Risk Factors Comparison 2024-03-28 to 2023-03-28 Form: 10-K

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

Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the following principal risk factors that make an investment in our company speculative or risky. You are encouraged to carefully review our full discussion of the material risk factors relevant to an investment in our business, which follows the brief bulleted list of our principal risk factors set forth below: ● We have **a limited operating history and have never generated any product revenue. ● We have** incurred significant losses since our inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability. ● We are dependent on the success of our Versamune **®** and Infectimune **®** products, which are still in early- stage clinical development, and if our Versamune **®** and Infectimune **®** products do not receive regulatory approval or are not successfully commercialized, our business may be harmed. ● We ~~have a limited operating history and have never generated any product revenue. ● We~~ will require additional capital to fund our operations, ~~,~~ and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our Versamune **®** and Infectimune **®** based products. ● Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights. ● We will need to expand our organization, and may experience difficulties in managing this growth, which could disrupt operations. ● Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations. ● **Our business and operations would suffer, and could be negatively affected, in the event of system failures or cyberattacks. ●** If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock. Further, we continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. ~~● Our business and operations would suffer, and could be negatively affected, in the event of system failures or cyberattacks.~~ Index ● Periodic reporting requirements under the Exchange Act and compliance with the Sarbanes- Oxley Act of 2002, including establishing and maintaining acceptable internal control over financial reporting, are costly and may increase substantially and, as a smaller reporting company, we may take advantage of reduced reporting requirements which may make our common stock less attractive to investors. ● **We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern. ●** Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize ~~PDS0101 and other~~ Versamune **®, Versamune ® in combination with PDS01ADC** and Infectimune **®** based products. ● Enrollment and retention of subjects in clinical trials is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside our control. ● We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively . ● Our product candidates are in..... prices we may obtain and our profitability . ● We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects. ● Our ~~stock price is expected to~~ **product candidates are in various stages of development and we will not** be ~~volatile,~~ **able to commercialize our product candidates if our preclinical studies do not produce successful results** and **/** ~~the market price of our~~ **or** ~~common stock may drop in~~ **our clinical trials do not demonstrate** the ~~future~~ **safety and efficacy of our product candidates; early results and early understanding of product candidate potential may not be predictive of later success** . ● We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success .● **Our product candidates are** ~~If we fail to comply with federal and state healthcare regulatory laws,including~~ in **various stages of development and we will not be able to commercialize our product candidates if our preclinical studies do not produce successful results and /** ~~our~~ **or** ~~relationships with healthcare providers~~ **our clinical trials do not demonstrate the safety** and ~~customers~~ **efficacy of our product candidates;early results** and **early understanding of product candidate potential may not be predictive of later success.● We have no manufacturing,sales,marketing or distribution capability and we must rely upon** third ~~- party payors,we could face criminal prosecution and sanctions,substantial civil penalties~~ -- **parties for such** ~~,damages,fines,disgorgement,exclusion from participation in governmental healthcare programs,contractual damages,reputational harm,and the curtailment of our operations,any of which could harm our business~~ .● If we are unable to establish sales,marketing and distribution capabilities either on our own or in collaboration with third parties,we may not be successful in commercializing PDS0101 ~~,PDS01ADC~~ and **our** other product candidates,if approved.● If we obtain approval to commercialize PDS0101 **and** ~~,PDS01ADC or~~ other ~~product~~ candidates outside of the United States,a variety of risks associated with international operations could harm our business.● Recently enacted and future healthcare legislation,regulations,and policy initiatives may increase the difficulty and cost for us to obtain marketing approval of and commercialize PDS0101 **and**

~~,PDS01ADC or~~ **our** other product candidates and affect the prices we may obtain and our profitability ~~.● We have no manufacturing~~ . ● If we are unable to establish or manage strategic collaborations in the future, our revenue and drug development may be limited. ● Our business could be adversely affected by the effects of health epidemics, pandemics, or outbreaks of infectious diseases ~~, including the recent COVID- 19 pandemic,~~ in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. ~~The COVID- 19 pandemic could materially affect our operations, including at our headquarters in New Jersey, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.~~ ● If we are unable to obtain and / or maintain patent protection for our Versamune ® , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** platforms, PDS0101, or other Versamune **® or Infectimune ®** based Products or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets. ● We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, or defend our products and methods against the property rights of others, which could be expensive, time consuming and unsuccessful. ● ~~If we fail~~ **Our stock price is expected** to **be volatile** ~~comply with federal and state healthcare regulatory laws~~ , ~~including in our relationships with healthcare providers~~ and ~~customers and third- party payors, we could face criminal prosecution and sanctions, substantial civil penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, and~~ the ~~curtailment~~ **market price** of our **common stock may drop in the future** ~~operations, any of which could harm our business~~ . ● Our effective tax rate may increase in the future, including as a result of tax legislation changes, which may have a material adverse effect on our business, financial condition and results of operations. ~~IndexRisks~~ **Risks** Related to Our Business, Financial Position and Capital RequirementsWe have no products approved for sale. We are a clinical- stage biopharmaceutical company with a limited operating history. Our operations to date have been limited to organizing our company and developing the Versamune ® platform and related immunotherapy product candidates that incorporate the technology of our Versamune ® platform. We have not yet successfully completed a large- scale, pivotal clinical trial, obtained marketing approval, manufactured Versamune ® at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize our Versamune ® products. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing immunotherapies. ~~Our~~ **IndexOur** product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. Our ability to generate revenue and achieve and maintain profitability will depend upon our ability to successfully complete the development of our Versamune ® based oncology products PDS0101, PDS0102, PDS0103, PDS0104 ~~,~~ **alone** or ~~PDS0301~~ **in combination with PDS01ADC** and Infectimune ® to treat infectious diseases and to obtain the necessary regulatory approvals. We have never generated any product revenue and have no immunotherapy candidate in late- stage clinical development or approved for commercial sale. Even if we receive regulatory approval for the sale of the Versamune ® , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® Products, we do not know when we will begin to generate revenue from PDS0101 or other products, if at all. Our ability to generate revenue depends on a number of factors, including our ability to: ● set **and obtain** an acceptable price for Versamune ® based immunotherapy candidates, including ~~the~~ Versamune ~~Products~~ **® in combination with PDS01ADC** , and obtain coverage and adequate reimbursement from third- party payors; ● establish sales, marketing, manufacturing and distribution systems; ● add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company; ● develop manufacturing capabilities for bulk materials and manufacture commercial quantities of **Versamune ®** PDS0101 **, PDS01ADC** and other Versamune ® ~~Products~~ **products** at acceptable cost levels; ● achieve broad market acceptance of PDS0101 and other Versamune ® , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® based- products in the medical community and with third- party payors and consumers; ● attract and retain an experienced management and advisory team; ● launch commercial sales of **Versamune ®** PDS0101 **in combination with PDS01ADC** and other ~~Versamune~~ **oncology products** , ~~Versamune plus PDS0301~~ and Infectimune ® based- products, whether alone or in collaboration with others; and ● maintain, expand and protect our intellectual property portfolio. Because of the numerous risks and uncertainties associated with immunotherapy development and manufacturing, we are unable to predict the timing or amount of increased development expenses, or when we will be able to achieve or maintain profitability, if at all. Our expenses could increase beyond expectations if we are required by the U. S. Food and Drug Administration, or FDA, or comparable non- U. S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if PDS0101 **alone or in combination with PDS01ADC** is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial- scale manufacturing requirements for PDS0101 ~~and~~ **, PDS01ADC,** other Versamune ® and Infectimune ® products. If we cannot successfully execute on any of the factors listed above, our business may not succeed, and your investment will be adversely affected. ~~IndexWe~~ **We** have incurred significant losses since our inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability. We have never generated any product revenues and expect to continue to incur substantial and increasing losses as we continue to develop ~~PDS0101 and other~~ Versamune **®, Versamune ® in combination with PDS01ADC** and Infectimune ® based products. None of our products have been approved for marketing in the United States and may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate revenue and achieve profitability is dependent on our ability to complete development, obtain necessary regulatory approvals, and have our products manufactured and successfully

