Risk Factors Comparison 2025-03-13 to 2024-03-05 Form: 10-K

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

Risks Related to Our Financial Position and Need for Additional Capital We **will need additional funding in order to advance development of our product candidates and commercialize our product candidates, if approved. If we** are **unable to raise capital or secure** a ~~commercial~~ **partnership when needed, we could be forced to delay, reduce or eliminate our product development programs or any potential future commercialization efforts. Our expenses may increase in connection with our ongoing activities, particularly if and as we further SER** ~~- stage company~~ **155 clinical studies,** and **research, develop and initiate clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur costs related to product manufacturing and commercialization, including marketing, sales and distribution, and may not generate meaningful product revenues or collaboration profit in the near future. Furthermore, we** have incurred ~~significant losses since~~ **and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital** ~~our~~ **or** ~~inception~~ **secure a partnership when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any current or potential future commercialization efforts** . We ~~expect to incur losses for the foreseeable future and may never achieve or maintain profitability. Since inception, we have incurred significant operating losses. Our net loss was $ 113. 7 million for the year ended December 31, 2023, and $ 250. 2 million for the year ended December 31, 2022. As of December 31, 2023, we had an accumulated deficit of $ 978. 2 million. As noted elsewhere in this Annual Report on Form 10- K, we~~ have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. ~~To date~~ **Our future capital requirements will depend on many factors** , **including: •** ~~we have financed our operations through~~ the **cost** ~~public offerings~~ of ~~our common stock, private placements of our common stock and preferred stock, payments under our collaboration agreements, and loan facility. We have devoted substantially all of our financial resources and efforts to developing our microbiome therapeutics platform, identifying potential product candidates and~~ conducting ~~preclinical studies and~~ clinical trials ~~. We have only had one product, VOWST, which was approved~~ for ~~marketing~~ **our lead candidate, SER- 155** in **allo- HSCT and the** ~~other~~ **other targeted indications** ~~United States to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI on April 26~~ , ~~2023,~~ and ~~launched in June 2023. We have not completed development of any of our~~ other product candidates **in** ~~, which we call microbiome therapeutic candidates, or~~ **our pipeline** ~~other drugs or biologies. We expect to continue to incur significant expenses and operating losses for the foreseeable future. While we plan to focus our investment on supporting commercialization of VOWST and on our SER- 155 Phase 1b study in the near- term, our expenses may increase substantially in connection with our ongoing and future activities, particularly if and as we: • commercialize and manufacture VOWST for adult patients with recurrent CDI with our collaborator Nestlé~~ ; • ~~continue~~ the ~~clinical development~~ **total amount** of **the Second Installment Payment** ~~SER- 155 to potentially reduce incidences of gastrointestinal infections, resulting bloodstream infections,~~ and ~~GvHD in patients~~ **Milestone Payments we may** ~~receiving~~ **receive** ~~allo- HSCT~~ **from the Transaction, and the amounts payable or due under the Profit Sharing Payments** ; • **the cost of manufacturing our product candidates** ~~advance research and development activities supported by partnerships~~ ; • ~~make strategic investments in manufacturing capabilities~~ **the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates** ; • ~~maintain~~ **the costs, timing** and ~~augment~~ **outcome of regulatory review of** our **product candidates and** ~~extensive proprietary microbiome therapeutic drug development know- how that may be used to support future~~ research **activities** ~~and development efforts, including our intellectual property portfolio and intellectual property that we may opportunistically acquire~~ ; • ~~establish a~~ **the costs, timing and revenue, if any, of potential future commercialization activities, including manufacturing, marketing,** sales and distribution **, for** ~~infrastructure and scale- up manufacturing capabilities to commercialize~~ any **of our** ~~products~~ **product candidates** for which we **receive marketing** ~~have obtained and in the future may obtain regulatory~~ approval; • ~~perform~~ **the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing** our ~~obligations under our agreements with our collaborators~~ **intellectual property rights and defending any intellectual property- related claims** ; • ~~seek~~ **the effect of competing technological and market developments; and • the extent** to ~~obtain regulatory approvals~~ **which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements** for ~~our~~ product candidates ~~; and • experience any delays~~ **. Any additional fundraising efforts may divert** ~~or~~ **our management from** ~~encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other~~ **their day- regulatory challenges. To become and remain profitable, we must succeed in developing and commercializing products that generate significant revenue. This will require us** to **- day** ~~be successful in a range of challenging~~ activities, ~~including completing preclinical testing~~ **which may adversely affect our ability to develop** and **commercialize** ~~clinical trials of~~ our product candidates **. In addition** , ~~discovering~~ **we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Additionally, market volatility resulting from current macroeconomic conditions, such as the conflicts involving Ukraine and Russia and Israel and its surrounding regions, or other factors could also adversely impact our ability to access capital as and when needed. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of** additional ~~the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional~~ securities,whether equity or debt,by us,or the possibility of such issuance,may cause the market price of our shares to decline.The sale of additional equity or convertible

