, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $ 1. 00 per share for a minimum of 10 consecutive business days as required under the Compliance Period Rule (unless the Staff exercises its discretion to extend this ten- day period pursuant to Nasdaq Listing Rule 5810 (c) (3) (H)). However, if during the compliance period our common stock has a closing bid price of $ 0. 10 or less for 10 consecutive trading days, Nasdaq will issue a Staff Delisting Determination with the potential opportunity for us to**

**appeal that determination. Since the closing bid price of our common stock has not met or exceeded $ 1. 00 per share for a minimum of 10 consecutive business days prior to the Compliance Date, we requested an additional 180 calendar day compliance period on November 6, 2023 in which to regain compliance, in which we provided written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. On November 14, 2023, we received a second notice from Nasdaq providing us with the additional 180 calendar days to regain compliance. If the Staff concludes that we will not be able to cure the deficiency, or if we do not regain compliance with the Bid Price Requirement within such additional 180 calendar day compliance period, the Staff will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal the Staff' s delisting determination to a Nasdaq Listing Qualifications Panel, or the Panel. However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by the Staff to the Panel, such appeal would be successful. If our common stock is delisted from Nasdaq, whether because Nasdaq determines we are a " public shell ", we fail to regain compliance with the bid price requirement, or otherwise, or if in the future we determine to delist our common stock, we would expect that such securities would qualify for trading over- the- counter, or OTC, in the United States on a market colloquially referred to as the " Pink Sheets. " Securities quoted OTC are generally subject to lesser requirements than securities listed for trading on a U. S. national stock exchange, such as Nasdaq, including reduced corporate governance and public reporting standards. If Nasdaq should delist our common stock from trading, or if in the future we determine to delist our common stock, a reduction in some or all of the following may occur, each of which could have a material adverse effect on holders of our common stock: the liquidity of our common stock; the market price of the common stock; the number of institutional and general investors that will consider investing in the common stock; the number of investors in general that will consider investing in the common stock; the number of market makers in our common stock; the availability of information concerning the trading prices and volume of the common stock; and the number of broker- dealers willing to execute trades in our common stock. In addition to the foregoing, there are certain consequences under the Securities Act of being a public shell company, including the unavailability of Rule 144 thereunder for the resale of restricted securities and the inability to utilize Form S- 8 for the registration of employee benefit plan securities. We may become involved in litigation, including securities class action litigation, that could divert management' s attention and harm the company' s business, and insurance coverage may not be sufficient to cover all costs and damages. In the past, litigation, including securities class action litigation, has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management' s attention and resources, which could adversely affect our business and cash resources and our ability to execute our strategy to capture potential milestones from licensing and collaboration agreements while maintaining the ability to consider other strategic opportunities. Any potential changes to our leadership structure as a result of our workforce reduction and restructuring could adversely affect our business. As a result of our decision to conduct a workforce reduction and additional restructuring, we may implement changes to our leadership and governance structure. Any personnel transition that may result could be difficult and inherently cause some loss of institutional knowledge and skills, which could negatively affect our results of operations and financial condition. Our ability to execute our business strategies may be adversely affected by the uncertainty associated with these transitions and changes to leadership and governance structures, and the time and attention of the board and management dedicated to such changes and transitions could disrupt our business. Further, we cannot guarantee that we will not face other transitions in the future. Although we generally enter into employment agreements with our executives, our executive officers may terminate their employment relationship with us at any time, and we cannot ensure that we will be able to retain the services of any of them. Our leadership' s knowledge of our business and industry could be difficult to replace, and management turnover could negatively affect our business, growth, financial conditions, results of operations and cash flows. Risks Related to** Our Business, Financial Position, Capital Requirements, Managing our Growth and Other Legal Compliance Matters **We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We currently have no product revenues and no approved products and will rely on our partnered IO programs to generate revenue.** We are a clinical- stage biopharmaceutical company. To date, we have not generated any commercial sales revenue, are not profitable, and have incurred losses since our inception in 2001. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, we reported net losses of $ **24. 5 million and $** 33. 3 million ~~and $ 45. 7 million~~, respectively. As of December 31, ~~2022~~ **2023**, we had an accumulated deficit of $ ~~290~~ **315** ~~4~~ **0** million. We expect to continue to incur losses for the foreseeable future ~~, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our drug candidates and the commercialization of approved products, if any. 48We are currently developing products in our therapeutic areas of respiratory diseases and IO~~. We have collaborations with ~~major multi- national pharmaceutical companies. In particular, we have alliances with AstraZeneca and Genentech to treat respiratory diseases, with Genentech also in ophthalmology. Our partner AstraZeneca is currently in phase 2a studies of clarekibep, our lead respiratory drug candidate, in multiple countries. We also have alliances with~~ Servier, ~~Seagen~~ **Pfizer**, and Boston Pharmaceuticals in IO. Our IO **partnered** ~~program~~ **programs** ~~includes~~ **include S095012 (** PRS- 344 **)** ~~/ S095012~~ in partnership with Servier, **SGN- BB228 (PRS- 346) in partnership with Pfizer, and BOS- 342 (PRS- 342) in partnership with Boston Pharmaceuticals,** which ~~is~~ **are all** currently in phase 1 studies. ~~Together~~ **In July 2023, AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, which terminations became effective October 15, 2023. AstraZeneca' s decision to terminate** these ~~programs will result~~ **agreements was based on non- clinical safety findings** in ~~our continued incurrence~~ **a 13-**

**week toxicology study** of **elarekibep in non- human primates** ~~significant research, development and other expenses and resources~~ . If our research and development efforts, including preclinical studies or clinical trials for any of our **partnered** drug candidates fail or produce unsuccessful results and those drug candidates do not gain regulatory approval, or if any of our drug candidates, if approved, fail to achieve market acceptance, we may never become profitable. In addition, the failure of one drug candidate or program may have an adverse impact on other drug candidates and programs within our class of Anticalin- based therapies. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. ~~The failure of a financial institution counterparty could adversely affect our current and projected business operations and our financial condition and results of operations.~~ On March ~~10~~ **27** , ~~2023~~ **2024** , ~~Silicon Valley Bank,~~ **we announced a strategy to maximize** ~~or~~ **our ability** ~~SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each placed into receivership. A statement by the Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access~~ to **collect potential milestones from** ~~all of their money after only one business day of closure, including funds held in uninsured deposit accounts. A failure of a depository institution to return deposits could impact access to our invested cash or~~ **our licensing** ~~cash equivalents~~ and ~~could adversely impact our operating liquidity and financial performance~~ **collaboration agreements while maintaining the ability to consider other strategic opportunities** . We are ~~highly dependent on the success of elarekibep, our lead candidate in our respiratory pipeline. We are executing a broad development program for elarekibep and clinical and regulatory outcomes for elarekibep, which, if~~ not ~~successful, will significantly harm our business. Our future success is highly dependent on our ability to successfully develop~~ **developing** ~~, obtain regulatory approval for~~ and ~~commercialize~~ **commercializing products and** ~~elarekibep. In general, most early- stage investigatory drugs, including inhaled drug candidates such as elarekibep,~~ do not **anticipate seeking to develop any new products with any of** ~~become approved drugs. Accordingly, there is a very meaningful risk that elarekibep will not succeed in one or~~ **our existing cash** ~~more clinical trials sufficient to support one or more regulatory approvals. To date, clinical and preclinical outcomes from elarekibep have had a significant impact on our~~ - **or any** ~~market valuation, financial position and business prospects, and we expect this to continue in~~ future ~~periods~~ **milestone payments we may receive** . **Our failure to achieve these potential milestone payments** ~~If one or more clinical trials of elarekibep is not successful, it~~ would ~~materially harm~~ **depress the value of our company. A decline in the value of our company could also cause our stockholders to lose all** ~~our~~ - **or part** ~~market valuation, prospects, financial condition and results~~ of ~~operations~~ **their investment** . ~~We~~ **30In the event we determine to pursue any future product development efforts, we** will need substantial additional funding to continue our operations ~~, which could result in significant dilution or restrictions on our business activities~~ . ~~We may not be~~ **In that case, if we are** ~~able~~ **unable** to raise capital when needed, **we** ~~if at all, or on terms acceptable to us, which~~ would **be** ~~force~~ **forced** ~~us~~ to delay, reduce **,** or eliminate **such** ~~some or all of our~~ product development programs or commercialization efforts ~~and could cause our business to fail~~ . Our operations have consumed substantial amounts of cash since our inception. ~~We~~ **Although we are not developing any drug product candidates and do not have any current plans to do so, if we determine to pursue any future product development efforts, we** expect ~~to~~ **that we would incur significant research and development expenses and will** need substantial additional funding ~~to continue the preclinical and clinical development of our drug candidates, as well as to launch and commercialize any drug candidates for which we receive regulatory approval. We will require additional capital for the further development and commercialization of our drug candidates and programs, and may need to raise additional funds sooner than we currently anticipate if we choose to and are able to expand more rapidly than we currently anticipate. Further, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue to advance, expand and monitor the performance of our preclinical and clinical programs, such as elarekibep, PRS- 220, PRS- 400 and PRS- 344 / S095012, as well as additional programs that we advance through preclinical development and into the clinic and whose performance we monitor. In addition, if we obtain regulatory approval for any of our drug candidates, we expect to incur significant commercialization expenses related to regulatory requirements, product manufacturing, marketing, sales and distribution~~ . Furthermore, we expect to continue to incur additional costs associated with operating as a public company. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our capital needs and / or cause us to spend our cash resources faster than we expect. To date, we have financed our operations through a mix of equity investments from private and public investors, the incurrence of debt, grant funding and the receipt of up- front and milestone payments due under our various collaboration agreements, and we **may require additional** ~~expect to continue to finance~~ **financing** ~~our~~ **to fund** operations in ~~part through equity investments~~ **order to execute our current business strategy and maintain our ability to receive some or all of the milestones** from **our IO partnered programs** ~~public investors for the foreseeable future~~ . Additional funding ~~from those or other sources~~ may not be available when or in the amounts needed, on acceptable terms, or at all. **As of the filing of this Annual Report on Form 10- K, we will be subject to the SEC general instructions of Form S- 3 known as the" baby shelf rules." Under these instructions, the amount of funds we can raise through primary public offerings of securities in any 12- month period using our registration statement on Form S- 3 is limited to one- third of the aggregate market value of the shares of our common stock held by non- affiliates. Therefore, we will be limited in the amount of proceeds it is able to raise by selling shares of our common stock using our Form S- 3, including under the ATM Program, until such time as our public float exceeds $ 75 million. Furthermore, if we are deemed to be a shell company, the baby shelf rules, and therefore our Form S- 3, would not be available to us.** Our ability to secure additional funding ~~from those or other sources~~ could be significantly impacted by a multitude of events that are beyond our control, including, but not limited to, changes in the macroeconomic environment and other events affecting the stock market, including the availability of research and other information, favorable or unfavorable, published by securities or industry analysts and news agencies. ~~49Raising~~ - **Raising** capital through the sale of equity or

securities convertible into equity would result in dilution to our then- existing stockholders, which could be significant depending on the price at which we may be able to sell our securities. If we raise additional capital through the incurrence of indebtedness, we would likely become subject to covenants restricting our business activities, and holders of debt instruments may have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities. If we obtain capital through collaborative or licensing arrangements, these arrangements could require us to relinquish rights to our Anticalin- based technology or drug candidates and could result in receipt of only a portion of the revenues associated with the potential commercialization of our partnered drug candidates. ~~If we are unable to obtain additional funding on acceptable terms when needed, we will defer or limit a substantial portion of our research, development and clinical projects, reduce discretionary expenditures and other fixed or variable personnel costs. For example, our budget and operating plan for 2023, approved by the Board, does not include such discretionary costs, and management is prepared to gate future investments on PRS- 220 and PRS- 400. Any of these events could significantly harm our business, financial condition, and prospects. We were formed in 2001, and since that time our focus has been on discovery of Anticalin- brand drug candidates. AstraZeneca is currently conducting clinical development of elarekibep, Seagen is conducting clinical development of SGN- BB228, and we are conducting clinical development in PRS- 220 and PRS- 344 / S095012, in partnership with Servier. We are also advancing other drug candidates, including PRS- 400, through preclinical development with the intention of initiating additional clinical- stage programs. In addition to our development plans for respiratory diseases, we are also exploring additional indications that may be suitable for Anticalin- based therapies. Our drug candidates are in the early stages of development, have not obtained marketing approval, have never generated any revenue from sales and will require extensive testing before commercialization. We have limited experience with clinical- stage operations, including manufacturing required to support clinical activities and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. In addition, the early- stage nature of our drug discovery and development operations can only provide limited operating results upon which investors can evaluate our business and prospects. Our limited operating history may adversely affect our ability to implement our business strategy and achieve our business goals, which include, among others, the following activities: • developing our drug candidates using unproven technologies; • undertaking preclinical development and clinical trials as well as formulating and manufacturing products; • obtaining the human, financial and other resources necessary to develop, test, manufacture, commercialize and market our drug candidates; • engaging corporate partners to assist in developing, testing, manufacturing and marketing our drug candidates; • continuing to build and maintain an intellectual property portfolio covering our technology and drug candidates; • satisfying the requirements of clinical trial protocols, including patient enrollment, establishing and demonstrating the clinical safety and efficacy of our drug candidates and obtaining necessary regulatory approvals; • achieving acceptance and use by the medical community of our Anticalin platform and drug candidates after they receive regulatory approvals; • maintaining, growing and managing our internal teams as and to the extent we increase our operations and develop new segments of our business; • developing and maintaining successful collaboration, strategic and other relationships for the development and commercialization of our drug candidates that receive regulatory approvals with existing and new partners; and • managing our cash flows and any growth we may experience in an environment where costs and expenses relating to clinical trials, regulatory approvals and commercialization continue to increase. If we are unsuccessful in accomplishing any or all of these objectives, we may not be able to raise capital, expand our business, develop our drug candidates or continue our operations. 50Our business is subject to certain risks associated with doing business globally. One of our growth strategies is to pursue opportunities for our business in several areas of the world, including the United States, Europe (including Germany), Asia and Australia, any or all of which could be adversely affected by the risks set forth below. Accordingly, we face significant operational risks as a result of doing business internationally, such as: • fluctuations in foreign currency exchange rates; • potentially adverse tax consequences and changes in tax laws; • challenges in providing solutions across a significant distance, in different languages, different time zones and among different cultures (particularly, for as long as travel is limited due to the COVID- 19 pandemic); • different, complex and changing laws governing intellectual property rights, sometimes affording reduced protection of intellectual property rights in certain countries, and data privacy and security laws; • difficulties in staffing and managing foreign operations, particularly in new geographic locations, and related compliance with employment, immigration and labor laws for employees or other staff living abroad; • restrictions imposed by local labor practices and laws on our business and operations; • economic weakness, including inflation, or rapid changes in government, economic and political policies and conditions, political or civil unrest or instability, economic or trade sanctions, closure of markets to imports, terrorism or epidemics and other similar outbreaks or events; • compliance with a wide variety of complex foreign laws, treaties and regulations; • compliance with the U. S. Foreign Corrupt Practices Act, or the FCPA, and other anti- corruption and anti- bribery laws; • unexpected changes in tariffs, trade barriers and other regulatory or contractual limitations on our ability to develop or sell our products in certain foreign markets; and • becoming subject to the laws, regulations and court systems of multiple jurisdictions. Our failure to manage the market and operational risks associated with our international operations could limit the future growth of our business and adversely affect our results of operations.~~ Our international operations pose currency risks, which may adversely affect our operating results and net income. Due to our operations outside of the United States, we are exposed to market risk related to changes in foreign currency exchange rates. Changes in the relative values of currencies occur regularly and, in some instances, could materially adversely affect our business, our financial condition, the results of our operations or our cash flows. Our operating results may be affected by volatility in currency exchange rates and our ability to effectively manage our currency transaction risks. Our reporting currency is the U. S. dollar, however, ~~75~~ **81** % of our operating expenses and all of our revenues are recorded in non- U. S. entities. As such, our financial statements are translated for reporting purposes as follows: (1) asset and liability accounts at year- end rates,