marketed. We cannot assure you that we will be profitable even if we successfully commercialize PDS0101 **, PDS01ADC** or other Versamune **®** and Infectimune **®** based products. If we successfully obtain regulatory approval to market PDS0101 **alone or in combination with PDS01ADC** , our revenues will be dependent, in part, upon, the size of the markets in the territories for which regulatory approval is received, the number of competitors in such markets for the approved indication, and the price at which we can offer our products. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our products, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become and remain profitable the market price of our common stock and our ability to raise capital and continue operations will be adversely affected. ~~We~~ **IndexWe** expect research and development expenses to increase significantly for ~~PDS0101 and other~~ Versamune **®, Versamune ® in combination with PDS01ADC** and Infectimune **®** based products. In addition, even if we obtain regulatory approval, significant sales and marketing expenses will be required to commercialize our products. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital. As of December 31, **2023 and** 2022 ~~and 2021~~ , we had an accumulated deficit of $ **144. 5 and $** 101. 6 ~~and $ 60. 7~~ million, respectively. We are dependent on the success of our Versamune **®, PDS01ADC** and Infectimune **®** products, which are still in ~~early- stage~~ clinical development, and if our Versamune **®, PDS01ADC** and Infectimune **®** products do not receive regulatory approval or are not successfully commercialized, our business may be harmed. PDS0101 ~~is only~~ **and PDS01ADC are** in mid clinical development, and as a consequence, it is too early to determine whether **our** ~~the Versamune and Infectimune based~~ products will ever be approved for commercial sale or be marketable. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to ~~PDS0101 and other~~ Versamune **®, Versamune ® in combination with PDS01ADC** and Infectimune **®** based products. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of PDS0101 **alone or in combination with PDS01ADC** . PDS0101 **and PDS01ADC** may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of PDS0101 **and PDS01ADC** is and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market PDS0101 **or PDS01ADC** in the United States until it receives approval of a biologics license application, or BLA, from the FDA, or in any foreign countries until it receives the requisite approval from such countries. To date, we have only completed Phase **2** ~~1 / 2a~~ clinical trials for certain applications of PDS0101. As a result, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of PDS0101 **or PDS01ADC** for many reasons, including: ● we may not be able to demonstrate that PDS0101 **alone or in combination with PDS01ADC** is safe and effective to the satisfaction of the FDA; ● the FDA may not agree that the completed Phase 2 clinical trials of PDS0101 **and PDS01ADC** satisfy the FDA' s requirements and may require us to conduct additional testing; ● the results of our future clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval; ● the FDA may disagree with the number, design, size, conduct or implementation of one or more of our clinical trials; ● the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially and adversely impact our clinical trials; ● the FDA may not find the data from our preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of PDS0101 **and PDS01ADC** outweigh the safety risks; ● the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials; ● the FDA may not accept data generated at our clinical trial sites; ● if our BLA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions; ● the FDA may require development of a risk evaluation and mitigation strategy, or REMS, as a condition of approval; ● the FDA may identify deficiencies in our manufacturing processes or facilities; or ● the FDA may change its approval policies or adopt new regulations. IndexWe will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our Versamune **®, PDSO1ADC** and Infectimune **®** based products. We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize PDS0101 **alone or in combination with PDS01ADC** . Even with our current cash reserves, we will require substantial additional capital to complete the development and potential commercialization of PDS0101 and **PDS01ADC and** the development of other Versamune **®** and Infectimune **®** based products. If we are unable to raise capital or find appropriate partnering or licensing collaborations or other nondilutive financing, when needed or on acceptable terms, if at all, we could be forced to delay, reduce or eliminate one or more of our development programs or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day- to- day activities and harm our development efforts ~~. Based upon our current operating plan, we believe that our cash reserves will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 24 months from the date of this report~~ . Our estimate as to what we will be able to accomplish is based on assumptions that may prove to be inaccurate, and we could exhaust our available capital resources sooner than is currently expected. Because the length of time and activities associated with successful development of PDS0101 **and PDS01ADC** is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: ● the initiation, progress, timing, costs and results of our planned clinical

trials; ● the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities; ● the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; ● the cost of defending potential intellectual property disputes, including any patent infringement actions brought by third parties against us now or in the future; ● the effect of competing technological and market developments; ● the cost of establishing sales, marketing and distribution capabilities in regions where we choose to commercialize PDS0101 **and PDS01ADC** on our own; and ● the initiation, progress, timing and results of the commercialization of PDS0101, if approved, for commercial sale. Additional funding may not be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of PDS0101 or potentially discontinue operations. **Raising** ~~In July 2019, we entered into a common stock purchase agreement, or the Aspire Purchase Agreement, with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, at our discretion, Aspire Capital is committed to purchase up to an aggregate of $ 20. 0 million of shares of our common stock, or the Purchased Shares, over the 30- month term of the Aspire Purchase Agreement. We may sell an aggregate of 1, 034, 979 shares of our common stock (which represented 19. 99 % of the Company' s outstanding shares of common stock on the date of the Aspire Purchase Agreement) without stockholder approval. We may sell additional shares of our common stock above the 19. 99 % limit provided that (i) we obtain stockholder approval or (ii) stockholder approval has not been obtained at any time the 1, 034, 979 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Aspire Purchase Agreement, is equal to or greater than $ 5. 76, which was the consolidated closing bid price of our common stock on July 26, 2019. On July 29, 2019, we issued 100, 654 shares of our common stock to Aspire Capital, as consideration for entering into the Aspire Purchase Agreement, which we refer to as the Commitment Shares. As of December 31, 2022, no Purchase Shares have been sold to Aspire Capital under the Aspire Purchase Agreement. The Aspire Purchase Agreement expired in January 2022 and we raised no capital under the Aspire Purchase Agreement. IndexRaising~~ additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights. We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. In February 2020, we completed an underwritten public offering, in which we sold 10, 000, 000 shares of common stock at a public offering price of $ 1. 30 per share. The shares sold included 769, 230 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price. We received gross proceeds of approximately $ 13 million and net proceeds of approximately $ 11. 9 million after deducting underwriting discounts and commissions. In July 2020, we filed a shelf registration statement, or the 2020 Shelf Registration Statement, with the SEC, for the issuance of common stock, preferred stock, warrants, rights, debt securities and units, which we refer to collectively as the Shelf Securities, up to an aggregate amount of $ 100 million. The 2020 Shelf Registration Statement was declared effective on July 31, 2020. The 2020 Registration Statement was terminated upon effectiveness of the 2022 Registration Statement (as discussed below). On August 13, 2020, we sold 6, 900, 000 shares of our common stock at a public offering price of $ 2. 75 per share pursuant to the 2020 Shelf Registration Statement, which includes 900, 000 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price, minus underwriting discounts and commissions. We received gross proceeds of approximately $ 19. 0 million and net proceeds of approximately $ 17. 1 million, after deducting underwriting discounts and offering expenses. In June 2021, we completed an underwritten public offering in which we sold 6, 088, 235 shares of common stock at a public offering price of $ 8. 50 per share pursuant to the 2020 Shelf Registration Statement, which includes 794, 117 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price, minus underwriting discounts and commissions. We received gross proceeds of approximately $ 51. 7 million and net proceeds of approximately $ 48. 5 million, after deducting underwriting discounts and offering expenses. ~~In~~ **IndexIn** August 2022, we filed a shelf registration statement, or the 2022 Shelf Registration Statement, with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities, and units up to an aggregate amount of $ 150 million, $ 50 million of which covers the offer, issuance and sale by the Company of its common stock under the Sales Agreement (as discussed below). The 2022 Shelf Registration Statement was declared effective on September 2, 2022. In August 2022, we entered into an At Market Issuance Sales Agreement, or the Sales Agreement, with B. Riley Securities, Inc. and BTIG, LLC, each an Agent and collectively the Agents, with respect to an at- the- market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, having an aggregate offering price of up to $ 50. 0 million, or the Placement Shares, through or to the Agents, as sales agents or principals. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, the Agents may sell the Placement Shares by any method permitted by law deemed to be an " at the market " offering as defined in Rule 415 of the Securities Act of 1933, as amended, including, without limitation, sales made through The Nasdaq Capital Market or on any other existing trading market for our common stock. The Agents will use commercially reasonable efforts to sell the Placement Shares from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay the Agents a commission equal to three percent (3 %) of the gross sales proceeds of any Placement Shares sold through the Agents under the Sales Agreement, and also has provided the Agents with customary indemnification and contribution rights. We are not obligated to make any sales of our common stock under the Sales Agreement. The offering of Placement Shares pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all Placement Shares subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms. ~~For~~ **During** the year ended December 31, ~~2022~~ **2023** , we sold ~~1~~ **2** , ~~238~~ **642** , ~~491~~ **269** shares of our common stock for a net value of $ ~~9~~ **16** , ~~9~~ **1** million pursuant to the Sales Agreement. ~~In~~ **For** the ~~first quarter of~~ **year ended December 31,** ~~2023~~ **2022** , we sold ~~553~~ **1** , ~~293~~ **238, 491** shares of our

common stock for a net value of $ ~~4~~ **9** . ~~6~~ **9 million pursuant to the Sales Agreement. As of the date of this Annual Report, in the first quarter of 2024 we sold 3, 428, 681 shares of our common stock for a net value of $ 19. 5** million pursuant to the Sales Agreement. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or Versamune ® Products or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our PDS0101 **and PDS01ADC** development or future commercialization efforts or grant rights to develop and market other Versamune ® and Infectimune ® products that we would otherwise develop and market. ~~IndexOur~~ **Our** operating activities may be restricted as a result of covenants related to the outstanding indebtedness under our venture loan and security agreement with Horizon and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business. In August 2022, we entered into a Venture **loan and security agreement, or the** Loan and Security ~~Agreement, or the Loan~~ Agreement, for separate term loans of up to an aggregate amount of $ 35. 0 million, with Horizon Technology Finance Corporation, or Horizon, in its capacity as a lender and collateral agent for itself and the other financial institutions that from time to time become parties to the Loan **and Security** Agreement, collectively referred to as the Lenders, secured ~~by a~~ by a security interest in all of our respective rights, title, interests, claims and demands in, to and under all of our respective properties and other assets, subject to limited exceptions and excluding our intellectual property. The Loan **and Security** Agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants **include requirements to maintain minimum cash balances as well as covenants** ~~limit~~ **limiting** our ability to, among other things, sell, transfer, lease or dispose of certain assets; incur indebtedness; encumber or permit liens on certain assets; make certain investments; make certain restricted payments, including paying dividends on, or repurchasing or making distributions with respect to, our common stock; and enter into certain transactions with affiliates. Our business may be adversely affected by these restrictions on our ability to operate our business. A breach of any of the covenants under the Loan **and Security** Agreement could result in a default. Upon the occurrence of an event of default, the Lenders could elect to declare all amounts outstanding, if any, to be immediately due and payable. If there are any amounts outstanding that we are unable to repay, the Lenders could proceed against the collateral granted to them to secure such indebtedness. ~~Our~~ **IndexOur** future success depends on our ability to retain executive officers and attract, retain and motivate qualified personnel. We are highly dependent on our executive officers and the other principal members of the executive and scientific teams, particularly our President and Chief Executive Officer, Dr. Frank K. Bedu- Addo, our Chief Medical Officer, Dr. ~~Lauren Wood~~ **Kirk Shepard** , our Chief Financial Officer, Mr. ~~Matthew Hill~~ **Lars Boesgaard** and our Chief Scientific Officer, Dr. Gregory L. Conn. The loss of the services of any of our senior executive officers could impede the achievement of our research, development and commercialization objectives. We do not maintain " key person " insurance for any executive officer or employee. Recruiting and retaining qualified scientific, clinical, and operational personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. ~~we~~ **We** also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our industry has experienced an increasing rate of turnover of management and scientific personnel in recent years. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in devising our research and development and commercialization strategy. Our consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to advance our strategic objectives. If any of these advisors or consultants can no longer dedicate a sufficient amount of time to **us** ~~the company~~ , our business may be ~~harmedIf~~ -- **harmed. If** we fail to obtain or maintain adequate coverage and reimbursement for PDS0101 **or PDS01ADC** , our ability to generate revenue could be limited. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of PDS0101 **or PDS01ADC** that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of PDS0101 **or PDS01ADC** will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payors. If reimbursement is not available, or is available only on a limited basis, we may not be able to successfully commercialize PDS0101 **alone or in combination with PDS01ADC** . Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow it to realize a sufficient return on our investment. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price PDS0101 **alone or in combination with PDS01ADC** on less favorable terms than we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of PDS0101 **or PDS01ADC** to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own

prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for PDS0101 **alone or in combination with PDS01ADC** . Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. ~~IndexMoreover~~ ----- **Moreover** , increasing efforts by governmental and third- party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for PDS0101 **or PDS01ADC** . We expect to experience pricing pressures in connection with the sale of PDS0101 **or PDS01ADC** due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. The Inflation Reduction Act, referred to as the IRA, was recently signed into law by President Biden, which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price- setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028. We have evaluated, and will continue to evaluate, the effect of the IRA on our business. At this time, we do not expect the IRA to have a material ~~effectWe~~ -- **effect on our financial position. We** are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. ~~Even~~ **IndexEven** if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success. If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well- established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenues from sales of drugs and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: ● the efficacy and safety of the product; ● the potential advantages of the product compared to alternative therapies; ● the prevalence and severity of any side effects; ● whether the product is designated under physician and other provider treatment guidelines as a first-, second- or third-line therapy; ● our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices; ● the product' s convenience and ease of administration for patients and healthcare practitioners compared to alternative treatments; ● the willingness of the target patient population to try, and of physicians to prescribe, the product; ● limitations or warnings, including distribution or use restrictions and safety information contained in the product' s approved labeling; ● the strength of sales, marketing and distribution support; ● changes in the standard of care for the targeted indications for the product; and ● the availability of coverage by, and the amount of reimbursement from, government payors, managed care plans and other third-party payors. ~~IndexOur~~ **Our** future financial performance and our ability to commercialize PDS0101 **alone or in combination with PDS01ADC** and compete effectively will depend, in part, on our ability to effectively manage any future growth. As of December 31, ~~2022~~ **2023** , we had ~~26~~ **25** employees and ~~3~~ **18** consultants. We expect to hire additional employees for our managerial, clinical, scientific and engineering, operational, manufacturing, sales and marketing teams. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of our attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of PDS0101. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenues could be reduced, and we may not be able to implement our business strategy. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than us. 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 and consultants than what it has to offer. If we are unable to continue to attract and retain high- quality personnel and consultants, the rate and success at which we can select and develop PDS0101 **or PDS01ADC** and our business will be limited. ~~Our~~ **IndexOur** employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations. We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, manufacturing standards, federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws, or laws that require the true,

complete and accurate reporting of financial information or data. Misconduct by these parties may also involve the improper use or misrepresentation 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 third- party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws 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 financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Our business and operations would suffer, and could be negatively affected, in the event of system failures or ~~cyberattacksOur~~ --- **cyberattacks. Our** computer systems and those of our service providers, including our CROs, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our or their operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of PDS0101 **and PDS01ADC** could be delayed. A cyberattack or similar incident could occur and result in information theft, data corruption, operational disruption, damage to our reputation or financial loss. Our industry has become increasingly dependent on digital technologies to conduct certain development and financial activities. Our technologies, systems, networks, or other proprietary information, and those of our vendors, suppliers and other business partners, may become the target of cyberattacks or information security breaches that could result in the unauthorized release, gathering, monitoring, misuse, loss or destruction of proprietary and other information, or could otherwise lead to the disruption of our business operations. Cyberattacks are becoming more sophisticated and certain cyber incidents, such as surveillance, may remain undetected for an extended period and could lead to disruptions in critical systems or the unauthorized release of confidential or otherwise protected information. These events could lead to financial loss from remedial actions, loss of business, disruption of operations, damage to our reputation or potential liability. Our systems and insurance coverage for protecting against cybersecurity risks may not be sufficient. Further, as cyberattacks continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any vulnerability to cyberattacks. ~~IndexOur~~ **Our** failure to comply with international data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. EU member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the EU, which was formerly governed by the provisions of the EU Data Protection Directive, was replaced with the EU General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide- ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the U. S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is greater. The GDPR requirements apply not only to third- party transactions, but also to transfers of information between us and our subsidiary, including employee information. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management' s attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business. ~~Our~~ **IndexOur** failure to comply with state and / or national data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. There are numerous other laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns, and some state privacy laws apply more broadly than the Health Insurance Portability and Accountability Act, or HIPAA, and associated regulations. For example, California recently enacted legislation – the California Consumer Privacy Act, or CCPA – which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The CCPA was recently amended by the California Privacy Rights Act, or CPRA, expanding certain consumer rights such as the right to know. It remains unclear what, if any, additional modifications will be made to these laws by the California legislature or how these laws will be interpreted and enforced. The potential effects of the CCPA and CPRA and implementing regulations are significant and may cause us to incur substantial costs and expenses to comply. If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock. Further, we continue to incur

significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. As a public company, we continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes- Oxley Act, as well as rules subsequently implemented by the SEC and Nasdaq, impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure controls and internal control over financial reporting and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time- consuming and costly. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews or becomes aware of either during the conduct of an audit, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Capital Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. ~~IndexPeriodic~~ ----- **Periodic** reporting requirements under the Exchange Act and compliance with the Sarbanes- Oxley Act of 2002, including establishing and maintaining acceptable internal control over financial reporting, are costly and may increase substantially and, as a smaller reporting company, we may take advantage of reduced reporting requirements which may make our common stock less attractive to investors. We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time- consuming and costly. ~~In~~ **IndexIn** addition, the Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In particular, Section 404 of the Sarbanes- Oxley Act will require us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. We are currently a " smaller reporting company, " but we will cease to be a smaller reporting company if we have a non- affiliate public float in excess of $ 250 million and annual revenues in excess of $ 100 million, or a non- affiliate public float in excess of $ 700 million, determined on an annual basis. As a smaller reporting company, we could take advantage of certain reduced governance and disclosure requirements, including not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting. As a result, investors and others may be less comfortable with the effectiveness of our internal controls and the risk that material weaknesses or other deficiencies in internal controls go undetected may increase. In addition, as a smaller reporting company, we take advantage of our ability to provide certain other less comprehensive disclosures in our SEC filings, including, among other things, providing only two years of audited financial statements in annual reports and simplified executive compensation disclosures. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects, as the information we provide to stockholders may be different from what one might receive from other public companies. ~~Risks~~ **We have incurred net losses and utilized cash in operations since inception. In addition, as of December 31, 2023, we had approximately $ 56. 6 million in cash and cash equivalents, and during the twelve months ended December 31, 2023, we used $ 33. 6 million of cash in operations and expect to continue to incur significant cash outflows and incur future additional losses to execute our operating plan. While we intend to finance our cash needs principally through collaborations, strategic alliances, or license agreements with third parties and / or debt or equity financings, there is no assurance that new financing will be available to us on commercially acceptable terms or in the amounts required, if at all. In addition, the Loan and Security Agreement allows for the lenders to call the outstanding balance of the term loans if the minimum cash balances outlined in the Loan and Security Agreement are not maintained. Due to the uncertainty in securing additional funding, and the insufficient amount of cash and cash equivalents as of December 31, 2023, we have concluded that substantial doubt exists about our ability to continue as a going concern within one year after the date of the filing of this Annual Report. If we are unsuccessful in securing sufficient financing, we may need to delay, reduce, or eliminate our research and development programs, which could adversely affect our business prospects, or cease operations. Our consolidated financial statements included in this Annual Report have been prepared on a going concern basis under which an entity is able to realize its assets and satisfy its liabilities in the ordinary course of business. The consolidated financial statements do not give effect to any adjustments relating to the carrying values and classification of assets and liabilities that would be necessary should we be unable to continue as a going concern within one year after the date that the financial statements are issued. Our future operations are dependent upon the successful**