securities would dilute all of our stockholders and may decrease our stock price.The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants,such as limitations on our ability to incur additional debt,limitations on our ability to acquire,sell,or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.We could also be required to seek funds through arrangements with collaborators or others at an **earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or** product candidates ~~, obtaining regulatory approval for~~ **or** ~~these~~ **otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay, or discontinue one or more of our research or development programs or any** product candidates ~~and manufacturing , marketing and selling any products for~~ **or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired,** which ~~we have already obtained and may in the future obtain regulatory approval. We are in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and~~ could **materially adversely affect** ~~impair our ability to raise capital, expand~~ our business, **financial condition** ~~maintain our research~~ and **results of** ~~development and commercialization efforts, diversify our product offerings or even continue our~~ operations. We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern. Based on our currently available cash resources **, including the capital obtained from the Transaction,** and ~~our current level~~ **the expected receipt** of **the fixed Second Installment Payment, which is subject to material compliance with the TSA, and considering our future** ~~operations~~ **operating plans** and **our ongoing obligations related** ~~cash flows for the 12- month period subsequent~~ to the **Transaction** ~~date of issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10- K~~ , **we anticipate that** we will require additional funding **in** ~~prior to~~ the ~~end~~ **first quarter** of ~~2024~~ **2026** . Because the ability to obtain ~~sufficient~~ **the Second Installment Payment and** additional equity or ~~debt~~ **other** financing **, including through partnerships,** with terms favorable or acceptable to us cannot be considered probable according to the applicable accounting standards because they are outside our control, there is substantial doubt about our ability to continue as a going concern for at least 12 months from the date that our consolidated financial statements for the year ended December 31, ~~2023~~ **2024** were issued. 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. We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our audited consolidated financial statements included in this Annual Report on Form 10- K do not include any adjustments to reflect the possible inability of the Company to continue as a going concern within 12 months after the issuance of such financial statements. We ~~will need additional funding in order to complete development of our product candidates and commercialize VOWST and our product candidates, if approved. If we~~ are **a clinical** ~~unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts. Our expenses may increase in connection with our ongoing activities, particularly if and as we scale up manufacturing operations and continue the commercialization of VOWST, continue the SER-~~ **stage company** ~~155 Phase 1b study,~~ and ~~research, develop and initiate clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur costs related to product manufacturing and commercialization, including marketing, sales and distribution, and may not generate meaningful product revenues or collaboration profit in the near future. Furthermore, we~~ have incurred ~~and~~ **significant losses since our inception. We** expect to ~~continue to~~ incur ~~additional costs associated with~~ **losses for the foreseeable future and may never achieve or maintain profitability. Since inception, we have incurred significant** operating **losses** ~~as a public company~~ . **Our net loss from** ~~Accordingly, we will need to obtain substantial additional funding in connection with our~~ continuing operations **was $ 125** . ~~If we are unable to raise capital when needed~~ **8 million, $ 190. 1 million, and $ 183. 6 million** ~~or~~ **for** ~~on attractive terms~~ **the years ended December 31** , **2024** ~~we could be forced to delay~~ , ~~reduce or eliminate our research~~ **2023, and 2022, respectively. As of December 31, 2024, we had** ~~and~~ **an accumulated deficit of $ 978. 1 million** ~~development programs or any current or future commercialization efforts~~ . As noted ~~above~~ **elsewhere in this Annual Report on Form 10- K** , we have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. ~~Our~~ **To date, we have financed our operations through the public offerings of our common stock, private placements of our common stock and preferred stock, payments under our prior collaboration agreements and loan facility. We have devoted substantially all of our financial resources and efforts to developing our live biotherapeutics platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We have only developed one FDA- approved product, VOWST, which was sold to SPN in September 2024. We have not completed development of any of our other product candidates, which we call live biotherapeutic candidates, or other drugs or biologics. We expect to continue to incur significant expenses and operating losses for the foreseeable** future ~~capital requirements will depend~~ **. While we plan to focus our investment** on **continuing the development of SER- 155 and advancing our other wholly- owned cultivated live biotherapeutic candidates, our expenses** ~~many~~ **may** ~~factors~~ **increase substantially in connection with our ongoing and future activities** , ~~including~~ **particularly if and as we** : • ~~the impact of a continued~~ **continue** ~~increase~~ **the clinical**