(2) income statement accounts at weighted average exchange rates for the year and (3) stockholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in stockholders' equity. We incur currency transaction risks whenever we enter into either a purchase or a sale transaction using a currency other than the euro, our functional currency, particularly in our arrangements for the purchase of supplies or licensing and collaboration agreements with partners outside of the United States. In such cases, we may suffer an exchange loss because we do not currently engage in currency swaps or other currency hedging strategies to address this risk. ~~As we continue to operate and enter into agreements and arrangements in the United States, Germany, Australia and elsewhere internationally, our exposure to currency risks will increase.~~ We do not manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Therefore, changes in exchange rates between these foreign currencies and the U. S. dollar will affect our revenues and expenses and could result in exchange losses in any given reporting period. Given the volatility of exchange rates ~~, especially as a result of ongoing developments of the COVID- 19 pandemic~~ , we can give no assurance that we will be able to effectively manage our currency transaction risks or that any volatility in currency exchange rates will not have an adverse effect on our results of operations. ~~51We~~ **We** are subject to anti- corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition. Our operations are subject to anti- corruption laws, including the FCPA, and other anti- corruption laws that apply in countries where we do business and may do business in the future. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We ~~may in the future operate in jurisdictions that pose a high risk of potential FCPA violations and we~~ may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti- corruption laws. ~~In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. We are also subject to other laws and regulations governing our international operations, including regulations administered by the government of the United States, the United Kingdom and authorities in the European Union, such as applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.~~ There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti- corruption laws, including the FCPA, or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, other anti- corruption laws or Trade Control laws by U. S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. **31If we fail to comply with environmental, health and safety laws and regulations that apply to us, we could become subject to fines or penalties or incur costs that could harm our business.** We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations **have historically involved and may continue to** involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations **have historically involved and may continue to** also produce hazardous waste products. We generally contract with third parties for the disposal of any hazardous materials and wastes. The use of these materials in our business could result in contamination or injury, which could cause damage for which we may be responsible but may not have sufficient resources to pay. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with these laws and regulations, which we may not be able to afford. Although we maintain workers' compensation insurance for our operations in Germany to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations applicable to us. These current or future laws and regulations may impair our research, development or production efforts or impact the research activities we pursue, particularly with respect to research involving human subjects or animal testing. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could cause our financial condition to suffer. ~~Health and safety regulations in the United States, Germany, and Australia and in the countries where our technology and potential products are or may be developed, licensed or sold may prevent the sale or use of our technology or products in the future.~~ We ~~are subject to a variety of regulations regarding worker health and safety in the United States, the European Union (Germany), Australia and in the countries where our technology and potential products are licensed or may be sold. These regulations may continue to change due to the ongoing developments of the COVID- 19 pandemic. Because our technology and potential products may frequently involve the manufacture or use of certain chemical or biological compounds, we are required to certify their safety for industrial use and development in a variety of countries and contexts. As there has not been sufficient testing to determine the long- term health and environmental risks of our Anticalin- based drug candidates and the materials used in the production of such drug candidates and any future products, future regulations may ban the use of our products due to the potential risk they pose to workers or may limit the use of our drug candidates in research and commercial settings. Any such regulations may have a substantial negative impact on our business and revenues and may cause our business to fail. Because we cannot guarantee the long- term safety of use or exposure to materials used during development or manufacture of our products, we may face liability for health risks or harms caused as a result of developing, manufacturing or other processes that use such materials. Any such~~

~~claims may have a negative impact on our revenues and may prove substantially disruptive to our business in the future. 52We~~ may be limited in our use of our net operating loss carryforwards. As of December 31, ~~2022~~ **2023**, we had net operating loss carryforwards for United States federal income tax purposes of $ ~~38~~ **43** ~~6~~ **4** million and net operating loss carryforwards for state income tax purposes of $ ~~42~~ **46** ~~4~~ **7** million. Tax loss carryforwards that were generated prior to December 31, 2017 expire through 2037; U. S. federal tax loss carryforwards generated after that date do not expire. State loss carryforwards expire starting in 2035. In the United States, utilization of the net operating loss carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income and tax, respectively. If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected. We completed a Section 382 study through December 31, 2020. Based on the study, we underwent an ownership change for Section 382 purposes which occurred in February 2018. As a result of the ownership change, our net operating loss and tax credit carryforwards as of the ownership change dates are subject to limitation under Section 382; however, these limitations are not expected to result in any of the impacted net operating loss and tax credit carryforwards to expire unutilized. Any net operating losses or tax credits generated after the February 2018 change are not subject to this annual limitation. However, subsequent ownership changes, as defined by Section 382, may potentially further limit the amount of net operating loss and tax credit carryforwards that could be utilized to offset future taxable income and tax. As of December 31, ~~2022~~ **2023**, we had German corporate income tax and trade tax net operating loss carryforwards of approximately $ ~~163~~ **187** ~~3~~ **6** million and $ ~~160~~ **183** ~~7~~ **4million** **million**, respectively, which may be used to reduce our future taxable income in Germany. Under current German laws, tax loss carryforwards may only be used to offset any relevant later assessment period (calendar year) by $ 1. 2 million plus 60 % of the exceeding taxable income and trade profit of such period and do not expire. In addition, certain transactions, including transfers of shares or interest in the loss holding entity, may result in the partial or total forfeiture of tax losses existing at that date. Partial or total forfeiture of tax losses may further occur in corporate reorganizations of the loss holding entity. Our business and operations would suffer in the event of system failures, and our operations are vulnerable to interruption by natural disasters, terrorist activity, power loss, adverse public health events and other events beyond our control, the occurrence of which could materially harm our business and drug development efforts. Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, hacking, ransomware, cyber- attacks, unauthorized access as well as telecommunication and electrical failures. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could materially disrupt our operations. Although we have invested significant resources to enhance the security of our computer systems, there can be no assurances we will not experience unauthorized intrusions into our computer systems, or those of our CROs, vendors, contractors and consultants, that we will successfully detect future unauthorized intrusions in a timely manner or that future unauthorized intrusions will not result in material adverse effects on our financial condition, reputation or business prospects. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material **impact** ~~disruption of our drug development programs and operations. For example, the loss of clinical trial data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce such data. Likewise, we currently rely, and expect to continue to rely,~~ on ~~third parties for the manufacture of our product candidates and any future product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on~~ our business. **In addition** ~~Certain~~ **certain** data security breaches must be reported to affected individuals and the government, and in some cases to the media, under provisions of HIPAA, other U. S. federal and state law and requirements of non- U. S. jurisdictions, and financial penalties may also apply. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability ~~and / or the further development of our drug candidates could be delayed~~. We are also vulnerable to accidents, electrical blackouts, labor strikes, terrorist activities, war, natural disasters, adverse public health events and other events beyond our control, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of all of such events and do not have an applicable recovery plan in place. Any disruption to our operations or the operations of our collaborators ~~or suppliers~~ from these kinds of events would likely impact our ~~drug development efforts,~~ operating results and ~~our~~ financial condition ~~. With respect to potential impacts of the ongoing COVID- 19 pandemic, see " The COVID- 19 pandemic and its emerging variants, or any future pandemic, could adversely affect our business, including research, clinical trials, supply chain interruptions and financial condition. " 53In addition, certain of our development efforts, particularly those related to the phase 2 study of elarekibep and phase 1 study of PRS- 220, which are being conducted in Australia, in addition to multiple other countries, are located in geographical areas that are known to be prone to certain natural disasters and weather events, including wildfires. In 2019 and 2020, dozens of wildfires erupted in New South Wales, Australia, prompting the government of Australia to declare a state of emergency. Should such a natural disaster that causes disruption to our development efforts occur again in Australia or elsewhere, thereby impeding our ability or the ability of our collaborators to timely conduct our clinical trials, our ability to conduct our business could be severely restricted and our business, clinical development efforts, prospects, and results of operations could be adversely affected as a result. The extent to which any natural disaster may impact our results will depend on future developments, which are highly uncertain and cannot be predicted~~. Although we carry insurance to protect us against some losses or damages resulting from certain types of disasters, the extent of that insurance is limited in scope and amount, and we cannot assure you that our insurance coverage will be sufficient to satisfy any damages and losses. ~~If our facilities are unable to operate because of an accident or incident or for any other reason, even~~

~~for a short period of time, any or all of our research and development programs may be harmed.~~ Any business interruption may have a material adverse effect on our business, financial position, results of operations, and prospects. ~~Our~~ **32Our failure** ~~current operations are largely concentrated in two~~ **to comply with data protection laws and regulations could lead to government enforcement** ~~locations~~ **actions** , **private litigation** and ~~any~~ **/ or** adverse ~~events~~ **publicity and could negatively** ~~affecting~~ --- **affect** ~~these locations may have material adverse consequences on~~ our **operating results and** business ~~. Our current operations are carried out primarily in our facilities located in Hallbergmoos, Germany and Boston, Massachusetts. Any unplanned event, such as a flood, fire, explosion, earthquake, extreme weather condition, medical epidemic or pandemic, power shortage, telecommunication failure, or other natural or man- made accident, or an incident that prevents us from fully utilizing our facilities in these two locations, may have a material adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates, or interruption of our business operations. In the event of an accident or incident at these facilities, we cannot assure you that our insurance coverage will be sufficient to satisfy any damages and losses. If our facilities are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material adverse effect on our business, financial position, results of operations and prospects~~ . We are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and there has been an increasing focus on privacy and data security issues with the potential to affect our business. In the United States, 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 govern the collection, use, disclosure and protection of health- related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions, which could include civil or criminal penalties, private litigation and / or adverse publicity and could negatively affect our operating results and business. For example, California ~~has~~ enacted the California Consumer Privacy Act, or CCPA, which went into effect in January 2020. The CCPA **creates data** ~~establishes a new~~ privacy ~~framework~~ **obligations** for covered businesses ~~by creating an~~ **and** ~~expanded definition of personal information, establishing~~ **establishes** ~~new~~ data privacy rights for California residents, ~~and creating a new and potentially severe statutory damages framework~~ **including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties** for violations **, as well as a private right** of **action** ~~the CCPA and~~ for ~~businesses that fail to implement reasonable security procedures and practices to prevent~~ data breaches. Additionally ~~, in 2020~~ , California voters passed the California Privacy Rights Act, or CPRA, **which became** effective January 1, 2023. The CPRA significantly amends the CCPA, **and imposes** ~~potentially resulting in further uncertainty,~~ additional **data protection obligations on covered businesses, including** ~~costs and expenses in an effort to comply and~~ additional ~~potential~~ **consumer rights processes, limitations on data uses, new audit requirements** for ~~harm~~ **higher risk data,** and ~~liability~~ **opt outs** for ~~failure to comply~~ **certain uses of sensitive personal information** . **The** ~~Among other things, the~~ CPRA **also** established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting new regulations under the CPRA and will have expanded enforcement authority ~~. Effective~~ **, which may result** in **increased privacy and information security enforcement in California. In addition to California, more U. S. states are enacting similar consumer privacy legislation, increasing compliance complexity and increasing risks of failures to comply. As of** 2023, Virginia, Colorado, Connecticut and Utah enacted similar **comprehensive** data protection laws ~~, and other U~~ . ~~S. states~~ **Additional consumer privacy laws** have ~~proposals under consideration~~ **also been enacted in Delaware** , ~~increasing~~ **Indiana, Iowa, Montana, New Jersey, Oregon, Tennessee, and Texas, which laws will take effect over the next** ~~the~~ **three years** ~~regulatory compliance risk~~ . ~~54Numerous~~ -- **Numerous** other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. For example, the European Union' s General Data Protection Regulation, or GDPR, ~~went into~~ **which took** effect in 2018 ~~and~~ **,** imposed a broad data protection framework that expanded the scope of ~~EU~~ data protection law ~~, including~~ **across the European Union and European Economic Area (" EEA ") and can apply** to non- EU entities that process, or control the processing of, personal data relating to individuals located in the ~~EU~~ **EEA** , including clinical trial data. The GDPR sets out a number of requirements that must be complied with when handling the personal data of ~~EU~~ **EEA-** based data subjects, including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis ~~in place~~ to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be " forgotten " and rights to data portability ~~, as well as enhanced current~~ **; an expansion of data subject** rights **with respect to access and control over their personal data** (e. g., access requests); **requirements for** ~~the principal of accountability and~~ demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach **reporting and notification** regime. In particular, medical or health data, genetic data and biometric data are all classified as " special category " data under the GDPR and **are therefore subject to** ~~afford greater protection and require~~ additional compliance obligations. Further, ~~EU~~ **EEA** member states have a broad right to impose additional conditions — including restrictions — on these data categories **in connection with permitted derogations** ~~. This is because the GDPR allows EU member states to derogate~~ from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). We are subject to the GDPR and the German federal data privacy law, the Bundesdatenschutzgesetz, and we are subject to the regulatory authority of the Bavarian data protection authority, the BayLDA. As the EU states continue to reframe their national legislation to harmonize with the GDPR, we will ~~need to~~ monitor compliance with all relevant EU member states' laws and regulations, including where permitted derogation from the GDPR are introduced. We are also subject to evolving EU laws on data export **since** ~~, because~~ we transfer data to countries outside of the ~~EU~~ **EEA** , including the United States and United Kingdom, to ourselves or third parties. The GDPR only permits exports of data outside of the ~~EU~~ **EEA** where there is a

suitable data transfer ~~solution~~ **mechanism** in place to safeguard personal data (e. g., the EU Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the EU, or the CJEU, issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C- 311 / 18) (Schrems II). This decision calls into question certain data transfer mechanisms as between the EU member states and the US. The CJEU is the highest court in Europe and the Schrems II decision heightens the burden on data importers to assess U. S. national security laws on their business **and to evaluate risks of potential fines and penalties and / or data transfers from the EU being halted. On July 10, 2023, the EU Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU- US Data Privacy Framework (the " Framework "). The Framework provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the Schrems II decision. Notably, the new obligations were geared to ensure that data can be accessed by US intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The EU Commission will continually review developments in the US along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction.** ~~future~~ **Future** actions of EU data protection authorities are difficult to predict ~~at the early date~~. ~~Consequently,~~ **Reliance on the Framework to enable cross- border transfers without certain contractual and** ~~there~~ - **other representations** is **dependent upon certification to** ~~some risk of any data transfers from~~ the ~~EU being halted~~ **Framework, which we have not yet done**. If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could **harm consumer confidence** ~~cause customers to lose trust~~ in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the processing of personal data from the ~~EU~~ **EEA** to us in the United States will require greater scrutiny and assessments as required under Schrems II and may have an adverse impact on cross- border transfers of personal data, or increase costs of compliance. The GDPR provides an enforcement authority to impose large penalties for noncompliance, including the potential for fines of up to € 20 million or 4 % of **total** ~~the annual~~ global ~~revenues~~ **turnover from the preceding fiscal year** of the noncompliant company, whichever is greater. Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we ~~may find that we are violating~~ **cannot be assured of compliance with** the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. That could require us to incur significant expenses, which could significantly affect our business. Failure to comply with data protection laws may expose us to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, and potential significant **fines and** penalties if we are found to be non- compliant. Furthermore, the number of government investigations related to data security incidents and privacy violations ~~continue~~ **continues** to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and reputation. **33U** ~~We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, among other things, trade secrets or other intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third- party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third- party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third- party vendors and / or business partners, or to cyber- attacks by malicious third parties. Cyber- attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber- attacks could include the deployment of harmful malware, ransomware, denial- of-service attacks, malicious websites, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber- attacks also include manufacturing, hardware or software supply chain attacks, which could cause a delay in the manufacturing of products or lead to a data privacy or security breach. 55Significant disruptions of our information technology systems, or those of our third- party vendors or business partners, or security breaches could adversely affect our business operations and / or result in the loss, misappropriation and / or unauthorized access, use or disclosure of, or the prevention of access to, confidential information, including, among other things, trade secrets or other intellectual property, proprietary business information and personal information, and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and / or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, including the imposition of significant fines, penalties, or other liability for any noncompliance with certain privacy and data security laws. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure and have adopted a business continuity plan to deal with a disruption to our information technology systems, there can be no assurance that such measures will prevent service interruptions or security breaches that~~