entry into collaborations, strategic alliances, or license agreements with third parties and / or on the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that we will be successful in completing these collaborations or alliances, equity or debt financing or in achieving profitability. As such, there can be no assurance that we will be able to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. If we are unable to continue as a going concern, you could lose all or part of your investment in our Company. IndexRisks Related to Clinical Development, Regulatory Approval and CommercializationClinical trials are very expensive, time- consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize ~~PDS0101 and other~~ Versamune **®, Versamune ® in combination with PDS01ADC** and Infectimune **®** based products. PDS0101 ~~is~~ **and PDS01ADC are** still in ~~early- stage~~ clinical development and will require ~~extensive~~ additional clinical testing before we are prepared to submit a BLA for regulatory approval for any indication or for any other treatment regime. We cannot predict with any certainty if or when ~~it~~ **we** might submit a BLA for regulatory approval for PDS0101 **, PDS01ADC** and other Versamune **®** based products or whether any such BLAs will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also time- consuming. We estimate that the clinical trials we need to conduct to be in a position to submit BLAs for PDS0101 **alone or in combination with PDS01ADC** will take several years to complete. We cannot predict the timeline for review of submissions to any regulatory authorities or when any of our product candidates will receive marketing approval, if at all. The timeline for regulatory approval can be affected by a variety of factors, including, budget and funding levels, agency staffing, and statutory, regulatory and policy changes. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In later stages of clinical trials, PDS0101 **and PDS01ADC** may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of current clinical trials of PDS0101 therefore may not be predictive of the results of our continued or planned Phase 2 and 3 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 stages of clinical trials. Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their immunotherapies performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects and different indications than we have studied in Phase 2 clinical trials to date, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. In particular, the small number of patients in our planned early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. ~~IndexProduct~~ **Product** development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize PDS0101 **alone or in combination with PDS01ADC** , could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize PDS0101 **or PDS01ADC** , any of which may harm our business and results of operations. Clinical drug development is a lengthy and expensive process, with an uncertain outcome. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs, experience delays in completing, or ultimately be unable to complete, the development of our product candidates or be unable to obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early- stage clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. ~~We~~ **IndexWe** do not know whether ongoing clinical trials will be completed on schedule or at all, or whether future clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to: ● obtaining regulatory authorization to commence a trial; ● reaching 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 clinical trial sites; ● obtaining institutional review board or ethics committee approval at each clinical trial site; ● recruiting suitable patients to participate in a trial; ● ~~the impact of COVID- 19 on patient screening, patient enrollment, and follow- up;~~ ● patients failing to comply with the clinical trial protocol or dropping out of a trial; ● clinical trial sites failing to comply with the clinical trial protocol or dropping out of a trial; ● addressing any conflicts with new or existing laws or regulations; ● the need to add new clinical trial sites; ● manufacturing sufficient quantities of product candidate for use in clinical trials and ensuring

clinical trial material is provided to clinical sites in a timely manner; or ● obtaining advice from regulatory authorities regarding the statistical analysis plan to be used to evaluate the clinical trial data or other trial design issues. ~~IndexWe~~ **We** may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including: ● we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; ● clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; ● the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; ● our third- party contractors, including our CROs, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ● we, our investigators, or any of the overseeing IRBs or ethics committees might decide to suspend or terminate clinical trials of our product candidates for various reasons, including non- compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks; ● the cost of clinical trials of our product candidates may be greater than we anticipate; ● the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; ● regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and ● any future collaborators that conduct clinical trials may face any of the above issues and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us. **Index ●** If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are insufficiently positive to support marketing approval, or if there are safety concerns, we may: ● incur unplanned costs; ● be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all; ● obtain marketing approval in some countries and not in others; ● obtain marketing approval for indications or patient populations that are narrower or more limited in scope than intended or desired; ● obtain marketing approval subject to significant use or distribution restrictions or with labeling that includes significant safety warnings, including boxed warnings; ● be subject to additional post-marketing testing requirements; or ● have the drug removed from the market after obtaining marketing approval. Our drug development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Furthermore, we rely on third- party CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring drugs to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. ~~IndexEnrollment~~ ----- **Enrollment** and retention of subjects in clinical trials is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside our control. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials. Once enrolled, we may be unable to retain a sufficient number of participants to complete any of our trials. Late- stage clinical trials of PDS0101 **alone or in combination with PDS01ADC or other agents** may require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, patients' and clinicians' perceived risks and benefits of the product candidate under study the proximity of subjects to clinical sites and the eligibility criteria for the study. ~~Moreover, the current pandemic is negatively impacting enrollment in many oncology clinical trials.~~ Furthermore, any negative results we may report in clinical trials of PDS0101 **and PDS01ADC** may make it difficult or impossible to recruit and retain participants in other clinical trials of PDS0101. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop PDS0101 **and PDS01ADC**, or could render further development impractical. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to our clinical development programs. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. ~~The~~ **IndexThe** successful development of immunotherapies is highly uncertain. Successful development of immunotherapies is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach, or be delayed in reaching, the market for several reasons including: preclinical study results that may show the immunotherapy to be less effective than desired (e. g., the study failed to meet its primary objectives) or to have harmful or problematic side effects; clinical study results that may show the immunotherapy to be less effective than expected (e. g., the study failed to meet its primary endpoint) or to have unacceptable side effects; failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, delays in receiving the necessary products or supplies for the conduct of clinical or preclinical trials, additional time requirements for data analysis, or Biologics License Application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, FDA delays in inspecting

manufacturing establishments, failure to receive FDA approval for manufacturing processes or facilities, or unexpected safety or manufacturing issues; manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized. Success in preclinical and early and interim clinical studies does not ensure that large- scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next and may be difficult to predict. Even if our product candidates are approved, they may be subject to limitations on the indicated uses and populations for which they may be marketed. They may also be subject to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post- market testing and surveillance, or other requirements, including the submission of a REMS, to monitor the safety or efficacy of the products. If we do not receive FDA approval for, and successfully commercialize our product candidates, we will not be able to generate revenue from these product candidates in the United States in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates will have a material adverse impact on our business and financial condition. ~~IndexIn~~ **In** addition, the success of our products will depend on several factors, including the following: ● successful initiation, successful patient enrollment and timely completion of clinical trials of these products; ● successful initiation and successful patient enrollment and completion of additional clinical trials, for ~~our product candidates; ● the impact of COVID- 19 on our operations, ability to conduct clinical trials and on the ability of our regulators to review and approve~~ our product candidates; ● our ability to demonstrate our products' safety, tolerability and efficacy to the FDA or any comparable foreign regulatory authority for marketing approval; ● timely receipt of marketing approvals for our products; ● obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally; ● successfully defending and enforcing our rights in our intellectual property portfolio; ● avoiding and successfully defending against any claims that we have infringed, misappropriated or otherwise violated any intellectual property of any third party; ● the performance of our future collaborators, if any; ● the extent of, and our ability to timely complete, any required post-marketing approval commitments imposed by FDA or other applicable regulatory authorities; ● establishment of supply arrangements with third- party raw materials and drug product suppliers and manufacturers who are able to manufacture clinical trial and commercial quantities of our products and their components and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP, at a scale sufficient to meet anticipated demand and over time enable us to reduce our cost of manufacturing; ● establishment of scaled production arrangements with third- party manufacturers to obtain finished products that are compliant with cGMP and appropriately packaged for sale; ● successful launch of commercial sales following any marketing approval; ● a continued acceptable safety profile following any marketing approval; ● commercial acceptance by patients, the medical community and third- party payors; ● the availability of coverage and adequate reimbursement and pricing by third- party payors and government authorities; ● the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments; and ● our ability to compete with other therapies. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of our product candidates. If we are not successful in commercializing our products, or are significantly delayed in doing so, our business will be materially harmed. IndexWe may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed. We may not be able to file INDs for our future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND- enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that lead FDA, IRBs, or other authorities to suspend, terminate, or require changes to our clinical trials. Additionally, even if such regulatory and other authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials or changes to existing clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory clearance or approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, PDS0101 **, PDS01ADC** or other Versamune **®** and Infectimune **®** based products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel

and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us. We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with PDS0101 **and PDS01ADC** even though their approach to may be different. We believe our top clinical-stage competitors pursuing cancer immunotherapies and / or vaccines for infectious diseases include, but not limited to ~~Jansen Pharmaceuticals~~ **Merus N. V., F- Star Therapeutics, Johnson & Johnson Innovative Medicine** (part of ~~J~~ **Johnson** & ~~J~~ **Johnson**), Sanofi- Aventis, GlaxoSmithKline plc, Merck and Pfizer, Inovio, ~~Advaxis,~~ Kite Pharma, Hookipa, Moderna, ZIOPHARM Oncology, Heat Biologics, Harpoon Therapeutics ~~, Oncosec Medical~~ , BioNTech, Osivax, Medicago, Vaxart, and Flugen. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). If one or more of these companies is successful in developing their technologies, it could materially impact our business. We also experience competition in the development of our immunotherapies from universities and other research institutions and ~~competes~~ **compete** with others in acquiring technology from such universities and institutions. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than PDS0101 **, PDS01ADC** or our other Versamune ® and Infectimune ® based products. We will face competition from other drugs currently approved or that will be approved in the future for the treatment of the other cancers and infectious diseases we are currently targeting. Therefore, our ability to compete successfully will depend largely on our ability to: ● develop and commercialize immunotherapies that are superior to other alternatives in the market; ● demonstrate through our clinical trials that PDS0101 **alone or in combination with PDS01ADC** is differentiated from existing and future therapies; ● attract qualified scientific, immunotherapy development and commercial personnel; ● obtain additional patent or other proprietary protection for PDS0101 **, PDS01ADC** and other Versamune ® and Infectimune ® - based products; ● obtain required regulatory approvals; ● obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third- party payors; and ● successfully develop and commercialize, independently or with collaborators, new applications for PDS0101 **, PDS01ADC** or immunotherapies. IndexThe availability of our competitors' immunotherapies and other treatments could limit the demand, and the price we are able to charge, for PDS0101 **alone or in combination with PDS01ADC** . The inability to compete with existing or subsequently introduced immunotherapies and other treatments would have an adverse impact on our business, financial condition and prospects. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to license novel compounds that could make PDS0101 **and PDS01ADC** less competitive. In addition, any new immunotherapy that competes with an approved treatment 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, discovering, developing, receiving the FDA' s approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations. PDS0101 **and PDS01ADC** may cause adverse effects or have other properties that could delay or prevent its regulatory approval or limit the scope of any approved label or market acceptance. Adverse events caused by PDS0101 **or PDS01ADC** could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If clinical trials for PDS0101 **and PDS01ADC** report an unacceptable frequency or severity of adverse events, our ability to obtain regulatory approval for PDS0101 **and PDS01ADC** may be negatively impacted. Furthermore, if PDS0101 **alone or in combination with PDS01ADC** is approved and then causes serious or unexpected side effects, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw their approval of PDS0101 **or PDS01ADC** or impose restrictions on its distribution or other risk management measures; ● regulatory authorities may require the addition of labeling statements, such as warnings or contraindications; ● we may be required to change the way PDS0101 **or PDS01ADC** is administered or to conduct additional clinical trials; ● we could be sued and held liable for injuries sustained by patients; ● we could elect to discontinue the sale of PDS0101 **or PDS01ADC** ; ● our entire Versamune ® and Infectimune ® - based pipeline could be then put at risk; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of PDS0101 and **PDS01ADC and** could substantially increase the costs of commercialization. In addition, if any of our product candidates are associated with adverse events or undesirable side effects or have properties that are unexpected, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. We, or any future collaborators, may abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. Drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, results of operations, financial condition and prospects significantly. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, PDS0101 **and PDS01ADC** , and our ability to generate revenue will be impaired. PDS0101 and **PDS01ADC and** the activities associated with ~~its~~ **their** development and commercialization, including ~~its~~ **their** design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for PDS0101 **alone or in combination with PDS01ADC** will prevent us from commercializing ~~PDS0101~~ **our products** . We have not received approval to market PDS0101 **or PDS01ADC** from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the