development of SER- 155 in ~~inflation rates~~ **patients receiving allo- HSCT and** ~~or~~ **for** ~~interest rates~~ **other medically vulnerable populations** ; • **perform** ~~the progress and results of~~ our ~~clinical studies~~ **obligations under the TSA** ; • ~~the cost of~~ **advance research and development activities supported by partnerships; • make strategic investments in** manufacturing ~~VOWST~~ **capabilities; • maintain** and **augment our extensive proprietary live biotherapeutic drug development know- how that may be used to support future research and development efforts, including our intellectual property portfolio and intellectual property that we may opportunistically acquire; • establish a sales and distribution infrastructure and scale- up manufacturing capabilities to commercialize any products for which we have obtained and in the future may obtain regulatory approval; • perform our obligations under any agreements with collaborators; • seek to obtain regulatory approvals for** our product candidates; **and** • **experience any delays or encounter any issues with any of** the ~~scope~~ **above** , ~~progress~~ **including but not limited to failed studies** , **complex** results **, safety issues or other regulatory challenges. To become** and ~~costs~~ **remain profitable, we must succeed in developing and commercializing products that generate significant revenue. This will require us to be successful in a range** of **challenging activities, including completing** preclinical ~~development, laboratory~~ testing and clinical trials ~~for~~ **of** our product candidates ~~; • our share of the profits and losses from commercial sales of VOWST pursuant to the 2021 License Agreement; • the revenue~~ , **discovering additional** ~~if any, received from commercial sales of any of our~~ product candidates **, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products** for which we ~~receive marketing~~ **have already obtained and may in the future obtain regulatory** approval ~~; •~~ **. We are in** the **preliminary stages** ~~costs and timing~~ of ~~preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any~~ **many of** ~~intellectual property- related claims; • the~~ **these activities. We may never succeed in** ~~effect of competing technological and market developments; • the~~ **these activities and** ~~success of our Restructuring Plan announced in November 2023~~ , ~~which has been~~ **even if** ~~substantially implemented; and • the extent to which~~ we **do** ~~acquire or invest in businesses~~ , ~~products~~ **may never generate revenue that is significant enough to achieve profitability. Because of the numerous risks** and **uncertainties associated with pharmaceutical** ~~technologies, including entering into licensing or collaboration arrangements for~~ product candidates. Any additional fundraising efforts may..... arrangements with collaborators or others at an **and biological development** ~~earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us~~ , ~~any of which may have a material adverse effect on our business, operating results and prospects. If~~ we are unable to ~~obtain funding~~ **accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability** on a ~~timely~~ **quarterly or annual** basis **. Our failure** ~~, we may be required~~ to ~~significantly curtail, delay,~~ **become and remain profitable would depress** ~~or~~ **our** ~~discontinue one~~ **value and could impair** ~~or~~ **our** ~~more of~~ **ability to raise capital, secure a partnership, expand our business, maintain** our research ~~or~~ **and** development ~~programs or the~~ **and any potential future** commercialization ~~of VOWST~~ **efforts, diversify** ~~or~~ **our** ~~any~~ product **offerings** ~~candidates, or be unable to expand our~~ **or** ~~operations~~ **even continue** ~~or~~ **our** ~~otherwise capitalize on our business opportunities, as desired, which could materially adversely affect our business, financial condition and results of~~ operations. Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability. Since our inception in October 2010, we have devoted substantially all of our resources to developing our clinical and preclinical program, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. Other than with respect to VOWST, which was **sold to SPN** ~~approved by the FDA~~ in ~~April~~ **September** ~~2023~~ **2024** , we have not yet demonstrated our ability to obtain regulatory approvals ~~. Moreover~~ , **and** ~~with the recent approval of VOWST,~~ we have limited experience in demonstrating our ability to manufacture a commercial- scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, including for example, the impact of **the sale of** our **VOWST Business to SPN** ~~Restructuring Plan announced in November 2023 and substantially implemented by December 31, 2023~~ , many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history. **The total amount of the Second Installment Payment and Milestone Payments we may receive from the Transaction, and the amounts payable or due under the Profit Sharing Payments, are subject to various** ~~Risks~~ **risks and uncertainties. In connection with the Closing, SPN assumed certain liabilities with respect to the VOWST Business and agreed to pay to us: • a cash payment, which was paid at Closing, of $ 100 million, less approximately $ 17. 