could adversely affect our business. In addition, our liability insurance may not be sufficient in type or amount to cover us against costs of or claims related to security breaches, cyber- attacks or other related liabilities. A cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenue, penalties and fines, or litigation. U. S. tax legislation and future changes to applicable U. S. or foreign tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations. We are subject to income and other taxes in the United States and foreign jurisdictions. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. This Annual Report on Form 10- K does not discuss any such tax legislation or changes to tax laws and regulations, or the manner in which it might affect us or purchasers of our securities. We urge our investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our securities. We are also subject to different tax regulations in each of the jurisdictions where we conduct our business or where our management is located. We expect the scope and extent of regulation in the jurisdictions in which we conduct our business, or where our management is located, as well as regulatory oversight and supervision, to generally continue to increase. Generally, future changes in applicable U. S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations. Inadequate funding for or other adverse actions taken by the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent our product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. During the global response to the COVID- 19 pandemic, moreover, there have been strategic redeployments of government resources to priority projects, including FDA and EMA resources and staff, which have affected routine and for- cause manufacturing inspections and could have an impact on the timeline for review and approval of new marketing applications. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown or slowdown occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or slowdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. 56The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological advances. In addition, the competition in the asthma and cancer markets is intense. We have competitors in the United States and internationally, including major multinational pharmaceutical companies, fully integrated pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, and other public and private research organizations. There are several third- party drug candidates that could compete with drug candidates in our pipeline. Drug candidates interfering with the function of type 2 helper T cells, or Th2, the biological pathway for clarekibep, and thus anticipated to compete with clarekibep, include those that are being developed or commercialized by Sanofi / Regeneron (dupilumab), GSK (mepolizumab), Teva (reslizumab), AstraZeneca (benralizumab, IL- 5Rα), Connect Biopharma (CBP- 201) and Amgen / AstraZeneca (tezepelumab). Drug candidates interfering with CTGF, the biological pathway for PRS- 220 and thus anticipated to compete with PRS- 220 include those that are being developed by Fibrogen (pamrevlumab). Drugs targeting immunomodulatory targets and thus anticipated to compete with our partnered IO programs include those that are currently marketed by Bristol- Myers Squibb (ipilimumab and nivolumab), Merck & Co (pembrolizumab), Roche (atezolizumab), Merck Serono / Pfizer (avelumab) and AstraZeneca (durvalumab), among others and drug candidates being developed by Bristol- Myers Squibb (for example, urelumab), Pfizer (for example, utomilumab) and other clinical stage drug candidates. Additionally, a number of other companies, such as Amgen, Affimed, Macrogenics, Daiichi Sankyo, F- star, Inhibrx, Xencor, Immunocore and Zymeworks, also are pursuing multispecific or targeted approaches in oncology, and have therapies in development or already commercialized. For additional information about third- party drug candidates that could compete with the drug candidates in our pipeline, see " Business -- Competition. " These existing or future competing products may provide therapeutic convenience or clinical or other benefits for a specific indication greater than our products or may offer comparable performance at a lower cost. If any of our products for which we receive regulatory approval fail to capture and maintain market share, we may not achieve sufficient product revenue and our business will suffer. Many of our competitors have substantially greater financial, technical and other resources than we do, such as larger research and development staff and experienced marketing and manufacturing organizations, as well as significantly greater experience in: • developing drugs; • undertaking preclinical testing and clinical trials; • obtaining FDA and other regulatory approvals of drugs; • prosecuting and enforcing intellectual property rights; • formulating and manufacturing drugs; and • launching, marketing and selling drugs. Established pharmaceutical companies may invest heavily to accelerate discovery and development of or in- license novel compounds that could make our drug candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA, MHRA or other regulatory approval, or discovering, developing and commercializing

~~medicines before we do, which would have an adverse effect on our business and ability to achieve profitability from future sales of our approved drug candidates, if any. For additional information about our competitors, please see" Business--Competition." 57We~~ could be subject to product liability lawsuits based on the use of our drug candidates in clinical testing or, if obtained, following our products' marketing approval and commercialization. If product liability lawsuits are brought against us, we may incur substantial liabilities ~~and may be required to cease clinical testing or limit commercialization of our drug candidates~~ . We could be subject to product liability lawsuits if any drug candidate we develop allegedly causes injury or is found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities ~~or be required to limit commercialization of our product candidates~~ . Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in ~~: •~~ **, among other things,** reduced resources of our management to pursue our business strategy **,** ~~; • decreased demand for any products that we may develop; •~~ injury to our reputation and significant negative media attention ~~; • withdrawal of~~ **, significant costs to defend the related litigation, substantial monetary awards to** clinical trial participants or ~~sites; • significant costs to defend the related litigation; • substantial monetary awards to clinical trial participants or~~ patients **, and** ~~; • loss of revenue; •~~ increased insurance costs ~~; and • the inability to commercialize any products that we may develop. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the clinical testing and commercialization of products we develop on our own or with collaborators~~ . While we currently carry insurance in an amount and on terms and conditions that are customary for similarly situated companies and that are satisfactory to our board of directors, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. ~~In the future, we will continue seek to obtain appropriate insurance coverage with respect to any future clinical trials of our other drug candidates, but we may not be able to obtain the levels of coverage desired on acceptable terms, or at all. If we do secure product liability insurance, we may subsequently determine that additional amounts of coverage would be desirable at later stages of clinical development of our drug candidates or upon commencing commercialization of any drug candidate that obtains required approvals, but we may not be able to obtain such additional coverage amounts when needed on acceptable terms, or at all. Unless and until we obtain such insurance, we would be solely responsible for any product liability claims relating to our preclinical and clinical development activities. Further, even after any such insurance coverage is obtained, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by any insurance policies we may then have or that is in excess of the limits of our insurance coverage. We would be required to pay any amounts awarded by a court or negotiated in a settlement that exceed the coverage limitations or that are not covered by any product liability insurance we may obtain, and we may not have, or be able to obtain, sufficient capital to pay such amounts. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business, operations, and prospects. We will need to grow the size of our organization, and we may not successfully manage any growth we may achieve. Our success will depend upon the expansion of our operations and our ability to successfully manage our growth. Our future growth, if any, may place a significant strain on our management and on our administrative, operational, and financial resources, requiring us to implement and improve our operational, financial, and management systems. In addition, our ability to manage our growth effectively will hinge upon our ability to expand, train, manage, and motivate our employees. As of December 31, 2022, we had 127 full- time employees and 17 permanent part- time employees. As our development and commercialization plans and strategies develop, these demands may also require the hiring of additional research, development, managerial, operational, sales, marketing, financial, accounting, legal, and other personnel. 58Moreover, future growth could require the development of additional expertise by management and impose significant added responsibilities on members of management, including: • effectively managing our clinical trials and submissions to regulatory authorities for marketing approvals; • effectively managing our internal research and development efforts such as discovery research and preclinical development; • identifying, recruiting, maintaining, motivating and integrating additional employees; • effectively managing our internal and external business development efforts with current or future partners, such as entering into additional collaboration arrangements and increasing out- licensing revenues; • establishing relationships with third parties essential to our business and ensuring compliance with our contractual obligations to such third parties; • developing and managing new divisions of our internal business, including any sales and marketing segment we elect to establish; • maintaining our compliance with public company reporting and other obligations, including establishing and maintaining effective internal control over financial reporting and disclosure controls and procedures; and • improving our managerial, development, operational and finance systems. We may not be able to accomplish any of those tasks, and our failure to do so could prevent us from effectively managing future growth, if any, and successfully growing our company. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial, and management systems could have a material adverse effect on our business, financial condition and results of operations. We may make future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our financial condition and operating results. We may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may: • issue common stock or other forms of equity that would dilute our existing stockholders' percentage of ownership; • incur debt and assume liabilities; and • incur amortization expenses related to intangible assets or incur large and immediate write- offs. We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by financial markets or investors.~~

Furthermore, future acquisitions could pose numerous additional risks to our operations, including: • problems integrating the purchased business, products or technologies; • challenges in achieving strategic objectives, cost savings and other anticipated benefits; • increases to our expenses; • the assumption of significant liabilities that exceed the limitations of any applicable indemnification provisions or the financial resources of any indemnifying party; • inability to maintain relationships with key business partners of the acquired businesses; • diversion of management' s attention from their day- to- day responsibilities; • difficulty in maintaining controls, procedures and policies during the transition and integration; • entrance into marketplaces where we have no or limited prior experience and where competitors have stronger marketplace positions; • potential loss of key employees, particularly those of the acquired entity; and • that historical financial information may not be representative or indicative of our results as a combined company. 59The United Kingdom' s withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business, including our ability to obtain regulatory approvals in the United Kingdom or the European Union. The United Kingdom officially withdrew from the European Union on January 31, 2020 in a decision commonly referred to as " Brexit, " and the consequent transitionary period came to an end on December 31, 2020. A substantial amount of uncertainty remains regarding the implementation of Brexit and changes to the relationship between the United Kingdom and the European Union. Depending on the ongoing implementation of Brexit, the full extent to which Brexit may impact the business and regulatory environment in the United Kingdom, the European Union or other countries, remains unknown. In addition, Brexit could also result in similar referendums or votes in other European countries in which we do business. In connection with Brexit, the United Kingdom and the European Union entered into a trade agreement known as the Trade and Cooperation Agreement, which was provisionally applicable as of January 1, 2021 and was ratified by the European Parliament on May 1, 2021. This agreement is intended to govern the legal relationship between the European Union and the United Kingdom post- Brexit. Any disputes or breakdowns in implementation of the Trade and Cooperation Agreement or other Brexit- related arrangements negotiated by the United Kingdom and the European Union could, among other outcomes, disrupt the free movement of goods, services and people between the United Kingdom and the European Union, and result in increased legal and regulatory complexities as well as potential higher costs of conducting business in Europe. Given the lack of comparable precedent, it remains unclear what financial, trade and legal implications Brexit will have and how it will affect us. In line with the Trade and Cooperation Agreement, the United Kingdom has established its own regulatory framework for product candidates, which is not identical to the European Union regulatory framework. Industry experience with navigating the two regulatory frameworks is limited at this point in time. Further regulatory divergences could arise. Any failure of the European Union and the United Kingdom to implement and maintain the Trade and Cooperation Agreement could result in the United Kingdom or the European Union significantly altering regulations affecting the clearance or approval of our product candidates that are developed in the United Kingdom or the European Union. Any delay in obtaining, or inability to obtain, any marketing approvals in the United Kingdom as a result of Brexit or failures in the implementation of the Trade and Cooperation Agreement or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and reduce our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business. Our business has been and could continue to be adversely affected by health epidemics in regions where we have our research and development operations, ongoing preclinical or clinical studies, contract research or manufacturing activities, collaboration partner activities or other business activities and could cause significant disruption in the operations of third- party manufacturers and contract research organizations upon which we rely. For example, the outbreak in late 2019 of the strain of virus named SARS- CoV- 2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID- 19, evolved into a global pandemic that spread to most regions of the world and is still ongoing. The COVID- 19 pandemic, and its emerging variants have spread to most countries, including the United States and European and Asia- Pacific countries, and this includes countries in which we have planned or currently have active clinical trial sites. As a result we have and may continue to experience disruptions that could severely impact our business, clinical trials and pre- clinical studies, including: • An impact on various aspects of our planned or ongoing clinical trials. Actual and potentially continuing impacts of the COVID- 19 pandemic on our various clinical trials include patient dosing and study monitoring, which have been and may continue to be paused or delayed due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, including quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials, interruption or delays in the operations of the FDA, or other reasons related to the COVID- 19 pandemic. As the pandemic continues, other aspects of our clinical trials have and may continue to be adversely affected, delayed or interrupted, including, site initiation, patient recruitment and enrollment, availability of clinical trial materials and data analysis. It is unknown how long these pauses or disruptions could continue. 60 • Our reliance on third parties to, among other things, manufacture and transport drug substance and drug product for our clinical trials, ship investigational drugs and clinical trial samples, perform quality testing and supply other goods and services to run our business. Third parties in our international supply chain for materials have and may continue to be adversely impacted by restrictions resulting from the COVID- 19 pandemic, or other infectious diseases, including staffing shortages, production slowdowns or halts, and disruptions in delivery systems, which has and may continue to disrupt our supply chain, limiting our ability to manufacture our product candidates for our clinical trials and conduct our research and development operations. For example, we or our partners currently rely on multiple CMOs to produce, package, and label some or all of the clinical supplies, including APIs, drug substances and finished drug products for the preclinical research and clinical trials, including the phase 2a study of elarekibep, phase 1 / 2 study for PRS- 344 / S095012 and the phase 1 study for PRS- 220, and any tariffs, differing regulatory requirements and other restrictions on the free movement of goods between the United Kingdom and the European Union, or between other countries, as a result of the pandemic may have an

~~adverse impact on this part of our supply chain. This could therefore negatively impact our clinical operations and, in particular, the advancement of our lead respiratory program, elarekibep which would adversely affect our business, our results of operations and financial condition. • Our request that most of our personnel in the United States, and some in Germany, work remotely, may negatively impact productivity, affect our ability to retain employees or disrupt, delay or otherwise adversely impact our business. In addition, this could increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. • Our employees and contractors conducting research and development activities who may not be able to access our laboratory for an extended period of time if they get sick and need to quarantine, or if we or governmental authorities potentially modify current restrictions. For example, during the first years of the pandemic, our lab operations experienced some impact due to our employees and contractors becoming sick and needing to quarantine at home. Although this only minimally affected our productivity, further restrictions limiting access to our laboratory for an extended period could delay timely completion of preclinical activities and initiation of additional clinical trials for our programs. • Health regulatory agencies globally may continue to experience disruptions in their operations as a result of the COVID- 19 pandemic. The FDA and comparable foreign regulatory agencies may continue to have slower response times or be under- resourced to continue to monitor our clinical trials and, as a result, review, inspection and other timelines may be materially delayed. It is unknown how long these disruptions could continue. Any elongation or de- prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. For example, regulatory authorities may require that we not distribute a product candidate lot until the relevant agency authorizes its release. Such release authorization may be delayed as a result of the COVID- 19 pandemic and could result in delays to our clinical trials. • The trading prices for our common stock and other biopharmaceutical companies have been highly volatile due to the COVID- 19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock. The COVID- 19 pandemic continues to evolve. The ultimate impact of the COVID- 19 pandemic and its emerging variants on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID- 19 and its emerging variants and the actions taken to contain coronavirus or address its impact in the short and long term, among others. We do not know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely. 61Risks --~~ **Risks** Related to the ~~Discovery and~~ Development **and Commercialization** of Our Drug Candidates **Although we have in the past depended heavily on the success of our drug candidates and programs, we do not have any product candidates currently in active development. Future clinical trials, if any, may not be successful and we cannot be certain that we will receive regulatory approvals or be able to successfully commercialize our products even if we receive regulatory approvals.** We currently have no products that are approved for commercial sale ~~. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our respiratory programs~~ , ~~including elarekibep, our other partnered programs with AstraZeneca, our proprietary respiratory programs, including PRS- 220~~ and **do not have plans to independently** ~~PRS- 400, as well as our other programs. In partnership with AstraZeneca, the phase 2a study for elarekibep is ongoing in multiple sites globally. In our proprietary PRS- 220 program, we dosed the first patient in October 2022 for the phase 1 study. We are engaged in research and development ----~~ **develop any** ~~activities with respect to a number of additional~~ drug **product** candidates ~~and programs~~ . All of our ~~other~~ **IO** drug candidates are **being developed** in ~~the discovery~~ **partnership with** ~~or~~ **our collaborators** ~~early preclinical to IND- enabling stage~~ . Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approval and commercialization of ~~elarekibep, PRS- 220, and~~ our **partnered** ~~other respiratory and IO~~ programs, which may never occur. ~~Before we can generate any revenues~~ **For example, in July 2023 AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, which terminations became effective October 15, 2023. AstraZeneca' s decision to terminate these agreements was based on non- clinical safety findings in a 13- week toxicology study of elarekibep in non- human primates. 34In order for us to achieve potential milestones or royalties** from ~~sales of~~ our **partnered programs** ~~lead drug candidates~~ , ~~we~~ **our partners** must complete **some or all of** the following activities ~~for each of them~~ , any one of which ~~we~~ may not be ~~able to~~ successfully ~~complete~~ **completed** : • conduct additional preclinical and clinical development with successful outcomes; • manage preclinical, manufacturing and clinical activities; • obtain regulatory approval from the FDA and other comparable foreign regulatory authorities; • establish manufacturing relationships for the clinical and post- approval supply of the applicable drug candidate in compliance with all regulatory requirements; • build a commercial sales and marketing team, either internally or by contract with third parties; • establish and maintain patent and trade secret protection or regulatory exclusivity for our product candidates; • develop and implement marketing strategies for successful commercial launch of our product candidates, if and when approved; • secure acceptance of our products, if and when approved, by patients, from the relevant medical communities and from third- party payors; • compete effectively with other therapies; • establish and maintain adequate health care coverage and reimbursement; • ensure continued compliance with any post- marketing requirements imposed by regulatory authorities, including any required post- marketing clinical trials or the elements of any post- marketing REMS that may be required by the FDA or comparable requirements in other jurisdictions to ensure the benefits of the product outweigh its risks; • maintain continued acceptable safety profile of the product candidates following approval; and • invest significant additional cash in each of the above activities. If ~~we~~ **our partners** are unable to address one or more of these factors