applications necessary to gain marketing approvals and expect to rely on ~~CROs~~ **contract research organizations** to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the safety and efficacy of PDS0101 **and PDS01ADC** . Securing regulatory approval also requires the submission of information about the product manufacturing process ~~to~~ , and inspection of manufacturing facilities by, the relevant regulatory authority. PDS0101 **and PDS01ADC** 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 it from obtaining marketing approval or prevent or limit commercial use. IndexThe process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of PDS0101 **and PDS01ADC** . Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any future collaborators, to market the drug could be compromised. Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives marketing approval and we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw their approval of the drug or seize the drug; ● we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials; ● additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug; ● we may be subject to fines, injunctions or the imposition of civil or criminal penalties; ● regulatory authorities may require the addition of labeling statements, such as a " black box " warning or a contraindication; ● we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients; ● we, or any future collaborators, could be sued and held liable for harm caused to patients; ● the drug may become less competitive in the marketplace; and ● our reputation may suffer. Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price. We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects. There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow- up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, certain of our scientific advisors or consultants who receive compensation from us are clinical trial investigators for our clinical trial. Although we believe our existing relationships are within the FDA' s guidelines, if these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA. Any such delay or rejection could prevent us from commercializing PDS0101 **, PDS01ADC** or any other product candidates. IndexEven if we obtain FDA approval in the United States, we may never obtain approval for or commercialize PDS0101 **or PDS01ADC** in any other jurisdiction, which would limit our ability to realize each product' s full market potential. In order to market PDS0101 **or PDS01ADC** in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials that could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of PDS0101 **or PDS01ADC** in those countries. PDS0101 **or PDS01ADC** is not approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international

markets are delayed, our target market will be reduced. Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more subject data ~~become~~ **becomes** available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, topline or preliminary data from our sponsored or investigator initiated clinical trials, such as preliminary topline results which are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. In addition, we may report preliminary analyses of only certain endpoints rather than all endpoints. As a result, the interim, topline or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data ~~have~~ **has** been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data ~~are~~ **is** available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data ~~become~~ **becomes** available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim, topline or preliminary data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular drug candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular program, drug candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to pursue strategic alternatives, including identifying and consummating transactions with third- party partners, to further develop, obtain marketing approval for and / or commercialize our drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition. ~~IndexThe~~ **The** outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim results of a clinical trial do not necessarily predict final results, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities. We currently have no drugs approved for sale and we cannot guarantee that we will ever have marketable drugs. 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 preclinical studies. We will be required to demonstrate with substantial evidence through adequate and well- controlled clinical trials that our product candidates are safe and effective for use in treating specific conditions in order to obtain 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 because product candidates in later- stage clinical trials may fail to demonstrate safety and efficacy to the satisfaction of the FDA and non- U. S. regulatory authorities despite having progressed through preclinical studies and early- stage clinical trials. Product candidates that have shown promising results in preclinical studies and early- stage clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Additionally, the outcome of preclinical studies and early- stage clinical trials may not be predictive of the success of later- stage clinical trials. ~~In~~ **IndexIn** addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and conduct a clinical trial to support marketing approval. Further, if our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain marketing approval for them and our business would be harmed. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in preclinical studies and earlier clinical trials. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. In addition, in the event that an adverse safety issue, clinical hold, or other adverse finding occurs in one of our clinical trials, that event could adversely affect any other clinical trials for the same product candidate. An adverse safety issue or other adverse finding in a clinical trial conducted by a third party with a similar mechanism of action could adversely affect clinical trials involving our product candidates. Further, our product candidates may not be approved even if they achieve their primary endpoints in clinical trials, including registration trials. The FDA or comparable foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or comparable foreign regulatory authorities. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post- marketing clinical trials. In addition, the FDA or other comparable foreign regulatory

authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates. Before obtaining marketing approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and adequate and well- controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA and elsewhere to the satisfaction of other comparable foreign regulatory authorities, that the product candidate is safe and effective for use for that target indication. There is no assurance that the FDA or other comparable foreign regulatory authorities will consider our future clinical trials to be sufficient to serve as the basis for approval of one of our product candidates for any indication. The FDA and other comparable foreign regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that a product candidate is safe and effective. If we are required to conduct ~~additional~~ **more** clinical trials of a product candidate than we expect prior to its approval, we will need substantial additional funds and there is no assurance that the results of any such additional clinical trials will be sufficient for approval. ~~IndexOur~~ **Our** product candidates are in various stages of development and we will not be able to commercialize our product candidates if our preclinical studies do not produce successful results and / or our clinical trials do not demonstrate the safety and efficacy of our product candidates; early results and early understanding of product candidate potential may not be predictive of later success. Our oncology and infectious disease product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies, preliminary study results, and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Our product candidates may not perform as we expect, may ultimately have a different or no impact than expected, may have a different mechanism of action than we initially understand or that we expect in humans, and may not ultimately prove to be safe and effective. Preliminary and final results from preclinical studies and early- stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer- term studies. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of a clinical trial, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage. ~~We~~ **IndexWe** may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. There may be emerging new data or regulatory questions or disagreements regarding interpretations of data and results at any stage. For example, the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate' s benefits do not outweigh its safety risks. Even if we obtain regulatory approval, we will still face extensive ongoing regulatory requirements **,** and PDS0101 **, PDS01ADC** and other candidates may face future development and regulatory difficulties. Marketing of PDS0101 **alone or in combination with PDS01ADC** , if approved, along with the manufacturing processes, post- approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for PDS0101, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post- marketing information and reports, establishment **of** registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current Good Clinical Practice, or cGCP requirements for any clinical trials that we conduct post- approval. Even if marketing approval of PDS0101 **or PDS01ADC** is granted, the approval may be subject to limitations on the indicated uses for which PDS0101 may be marketed or to the conditions of approval. If PDS0101 **or PDS01ADC** receives marketing approval, an accompanying label may limit the approved use of ~~PDS0101~~ **the product (s)** , which could limit sales. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety and / or efficacy of PDS0101 **and PDS01ADC** . The FDA closely regulates the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use and if we promote or otherwise market PDS0101 **or PDS01ADC** for indications other than those for which it is approved, we may be subject to certain enforcement actions. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription biopharmaceutical products may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. ~~IndexIn~~ **In** addition, later discovery of previously unknown adverse events or other problems with PDS0101, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: ● restrictions on manufacturing PDS0101 **or PDS01ADC** ; ● restrictions on the labeling or marketing of PDS0101 **or PDS01ADC** ; ● restrictions on **distribution or use of** PDS0101 ~~distribution~~ or ~~use~~ **PDS01ADC** ; ● requirements to conduct post- marketing studies or clinical trials; ● suspension of any of our ongoing clinical trials; ● warning letters; ● withdrawal of PDS0101 **or PDS01ADC** from the market; ● refusal to approve pending applications or supplements to approved applications that we

submit; ● recalls of PDS0101 **or PDS01ADC** ; ● fines, restitution or disgorgement of profits or revenues; ● suspension or withdrawal of marketing approvals; ● refusal to permit the import or export of PDS0101 **or PDS01ADC** ; ● seizures of PDS0101 **or PDS01ADC** ; or ● injunctions or the imposition of civil or criminal penalties. ~~Any~~ **IndexAny** government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. The regulatory requirements and policies may change, and additional government regulations may be enacted for which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we or any future collaboration partner are not able to maintain regulatory compliance, we or such collaboration partner, as applicable, may face government enforcement action and our business will suffer. Moreover, our or our future collaborators' ability to market any future drugs could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition. ~~IndexEven~~ **Even** if PDS0101 **or PDS01ADC** receives licensure, it may fail to achieve market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success. If PDS0101 **alone or in combination with PDS01ADC** receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If PDS0101 **or PDS01ADC** does not achieve an adequate level of acceptance, we may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to: ● the efficacy and potential advantages compared to alternative treatments; ● effectiveness of sales and marketing efforts; ● the cost of treatment in relation to alternative treatments; ● our ability to offer PDS0101 **or PDS01ADC** for sale at competitive prices; ● the convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the willingness of the medical community to offer customers PDS0101 **or PDS01ADC** in addition to or in the place of other immunotherapies; ● the strength of marketing and distribution support; ● the availability of third- party coverage and adequate reimbursement; ● whether the product is designated under physician and other provided treatment guidelines as a first, second, or third line therapy; ● the prevalence and severity of any side effects; and ● any restrictions on the use of PDS0101 **or PDS01ADC** together with other medications. Because we expect sales of PDS0101 **alone or in combination with PDS01ADC** , if approved, to generate substantially all of our revenues for the foreseeable future, the failure of PDS0101 **or PDS01ADC** to achieve market acceptance would harm our business and could require us to seek additional financing sooner than we otherwise plan. ~~We~~ **IndexWe** may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we are initially developing our ~~lead~~ product ~~candidate~~ **candidates** ~~,~~ PDS0101 **, PDS01ADC** and the other Versamune and Infectimune based products. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. ~~IndexIf~~ **If** we fail to comply with federal and state healthcare regulatory laws, including in our relationships with healthcare providers and customers and third- party payors, we could face criminal prosecution and sanctions, substantial civil penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, and the curtailment of our operations, any of which could harm our business. Although we do not provide healthcare services or submit claims for third-party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact our business, particularly if and when we commercialize any product candidates and if and when payment becomes available from payors for our products. Additionally, our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our medicines for which we obtain marketing approval. The laws that may affect our ability to operate include, but are not limited to: The Federal Anti- Kickback Statute (AKS), which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. The Affordable Care Act, among other things, amended the intent requirements of the federal AKS. A person or entity can now be found guilty of violating the AKS without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the FCA. The False Claims Act' s civil provisions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third- party payors that are false or fraudulent; knowingly making **,** using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government.