9 million owed by us to SPN under the prior license agreement between us and the SPN affiliate, less approximately CHF 2. 0 million in satisfaction of fees due under the Bacthera Agreement; • cash installment payments of $ 50 million, which was received on January 15, 2025, and $ 25 million due on July 1, 2025, or the Second Installment Payment (to be reduced by approximately $ 1. 5 million** ~~Related~~ **related** to **certain employment obligations assumed by SPN, as described below), conditioned on our material compliance with obligations under the TSA entered into at Closing between us and NESA; • prepayment of the $ 60 million Prepaid Milestone tied to the achievement of the First Sales Milestone of worldwide annual net sales of the Product of $ 150 million, which was paid in cash at Closing, which Prepaid Milestone will accrue interest at a fixed rate of 10 % per annum until the First Sales Milestone is achieved and 5 % per annum thereafter until the earlier of (x) the date on which the Prepaid Milestone, plus accrued interest thereon, has been repaid in full by set- off and (y) the last day of the Milestone Period; and • future Milestone Payments of (x) $ 125 million tied to the achievement of worldwide annual net sales of the Product of $ 400 million and (y) $ 150 million tied to the achievement of worldwide annual net sales of the Product of $ 750 million, during the Milestone Period from Closing until December 31 of the calendar year in which the tenth anniversary of Closing occurs. As** ~~the~~ **they** ~~Discovery~~ **are earned** , ~~Development and~~

~~Regulatory Approval~~ **the Milestone Payments will be satisfied as follows: (1) first, by set-** ~~of~~ **off against all accrued interest on the Prepaid Milestone, (2) second, by set- off against the outstanding balance of the Prepaid Milestone until the Prepaid Milestone has been repaid in full and (3) thereafter, in cash. If any amount of the Prepaid Milestone (and any accrued interest thereon) remains outstanding as of following the last day of the Milestone Period, the balance thereof (together with any interest accrued thereon) will be forgiven and the right of set- off of SPN with respect thereto will be deemed forfeited. The Second Installment Payment due on July 1, 2025 will be reduced by approximately $ 1. 5 million related to certain employment obligations assumed by SPN through the period prior to the Closing Date. The Second Installment Payment and the Milestone Payments are subject to various risks and uncertainties. We must be in material compliance with our obligations under the TSA in order to receive the Second Installment Payment and, if we are not or if there is a dispute as to compliance, such payment could be withheld or delayed, pending resolution. The Milestone Payments will be based on the achievement of specified worldwide net sales targets for the Product. Interest on the Prepaid Milestone will accrue and will reduce any corresponding Milestone Payments based on the length of time it takes to achieve the milestones. It is not possible to determine with precision as of the date of this Annual Report on Form 10- K the amount or timing of worldwide net sales the Product will generate in the future and, therefore, it is possible that the Milestone Payments will not be earned or will be limited by lower Product net sales than anticipated. The specified worldwide net sales targets for the Product were based on certain assumptions about the future financial performance of the Product, and there can be no assurance that such projections will be achieved or that the Milestone Payments will become payable. Further, during the Profit Sharing Period, we and SPN share 50 / 50 in the net profit or net loss achieved during the period. Amounts payable or due under the Profit Sharing Payments are uncertain and could result in financial losses or financial gains that are less than expected. We may not be able to realize the anticipated benefits of the Transaction, and we may face new challenges as a smaller, less diversified company. We may not be able to realize the anticipated benefits from the Transaction, including deploying the proceeds from the Transaction to advance SER- 155 and support our pipeline of wholly- owned cultivated live biotherapeutic candidates.** Our ~~Product Candidates~~ **ability to realize** ~~Other --~~ **the anticipated benefits of the Transaction and the success of the remaining company is subject to various risks and uncertainties, including the possibility** ~~than~~ **that** ~~VOWST,~~ we ~~are early in our development efforts of our product candidates and~~ may not be **able to** ~~successful~~ **successfully** ~~in our efforts to~~ use our **live** ~~reverse translational microbiome therapeutics~~ **biotherapeutics** platform to build a pipeline of product candidates and develop additional marketable drugs **, and the possibility that we will not be able to obtain, or experience delays in obtaining, required regulatory approvals. The Transaction resulted in the Company being a smaller, less diversified company with a more limited remaining business concentrated on SER- 155, which recently completed a Phase 1b study in patients undergoing allogeneic hematopoietic stem cell transplantation, and our other wholly- owned cultivated live biotherapeutic candidates. As a result, we may be more susceptible to changing market conditions, including fluctuations and risks particular to preclinical and clinical- stage companies, than a more diversified company, which could adversely affect our