in a timely manner or at all, ~~we~~ **there** could ~~experience~~ **be** significant delays in the successful commercialization of, or an inability to successfully commercialize, our product candidates, which would materially harm our business. If ~~we do not receive~~ regulatory approvals **are not received** for one or more of our product candidates, we may not be able to continue our operations. Even if ~~we~~ **our partners** successfully obtain regulatory approvals to manufacture and market our product candidates, ~~our~~ revenues will be dependent, in part, upon the size of the markets in the territories for which ~~we gain~~ regulatory approval **is obtained** and ~~have~~ **where there is** commercial rights, competitors products in the same markets, market acceptance, and other factors. If the markets for patient subsets that ~~we~~ are ~~targeting~~ **targeted** are not as significant as we estimate, ~~we may not generate~~ significant revenues **may not be generated** from sales of such products, if approved. Clinical testing of **our** ~~clarekibep and PRS- 220, and certain other~~ IO **partnered** programs is ongoing, while clinical testing for other **IO** programs, ~~including our for example other~~ -- **the** ~~respiratory~~ **preclinical** programs **with Pfizer** , ~~has~~ **have** not yet commenced, and the results of any future clinical trials or preclinical studies of these programs, if unsuccessful, could lead to ~~our~~ abandonment of the development of those drug candidates. If studies of these drug candidates produce unsuccessful results and ~~we~~ **our partners** are forced or elect to cease their development, our business and prospects could be substantially harmed. **Preclinical and clinical testing of drug candidates that has been conducted to date or will be conducted in the future may not have been or may not be performed in compliance with applicable regulatory requirements, which could lead to increased costs or material delays for their further development.** ~~62Given~~ -- **Given** the complexity as well as the uncertainty inherent in preclinical and other nonclinical studies and clinical trials, and because of our limited operating experience, we may discover that our own development activities are not in compliance with applicable regulatory requirements or are otherwise deficient, and therefore, determine that the development of our drug candidates on the basis of those trials and studies is not warranted or will be delayed. We have ~~also~~ entered into license, partnership and option arrangements, such as with Servier, ~~AstraZeneca~~ **Pfizer** , **and** ~~Seagen,~~ Boston Pharmaceuticals ~~and Genentech~~ , relating to certain drug candidates and we may continue to do so in the future. Under some of these arrangements, the development of some of those drug candidates has been, or in the future may be, conducted wholly by such partners or third parties with which the partners contract. As a result, we have not been or may not be closely involved with or have any control over those development activities. Although some of our partners have provided information regarding those drug candidates and the related studies conducted to date, including data that ~~is~~ **has been** included in ~~this~~ **our** Annual ~~Report~~ **Reports** on Form 10- K, we have not received and may not receive in the future, comprehensive information regarding all of those development activities, including the raw data from certain studies that have been conducted, information regarding the design, procedural implementation and structure and information regarding the manufacture of the drug candidates used in the studies. Because we may have limited or no input on the development of these drug candidates, we may discover that all or certain elements of the trials and studies our partners have performed have not been, or may not in the future be, in compliance with applicable regulatory standards or have otherwise been or may be deficient, and that advancement of the development of these drug candidates on the basis of those trials and studies is not warranted. Further, the majority of our development activities for each of our drug candidates, ~~including our ongoing phase 1 study with PRS- 220 in Australia, phase 2a study with clarekibep at multiple sites globally,~~ and **any** ~~our anticipated~~ future clinical trials, have been, are being or may in the future be conducted in whole or in part outside of the United States, including in Europe, Australia or Asia. ~~We~~ **Our partners** may also conduct ~~some of our~~ future development activities in other countries or regions. As a result, although those studies may meet the standards of applicable foreign regulatory bodies, the structure and design of those clinical trials and preclinical studies may not meet applicable FDA requirements and also may not meet the requirements of the applicable regulatory authorities in other foreign countries in which we desire to pursue marketing approval. If the studies conducted by us or our partners or collaborators do not comply with applicable regulatory requirements or are otherwise not eligible for continued development in the United States or abroad, then ~~we or our partners may be forced to conduct~~ new studies **may be required** in order to progress the development of our drug candidates. **Our** ~~We, or our~~ partners ~~,~~ may not have the funding or other resources to conduct or complete these additional studies, which would severely delay or prevent the development plans for these drug candidates and their commercialization. Any such deficiency and delay in the development of these drug candidates could significantly harm our business plans, product revenues and prospects. ~~Biopharmaceutical product~~ **Clinical drug** development ~~is generally a highly speculative undertaking and by its nature~~ involves a **lengthy** ~~substantial degree of risk. Our specific line of business, the discovery of Anticalin- brand~~ -- **and expensive process** ~~drug therapeutics for patients~~ with **uncertain outcomes** ~~a variety of diseases and conditions~~ , **clinical trials** ~~such as asthma and cancer, is an emerging field, and the scientific discoveries that form the basis for our efforts to develop drug candidates~~ are **difficult** ~~relatively new. Further, the scientific evidence~~ to **design** ~~support the feasibility of developing drug candidates based on those discoveries is both preliminary and limited. In contrast to companies that focus on more traditional drug classes, such as antibodies and small molecules, we believe that we are the first, if not the only, company to work with Anticalin- brand~~ -- **and** ~~drug therapeutics~~ **implement,** and **any of our partners'** ~~work to advance these to a~~ clinical **trials could produce unsuccessful results or fail at any** stage ~~of development. We are not aware of any company that has successfully developed and obtained approval for a drug based on Anticalin proteins. As a result, identifying drug targets based~~ in ~~part on their suitability with Anticalin- brand drug therapeutics, which is a fundamental aspect of our business approach, may not lead to the discovery or development of any drugs that successfully treat patients with the diseases and conditions we intend to target. Moreover, the lack of successful precedents in the development of Anticalin proteins could result in added complexities or delays in our development efforts. The failure of the scientific underpinnings of our business model to produce viable drug candidates would substantially harm our operations and prospects. 63We may not be successful in our efforts to build a pipeline of drug candidates. A key element of our strategy is to use and expand our Anticalin- based drug platform to build a pipeline of drug candidates to address different targets and advance those drug candidates through clinical development for the treatment of a variety of different types of diseases. Although our research efforts to date have resulted in identification of a series of targets, we may not be able to develop drug candidates that~~

~~have good drug- like properties (including characteristics such as target affinity, stability and half- life) and are safe and effective inhibitors or promoters of all or any of these targets. Even if we are successful in building a product pipeline, the potential drug candidates that we identify may not be suitable for clinical development for a number of reasons, including that they~~ **the process** ~~may cause harmful side effects or demonstrate other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential drug candidates fail to produce a pipeline of potentially viable drug candidates, then our success as a business will be dependent on the success of fewer potential drug candidates, which introduces risks to our business model and potential limitations to any success we may achieve~ . Clinical trials conducted on humans are expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the process. Additionally, any positive results of preclinical studies and early clinical trials of a drug candidate may not be predictive of the results of later- stage clinical trials, such that drug candidates may reach later stages of clinical trials and fail to show the desired safety and efficacy traits despite having shown indications of those traits in preclinical studies and early- stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier phases of the trials. Therefore, the results of any ongoing or future clinical trials ~~we~~ **our partners** conduct may not be successful. ~~A~~ **35For example, in June 2023, AstraZeneca communicated to us its decision to discontinue and cease dosing in the ongoing clinical studies of elarekibep. This decision was based on lung findings from a non- clinical 13- week GLP toxicology study with dry powder inhaler- formulated elarekibep, which did not support long- term use and progression to later- stage development. The 13- week non- human primate study included three active dose cohorts. AstraZeneca concluded that there were no clinical observations across any of the doses but that there were respiratory tract pathology findings. These findings included inflammation- mediated lung tissue damage, which did not appear to be dose related. AstraZeneca' s decision was made independent of any data from the** ~~phase~~ **Phase** 2a study ~~for~~ **. In July 2023, AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, which terminations became effective October 15, 2023. AstraZeneca' s decision to terminate these agreements was based on non- clinical safety findings in a 13- week toxicology study of** elarekibep ~~was initiated~~ in **non** ~~2021, a phase 1 study for PRS-~~ **human primate** ~~220 was initiated in October 2022, a phase 1 / 2 study for PRS- 344 / S095012 was initiated in November 2021, and a phase 1 study for SGN- BB228 was initiated in January 2023~~ . ~~We or our partners may, however, experience delays in pursuing those or any other clinical~~ **Clinical** trials ~~, and any planned clinical trials~~ may **also** ~~not begin on time, may require redesign, may not enroll sufficient healthy volunteers or patients in a timely manner and may not be completed on schedule, if at all. Additional clinical trials may~~ be delayed, suspended or prematurely terminated ~~because costs are greater than we anticipate or~~ for a variety of other reasons ~~(which may be heightened as a result of the ongoing COVID- 19 pandemic)~~ , such as: • delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design ~~that we are able to execute~~ ; • delay or failure in obtaining authorization to commence a trial, including approval from the appropriate IRB to conduct testing of a candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial ~~; • delay in reaching, or failure to reach, agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites~~ ; • inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs; • delay or failure in recruiting and enrolling suitable volunteers or patients to participate in a trial; • delay or failure in developing and validating companion diagnostics, if they are deemed necessary, on a timely basis; • failure of trial participants to complete a trial or return for post- treatment follow- up; • inability to monitor trial participants adequately during or after treatment; • clinical sites and investigators deviating from trial protocols, failing to conduct the trial in accordance with regulatory requirements or dropping out of a trial; • failure to initiate or delay of or inability to complete a clinical trial as a result of a clinical hold imposed by the FDA or comparable foreign regulatory authority due to observed safety findings or other reasons; • negative or inconclusive results in our clinical trials, and ~~our~~ **a** decision to or regulators' requirement that ~~we conduct~~ additional non- clinical studies ~~,~~ **or** clinical trials **be conducted** or that ~~we abandon~~ one or more of our **partnered** product development programs **be abandoned** ; or • inability to manufacture sufficient quantities of a drug candidate of acceptable quality for use in clinical trials. ~~64We rely and plan to continue to rely on CROs, CMOs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Although we have and expect that we will continue to have agreements in place with CROs and CMOs governing their contracted activities and conduct, we have limited influence over their actual performance. As a result, we ultimately do not and will not have control over a CRO' s or CMO' s compliance with the terms of any agreement it may have with us, its compliance with applicable regulatory requirements or its adherence to agreed- upon time schedules and deadlines, and a future CRO' s or CMO' s failure to perform those obligations could subject any of our clinical trials to delays or failure.~~ Further, ~~we~~ **our partners** may also encounter delays if a clinical trial is suspended or terminated by us, by any IRB or ethics committee, by a Data Safety Monitoring Board, or DSMB, or by the FDA, EMA, MHRA, or other regulatory authority. A suspension or termination may occur due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, inspection of the clinical trial operations or trial site by the FDA, EMA, MHRA or other regulatory authorities, exposing participants to health risks caused by unforeseen safety issues or adverse side effects, development of previously unseen safety issues, failure to demonstrate a benefit from using a drug candidate or changes in governmental regulations or administrative actions. We cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials. ~~Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our product candidates.~~ If ~~we~~ **our partners** experience delays in the commencement or completion of, or suspension or termination of, any clinical trial for our drug candidates, the commercial prospects of the drug candidate could be

harmed, and ~~our~~ ability to ~~generate product revenues from the drug candidate may be delayed or eliminated. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development~~ and ~~approval process and jeopardize regulatory approval of our drug candidates and our~~ ability to **realize milestones or royalties** ~~commence sales and generate revenues~~. The occurrence of any of these events could harm our business, financial condition, results of operations and prospects significantly. ~~We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of research subjects to participate in these trials, including as a result of challenges posed by the ongoing COVID- 19 pandemic. In particular, for some diseases and conditions we are or will be focusing on, our pool of suitable patients may be smaller and more selective and our ability to enroll a sufficient number of suitable patients may be limited or take longer than anticipated. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and volunteers or patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates. Patient enrollment for any of our clinical trials may also be affected by other factors, including without limitation: • the size and nature of the target patient population; • the severity of the disease under investigation; • the frequency of the molecular alteration we are seeking to target in the applicable trial; • the patient eligibility criteria for the clinical trial in question; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • the perceived risks and benefits of the drug candidate under study in the clinical trial; • the approval and availability of other therapies to treat the disease or disorder that is being investigated in the clinical trial; • the extent of the efforts to facilitate timely enrollment in clinical trials; • the patient referral practices of physicians; • the ability to monitor volunteers or patients adequately during and after treatment; • the presence of other drug candidates in clinical development for the same indication or against the same target; and • the proximity and availability of clinical trial sites for prospective participants. Our inability to enroll a sufficient number of participants for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, and we may not have or be able to obtain sufficient cash to fund such increased costs when needed, which could result in the further delay or termination of clinical trials. 65We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. We will be required to demonstrate with substantial evidence through well- controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early- stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later- stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities despite having progressed through preclinical studies and early- stage clinical trials. In particular, no Anticalin- based drug products have been approved or commercialized in any jurisdiction, and the outcome of our preclinical studies and early- stage clinical trials may not be predictive of the success of later- stage clinical trials. From time to time, we may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are, and will remain, subject to extensive regulation by the FDA in the United States and by the respective regulatory authorities in other countries where regulations differ. We are not permitted to market our biological product candidates in the United States until we receive the respective approval of a BLA from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory authorities in such countries. The time required to obtain approval, if any, by the FDA, EMA, MHRA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials, if approval is obtained at all, and depends upon numerous factors, including the substantial discretion of the regulatory authorities and the type, complexity and novelty of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical studies or clinical trials. We have not submitted a marketing application such as a BLA to the FDA, an MAA to the EMA or any similar application to any other jurisdiction. We have limited experience in planning and conducting the clinical trials required for marketing approvals, and we have and expect to continue to rely on third- party CROs to assist us in this process. Obtaining marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing and packaging facilities by the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in cGMP compliance by us or by our CMOs that could result in the candidate not being approved. Moreover, we have not obtained regulatory approval for any drug candidate in any jurisdiction and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval. Our drug candidates could fail to receive, or could be delayed in receiving, regulatory approval for many reasons, including any one or more of the following: • the FDA, EMA, MHRA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA, EMA, MHRA or comparable foreign regulatory authorities that a drug~~

candidate is safe and effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA, MHRA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a drug candidate' s clinical and other benefits outweigh its safety risks; 66 • the FDA, EMA, MHRA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of a BLA, MAA or other submission or to obtain regulatory approval in the United States or elsewhere; • upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate; • the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA, EMA, MHRA or comparable foreign regulatory authorities; • the FDA, EMA, MHRA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing internally or with partners; and • the change of the medical standard of care or the approval policies or regulations of the FDA, EMA, MHRA or comparable foreign regulatory authorities may significantly change in a manner that renders our clinical data insufficient for approval. The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in one or more jurisdictions, clarekibep, PRS- 220, our other respiratory programs, our discovery stage programs or any other drug candidates we are developing or may seek to develop in the future, which would significantly harm our business, results of operations and prospects. In such case, we may also not have the resources to conduct new clinical trials and / or we may determine that further clinical development of any such drug candidate is not justified and may discontinue any such programs. In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve prices we may propose to charge for our products, may grant approval contingent on the performance of costly post- marketing clinical trials (referred to as " conditional " or " accelerated " approval depending on the jurisdiction), or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate or that includes significant warnings or contraindications. Any of the foregoing circumstances could materially harm the commercial prospects for our drug candidates. Our failure to obtain marketing approval in jurisdictions other than the United States, the U. K. and Europe would prevent our product candidates from being marketed in these other jurisdictions. Any approval that we are granted for our product candidates in the United States, U. K. or Europe would not assure approval of product candidates in the other or in any other jurisdiction. In order to market and sell our future products in jurisdictions other than the United States, United Kingdom or Europe, we or our third- party collaborators must obtain separate marketing approvals in that jurisdiction and comply with numerous and varying regulatory requirements. The review and approval procedures can vary drastically among jurisdictions, and each jurisdiction may impose different testing and other requirements to obtain and maintain marketing approval. Further, the time required to obtain those approvals, if any, may differ substantially among jurisdictions. In addition, some countries or regions outside the United States, the U. K. and Europe require approval of the sales price of a drug before it can be marketed in that country or region. In many countries, separate procedures must be followed to obtain reimbursement. Moreover, approval by the FDA, EMA, MHRA or an equivalent foreign authority does not ensure approval by regulatory authorities in any other countries or regions. As a result, the ability to market and sell a drug candidate in more than one jurisdiction can involve significant additional time, expense and effort, and would subject us and our collaborators to the numerous and varying post- approval requirements of each jurisdiction governing commercial sales, manufacturing, pricing and distribution of our drug candidates. We or any third parties with whom we may collaborate may not have the resources to pursue those approvals, and we or they may not be able to obtain any approvals that are pursued. The failure to obtain marketing approval for our drug candidates in foreign jurisdictions could severely limit their potential market and ability to generate revenue. 67Undesirable side effects caused by our product candidates could cause us or the FDA, EMA, MHRA or other regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other regulatory authorities of our product candidates. In the event that our clinical trials produce undesirable side effects, our trials could be suspended or terminated and the FDA, EMA or MHRA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. In addition to this, the product- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw or limit their approval of such product candidates; • regulatory authorities may require the addition of labeling statements, specific warnings or a contraindication; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients, or we may be required to implement a REMS in the U. S. or a comparable risk mitigation plan in other jurisdictions to ensure that the benefits of the product outweigh the risks; • we may be required to change the way such product candidates are distributed or administered, or change the labeling of the product candidates; • we may be subject to regulatory investigations and government enforcement actions; • the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post- marketing testing and surveillance to monitor the safety and efficacy of the product; • we may decide to recall or withdraw such product candidates from the marketplace after they are approved; • we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and • our reputation may suffer. We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of

commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues. Because we have limited financial and managerial resources, we must focus our efforts on particular research programs and drug candidates for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Further, our resource allocation decisions may result in our use of funds for research and development programs and drug candidates for specific indications that may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, or if market conditions change, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate. Any such failure to properly assess potential drug candidates could result in missed opportunities and / or our focus on drug candidates with low market potential, which would harm our business and financial condition. 68Risks -- **Risks** Related to Our Dependence on Third Parties We depend upon independent investigators and contractors, such as CROs, universities and medical institutions, to conduct our clinical trials and preclinical studies. We rely upon, and plan to continue to rely upon, such third- party entities to execute our clinical trials and preclinical studies and to monitor and manage data produced by and relating to those studies and trials. However, in the future, we may not be able to establish arrangements with CROs when needed or on terms that are acceptable to us, or at all, which could negatively affect our development efforts with respect to our drug candidates and materially harm our business, operations and prospects. As a result of the use of third- party contractors, we will have only limited control over certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies, including each of our clinical trials, is conducted in accordance with the applicable protocol, legal and regulatory requirements as well as scientific standards, and our reliance on any third- party entity will not relieve us of our regulatory responsibilities. In addition, we and our third- party contractors will be required to comply with cGCP for all of our drug candidates in clinical development. Regulatory authorities enforce cGCP through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our contractors fail to comply with applicable cGCP, the clinical data generated in the applicable trial may be deemed unreliable and the FDA, EMA, MHRA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a drug candidate for marketing, which we may not have sufficient cash or other resources to support and which would delay our ability to generate revenue from future sales of such drug candidate. Any agreements governing our relationships with CROs or other contractors with whom we currently engage or may engage in the future may provide those outside contractors with certain rights to terminate a clinical trial under specified circumstances.. If our contractors 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 a failure to adhere to our clinical protocols, legal and regulatory requirements or for other reasons, such as the COVID- 19 pandemic, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for, or successfully commercialize, the affected drug candidates. In addition, we will be unable to control whether or not they devote sufficient time and resources to our preclinical and clinical programs. These outside contractors may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. As a result, our operations and the commercial prospects for the affected drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. These contractors may also have relationships with other commercial entities, some of whom may compete with us. If our contractors assist our competitors to our detriment, our competitive position would be harmed. If our relationships with any third parties conducting our studies are terminated, we may be forced to seek an engagement with a substitute third party and may be unable to enter into arrangements with such third parties on commercially reasonable terms, or at all. Switching or adding third parties to conduct our studies involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines, or may result in the clinical trial not being completed. These difficulties may be exacerbated as a result of the COVID- 19 pandemic. Although we carefully manage our relationships with third parties conducting our studies, we cannot assure you that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material and adverse effect on our business, financial condition and results of operations. We rely and expect to continue to rely completely on third parties to formulate and manufacture our preclinical, clinical trial and commercial drug supplies. The development and commercialization of any of our drug candidates could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of such drug supplies or fail to do so at acceptable quality levels, including in accordance with applicable regulatory requirements or contractual obligations, and our operations could be harmed as a result. We have no experience in drug formulation or manufacturing. We do not currently have, nor do we plan to acquire, the infrastructure or capability internally, such as our own manufacturing facilities, to manufacture our preclinical and clinical drug supplies for our clinical trials and preclinical studies or commercial quantities of any drug candidates that may obtain regulatory approval. Therefore, we lack the resources and expertise to formulate or manufacture our own drug candidates. We have entered into agreements with CMOs for the clinical- stage manufacturing of certain drug candidates, including elarekibep, PRS- 220, and PRS- 344 / S095012 as well as other drugs involved in our clinical trials and preclinical studies. We plan to enter into agreements with one or more manufacturers to manufacture, supply, store and distribute drug supplies for our current and future clinical trials and / or commercial sales, if any. We intend to establish or continue those relationships for the supply of our drug candidates; however, there can be no assurance that we will be able to retain those relationships on commercially reasonable terms, if at all. If we are unable to maintain those relationships, we could experience delays in our development efforts as we locate and qualify new CMOs. If any of our current drug candidates or any drug candidates we may develop or acquire in the future receives regulatory approval, we will rely on one or more CMOs to manufacture the commercial supply of such drugs. 69Our reliance on a limited

~~number of CMOs exposes us to the following risks: • We may be unable to identify manufacturers on acceptable terms, or at all, because the number of qualified potential manufacturers is limited. Following BLA approval, or its foreign equivalent, if successful, a change in the manufacturing site could require additional approval from the FDA, or the respective comparable foreign regulatory authorities. This approval would require new testing and compliance inspections. • Our third- party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality and cost required to meet our clinical and commercial needs, if any. • Our future CMOs may not perform as contractually agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products. • Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and some state agencies to ensure strict compliance with cGMP regulations and other U. S. and corresponding foreign requirements. We do not have control over third- party manufacturers' compliance with these regulations and standards. • If any third- party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. Each of these risks could delay our clinical trials, the marketing approval, if any, of our drug candidates or the commercialization of our drug candidates, which could result in higher costs or could deprive us of potential product revenues. Although our agreements with our CMOs require them to perform according to certain cGMP requirements such as those relating to quality control, quality assurance and qualified personnel, we cannot control the conduct of our CMOs to implement and maintain these standards. If any of our CMOs cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA, EMA, MHRA or other comparable foreign authorities, we would be prevented from obtaining regulatory approval for our drug candidates unless and until we engage a substitute CMO that can comply with such requirements, which we may not be able to do. Any such failure by any of our CMOs would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved. Further, we plan to rely on our manufacturers to purchase from third- party suppliers the materials necessary to produce our drug candidates for our clinical trials. We do not have, nor do we expect to enter into, any agreements for the commercial production of these raw materials, and we do not expect to have any control over the process or timing of our CMOs' acquisition of raw materials needed to produce our drug candidates. Any significant delay in the supply of a drug candidate or the raw material components of an ongoing clinical trial due to a manufacturer' s need to replace a third- party supplier of raw materials could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our drug candidates. Additionally, if our future manufacturers or we are unable to purchase these raw materials to commercially produce any of our drug candidates that gains regulatory approvals, the commercial launch of our drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our drug candidates.~~ The rights and obligations of the partners to which we may license our Anticalin- based technology are governed by the licensing and collaboration agreements we enter into with those partners. **Our** ~~In addition, our relationships with CMOs are governed by the service agreements between us and each of the manufacturers. Although we attempt to address the full range of possible events that may occur during the development or the manufacturing of Anticalin- based drug candidates and products, unanticipated or extraordinary events may occur beyond those contemplated by such agreements. Furthermore, our business relationships with our product manufacturers and our~~ collaborators may include assumptions, understandings or agreements that are not included in our agreements with them, or that are inaccurately or incompletely represented by their terms. In addition, key terms in such agreements may be misunderstood or contested, even when we and the other party previously believed that we both had a mutual understanding of such terms. Any differences in interpretation or misunderstandings between us and other parties may result in substantial costs ~~and delays with respect to the development, manufacturing or sale of Anticalin- based drugs~~, and may negatively impact our revenues and operating results. ~~Product manufacturers may fail to produce the products at the quality or standard required or on the agreed timeline, and partners~~ **Partners** may fail to develop the drug candidates with the diligence or under the timeline or in the manner we anticipated, and results may differ from the terms upon which we had agreed ~~. As a result, we may be unable to supply drugs of the quality or in the quantity demanded or required. We may suffer harm to our reputation in the market from missed development goals or deadlines and may be unable to capitalize upon market opportunities as a result~~. Resolution of these problems may entail costly and lengthy litigation or dispute resolution procedures. In addition, there is no guarantee that we will prevail in any such dispute or, if we do prevail, that any remedy we receive, whether legal or otherwise, will adequately redress the harm we have suffered. The delays and costs associated with such disputes may themselves harm our business and reputation ~~and limit our ability to successfully compete in the market~~. ~~70We~~ **We** depend on third parties and ~~intend~~ **may** to continue to license or collaborate with third parties, and events involving these strategic partners or any future collaboration could delay or prevent ~~us from developing~~ **development** or ~~commercializing~~ **commercialization of drug** products. Our business strategy, along with our short- and long- term operating results, depend in part on our ability to execute on existing strategic collaborations and to license or partner with new strategic partners. We have entered into and ~~expect~~ **may** in the future to enter into collaborative arrangements with both U. S.- based and foreign pharmaceutical and drug development companies, which will lead ~~, finance~~ or otherwise collaborate with us or assist us in the development, manufacturing and marketing of our drug products. We believe collaborations allow us to leverage our resources and technologies and we ~~anticipate deriving~~ **may derive** some revenues from research and development fees, license fees, milestone payments, and royalties from our collaborative partners. Our prospects, therefore, may depend to some extent upon our ability to attract and retain ~~collaborative partners and to develop technologies and products that meet the requirements of current or prospective~~ collaborative partners. We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborations or potential products, in particular with respect to our collaborations with ~~AstraZeneca for the development of elarekibep, with~~ Servier for the development of ~~PRS- 344 /~~S095012, with Boston Pharmaceuticals for the development of ~~PRS- 342 /~~BOS- 342, with ~~Seagen~~ **Pfizer** for the development of SGN-BB228 and other programs ~~, and our other collaborations with Genentech~~. These collaborators may breach or terminate their

agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely and reasonable manner. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new, amended or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Further, our collaborators may not develop or commercialize products that arise out of our collaborative arrangements or devote sufficient resources to the development, manufacturing, marketing or sale of these products. In addition, our collaborative partners may have the right to guide strategy regarding prosecution of relevant patent applications, abandon research projects and / or terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed- upon research terms **. 36Our collaborators may also decide to terminate these agreements based on findings in our clinical trials. For example, in July 2023, AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, effective October 15, 2023. AstraZeneca' s decision to terminate the AstraZeneca Agreements was based on non- clinical safety findings in a 13- week toxicology study of elarekibep in non- human primates** . By entering into such collaborations, we may forego opportunities to collaborate with other third parties who do not wish to be associated with our existing third- party strategic partners. In the event of termination of a collaboration agreement, termination negotiations may result in less than favorable terms. There can be no assurance that we will be successful in establishing collaborative arrangements on acceptable terms or at all, that collaborative partners will not terminate funding before the completion of projects, that our collaborative arrangements will result in successful product commercialization, or that we will derive any revenues from such arrangements. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Additionally, the negotiation, documentation and implementation of collaborative arrangements are complex and time- consuming. ~~Our~~ **Any** discussions with potential collaborators may not lead to new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property rights **. Our success depends in part on the efforts of our current and possible future collaborators, who will likely have substantial control and discretion over the continued development and commercialization of drug candidates that are the subject of our collaborations** . Our current collaborators and future collaborators will have significant discretion in determining the effort and amount of resources that they dedicate to our collaborations. Our collaborators may determine not to proceed with clinical development or commercialization of a particular drug candidate for a number of reasons that are beyond our control, even under circumstances where we might have continued such a program, currently including ~~elarekibep, PRS- 342 /~~BOS- 342, SGN- BB228 and ~~PRS- 344 /~~S095012. In addition, our rights to receive milestone payments and royalties from our collaborators will depend in part on our collaborators' abilities to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates. We may also depend on our collaborators to manufacture clinical scale quantities of some of our drug candidates and, possibly, for commercial scale manufacture, distribution, marketing and sales. Our collaborators may not be successful in manufacturing our drug candidates or successfully commercializing them. We face additional risks in connection with our existing and future collaborations, including the following: • our collaborators may develop and commercialize, either alone or with others, products that are similar to or competitive with the products that are the subject of the collaboration with us; • our collaborators may underfund, not commit sufficient resources to, or conduct in an unsatisfactory manner the development, testing, marketing, distribution or sale of our drug candidates; • our collaborators may not properly maintain or defend our intellectual property rights or utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our intellectual property or proprietary information or expose us to potential liability; • our collaborators may encounter conflicts of interest, changes in business strategy or other business issues that could adversely affect their willingness or ability to fulfill their obligations to us (for example, pharmaceutical and biotechnology companies historically have re- evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries); ~~71~~ • we do not control the conduct and communications of our collaborators, and, thus, we are subject to the risk that their actions may negatively impact our reputation and potentially harm our business; • disputes may arise between us and our collaborators delaying or terminating the research, development, manufacture or commercialization of our drug candidates, resulting in significant litigation or arbitration that could be time- consuming and expensive, or causing collaborators to act in their own self- interest and not in the interest of our stockholders; • we might not have the financial or human resources to meet our obligations or take advantage of our rights under the terms of our existing and future collaborations; and • our existing collaborators may exercise their respective rights to terminate their collaborations with us without cause, in which event, we ~~might~~ **do** not **currently expect to** be able to complete development and commercialization of ~~our~~ **such** drug candidates on our own ~~. Certain of our research and development and manufacturing activities take place in China through third- party manufacturers. A significant disruption in the operation of those manufacturers could materially adversely affect our business and results of operations. We have relied on certain third parties located in China to manufacture and supply certain drug substance for our drug product candidates, and we expect to continue to use such third- party manufacturers for such purposes. A natural disaster, epidemic or pandemic, including the ongoing COVID- 19 pandemic, trade war, trade sanctions, political unrest, economic conditions, changes in legislation, including the passage of the People' s Republic of China Biosecurity law, which became effective on April 15, 2021, or other events in China could disrupt the business or operations of manufacturers or other third parties with whom we conduct business now or in the future. Any disruption in China that significantly impacts such third parties, including our manufacturers' ability to produce drug substance or drug product in adequate quantities to meet our needs could impede, delay, limit or prevent the research, development or commercialization of our current and future products or product candidates. In addition, for any activities conducted in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U. S. or Chinese governments, political unrest or unstable economic conditions including sanctions on China or any of our China- based vendors.~~