Intent to deceive is not required to establish liability under the civil False Claims Act. The False Claims Act' s criminal provisions, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, prohibits, among other actions, executing or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. HIPAA, as amended by the HITECH Act, and its respective implementing regulations, now makes HIPAA' s privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. ~~Section~~ **IndexSection** 5 (a) of the Federal Trade Commission Act, or the FTCA, 15 USC § 45 (a), given that even for entities that are not deemed " covered entities " or " business associates " under HIPAA, according to the United States Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of its laws. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC' s guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. The federal " Sunshine " and " Open Payments " requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or collectively, the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U. S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $ 150, 000 per year and up to an aggregate of $ 1 million per year for " knowing failures. " In 2022 the Sunshine Act was extended to payments and transfers of value to physician assistants, nurse practitioners, and other mid- level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021). In addition, Section 6004 of the ACA requires annual reporting of information about drug samples that manufacturers and authorized distributors provide to healthcare providers. ~~IndexState~~ **State** law equivalents of each of the above federal laws and state laws otherwise addressing the pharmaceutical and healthcare industries, such as anti- kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including commercial insurers, and in some cases that may apply regardless of payor, i. e., even if reimbursement is not available; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines (the PhRMA Code) and the relevant compliance program guidance promulgated by the federal government (HHS- OIG), or otherwise prohibit, restrict or impose tracking and disclosure requirements related to payments, gifts, or others remuneration that may be made to healthcare providers and other potential referral sources, or marketing practices to such persons and entities or drug pricing information; data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018) and state laws governing the privacy and security of information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and may apply more broadly than HIPAA, thus complicating compliance efforts. In our business, healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of our product candidates, if approved for marketing. Moreover, while we do not plan to submit claims and our customers will make the ultimate decision on how to submit claims, from time to time, we may provide reimbursement guidance to our customers. Current or future arrangements with physicians and other healthcare providers and customers, and third- party payors, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our medicines for which we obtain marketing approval. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement or failed to comply with government price reporting requirements, or engaged in off- label promotion of products, we could face action by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition. We have entered into consulting and employment arrangements with individuals, physicians and other healthcare providers. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far- reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who serve as clinical investigators in our clinical trials, or influence the ordering of and use our products to be in violation of applicable laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Additionally, as a result of these

investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. ~~Even~~ **IndexEven** if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations, third- party coverage and reimbursement policies or healthcare reform initiatives, which could harm our business. The regulations that govern marketing approval, pricing, coverage and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. ~~IndexOur~~ **Our** ability to commercialize any products successfully also will depend in part on the extent to which reimbursement and coverage for these products and related treatments will be available from government authorities, private health insurers and other organizations, and if reimbursement and coverage is available, the level of reimbursement and coverage. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the healthcare industry in the United States and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, the third- party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for medical products. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if coverage and reimbursement are available, we cannot be sure as to the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be reimbursed 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, may be incorporated into existing payments for other items or services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for new products that we develop and for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of PDS0101 **and PDS01ADC** . We face an inherent risk of product liability exposure related to the testing of PDS0101 **alone or in combination with PDS01ADC** in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop after approval. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for PDS0101 **, PDS01ADC** or other immunotherapies that we may develop; ● injury to our reputation and significant negative media attention; ● withdrawal of clinical trial participants; ● significant costs to defend any related litigation; ● substantial monetary awards to trial subjects or patients; ● loss of revenue; and ● the inability to commercialize any products we may develop. Although we maintain product liability insurance coverage in the amount of up to $ 10 million per claim and $ 10 million in the aggregate, it may not be adequate to cover all liabilities that it may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. IndexIf we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing PDS0101 **, PDS01ADC** and other product candidates, if approved. We do not have any infrastructure for the sales, marketing or distribution of PDS0101 **, PDS01ADC** or other product candidates, and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. In order to market PDS0101 **, PDS01ADC** or other product candidates, we must build our sales, distribution, marketing, managerial and other non- technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for PDS0101 **, PDS01ADC** or other product candidates, we will need either our own, or a third party' s, sales and marketing organization. There are significant expenses and risks involved with creating teams for, or contracting for, sales, marketing and distribution capabilities. Any failure or delay in the development of our sales, marketing and distribution capabilities, either internally or in collaboration with third parties, could delay the launch of PDS0101 **, PDS01ADC** or other product candidates, which would adversely affect commercialization. We may be competing with many companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third- party to perform marketing and sales functions, we may be unable to compete successfully against these more established

companies. If we obtain approval to commercialize PDS0101 **, PDS01ADC** or other product candidates outside of the United States, a variety of risks associated with international operations could harm our business. If PDS0101 **, PDS01ADC** or other product candidates is approved for commercialization, we may enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including: ● different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries; ● reduced protection for intellectual property rights; ● unexpected changes in tariffs, trade barriers and regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● foreign reimbursement, pricing and insurance regimes; ● foreign taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● potential noncompliance with the U. S. Foreign Corrupt Practices Act, the U. K. Bribery Act 2010 and similar anti- bribery and anticorruption laws in other jurisdictions; ● shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires. We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply. IndexRecently enacted and future healthcare legislation, regulations, and policy initiatives may increase the difficulty and cost for us to obtain marketing approval of and commercialize PDS0101 **, PDS01ADC** or other product candidates and affect the prices we may obtain and our profitability. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of PDS0101 **alone or in combination with PDS01ADC** and our other product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell PDS0101 **, PDS01ADC** and other product candidates. For example, in March 2010, the Affordable Care Act, or ACA, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to **the** ACA brought by several states without specifically ruling on the constitutionality of the Act. Prior to the Supreme Court' s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact health care laws and regulations or our business. As another example, the Drug Supply Chain Security Act imposes obligations on manufacturers of prescription biopharmaceuticals in finished dosage forms for commercial distribution. We have not yet adopted the significant measures that will be required to comply with this law. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for immunotherapies, which could result in reduced demand for PDS0101 and other product candidates or additional pricing pressures. Risks Related to Our Dependence on Third PartiesWe currently have agreements with various third- party manufacturing facilities for production of our products for research and development and testing purposes. We depend on third- party manufacturers to supply our preclinical and clinical materials and will be reliant on a third- party manufacturer to produce PDS0101 **or PDS01ADC** on a commercial scale, should that product receive regulatory approval. Third- party manufacturers must be able to meet our deadlines and adhere to quality standards and specifications. Our predominant reliance on third parties for the manufacture of PDS0101 **, PDS01ADC** and all of our Versamune ® and Infectimune ® based products creates a dependency that could severely disrupt our research and development, clinical testing, and sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. There is no assurance that any third- party manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or cGMP. We expect to rely on third- party manufacturers or third- party collaborators for the manufacture of our product candidates for commercial supply of any of our product candidates for which we or any of our future collaborators obtain marketing approval. We may be unable to establish any agreements with third- party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: ● the possible failure of the third party to manufacture our product candidate according to our schedule, or at all, including if our third- party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them; ● the possible termination or nonrenewal of agreements by our third- party contractors at a time that is costly or inconvenient for us; ● the possible breach by the third- party contractors of our agreements with them; ● the failure of third- party contractors to comply with applicable regulatory requirements; ● the possible failure of the third party to manufacture our product candidates according to our specifications ~~; ● the impact of COVID- 19 on the facilities of our manufacturers and their supply lines~~ ; ● the possible mislabeling of clinical supplies, potentially resulting in issues including the wrong dose amounts being supplied or active drug or placebo not being properly identified; ● the possibility of clinical supplies

not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and ● the possible misappropriation of our proprietary information, including our trade secrets and know- how. IndexThe facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or the EMA pursuant to inspections that will be conducted after we submit our BLA to the FDA or our MAA to the EMA. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory bodies, they will not be able to secure and / or maintain marketing approval for their manufacturing facilities. In addition, we do not have complete control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, the EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations. Any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply of the components of our product candidates. If our current contract manufacturer cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis. We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. We intend to rely upon CROs to monitor and manage data for our clinical programs. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for our products. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process. Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize PDS0101 **alone or in combination with PDS01ADC** . As a result, our financial results and the commercial prospects for PDS0101 **and PDS01ADC** would be harmed, our costs could increase, and our ability to generate revenues could be delayed. IndexIf our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. Our strategy may include potential reliance upon strategic collaborations for marketing and commercialization of PDS0101 and other Versamune **®** , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune **®** Products. We also rely on strategic collaborations for research, development, marketing and commercialization for PDS0101 and other Versamune **®** Products. We have also been heavily reliant upon third **-** party outsourcing for our clinical trials execution and production of drug supplies for use in clinical trials. Establishing strategic collaborations is difficult and time- consuming. Our discussions