remaining business, financial condition and results of operations. In addition, the diversification of our costs and cash flows diminished following the Transaction, such that our results of operations, cash flows, working capital and financing requirements may be subject to increased volatility and our ability to fund capital expenditures and investments or satisfy other financial commitments may be diminished. We will need to secure additional funding to maintain operations beyond our current cash runway. Based on our currently available cash resources, including the capital obtained from the Transaction, and the expected receipt of the Second Installment Payment, which is subject to material compliance with the TSA, and considering our future operating plans and our ongoing obligations related to the Transaction, we anticipate that we will require additional funding in the first quarter of 2026. However, due to our smaller business size and the early stage of development of our remaining assets, there can be no assurance that we will be able to raise the required capital on favorable terms, or at all. This potential inability to obtain necessary funding could have a material adverse effect on our growth prospects, financial condition, and results of operations. We may also face new challenges with maintaining employee morale and retaining key management and other employees and retaining existing business and operational relationships, including with third parties, employees and other counterparties that otherwise prefer to transact with larger companies (or will only transact with smaller companies on less favorable terms). We have broad discretion as to the use of the proceeds from the Transaction, and may not use the proceeds effectively. We were obligated to use the proceeds from the completion of the Transaction to fully repay our indebtedness under the Oaktree Credit Agreement. We have broad discretion with respect to the use of the remaining proceeds of the Transaction, including to support the further advancement of SER- 155 and our other cultivated live biotherapeutic product candidates. The results and effectiveness of the use of proceeds are uncertain, and we could spend the proceeds in ways that do not improve our remaining business, financial condition or results of operations. Our failure to apply these funds effectively could have an adverse effect on its business, financial condition and results of operations. Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates We are early in our development efforts of certain of our product candidates and may not be successful in our efforts to use our reverse translational platform to build a pipeline of product candidates and develop additional marketable drugs** . We are using our reverse translational ~~microbiome therapeutics~~ platform to develop ~~microbiome~~ **live** ~~therapeutic~~ **biotherapeutic** candidates. **We** ~~Other than VOWST, which launched in the United States in June 2023, we~~ are at an early stage of development of our product candidates and our platform ~~has not yet, and~~ may never ~~,~~ lead to ~~other~~ approvable or marketable drugs. We are developing ~~additional~~ product candidates that **are designed** ~~we intend to develop~~ to reduce infection and treat diseases where the microbiome is implicated. We may have problems applying our technologies to these areas, and our product candidates may not be effective in reducing infection and disease. Our product candidates may not be suitable for clinical development,

including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and, if approved, achieve market acceptance. The success of our ~~product and~~ product candidates will depend on several factors, including the following: • completion of preclinical studies and clinical trials with positive results; • receipt of marketing approvals from applicable regulatory authorities; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; • making arrangements with third- party manufacturers for, or establishing our own, commercial manufacturing capabilities; • launching commercial sales of our ~~products~~ **product candidates**, if and when approved, whether alone or in collaboration with others; • entering into new collaborations throughout the development process as appropriate, from preclinical studies through to commercialization; • acceptance of ~~our products and~~ our product candidates, if and when approved, by patients, the medical community and third-party payors; • effectively competing with other therapies; • obtaining and maintaining coverage and adequate reimbursement by third- party payors, including government payors, for our ~~products~~ **product candidates**, if approved; • protecting our rights in our intellectual property portfolio; • operating without infringing or violating the valid and enforceable patents or other intellectual property of third parties; • maintaining a continued acceptable safety profile of our ~~products~~ **product candidates, if approved,** following approval; and • maintaining and growing an organization of scientists and business people who can develop and commercialize our ~~products~~ **product candidates** and technology. If we or our collaborators do not successfully develop and commercialize our ~~products or~~ product candidates we will not be able to obtain product revenue or collaboration profit in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price. **Our** ~~VOWST and our~~ product candidates are based on ~~microbiome~~ **live** ~~therapeutics~~ **biotherapeutics**, which is a novel approach to therapeutic intervention. **Our** ~~VOWST and our~~ product candidates are based on ~~microbiome~~ **live** ~~therapeutics~~ **biotherapeutics**, a novel class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non- disease state. To our knowledge, VOWST is the first oral product based on this approach to receive FDA approval. We cannot be certain that our approach will lead to the development of additional approvable or marketable products or that we will be able to manufacture at commercial scale. Finally, the FDA or other regulatory authorities may lack experience in evaluating the safety and efficacy of novel product candidates based on ~~microbiome~~ **live** ~~therapeutics~~ **biotherapeutics**, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent **any potential future** commercialization of ~~our product candidates. Our reverse translational microbiome therapeutics platform relies on third parties for biological materials, including human stool. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. For example, if any supplied biological materials are contaminated with disease organisms, we would not be able to use such biological materials. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper storage of these materials, by us or any third- party suppliers, may require us to destroy some of our materials or products, which could delay the development or commercialization of VOWST or~~ our product candidates. Clinical drug development involves a risky, lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and **potential future** commercialization of our product candidates. **It** ~~Other than VOWST, which received FDA approval in April 2023 to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, it~~ is difficult to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. 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, and our clinical trials may not be successful. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial, that we may from time to time announce, do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. In addition, we cannot be certain as to what type and how many clinical trials the FDA, or other regulatory authorities, will require us to conduct before we may successfully gain approval to market any of our product candidates. Prior to approving a new therapeutic product, the FDA (or other regulatory authorities) generally requires that safety and efficacy, or with respect to biological products such as our ~~microbiome~~ **live** ~~therapeutic~~ **biotherapeutic** candidates, safety, purity and potency, be demonstrated in two adequate and well- controlled clinical trials. In some situations, evidence from a Phase 2 trial and a Phase 3 trial or from a single Phase 3 trial can be sufficient for FDA approval, such as in cases where the trial or trials provide highly reliable and statistically strong evidence of an important clinical benefit. 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: • inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials; • regulatory authorities or institutional review boards or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • failures or delays in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • clinical trials of our product candidates may demonstrate undesirable side effects or produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product 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 may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks; • regulatory authorities or institutional review boards or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements 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; • regulatory authorities may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and • regarding trials managed by any current or future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us. 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 only modestly positive or if there are safety concerns, we may: • be delayed in obtaining marketing approval for our product candidates; • lose the support of current or any future collaborators, requiring us to bear more of the burden of development of certain compounds; • not obtain marketing approval at all; • obtain marketing approval in some countries and not in others; • obtain approval for indications or patient populations that are not as broad as we intend or desire; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; • be subject to additional post- marketing testing requirements; • be subject to increased pricing pressure; or • have the product removed from the market after obtaining marketing approval. Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. These authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators, IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Additional clinical trials or changes in our development plans could cause us to incur significant development costs, delay or prevent the **potential future** commercialization of our product candidates or otherwise adversely affect our business. In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or 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 products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. In addition, the FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted with respect to clinical trials. For instance, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi- center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state' s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR ~~foresees a three- year~~ transition period **ended on** ~~. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to~~ January 31, ~~2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31,~~ 2025 ~~. After this date~~ , **and** all clinical trials (~~including those which~~ **and related applications)** are **now fully** ~~ongoing) will become~~ subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third- party service providers, such as contract research organizations, or CROs, may impact our developments plans. It is currently unclear to what extent the ~~United Kingdom, or~~ UK ~~,~~ will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from ~~existing~~ **the now- repealed** EU ~~legislation~~ **Clinical Trials Directive** (as implemented into UK law, through ~~secondary legislation~~ **the Medicines for Human Use (Clinical Trials**) **Regulations 2004** ~~. On January 17~~ , ~~2022,~~ **as amended). The extent to which the regulation of clinical trials in** the UK **will mirror the (EU) CTR in the long term is not yet certain, however, on December 12, 2024, the UK government introduced a legislative proposal- the** Medicines ~~and Healthcare products Regulatory Agency, or~~ **for** ~~MHRA, launched an eight~~ **Human Use (Clinical Trials) Amendment Regulations 2024** ~~- week consultation on reframing~~