Separately, we may also be exposed to fluctuations in the value of the local currency in China for goods and services. Our costs for any of these services or activities could also increase as a result of future appreciation of the local currency in China or increased labor costs if the demand for skilled laborers increases and / or the availability of skilled labor declines in China . Our collaborative relationships may not produce the financial benefits that we are anticipating, which could cause our business to suffer. Part of our strategy is to partner with, or out- license selective products to, other pharmaceutical companies in order to mitigate the cost of developing a drug through clinical trials to commercialization. Our exclusive option **For example, in July 2023, AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration** agreement **Agreement** with ASKA Pharmaceuticals Co. **and the AstraZeneca Platform License** , Ltd. **effective October 15** , or ASKA, entered into **2023. AstraZeneca' s decision to terminate the AstraZeneca Agreements was based** on **non- clinical safety findings in a 13- week toxicology** February 27, 2017, is an example of this strategy. In January 2020, following the phase 2a study **of elarekibep in non** we conducted, ASKA had an option to obtain an exclusive license to develop and commercialize PRS- **human primates** 080, our anemia drug, in Japan, South Korea and certain other Asian markets under the option agreement, which they did not exercise for strategic reasons. Exercising this option could have made us eligible to receive more than $ 80 million in combined option exercise fee and milestones associated with development and commercialization of PRS- 080 in the first indication in Japan with further development milestones in additional indications from Japan and other countries within the ASKA territory . If our collaboration with other similar partners is not successful, our future revenues and business will be harmed. Although we have received upfront, milestone and other payments to date under our current drug development collaborations, we may not receive any royalty payments or additional license and milestone fees under such agreements. In general, our receipt of milestone, royalty or license payments depends on many factors, including whether our collaborators want and are able to continue to pursue potential drug candidates, intellectual property issues, the approval of biosimilars, unforeseen complications in the development or commercialization process, and the ultimate commercial success of the drugs. 72Risks Related to the Commercialization of Our Drug Candidates Any product candidate for which we obtain marketing approval will be subject to extensive post- marketing regulatory requirements and could be subject to post- marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved. If the FDA, EMA, MHRA or a comparable foreign regulatory authority approves any of our drug candidates, activities such as the manufacturing processes, labeling, packaging, distribution, adverse event, or AE, reporting, storage, advertising, promotion and record keeping for the products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP. The FDA or a comparable foreign regulatory authority may also impose requirements for costly post- marketing nonclinical studies or clinical trials (often called " Phase 4 trials ") and post- marketing surveillance to monitor the safety or efficacy of the product. If we or a regulatory authority discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, production issues with the facility where the product is manufactured or processed, such as product contamination or significant non- compliance with applicable cGMPs, a regulator may impose restrictions on that product, the manufacturing facility or us. If we or our third- party providers, including our CMOs, fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products. In addition, later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in the following, among other things: • restrictions on the manufacturing of the product, the approved manufacturers or the manufacturing process; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • withdrawal of the product from the market; • product recalls; • warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities; • refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • suspension of any of our ongoing clinical trials; • product seizure or detention or refusal to permit the import or export of products; and • consent decrees, injunctions or the imposition of civil or criminal penalties. In addition, regulatory authorities' policies (such as those of the FDA, MHRA, or EMA) may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug 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 otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. Non- compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union requirements regarding the protection of personal information can also lead to significant penalties and sanctions. 73Our commercial success depends upon attaining and maintaining significant market acceptance of our drug candidates, if approved, among physicians, patients, third- party payors and other members of the medical community. Even if we obtain regulatory approval for our drug candidates, the approved products may nonetheless fail to gain or maintain sufficient market acceptance among physicians, third- party payors, patients and other members of the medical community, which is critical to commercial success. If an approved product does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any drug candidate for which we receive approval depends on a number of factors, including: • the efficacy and potential advantages compared to alternative treatments or competitive products; • perceptions by the medical community, physicians and patients regarding the safety and effectiveness of our products and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the size of the market for such drug candidate, based on the size of the patient subsets that we are targeting, in the territories for which we gain regulatory approval and have commercial rights; • the

safety of the drug candidate as demonstrated through broad commercial distribution; • the ability to offer our product candidates for sale at competitive prices; • the availability of competing drug products; • the availability of adequate reimbursement and pricing for our products from governmental health programs and other third- party payors; • relative convenience and ease of administration compared to alternative treatments; • the prevalence and severity of any side effects; • the adequacy of supply of our product candidates; • the timing of any such marketing approval in relation to other product approvals; • any restrictions on concomitant use of other medications; • support from patient advocacy groups; and • the effectiveness of sales, marketing and distribution efforts by us and our licensees, partners, and distributors, if any. If our drug candidates are approved but fail to achieve an adequate level of acceptance by key market participants, we will not be able to generate significant revenues, and we may not become or remain profitable, which may require us to seek additional financing. Our ability to negotiate, secure and maintain third- party coverage and reimbursement for our product candidates may be affected by political, economic, legal and regulatory developments in the United States, the U. K., the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third- party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any product candidate of ours that receives marketing approval in the future. Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturers will be successful in establishing a larger- scale commercial manufacturing process for clarekibep, PRS- 220, PRS- 344 / S095012 or other product candidates that achieves our objectives for manufacturing capacity and cost of goods. Even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA, EMA, MHRA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce timely or sufficient quantities of the approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. 74The successful discovery, development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture and sell our biological product candidates would adversely impact our business and future results of operations. Our product candidates for which we intend to seek approval may face follow- on or biosimilar competition sooner than anticipated. Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our product candidates may face competition from biosimilar products. In the United States, our Anticalin- based product candidates are expected to be regulated by the FDA as biological products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The BPCIA created an abbreviated pathway for FDA approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12- year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow- on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient- provider relationship and a patient' s specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off- label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved. In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class- specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved. If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if

approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval. Even if we are able to commercialize any of our drug candidates, such products may become subject to unfavorable pricing regulations, third- party reimbursement practices or health care reform initiatives, which would harm our business. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug and biological products vary widely from country to country. Current and future legislation may change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted and, in some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. 75Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the United States, reimbursement varies from payor to payor. Reimbursement agencies in Europe may be more conservative than federal health care programs or private health plans in the United States. For example, a number of cancer drugs are generally covered and paid for in the United States, but have not been approved for reimbursement in certain European countries. A primary trend in the U. S. health care industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of payments for particular products. For example, payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA- approved drugs for a particular indication. Payors may require use of alternative therapies or a demonstration that a product is medically necessary for a particular patient before use of a product will be covered. Additionally, payors may seek to control utilization by imposing prior authorization requirements. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Patients are unlikely to use our products, if they are approved for marketing, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such products. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs and biologics, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA, MHRA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by federal health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Further, there have been, and may continue to be, legislative and regulatory proposals at the U. S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. The continuing efforts of the government, insurance companies, managed care organizations and other third- party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability. Most recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product' s price increases faster than the rate of inflation. This calculation is made on a drug product- by- drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026 Centers for Medicare & Medicaid Services, or CMS, will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain biopharmaceutical products or additional pricing pressures In some foreign countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these

countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a drug candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, we may be required to conduct additional clinical trials that compare the cost- effectiveness of our drug candidates to other available therapies in order to obtain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to successfully commercialize and achieve or sustain profitability for sales of any of our drug candidates that are approved for marketing in that country and our business could be adversely affected. 76We have no experience selling, marketing or distributing products and currently have no internal marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not be able to effectively market and sell our drug candidates, if approved, or generate product revenues. We currently have no sales, marketing or distribution capabilities and have no experience as a company in the sale or marketing of pharmaceutical products. There can be no assurance that we will be able to market and sell our products in the United States or overseas. In order to commercialize any drug candidates, we must build on a territory- by- territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Therefore, with respect to the commercialization of all or certain of our drug candidates, we may choose to collaborate, either globally or on a territory- by- territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If so, our success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, such collaborators' strategic interest in the products under development and such collaborators' ability to successfully market and sell any such products. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our drug candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. Further, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our products, we may in the future need to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our drug candidates, which could be expensive, time-consuming and requiring significant attention of our executive officers to manage. Further, we may not have sufficient resources to allocate to the sales and marketing of our products. Any failure or delay in the development of sales, marketing and distribution capabilities, through collaboration with one or more third parties or through internal efforts, would adversely impact the commercialization of any of our products that we obtain approval to market. As a result, our future product revenue will suffer and we may incur significant additional losses. In addition, certain of our collaboration agreements that provide us with co- commercialization rights with respect to certain partnered programs contain specific commercialization obligations. If we fail to meet those obligations, our commercialization rights could be impaired. Our relationships with prescribers, purchasers, third- party payors and patients will be subject to applicable anti- kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Although we do not currently have any products on the market, upon commercialization of our drug candidates, if approved, we will be subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Physicians, other health care providers and third- party payors will play a primary role in the recommendation, prescription and use of any product candidates for which we obtain marketing approval. Our future arrangements with such third parties may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain our business or financial arrangements and relationships through which we market, sell and distribute any products for which we may obtain marketing approval. Restrictions under applicable domestic and foreign health care laws and regulations include, but are not limited to, the following: • the U. S. federal Anti- Kickback Statute, or AKS, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal health care program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate it to have committed a violation. Certain arrangements are protected from enforcement through AKS safe harbors and exceptions, but an arrangement must meet every element of the applicable safe harbor or exception in order to obtain this protection. The fact that an arrangement does not meet the requirements of a safe harbor or exception does not mean that it violates the AKS; such arrangements would be subject to a facts and circumstances analysis to determine compliance with the AKS or lack thereof. The definition of " remuneration " has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments, and providing anything at less than its fair market value. The AKS is broadly interpreted and aggressively enforced with the result that beneficial commercial arrangements can be criminalized in the healthcare industry because of the AKS. The penalties for violating the federal AKS include imprisonment for up to ten years, fines of up to $ 100, 000 per violation and possible exclusion from federal health care programs such as Medicare and Medicaid. Additionally, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the

False Claims Act; 77 • the U. S. False Claims Act, or FCA, prohibits knowingly presenting, or causing to be presented a false claim or the knowing use of false statements or records to obtain payment from the federal government. The FCA also prohibits the knowing retention of overpayments (sometimes referred to as " reverse false claims "). When an entity is determined to have violated the FCA, it must pay three times the actual damages sustained by the government, plus mandatory and substantial civil penalties for each separate false claim. The entity also faces the possibility of exclusion from federal healthcare programs. Suits filed under the False Claims Act, known as " qui tam " actions, can be brought by any individual on behalf of the government and such individuals (known as " relators " or, more commonly, as " whistleblowers ") may share in any amounts paid by the entity to the government in fines or settlement. Claims for payment by federal health care programs for items and services which results from a violation of the federal AKS may also constitute a false or fraudulent claims for purposes of the False Claims Act; • the U. S. Civil Monetary Penalties Law, or CMPL, authorizes the imposition of substantial civil money penalties and the possibility of exclusion against an individual or entity that engages in certain prohibited activities including but not limited to violations of the AKS, knowing submission of a false or fraudulent claim, employment of an excluded individual, and the provision or offer of anything of value to a Medicare or Medicaid beneficiary that the transferring party knows or should know is likely to influence beneficiary selection of a particular provider for which payment may be made in whole or part by a federal health care program, commonly known as the Beneficiary Inducement CMP; • HIPAA, which created two new federal crimes: health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti- kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non- governmental third- party payors, including private insurers. Penalties for violating these laws can range from fines to criminal sanctions; • the FCPA and other anti- corruption laws and regulations pertaining to our financial relationships and interactions with foreign government officials; • the U. S. federal physician payment transparency requirements, sometimes referred to as the Sunshine Act, which requires, among other things, manufacturers of drugs, devices, biologies and medical supplies that are reimbursable under Medicare, Medicaid or the Children' s Health Insurance Program to track and annually report to the Centers for Medicare & Medicaid Services, or CMS, information related to certain payments and other transfers of value made to U. S.- licensed physicians (defined broadly to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain advanced non- physician health care practitioners (such as physician assistants) and teaching hospitals. Manufacturers are also required to report certain ownership and investment interests held by physicians and their immediate family members. The law carries penalties of up to $ 1. 15 million per year for violations, depending on the circumstances, and payments reported also have the potential to draw scrutiny on payments to and relationships with physicians, which may have implications under the AKS and other healthcare laws; • analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and / or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other health care providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the health care industry; • the U. S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal health care programs; • HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and • state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. 78Efforts to ensure that our business arrangements with third parties will comply with applicable health care and information laws and regulations will involve substantial costs. If the FDA or a comparable foreign regulatory authority approves any of our product candidates, we will be subject to an expanded number of these laws and regulations and will need to expend resources to develop and implement policies and processes to promote ongoing compliance. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations, resulting in government enforcement actions. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from federal health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from federal health care programs. Risks Related to Our Intellectual Property We in- license significant intellectual property related to our Anticalin platforms from TUM. Under the terms of the TUM License, TUM assigns to us certain materials and records resulting from the research. We retain rights to inventions made by our employees, and TUM assigns to us all inventions made under the agreement jointly by our employees and TUM personnel, provided that our employees have made a certain

inventive contribution. With respect to all other inventions made in the course of the research, TUM grants to us worldwide exclusive license rights under patents and patent applications claiming such inventions. TUM retains rights to practice these inventions for research and teaching purposes. We bear the costs of filing, prosecuting and maintaining the patents assigned or licensed to us under the TUM License. ~~As~~ **37As** consideration for the assignments and licenses, we are obliged to pay milestone payments to TUM on development of our proprietary products claimed by patents assigned or licensed to us by TUM. We are also obliged to pay low single- digit royalties, including annual minimum royalties, on the sales of such products. Should we grant licenses or sublicenses to those patents to third parties, we are obliged to pay to TUM certain undisclosed fees as a function of out- licensing revenues in connection with those patents, or Out- License Fees, where such Out- License Fees are creditable against annual license payments to TUM. Our payment obligations are reduced by our proportionate contribution to a joint invention. Payment obligations terminate on expiration or annulment of the last patent covered by the TUM License that covers a proprietary product or is sublicensed, as applicable. We and TUM initiated discussions in the second quarter of 2018, and **may enter into** ~~are in the process of negotiating~~ an amendment to our license agreement **in the future** , to clarify, expand and restructure the TUM License, including the parties' obligations under such license agreement. The contemplated amendment relates to revised commercial terms. We recorded the probable expected impact of the amendment in research and development expense in 2019, although the final expense could be different than what we currently have recorded. **In** ~~These discussions may also lead to an increase in our collaborative research activities with TUM. 79In~~ connection with our efforts to develop multispecific Anticalin- based proteins designed to engage immunomodulatory targets, during the second quarter of 2017, we entered into the Kelun Agreement. Under the Kelun Agreement, Kelun has granted to us a non- exclusive worldwide license (with the right to sublicense) under certain intellectual property owned or controlled by Kelun to research, develop, manufacture and commercialize bi- and multi- specific fusion proteins that include an antibody developed by Kelun specific for an undisclosed target and one or more Anticalin proteins. In addition to the TUM License and the Kelun Agreement, we have other in- license agreements and may seek to enter into additional agreements with other third parties in the future granting similar license rights with respect to other potential drug candidates. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of the TUM License, the Kelun Agreement or any future license agreement we may enter on which our business or drug candidates are dependent, TUM, Kelun or other licensors may have the right to terminate the applicable agreement in whole or in part and thereby extinguish our rights to the licensed technology and intellectual property and / or any rights we have acquired to develop and commercialize certain drug candidates, including, with respect to the TUM License and Kelun Agreement, our Anticalin- based drug therapies. Under the TUM License, we can terminate the licenses to any or all licensed patents upon specified advance notice to TUM. TUM may terminate the license provisions of the agreement only for cause. Termination of the TUM License does not terminate our rights in patents assigned to us but would terminate our rights to patents licensed to us under the agreement. The loss of the rights licensed to us under our license agreement with TUM or Kelun Agreement, or any future license agreement that we may enter granting us rights on which our business or drug candidates are dependent, would eliminate our ability to further develop the applicable drug candidates and may materially harm our business, prospects, financial condition and results of operations. **If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively and our business could be harmed.** We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to, or misappropriation by, third parties of our proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding any competitive advantage we may derive from the proprietary information. The strength of patents in the biotechnology and pharmaceutical fields can be uncertain and involve complex legal and scientific questions. No consistent policy regarding the breadth of claims allowed in patents has emerged to date in the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced, or that the scope of any patent rights could provide a sufficient degree of protection that could permit us to gain or keep our competitive advantage with respect to these products and technologies. For example, we cannot predict: • the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to make, use, sell, offer to sell or import competitive products without infringing our patents; • if and when patents will be issued; • how laws in the various jurisdictions, such as the USPTO or the European Patent Office, or the EPO, will change thus affecting our ability to obtain patents or maintain and enforce existing patents; • whether or not others will obtain patents claiming inventions similar to those covered by our patents and patent applications; or • whether we will need to initiate litigation or administrative proceedings (for example, at the USPTO or the EPO) in connection with patent rights, which may be costly whether we win or lose. As a result, the patent applications we own or license may fail to result in issued patents in the United States or in foreign countries. Third parties may challenge the validity, enforceability or scope of any issued patents we own or license or any applications that may issue as patents in the future, which may result in those patents being narrowed, invalidated or held unenforceable. Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from developing similar products that do not fall within the scope of our patents. If the breadth or strength of protection provided by the patents we hold or pursue is threatened, our ability to commercialize any drug candidates with technology protected by those patents could be threatened. Further, if we encounter delays in our clinical trials, the period of time during which we would have patent protection for any covered drug candidates that obtain regulatory approval would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain at the time of filing that we are the first to file any patent application related to our drug candidates. ~~80While~~ -- **While** patent term extensions under the Hatch- Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend our patent exclusivity for our drug candidates, the applicable patents may not meet the specified conditions for eligibility for any such term extension and, even if eligible, we may not be able to obtain any such term extension. Further, because filing,