with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for PDS0101 and other Versamune ® and Versamune ~~plus PDS0301~~ ® **in combination with PDS01ADC** Products, the costs and complexities of manufacturing and delivering PDS0101 and other Versamune ® and Versamune ~~plus PDS0301~~ ® **in combination with PDS01ADC** Products to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative immunotherapies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for PDS0101 and other Versamune ® and Versamune ~~plus PDS0301~~ ® **in combination with PDS01ADC** Products. Our current collaborations, as well as any future new collaborations, may never result in the successful development or commercialization of PDS0101 and other Versamune ® , Versamune ~~plus PDS0301~~ ® **in combination with PDS01ADC** and Infectimune ® Products or the generation of sales revenue. To the extent that we have entered or will enter into co- promotion or other collaborative arrangements, PDS0101 and other Versamune ® and Versamune ~~plus PDS0301~~ ® **in combination with PDS01ADC** Products revenues are likely to be lower than if we directly marketed and sold any products that we develop. Management of our relationships with our collaborators will require: ● significant time and effort from our management team; ● financial funding to support said collaboration; ● coordination of our research and development programs with the research and development priorities of our collaborators; and ● effective allocation of our resources to multiple projects. If we continue to enter into research and development collaborations, our success will in part depend on the performance of our collaborators. We will not directly control the amount or timing of resources devoted by our collaborators to activities related to PDS0101 and other Versamune ® and Versamune ~~plus PDS0301~~ ® **in combination with PDS01ADC** Products. Our collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of PDS0101 and other Versamune ® and Versamune ~~plus PDS0301~~ ® **in combination with PDS01ADC** Products. If any collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development- stage products or alternative technologies in preference to those being developed in collaboration with us. If we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements. Additionally, our collaborators may seek to renegotiate agreements we have entered into, or may disagree with us about the terms and implementation of these agreements. If collaborators disagree with us about the terms or implementation of our agreements, we may face legal claims that may involve considerable expense and could negatively affect our financial results. IndexWe enter into various contracts in the normal course of our business in which we agree to indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations. In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically agree to indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sub licensees' exercise of rights under the agreement. With respect to our commercial agreements, we have agreed to indemnify our vendors from any third- party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we typically agree to indemnify them from claims arising from the good faith performance of their services. Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage or not covered by insurance, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator or other third party to indemnify us and the collaborator or other third party is denied insurance coverage or otherwise does not have assets available to indemnify us, our business, financial condition and results of operations could be adversely affected. The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business. We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products and manage certain parts of our business. Using these third parties poses a number of risks, such as: ● they may not perform to our standards or legal requirements; ● they may not produce reliable results; ● they may not perform in a timely manner; ● they may not maintain confidentiality of our proprietary information; ● disputes may arise with respect to ownership of rights to technology developed with our partners, and those disputes may be resolved against us; and ● disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country- specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, legal and other obligations may materially affect our business. Our business could be adversely affected by the effects of health epidemics, pandemics, or outbreaks of infectious diseases ~~, including the recent COVID- 19 pandemic,~~ in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations ~~. The COVID- 19 pandemic could materially affect our operations, including at our headquarters in New Jersey, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business~~ . Our business could

be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations and could cause significant disruption in the operations of third- party manufacturers and CROs upon whom we rely. ~~IndexAs~~ **As** a result of ~~the COVID- 19 outbreak, or similar~~ pandemics, and related " shelter in place " orders and other public health guidance measures, we have and may in the future experience disruptions that materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to: ● delays or difficulties in enrolling patients in our clinical trials; ● delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff ~~;● increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID- 19 or other health conditions or being forced to quarantine~~ ; ● diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; ● interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints; ● interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; ● delays or disruptions in preclinical experiments and investigational new drug application- enabling studies due to restrictions of on- site staff and unforeseen circumstances at contract research organizations and vendors; ● interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; ● limitations on our ability to recruit and hire key personnel due to our inability to meet with candidates because of travel restrictions and " shelter in place " orders; ● limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and ● interruption or delays to our sourced discovery and clinical activities. ~~Risks~~ **IndexRisks** Related to Our Intellectual PropertyIf we are unable to obtain and / or maintain patent protection for our Versamune ® , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** platforms, PDS0101, ~~or~~ other Versamune ® based Products **or Infectimune ®,** or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to Versamune **® and Infectimune ®** . Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to Versamune ® , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® based products. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or license may fail to result in issued patents with claims that cover Versamune ® , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® based products or applications in the United States or in other countries. There is no assurance that all potentially relevant prior art relating **to inventions** , which can invalidate a patent or prevent a patent from issuing from a pending patent application **,** is known to us. Even if patents **are** ~~do successfully issue~~ **issued to us** , third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of PDS0101 and other Versamune ® , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® based products that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could exclusively market PDS0101 and other Versamune ® , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® based products under patent protection could be reduced. ~~IndexThe~~ **The** patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect PDS0101 or other Versamune ® , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® based products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and immunotherapies. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Recent Russian Federal Law, No. 46- FZ of March 8, 2022, allows the Russian Government to designate goods for which IP rights are exempted and this rule applies to all IP rights, including trademarks **,** and this rule may affect our IP in the Russian Federation. There is no guidance on how broadly this rule will be applied, though the rule appears to be limited only to the year 2022. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the U. S. Patent Office, or become involved in derivation, reexamination, inter parties review, post- grant review or interference proceedings challenging its patent rights or the patent rights of others. In other countries, we may be subject to or become involved in opposition proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize

our technology or immunotherapies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize PDS0101 without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize PDS0101 and other Versamune ®, Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® based products. The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and immunotherapies, or limit the duration of the patent protection of our technology and immunotherapies. Moreover, patents have a limited lifespan. In the United States and other countries, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for PDS0101 and other Versamune ®, Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® based products, we may be open to competition from generic versions of PDS0101 or other similar products using our technology. Given the amount of time required for the development, testing and regulatory review of new immunotherapy candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing immunotherapies similar or identical to ours. ~~We~~ **IndexWe** may have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world. We may have limited intellectual property rights outside the U. S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U. S. can be less extensive than those in the U. S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions in and into the U. S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U. S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. ~~IndexWe~~ **We** may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, or defend our products and methods against the property rights of others, which could be expensive, time consuming and unsuccessful. Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that such patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third- party may also cause the third- party to bring counter claims against us, such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent **,** withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post- grant proceedings such as inter partes review, or post- grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third- party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on PDS0101 and other Versamune ®, Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune ® based products. Such a loss of patent protection could harm our business. We may also face claims that our products infringe patents that our competitors hold. Claims for alleged infringement and any resulting lawsuit, if successful, could subject us to significant liability for damages and invalidations of our proprietary rights. Any such lawsuit, regardless of our success, would likely be time consuming and expensive to resolve and would divert management time and attention. Any potential intellectual property litigation could also force us to do one or more of the

following: (a) stop selling our products; (b) obtain a license (s), from the owner of any asserted intellectual property, to sell or use the relevant technology, which license may not be available on reasonable terms, or at all; or (c) redesign our products to avoid using the relevant technology. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock. ~~Changes~~ **IndexChanges** in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. Patent reform legislation in the United States and in other jurisdictions could increase those uncertainties and costs. The United States has enacted and implemented wide- ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. ~~IndexWe~~ **We** may not be able to protect our intellectual property rights throughout the world, which could impair our business. Filing, prosecuting and defending patents covering Versamune **®** , Versamune ~~plus PDS0301~~ **® in combination with PDS01ADC** and Infectimune **®** based products throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own immunotherapies and, further, may export otherwise infringing immunotherapies to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These immunotherapies may compete with PDS0101 in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our ability to pursue strategic alternatives, including identifying and consummating transactions with potential third- party partners, to further develop, obtain marketing approval for and / or commercialize our drug candidates, and consequently our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We seek to protect our proprietary technology in part by entering into confidentiality agreements with third parties and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third- party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties and our employees and contractors. In addition, we employ or may employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against or pursue these claims. Even if we are successful in resolving these claims, litigation could result in substantial cost and be a distraction to our management and employees. IndexGeneral Market Risk FactorsThe market price of our common stock may be subject to significant fluctuations in the future. Market prices for securities of early- stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include: ● the ability of us and our partners to develop product candidates and conduct clinical trials that demonstrate such product candidates are safe and