that, if implemented, will replace the ~~UK legislation~~ **current regulatory framework** for clinical trials ~~with~~ **in** the **UK. The legislative proposal** ~~aim~~ **aims** to ~~streamline~~ **provide a more flexible regime to make it easier to conduct** clinical trials ~~approvals~~ **in the UK** , ~~enable innovation, enhance~~ **increase the transparency of** clinical trials **conducted** ~~transparency, enable greater risk proportionality, and promote patient and public involvement~~ in **the UK and make** clinical trials **more patient centered** . The UK ~~Government~~ **government** ~~published~~ **has provided the legislative proposal to the UK Parliament for** its ~~response to~~ **review and approval. Once** the ~~consultation on March 21~~ **legislative proposal is approved (with or without amendment)** , ~~2023 confirming that~~ it ~~would bring forward changes to the legislation. These resulting legislative amendments~~ will be **adopted into** ~~closely watched and will determine how closely the~~ UK **law** ~~regulations are aligned with the CTR. Under the terms of the Protocol on Ireland / Northern Ireland, provisions of the CTR~~ which ~~relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. On February 27, 2023, the UK Government and the European Commission reached a political agreement on the " Windsor Agreement " which will revise the Protocol on Ireland / Northern Ireland in order to address some of the perceived shortcomings in its~~ **is expected** ~~operation. Once implemented, this may have further impact on the application of the CTR~~ in ~~Northern Ireland~~ **early 2026** . A decision by the UK ~~Government~~ **government** not to closely align any new legislation with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our business may be impacted. Delays or difficulties in the enrollment of patients in clinical trials, could result in our receipt of necessary regulatory approvals being delayed or prevented. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. These types of developments could cause us to delay the trial or halt further development. Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Patient enrollment is also affected by other factors including: • the severity of the disease under investigation; • the patient eligibility criteria for the study in question; • the perceived risks and benefits of the product candidate under study; • the availability of other treatments for the disease under investigation; • the existence of competing clinical trials; • the efforts to facilitate timely enrollment in clinical trials; • our payments for conducting clinical trials; • the patient referral practices of physicians; • the burden, or perceived burden, of the clinical study; • the ability to monitor patients adequately during and after treatment; and • the proximity and availability of clinical trial sites for prospective patients. Our inability to enroll a sufficient number of patients for our clinical trials or a delayed rate of enrollment would result in significant delays and could require us to abandon one or more clinical trials altogether. Interim " top- line " and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, top- line or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or 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. As a result, the top- line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top- line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top- line or preliminary data we previously published. As a result, top- line and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top- line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or ~~our~~ **any** collaborators will not be able to commercialize our product candidates or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired. Our product candidates and the activities associated with their development and **potential future** commercialization, including 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 similar regulatory authorities outside the United

States. Failure to obtain marketing approval for a product candidate in any jurisdiction will prevent us and ~~our~~ **any** collaborators from commercializing the product candidate in that jurisdiction and may affect our plans for **potential future** commercialization in other jurisdictions as well. **We** ~~Other than FDA approval for VOWST in the United States to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, we~~ have not received approval to market any of our product candidates 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 third parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy, or with respect to biologics such as our ~~microbiome~~ **live** ~~therapeutic~~ **biotherapeutic** candidates, safety, purity and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The process of obtaining marketing approvals, both in the United States and abroad, is expensive, risky and may take many years. The scope and amount of clinical data required to obtain marketing approvals