prosecuting, defending and enforcing patents in multiple jurisdictions can be expensive, we may elect to pursue patent protection relating to our drug candidates in only certain jurisdictions. As a result, competitors would be permitted to use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, any of which could compete with our drug candidates. ~~In~~ **38In** addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery platform and drug development processes that involve proprietary know- how, information or technology that is not covered by patents or not amenable to patent protection. Although we require all of our employees and certain consultants, third parties and advisors to assign inventions to us, they may refuse to assign the inventions which could create delay or risk assignment of inventions. We also require 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, our trade secrets and other proprietary information may be disclosed or competitors may otherwise gain access to such information or independently develop or reverse engineer substantially equivalent information. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant difficulty in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the trade secrets and other intellectual property related to our technologies to third parties, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, adversely affecting our market position and business and operational results. **Claims that we or our partners infringe the intellectual property rights of others may prevent or delay drug discovery and development efforts.** Our **partnered** ~~research, development and commercialization activities, as well as any~~ drug candidates ~~or products resulting from those activities~~, may infringe or be accused of infringing a patent or other form of intellectual property under which we do not hold a license or other rights. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents of which we are currently unaware with claims that cover the use or manufacture of our drug candidates or the practice of our related methods. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our **partnered** drug candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of ~~our~~ **such** drug candidates infringes upon one or more claims of these patents. If our **partnered** ~~activities or~~ drug candidates infringe the patents or other intellectual property rights of third parties, the holders of such intellectual property rights may be able to block ~~our~~ **the** ability to commercialize such drug candidates ~~or practice our methods~~ unless we **or our partners** obtain a license under the intellectual property rights or until any applicable patents expire or are determined to be invalid or unenforceable. Defense of any intellectual property infringement claims against us, regardless of their merit, would involve substantial litigation expense and would be a significant diversion of resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties, limit our business to avoid the infringing activities, pay royalties and / or redesign our infringing drug candidates or alter related formulations, processes, methods or other technologies, any or all of which may be impossible or require substantial time and monetary expenditure. Further, if we were to seek a license from the third- party holder of any applicable intellectual property rights, we may not be able to obtain the applicable license rights when needed or on reasonable terms, or at all. Some of our competitors may be able to sustain the costs of complex patent litigation or proceeding more effectively than us due to their substantially greater resources. The occurrence of any of the above events could **cause** ~~prevent us from continuing to develop and commercialize one or more of our drug candidates and~~ our business ~~could~~ **to** materially suffer. ~~Third parties may also hold intellectual property, including patent rights that are important or necessary to the development of our drug candidates, in which case we would need to obtain a license from that third party or develop a different formulation of the product that does not infringe upon the applicable intellectual property, which may not be possible. Additionally, we may identify drug candidates that we believe are promising and whose development and other intellectual property rights are held by third parties. In such a case, we may desire to seek a license to pursue the development of those drug candidates. Any license that we may desire to obtain or that we may be forced to pursue may not be available when needed on commercially reasonable terms, or at all. Inability to secure any license that we need or desire could have a material adverse effect on our business, financial condition and prospects. 81The~~ -- **The** patent protection covering some of our drug candidates may be dependent on third parties, who may not effectively maintain that protection. While we expect the right to fully prosecute any patents covering drug candidates we may in- license from third-party owners, there may be instances when the prosecution and maintenance of issued patents and pending patent applications that cover our drug candidates remain controlled by our licensors. Similarly, some of our future licensing partners may retain the right, or may seek the rights, to prosecute patents covering the drug candidates we license to them and we may grant such rights to those partners for business reasons. If such third parties fail to appropriately maintain that patent protection, we may not be able to prevent competitors from developing and selling competing products or practicing competing methods and our ability to generate revenue from any commercialization of the affected drug candidates may suffer. We ~~have entered into agreements with a number of commercial partners, including university partners, which cover intellectual property. We have, in some cases individually and in other cases along with our partners, filed for patent protection for a number of technologies developed under these agreements and may in the future file for further intellectual property protection and / or seek to commercialize such technologies. Under some of these agreements, certain intellectual property developed by us and the relevant partner may be subject to joint ownership and our commercial use of such intellectual property may be restricted, or may require written consent from, or a separate agreement with, the partner. In other cases, we may not have any rights to use intellectual property solely developed and owned by the partner. If we cannot obtain commercial use rights for such jointly owned intellectual property or partner- owned intellectual property, our future product development and commercialization plans may be adversely affected. We~~ may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-

consuming and unsuccessful. Competitors may infringe our patents or the patents of our current or potential licensors. To attempt to stop infringement or unauthorized use, we may need to enforce one or more of our patents, which can distract our management and divert our limited time and resources. Our standing to enforce such patents may sometimes be dependent on the licensor joining such suit, and a licensor' s failure to join such suit may prevent us from enforcing the patent. If we pursue any litigation, a court may decide that a patent of ours or any of our licensors' is not valid or is unenforceable or may refuse to stop the other party from using the relevant technology on the grounds that our patents do not cover the technology in question. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, which could reduce the likelihood of success of, or the amount of damages that could be awarded resulting from, any infringement proceeding we pursue in any such jurisdiction. An adverse result in any infringement litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing, which could limit our ability to exclude competitors from directly competing with us in those jurisdictions. Interference proceedings may also be provoked or suggested by third parties, or brought by the USPTO or at its foreign counterparts (such as the EPO), to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to use it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. ~~82If~~ **If** we are unsuccessful in obtaining or maintaining patent protection for intellectual property in development, our business and competitive position would be harmed. We ~~are seeking~~ **may continue to seek** patent protection of our technology and for our drug candidates. Patent prosecution is a challenging process and is not assured of success. If we are unable to secure patent protection for our technology and drug candidates, our business may be adversely impacted. Furthermore, issued patents and pending applications require regular maintenance. Failure to maintain our portfolio may result in loss of rights that may adversely impact our intellectual property rights, such as rendering issued patents unenforceable or terminating pending applications prematurely. ~~In~~ **39In** addition, under the European Union regulation on classification, labeling and packaging of substances and mixtures, and under other regulations in the United States or other countries related to the clinical development of our drug candidates (including, for example, submissions to regulatory authorities such as the FDA and EMA as well as submissions related to obtaining a non- proprietary, or INN and USAN, name for our clinical drug candidates to the World Health Organization, and United States Adopted Name Council, or the USAN Council), we **or our partners** may be required to publicly disclose the composition of our proprietary products or substances, which may facilitate infringement or avoidance of our intellectual property by third parties and may potentially reduce the margin we are able to charge for our products by allowing competitors to more accurately determine our production costs. Future development of these regulations may have a further negative impact on our revenues and a substantial negative impact on our business. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for our Anticalin- brand technology and some of our drug candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We currently, and expect in the future to continue to, seek to protect these trade secrets, in part by entering into confidentiality agreements with parties who have access to them, such as our employees, collaborators, CMOs, consultants, advisors, investigators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such disclosure. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose the trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed ~~.~~ **Risks Related to Our Personnel** If we **are not** ~~fail to protect our trademark rights, competitors may be~~ able to ~~take advantage of our goodwill, which would weaken our competitive position, reduce our revenues and increase our costs. We believe that the protection of our trademark rights is an important factor in product recognition, maintaining goodwill, and maintaining or increasing market share. We may expend substantial cost and effort in an attempt to register, maintain and enforce our trademark rights. If we do not adequately protect our rights in our trademarks from infringement, any goodwill that we have developed in those trademarks could be lost or impaired. Third parties may claim that the sale or promotion of our products, when and if we have any, may infringe on the trademark rights of others. Trademark infringement problems occur frequently in connection with the sale and marketing of pharmaceutical products. If we become involved in any dispute regarding our trademark rights, regardless of whether we prevail, we could be required to engage in costly, distracting and time- consuming litigation that could harm our business. If the trademarks we use are found to infringe upon the trademark of another company, we could be liable for damages and be forced to stop using those trademarks, and as result, we could lose all of the goodwill that has been developed in those trademarks. The future growth of our business may expose our intellectual property to a high risk of counterfeiting or unauthorized use. As part of our business strategy, we intend to license our Anticalin- based technology and sell our potential products, if any, in many different countries. As a result, we may do business with third parties in countries where intellectual property rights have been or are routinely disregarded, and the future growth of our business may expose our intellectual property to a high risk of counterfeiting or unauthorized use. Although we attempt to obtain broad international intellectual property rights for our Anticalin technology and proteins, we cannot guarantee that such rights, to the extent we can obtain them, will be enforceable in a timely fashion or at all in any particular country or jurisdiction, or that if enforced, will offer us adequate commercial~~

~~protection or adequate redress for any harm suffered. Counterfeiting or unauthorized use of our technologies or products may also expose our business to harm for which no adequate monetary redress exists, and to the extent we are unable to stop such use, may cause us to lose rights with respect to intellectual property that is crucial to our business. Any such misuse of our intellectual property may have a substantial negative impact on our business and revenues and may cause our business to fail. 83Risks Related to Our Employees Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and~~ retain highly qualified personnel **, we may not be able to successfully implement our business objectives** . We ~~are highly dependent~~ **continue to rely** on **a limited number of employees and may rely on external consultants in the future for the operation of the company. Any of these employees** ~~our~~ **or** ~~management, scientific~~ **external consultants may terminate their relationship with us at any time. We may not be able to attract** and ~~medical~~ **retain consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar** personnel ~~, especially Stephen S~~. ~~Yoder,~~ **Any future consultant** ~~our~~ **or advisor may be employed by employers** ~~Chief Executive Officer and President, whose services are critical to the~~ **other** ~~successful implementation of~~ **than us and may have commitments under consulting** ~~our~~ **or advisory contracts with** ~~drug candidate development, our business development and partnerships, and our regulatory and commercialization strategies. Further, as our approach is built upon the~~ **other entities that may limit their availability** ~~drug discovery and development experience of our drug development team, which we believe is a significant contributor~~ to ~~our competitive advantage, we are dependent~~ **us. We do not maintain " key person " insurance** on **any** ~~the maintenance and growth~~ of **our** ~~that team with qualified members containing high levels of expertise in specific scientific fields. We may in the future hire additional~~ employees ~~for~~ **or consultants** ~~research and development or general and administrative activities~~ . **In addition** ~~We are not aware of any present intention of any of our executive officers or other members of our senior management team to leave our company. However~~ , our industry tends to experience a high rate of turnover of management personnel and our employees are generally able to terminate their relationships with us on short notice. Pursuant to German employment law, our employment arrangements with employees of Pieris GmbH are governed by employment contracts, which provide certain defined terms for either party to terminate the employment relationship. ~~The~~ **Furthermore, to the extent we pursue any strategic opportunities, our ability to consummate such opportunities depends upon our ability to retain our employees and consultants required to consummate such a transaction, the** loss of ~~the~~ **whose** services **may adversely impact** ~~of any of our executive officers, in particular Mr. Yoder, or other~~ -- **the** ~~key employees, and our inability to find suitable replacements, could potentially harm our business, financial condition and prospects. Our success also depends on our~~ ability to **consummate such transaction** ~~continue to attract, retain and motivate highly skilled junior and mid- level managers as well as junior and mid- level scientific and medical personnel. Moreover, there is intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other related businesses. Many of the other companies against which we compete for qualified personnel have greater financial and other resources, different risk profiles, longer histories in the industry and greater ability to provide valuable cash or stock incentives to potential recruits than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we are able to offer as an early stage company. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize our drug candidates will be limited~~ . We may be subject to labor claims brought by our employees against us. In the United States, an employment relationship with no specified duration is presumed to be employment " at- will " and the employer or employee may terminate the employment relationship at any time, with or without cause, except for public policy reasons including discrimination, participating in union activity, or refusing to carry out an activity that violates the law. In contrast, in Germany, there is no analogous doctrine of " employment at will. " By law, German employees must have written employment contracts that reflect the key aspects of the employment relationship. Our relations between German employers and employees are extensively regulated under German labor and employment laws and regulations. Employment relationships may be terminated for cause without observing the ordinary notice period. If terminated without cause, the applicable ordinary notice period must be observed. German employees have special protection against dismissals provided the employee has been employed by a company for more than six months and such company employs more than 10 full- time employees. German employment termination law is regulated by various codes, in particular the Kündigungsschutzgesetz, or the German Termination Protection Act, and is intended to give the employee maximum protection against unfair dismissal, including among other things: • the employer must observe the applicable notice period, which is ordinarily determined by law (between four weeks and seven months, depending upon the length of employment, though it is possible for the notice period to be two weeks, if a probationary period, lasting up to the first six months of employment, is agreed upon), if a longer period is not otherwise agreed by the parties, and has to deliver a written notice of termination to the employee; • for companies with more than 10 full- time employees, the German Termination Protection Act generally restricts termination of employment if the employee has been employed for more than six months, wherein the employee may be terminated only for a particular reason, including certain behavioral or personal reasons relating to the employee or certain developments relating to the business of the employer, such as a business restructuring which reduces the number of employee positions; ~~84~~ • special termination protection against unlawful dismissal applies to several other groups of employees, such as an employee that is an officially acknowledged handicapped person, an employee who was appointed as a company' s data protection officer or as a member of the works council of a company, if any, an employee on maternity leave or a pregnant employee (in these cases, approval of various German authorities is required prior to termination but usually very difficult to obtain); and • if a company engages in a mass layoff, which is deemed to occur when the employer intends to dismiss a large percentage of its employees during a 30 calendar day period, prior written notification to the German employment office is required. In **July 2023, we conducted a reduction in force that impacted 70 % of our employees, and in March 2024 we announced additional measures that would result in a further reduction in workforce that is intended**

**to be implemented in the second quarter of 2024. In** this regard, if we downsize for any reason and fail to adhere to the complex requirements articulated by the employee protection law, we could face legal actions brought by affected employees or former employees, and, as a result, we may incur operational or financial losses and divert the attention of our executive officers from managing our business. ~~We~~ **40We** may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employers. Litigation may be necessary to defend against any such claims. In addition, while it is our policy to require our employees and contractors, who may be involved in the development of intellectual property, to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who contributes to the development of intellectual property that we regard as our own. Further, the terms of such assignment agreements may be breached and we may not be able to successfully enforce their terms, which may force us to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of intellectual property rights we may regard and treat as our own. Our employees, independent contractors, principal investigators, CROs, consultants, or vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause our business to suffer. We are exposed to the risk that our employees, independent contractors, principal investigators, contract research organizations, or CROs, consultants, or vendors may engage in fraudulent or other illegal activity. Misconduct by any of these parties could include intentional, reckless, and / or negligent conduct that may include failures to comply with FDA, MHRA, EMA or other foreign jurisdiction regulations, provide accurate information to the FDA, MHRA, EMA or their comparable foreign equivalents, comply with manufacturing standards we have established, comply with federal, state and international healthcare fraud and abuse laws and regulations as they may become applicable to our operations, report financial information or data accurately or disclose unauthorized activities to us. Employee and other third- party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions and procedures we currently take or may establish in the future as our operations and employee and third- party base expand to detect and prevent this type of activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished potential profits and future earnings, and curtailment of our operations. Certain of our employees and their inventions are subject to German law. Many of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants are subject to the provisions of the Gesetz über Arbeitnehmererfindungen, or the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. We **have experienced disputes and** face the risk that disputes ~~can~~ **may** occur **in the future** between us and such employees or ex- employees pertaining to alleged non- adherence to the provisions of this act. Such disputes ~~may~~ **can** be costly to defend and take up our management' s time and efforts whether we prevail or not. In addition, under the German Act on Employees' Inventions, certain employees retained rights to patents they invented or co- invented prior to 2009. Although most of these employees have subsequently assigned their interest in these patents to us, there is a risk that the compensation we provide to them may be deemed insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases where employees have not assigned their interests to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our results of operations could be adversely affected. ~~85Risks~~ -- **Risks** Related to the Ownership of Our Common Stock Our share price is volatile and may be influenced by numerous factors, some of which are beyond our control. Market prices for shares of biotechnology companies such as ours are often volatile. Thus, the quoted price of our common stock has been, and is likely to continue to be, highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K, these factors include: • the **timing** ~~drug candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those drug candidates; • our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an~~ **and amount** ~~existing clinical trial; • actual or anticipated adverse results or delays in our clinical trials; • our failure to commercialize our drug candidates, if approved; • unanticipated serious safety concerns related to the use~~ of ~~any of our drug candidates; • adverse regulatory decisions~~ **potential milestone payments that we may receive from Pfizer, Boston Pharmaceuticals, and Servier** ; • additions or departures of key scientific or management personnel; • changes in laws or regulations applicable to our drug candidates, including without limitation clinical trial requirements for approvals; • the perception of the pharmaceutical and biotechnology industry by the public, legislatures, regulators and the investment community; • disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our drug candidates; • significant lawsuits, including patent and stockholder class action litigation; • our ~~dependence~~ **potential inability to maintain the listing of our common stock** on ~~third parties, including CROs and CMOs as well as our current and potential partners that produce companion diagnostic products; • failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to~~ the ~~public~~ **Nasdaq Capital Market** ; • actual or anticipated variations in quarterly operating results; • failure to meet or exceed the estimates and