effective; ● the ability of us or our partners to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals; ● failure of any of our product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success; ● failure by us to maintain our existing third- party license, manufacturing and supply agreements ~~;~~ ~~● impact of COVID- 19 and its variants on business operations and clinical trials~~ ; ● failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights; ● changes in laws or regulations applicable to our product candidates; ● any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices; ● adverse regulatory authority decisions; ● introduction of new or competing products by our competitors; ● failure to meet or exceed financial and development projections we may provide to the public; ● the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; ● announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors; ● disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies; ● additions or departures of key personnel; ● significant lawsuits, including intellectual property or stockholder litigation; ● if securities or industry analysts do not publish research or reports about us, or if they issue ~~an~~ adverse or misleading opinions regarding our business and stock; ● if large short positions are taken in our stock and or negative reports are provided, whether they are based in fact or otherwise; ● changes in the market valuations of similar companies; ● general market or macroeconomic conditions; ● sales of our common stock by us or our stockholders in the future; ● trading volume of our common stock; ● adverse publicity relating to our markets generally, including with respect to other products and potential products in such markets; ● changes in the structure of health care payment systems; and ● period- to- period fluctuations in our financial results. IndexMoreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. We are required to meet the Nasdaq Capital Market' s continued listing requirements and other Nasdaq rules, and if we fail to meet such rules and requirements, we may be subject to delisting. Delisting could negatively affect the price of our common stock, which could make it more difficult for us to sell securities in a future financing or for you to sell our common stock. We are required to meet the continued listing requirements of the Nasdaq Capital Market and other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed common stock of $ 1. 00 per share. If we do not meet these continued listing requirements, our common stock could be delisted. Delisting from the Nasdaq Capital Market would cause us to pursue eligibility for trading of these securities on other markets or exchanges, including the **over- the- counter (** OTC **)** BB or QB markets, or on the OTC " pink sheets. " In such case, our stockholders' ability to trade, or obtain quotations of the market value of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of our securities. There can be no assurance that our securities, if delisted from the Nasdaq Capital Market in the future, would be listed on a national securities exchange, a national quotation service, the OTC markets or the pink sheets. Delisting from the Nasdaq Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, cause us to lose eligibility to register the sale or resale of our shares on Form S- 3 and the automatic exemption from registration under state securities laws for exchange- listed securities, adversely affect the market liquidity of our securities, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence. We do not anticipate that we will pay any cash dividends in the foreseeable future. We currently expect to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our company will be the sole source of our stockholders' gain, if any, for the foreseeable future. Future sales of shares by existing stockholders could cause our stock price to decline. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after certain legal restrictions on resale lapse, the trading price of our common stock could decline. As of December 31, ~~2022~~ **2023** , we had ~~30~~ **33** , ~~170~~ **094** , ~~317~~ **521** shares of common stock outstanding. Approximately ~~28~~ **31** , ~~794~~ **708** , ~~124~~ **392** of such shares are freely tradable, without restriction, in the public market. Approximately 1, ~~376~~ **383** , ~~193~~ **670** of such shares of common stock are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements. Because the Merger resulted in an ownership change under Section 382 of the Code for Edge, pre- merger U. S. net operating loss carryforwards and certain other tax attributes will be subject to limitations. On March 15, 2019, we, then operating as Edge Therapeutics, Inc., or Edge, completed a reverse merger with privately held PDS Biotechnology Corporation, or Private PDS, pursuant to and in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of November 23, 2018, as amended on January 24, 2019, by and among us, Echos Merger Sub, a wholly- owned subsidiary of Edge, or Merger Sub, and Private PDS, whereby Private PDS merged with and into Merger Sub, with Private PDS surviving as our wholly- owned subsidiary, which we refer to as the Merger. In connection with and immediately following completion of the Merger, we changed our corporate name from Edge Therapeutics, Inc. to PDS Biotechnology Corporation, and Private PDS changed its name to PDS Operating Corporation. As of December 31, 2018, prior to completion of the Merger, Edge had federal and state net operating loss carryforwards, or NOLs, of $ 128. 6 million and $ 27. 1 million, respectively, due to prior period losses. If a corporation undergoes an " ownership change " within the meaning of Section 382 of the Code, the corporation' s U. S. net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation' s equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three- year period.

Similar rules may apply under state and foreign tax laws. We believe that Edge may have already undergone one or more ownership changes prior to the Merger. However, the Merger also resulted in an ownership change for Edge and, accordingly, Edge' s U. S. net operating loss carryforwards and certain other tax attributes available to us are subject to limitations on their use. IndexOur effective tax rate may increase in the future, including as a result of tax legislation changes, which may have a material adverse effect on our business, financial condition and results of operations. Our effective tax rate may be impacted by changes in or interpretations of tax laws in the United States or in any given jurisdiction in which we operate, utilization of or limitations on our ability to utilize any tax credit carry- forwards, changes in geographical allocation of revenue and expense and changes in management' s assessment of matters such as our ability to realize the value of deferred tax assets. In particular, the U. S. government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income, significant changes to the taxation of income derived from international operations, and an addition of further limitations on the deductibility of business interest. While certain draft legislation has been publicly released and is under development in Congress at this time, the likelihood of these changes being enacted or implemented is unclear. Our effective tax rate could also increase due to several factors, including: ● changes in tax rates, tax treaties, and regulations or the interpretation of them; ● changes to our assessment about our ability to realize deferred tax assets that are based on estimates of our future results, the prudence and feasibility of possible tax planning strategies, and the economic and political environments in which we do business; ● the outcome of any future tax audits, examinations, or administrative appeals; and ● the effects of any acquisitions. There can be no assurance that our effective income tax rate will not change in future periods. Accordingly, if our effective tax rate were to increase, it may have a material adverse effect on our business, financial condition and results of operations. Anti- takeover provisions under Delaware law could make an acquisition more difficult and may prevent attempts by our stockholders to replace or remove our current or future management. Because we are incorporated in Delaware, our company is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15 % of our voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management. Our eighth amended and restated certificate of incorporation, as amended, provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum, to the fullest extent permitted by law, for: (a) any derivative action or proceeding brought on our behalf; (b) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (c) any action asserting a claim arising pursuant to the DGCL, our eighth amended and restated certificate of incorporation, as amended, or our amended and restated bylaws; or (d) any action asserting a claim against us governed by the internal affairs doctrine. This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive- forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum of its' choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our eighth amended and restated certificate of incorporation, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees. IndexProvisions in our amended and restated bylaws could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U. S. shall be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. This provision limits the ability of our stockholders to bring claims under the Securities Act in any court other than the U. S. federal courts, which ultimately may disadvantage our stockholders or be cost prohibitive. Notwithstanding the foregoing, there is uncertainty as to whether a court (other than state courts in the State of Delaware, which have recently upheld the validity of such a provision) would enforce such a provision and whether investors can waive compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the exclusive forum provision only applies to claims brought under the Securities Act and does not apply to actions arising under the Exchange Act, which is already subject to federal courts as the exclusive forum. If a court were to find these provisions of our amended and restated bylaws 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, results of operations and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees. We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, an ongoing military conflict between Russia and Ukraine, **Israel and Hamas** and record inflation. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine, **the Middle East,** geopolitical tensions ~~,~~ or record inflation. **U. S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and**

the start of the military conflict between Russia and Ukraine. On February 24, 2022, a full- scale military invasion of Ukraine by Russian troops was reported. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which has led to record inflation globally. We are ~~exposed~~ **continuing** to **monitor inflation** ~~the risk of changes in social~~ , ~~geopolitical, legal,~~ **the situation in Ukraine** and ~~economic conditions~~ **global capital markets and assessing the potential impacts on our business** . The global economy has been, and may continue to be, negatively impacted by Russia' s invasion of Ukraine. As a result of Russia ~~'~~**'** s invasion of Ukraine, the ~~United States~~ **U. S.** , the European Union, the United Kingdom, and other G7 countries, among other countries, have imposed substantial financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on exports to Russia have also been imposed. These measures include: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia ~~'~~**'** s ability to import various goods. ~~Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit markets, as well as supply chain interruptions, which has contributed to record inflation globally. In addition, the ongoing~~ Russian military actions and the resulting sanctions could continue to adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. ~~We~~ **There** are ~~continuing to monitor inflation, the situation in Ukraine and global capital markets and assessing its potential impact on our business. Furthermore, because of~~ current geopolitical tensions **with China. Recently** , the Biden administration has ~~recently~~ signed multiple executive orders regarding China. One particular executive order titled Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy ~~,~~ signed on September 12, 2022 ~~,~~ will likely impact the pharmaceutical industry to encourage U. S. domestic manufacturing of pharmaceutical products. Any additional executive orders ~~regarding~~ or potential sanctions ~~on~~ **with** China could materially impact our **current** manufacturing partners. ~~To date~~ **In addition** , **on October 7, 2023, Hamas militants and members of other terrorist organizations infiltrated Israel' s southern border from the Gaza Strip and conducted a series of terror attacks on civilian and military targets. Thereafter, Hamas launched extensive rocket attacks on Israeli population and industrial centers located along the Israeli border within the Gaza Strip. Shortly following the attack, Israel' s security cabinet declared war against Hamas and launched an aerial bombardment of various targets within the Gaza Strip. It is possible that other terrorist organizations will join the hostilities as well, including Hezbollah in Lebanon, the Houthi in Yemen and Palestinian military organizations in the West Bank, resulting in a widening of the conflict. The intensity and duration of Israel' s current war against Hamas is difficult to predict as are such war' s economic implications on the global economy. Although** our business has not been materially impacted by the ongoing military conflict between Russian and Ukraine, **Israel and Hamas,** geopolitical tensions, or record inflation **to date** , it is impossible to predict the extent to which our operations **, or those of our suppliers and manufacturers,** will be impacted in the short and long term, or the ways in which ~~such matters~~ **the conflict** may impact our business. The extent and duration of the conflict in Ukraine, **the Middle East,** geopolitical tensions, record inflation **, sanctions** and resulting market disruptions are impossible to predict **,** but could be substantial. Any such disruptions may also magnify the impact of other risks described herein. ~~Our~~ **IndexOur** results of operations and liquidity needs could be materially affected by market fluctuations and general economic conditions. Our results of operations could be materially affected by economic conditions generally, both in the United States and elsewhere around the world. Concerns over inflation, energy costs, geopolitical issues, and the availability and cost of credit have in the past and may continue to contribute to increase volatility and diminished expectations of the economy and markets going forward. Market upheavals may have an adverse effect on us. In the event of a market downturn, our results of operations could be adversely affected. Our future cost of equity or debt capital and access to the capital markets could be adversely affected, and our stock price could decline. There may be disruption or delay in the performance of our third- party contractors and suppliers. If our contractors, suppliers and partners are unable to satisfy their contractual obligations, our business could suffer. ~~IndexAdverse~~ **Adverse** developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non- performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and

uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008- 2010 financial crisis. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by parties with whom we conduct business, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could result in material losses to us and may material adverse impacts on our business. IndexITEM 1B. Unresolved Staff Comments