projections of the investment community; • overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; • conditions or trends in the biotechnology and biopharmaceutical industries; • introduction of new products by ~~us or~~ our competitors; • announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; • **issuances of debt** ~~our~~ **or equity securities** ~~ability to maintain an adequate rate of growth and manage such growth~~ ; • ~~issuances~~ **execution, cost and timing** of ~~debt or~~ **our** ~~equity securities~~ **reduction in force and operations** ; • sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur; • trading volume of our common stock; • ineffectiveness of our internal control over financial reporting or disclosure controls and procedures; • general political and economic conditions; • effects of natural or man- made catastrophic events; and • other events or factors, many of which are beyond our control. ~~In~~ **41In** addition, the stock market in general, and the stocks of biotechnology 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. Furthermore, other biotechnology companies or our competitors' programs could have positive or negative results that impact their stock prices and their results or stock fluctuations could have a positive or negative impact on our stock price regardless of whether such impact is direct or not. The realization of any of the above risks or any of a broad range of other risks, including those described in these " Risk Factors, " could have a dramatic and material adverse impact on the market price of our common stock. ~~86Our~~ -- **Our** management has considerable discretion in the application of our cash, cash equivalents and investments, including the fees and milestone payments from our collaborations and the net proceeds of our securities offerings ~~. We intend to use the cash, cash equivalents and investments to advance our product candidates and for working capital and other general corporate purposes, which will include the hiring of additional personnel and capital expenditures~~ . As a result, investors will be relying upon management' s judgment with only limited information about our specific intentions for the use of the cash, cash equivalents and investments. We may use the cash, cash equivalents and investments for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the financial resources from our collaborations and securities offerings in a manner that does not produce income or that loses value. **We may also use the cash to pay out dividends to stockholders if we determine that there is sufficient cash and investments to achieve our near and long- term objectives.** If securities or industry analysts do not publish, or cease publishing, research or publish inaccurate or unfavorable research about our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and any trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If only a few securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively affected and there can be no assurance that analysts will provide favorable coverage. If securities or industry analysts who initiate coverage downgrade our stock or publish inaccurate or unfavorable research about our business or our market, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and any trading volume to decline. ~~We have had, and have previously reported material weaknesses in our internal controls over financial reporting.~~ If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, ~~while~~ **as** we remain a smaller reporting company with less than $ 100 million in revenue, we ~~will~~ **are** not ~~be~~ **currently** required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we cannot favorably assess the effectiveness of our internal controls over financial reporting, investor confidence and, in turn, our stock price could be materially adversely affected. ~~As previously reported in our Annual Report on Form 10- K for the year ended December 31, 2019, we concluded that we had a material weakness in 2019 in our internal controls. No material financial statement misstatement was identified in relation to the previously reported material weaknesses in our internal control over financial reporting. While we took steps to address these material weaknesses and concluded in 2020 that the material weaknesses had been remediated, there is a reasonable possibility that material weaknesses may be identified in the future and that a material misstatement of our annual or interim consolidated financial statements may not be prevented or detected on a timely basis. Management, including our principal executive officer and principal financial officer, believes the consolidated financial statements included in this Annual Report on Form 10- K fairly represent in all material respects our financial condition, results of operations and cash flows in accordance with U. S. GAAP. However, we cannot assure you that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future.~~ Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes- Oxley Act could have a material adverse effect on the tradability of our common stock, which in turn would negatively impact our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. ~~87Shares~~ -- **Shares** of our common stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144 of the Securities Act, including those set forth in Rule 144 (i) which apply to a former " shell company. " We were previously deemed a " shell company " under applicable SEC rules and regulations, prior to

the reverse merger transaction in which we became a public company, because we had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. ~~Pursuant to Rule 144 of the Securities Act, sales~~ **Sales** of the **restricted** securities of a former shell company, such as us, are not permitted **pursuant to Rule 144 of the Securities Act,** unless at the time of a proposed sale, (i) we are subject to the reporting requirements of Section 13 or 15 (d) of the Exchange Act; and (ii) we have filed all reports and other materials required to be filed by Section 13 or 15 (d) of the Exchange Act, as applicable, during the preceding 12 months, other than current reports on Form 8- K. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future. The lack of liquidity of our securities as a result of the inability to sell under Rule 144 for a longer period of time than a non- former shell company could cause the market price of our securities to decline. ~~If~~ **42If** we issue additional shares of our capital stock in the future, our existing stockholders will be diluted. Our Amended and Restated Articles of Incorporation authorize the issuance of up to 300, 000, 000 shares of our common stock and up to 10, 000, 000 shares of preferred stock with the terms, limitations, voting rights, relative rights and preferences and variations of each series that our Board of Directors may determine from time to time. Possible business and financial uses for our authorized capital stock include, without limitation, equity financing, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plan, or other transactions and corporate purposes that our Board of Directors deems are in the interests of our company. Furthermore, issuances of shares of our capital stock could have the effect of delaying or preventing changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may have rights, preferences and privileges that are superior to those of our common stock and may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders. Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, 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 trading price of our common stock could decline. As of December 31, ~~2022~~ **2023**, a total of ~~74~~ **98**, ~~519~~ **935**, ~~103~~ **025** shares of our common stock were outstanding. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline. In addition, shares of our common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plan, or issuable upon the conversion of our outstanding preferred stock or upon the exercise of our outstanding warrants, will be eligible for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and / or terms of such securities. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. The resale of shares covered by our effective resale registration statements could adversely affect the market price of our common stock in the public market, which result would in turn negatively affect our ability to raise additional equity capital. The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional equity capital. Pursuant to registration statements filed with the SEC, we previously registered for resale shares of our common stock, which included all of the shares of our common stock issued in our private placements and in connection with the closing of the reverse merger transaction in which we became a public company. For example, in March 2021, we registered for resale 3, 706, 174 shares of common stock in connection with a private placement transaction with ~~Seagen~~ **Pfizer**, and 3, 584, 320 shares of common stock in connection with a private placement transaction with AstraZeneca. The resale registration statements permit the resale of these shares at any time without restriction. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for investors to sell shares of our common stock at times and prices that investors feel are appropriate. Furthermore, because there are a large number of shares registered pursuant to the resale registration statements, we may continue to offer shares covered by the resale registration statements for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the resale registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital ~~. 88Even after giving effect to the funds raised in the past~~, **if** we **seek to do so** ~~expect that significant additional capital will be needed~~ in the future ~~to continue our planned operations~~. ~~To~~ **If we seek to** raise capital **in the future**, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, in which we may determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline. As of December 31, ~~2022~~ **2023**, there were ~~4~~ **9**, ~~314~~ **284**, ~~513~~ **808** shares reserved for future issuance under our equity compensation plans, and ~~13~~ **14**, ~~773~~ **803**, ~~366~~ **071** shares reserved for issuance upon the exercise of outstanding equity awards. Pursuant to our ~~2018~~ **2023** Employee Stock Purchase Plan, we are authorized to sell ~~500~~ **750**, 000 shares to our employees. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock. Anti- takeover provisions in our organizational documents could delay or prevent a change of control. Certain provisions of our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws may have an anti- takeover effect and may delay, defer or prevent a merger,

acquisition, tender offer, takeover attempt or other change of control transaction that a stockholder might consider to be in its interests, including attempts that might result in a premium over the market price for the shares held by our stockholders. These provisions provide, among other things: • a classified Board of Directors with staggered three- year terms; • the ability of our Board of Directors to issue one or more series of preferred stock with voting or other rights or preferences that could have the effect of impeding the success of an attempt to acquire us or otherwise effect a change of control; • advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered at stockholder meetings; • certain limitations on convening special stockholder meetings and the prohibition of stockholder action by written consent; and • directors may only be removed for cause and only by the affirmative vote of the holders of at least 80 % of the voting power of all of the then- outstanding shares of our capital stock entitled to vote at an election of directors, voting together as a single class. These anti- takeover provisions, including those noted above, could make it more difficult for a third party to acquire us, even if the third party' s offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. ~~We~~ **43We** may incur significant costs from class action litigation due to our expected stock volatility. Our stock price may fluctuate for many reasons, including as a result of public announcements regarding ~~the progress of~~ our ~~development efforts~~ **strategic updates** or the development efforts of current or future collaborators or competitors, the addition or departure of our key personnel, variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit were without merit, it could result in substantial costs incurred defending the lawsuit and diversion of the time, attention and resources of our Board of Directors and management, which could significantly harm our profitability and reputation. ~~89Our~~ -- **Our** Amended and Restated Articles of Incorporation designates the Eighth Judicial District Court of Clark County, Nevada, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, and therefore limit our stockholders' ability to choose a forum for disputes with us or our directors, officers, employees or agents. Our Amended and Restated Articles of Incorporation provide that, to the fullest extent permitted by law, and unless we consent to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for any (i) derivative action or proceeding brought in the name or right of the corporation or on its behalf, (ii) action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to the corporation or any of our stockholders, (iii) any action arising or asserting a claim arising pursuant to any provision of Chapters 78 or 92A of the Nevada Revised Statutes or any provision of our articles of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. Our Amended and Restated Articles of Incorporation further provide that any person purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed, to the fullest extent permitted by law, to have notice of and consented to the foregoing provision. We believe the choice- of- forum provision in our Amended and Restated Articles of Incorporation will help provide for the orderly, efficient and cost- effective resolution of Nevada- law issues affecting us by designating courts located in the State of Nevada (our state of incorporation) as the exclusive forum for cases involving such issues. However, this provision may limit a stockholder' s ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or our directors, officers, employees or agents, which may discourage such actions against us and our directors, officers, employees and agents. While we are not aware of any Nevada case law addressing the enforceability of this type of provision, Nevada courts have on prior occasion found persuasive authority in Delaware case law in the absence of Nevada statutory or case law specifically addressing an issue of corporate law. The Court of Chancery of the State of Delaware ruled in June 2013 that choice- of- forum provisions of a type similar to those included in our Amended and Restated Articles of Incorporation are not facially invalid under corporate law and constitute valid and enforceable contractual forum selection clauses. However, if a court were to find the choice- of- forum provision in our Amended and Restated Articles of Incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations. The elimination of personal liability of our directors and officers under Nevada law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses. Our Amended and Restated Articles of Incorporation eliminate, to the furthest extent permitted under Nevada law, the personal liability of our directors and officers to us, our stockholders and creditors for damages as a result of any act or failure to act in his or her capacity as a director or officer. Further, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws and individual indemnification agreements that we have entered with each of our directors and officers provide that we are obligated to indemnify, subject to certain exceptions, each of our directors or officers to the fullest extent authorized by Nevada law and, subject to certain conditions, to advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for such damages, even if such actions might otherwise benefit our stockholders. ~~We do not intend~~ **Our Board of Directors may, at their sole discretion, elect** to pay cash dividends on our capital stock ~~in the foreseeable future~~ . We have never declared or paid any cash dividends on our common stock **. We may pay out** ~~and do not anticipate paying any~~ dividends ~~in~~ **to stockholders if it is determined that** ~~the~~ **there** ~~foreseeable future~~ **is sufficient cash and investments to achieve our near and long- term objectives** . We ~~currently intend~~ **may choose** to retain all future earnings to fund **strategic opportunities in** the **future** ~~development and growth of our business~~ . Any future payment of cash dividends ~~in~~

~~the future~~ will be at the discretion of our Board of Directors and will depend on, among other things, our earnings, financial condition, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of dividends and other considerations that the Board of Directors deems relevant. **We** ~~Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock. Any return to our stockholders will therefore be limited to the appreciation of their stock. 90We~~ can issue and have issued shares of preferred stock, which may adversely affect the rights of holders of our common stock. Our amended and restated Certificate of Incorporation authorizes us to issue up to 10, 000, 000 shares of preferred stock with designations, rights, and preferences determined from time- to- time by our Board of Directors. Accordingly, our Board of Directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights superior to those of holders of our common stock. For example, an issuance of shares of preferred stock could: • adversely affect the voting power of the holders of our common stock; • make it more difficult for a third party to gain control of us; • discourage bids for our common stock at a premium; • limit or eliminate any payments that the holders of our common stock could expect to receive upon our liquidation; or • otherwise adversely affect the market price or our common stock. ~~We~~ **44We** have in the past issued, and we may at any time in the future issue, shares of preferred stock. In connection with our June 2016 private placement, we issued 4, 963 shares of our Series A convertible preferred stock to certain affiliates of Biotechnology Value Fund, L. P., or BVF, each share of which is convertible into 1, 000 shares of our common stock, subject to certain ownership restrictions. In January 2019, we entered into an exchange agreement with BVF to exchange 5, 000, 000 shares of our common stock previously held by BVF for 5, 000 shares of our Series B convertible preferred stock, each share of which is convertible into 1, 000 shares of our common stock, subject to certain ownership restrictions. In connection with our November 2019 private placement, we issued 3, 522 shares of our Series C convertible preferred stock to certain affiliates of BVF each share of which is convertible into 1, 000 shares of our common stock, subject to certain ownership restrictions. In March 2020, we entered into another exchange agreement with BVF to exchange 3, 000, 000 shares of our common stock previously held by BVF for 3, 000 shares of our Series D convertible preferred stock, each share of which is convertible into 1, 000 shares of our common stock, subject to certain ownership restrictions. In May 2021, we entered into another exchange agreement with BVF to exchange 5, 000, 000 shares of our common stock previously held by BVF for 5, 000 shares of our Series E convertible preferred stock, each share of which is convertible into 1, 000 shares of our common stock, subject to certain ownership restrictions. If the holders of our shares of preferred stock convert their shares into common stock, existing holders of our common stock will experience dilution. Requirements associated with being a public company have increased our costs significantly and have diverted significant company resources and management attention. ~~Since~~ **As a public company,** we are **subject** ~~no longer an " emerging growth company " as defined in the JOBS Act, we are no longer able~~ to **the** ~~take advantage of certain exemptions from various~~ reporting requirements **of the Exchange Act and the Sarbanes- Oxley Act. The Exchange Act requires the filing of annual, quarterly and current reports with respect to a public company' s business and financial condition. The Sarbanes- Oxley Act requires, among other things,** that **a** ~~were previously available to us, but which were not available to other~~ public ~~companies that are not emerging growth companies. Accordingly, we are now required to comply~~ **company establish and maintain** ~~with increased disclosure obligations regarding executive~~ **effective internal control over financial** ~~compensation in our periodic reports and proxy statements and the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, we will incur greater expenses associated with such~~ reporting ~~requirements~~. ~~These expenses would further increase if we ceased to be a " smaller reporting company. "~~ Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to ~~increase~~ **negatively impact** our legal and financial compliance costs and will make some activities more time- consuming and costly. Having availed ourselves of scaled disclosure available to smaller reporting companies, we cannot be certain if such reduced disclosure will make our common stock less attractive to investors. Under Rule 12b- 2 of the Exchange Act, a " smaller reporting company " is a company that is not an investment company, an asset- backed issuer or a majority- owned subsidiary of a parent company that is not a smaller reporting company, and had a public float of less than $ 250 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is less than $ 700 million, had annual revenues of less than $ 100 million during the most recently completed fiscal year. Smaller reporting companies are permitted to provide simplified executive compensation disclosure in their filings; and they have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. We qualify as a smaller reporting company. For as long as we continue to be a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. Decreased disclosure in our SEC filings as a result of our having availed ourselves of scaled disclosure may make it harder for investors to analyze our results of operations and financial prospects. ~~91Item~~ **45Item** 1B. UNRESOLVED STAFF COMMENTS