can vary substantially from jurisdiction to jurisdiction, and it may be difficult to predict whether a particular regulatory body will require additional or different studies than those conducted by a sponsor, especially for novel product candidates such as our ~~microbiome~~ **live** ~~therapeutic~~ **biotherapeutic** candidates. The FDA or foreign regulatory authorities may delay, limit, or deny approval to market our product candidates for many reasons, including: our inability to demonstrate that the clinical benefits of our product candidates outweigh any safety or other perceived risks; the regulatory authority' s disagreement with the interpretation of data from nonclinical or clinical studies; the regulatory authority' s requirement that we conduct additional preclinical studies and clinical trials; changes in marketing approval policies during the development period; changes in or the enactment of additional statutes or regulations, or changes in regulatory review process for each submitted product application; or the regulatory authority' s failure to approve the manufacturing processes or third-party manufacturers with which we contract. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission' s proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council ~~(~~ **and the proposals may therefore be substantially revised before adoption, which is** not ~~expected~~ **anticipated** before early 2026 ~~) and~~ **. The revisions** may **however** have a significant impact on the biopharmaceutical industry in the long term. Additionally, regulatory authorities have substantial discretion in the approval process and may refuse to accept or file a marketing application if deficient. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. 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. Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. Furthermore, our product candidates may not receive marketing approval even if they achieve their specified endpoints in clinical trials. Clinical data are often susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory authority approval for their products. The FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from nonclinical and clinical studies, or they may require additional confirmatory or safety evidence beyond our existing clinical studies. Upon the FDA' s review of data from any pivotal trial, it may request that the sponsor conduct additional analyses of the data or gather more data and, if it believes the data are not satisfactory, could advise the sponsor to delay submitting a marketing application. Even if we eventually complete clinical testing and receive approval of a biologics license application, or BLA, or foreign marketing authorization for one of our product candidates, the FDA or the applicable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, which may be required after approval. The FDA or the applicable foreign regulatory authority may also approve our product candidates for a more limited indication and / or a narrower patient population than we originally request, and the FDA, or applicable foreign regulatory authority, may not approve the labeling that we believe is necessary or desirable for the successful **potential future** commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent **potential** commercialization of our product candidates and would materially adversely impact our business and prospects. The development of therapeutic products targeting the underlying biology of the human microbiome is an emerging field, and it is possible that the FDA and other regulatory authorities could issue regulations or new policies in the future that could adversely affect our ~~microbiome~~ **live** ~~therapeutic~~ **biotherapeutic** candidates. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. A Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process. We have and may in the future seek Fast Track designation for some of our product candidates. If a drug or biologic is intended for the treatment of a serious or life- threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug or biologic sponsor may apply for Fast Track designation. **We** ~~In December 2023, we~~ received Fast Track designation for SER- 155 to reduce the risk of infection and GvHD in patients undergoing allo- HSCT ~~, and for SER- 287 for the induction and maintenance of clinical remission in adults with mild- to- moderate UC~~ . Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. Once granted, Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and

clinical development, and a BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The FDA has broad discretion whether or not to grant this designation, and even if we believe another particular product candidate is eligible for this designation, we cannot be certain that the FDA would decide to grant it. Even with Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Fast Track designation does not assure ultimate approval by the FDA. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. A Breakthrough Therapy **, or other similar** ~~designation~~ **designations** by the FDA for our product candidates may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval. **In December 2024** ~~Prior to receiving FDA approval for VOWST~~ , we received Breakthrough Therapy designation for SER- ~~109~~ **155** for ~~treatment~~ **the reduction** of ~~CDI,~~ **BSIs in patients 18 years** and ~~we~~ **older undergoing allo- HSCT. We** may seek ~~a Breakthrough Therapy~~ **these or other** ~~designation~~ **designations** for ~~other~~ **future** product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed in early clinical development. For drugs or biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA also receive all of the Fast Track program features, including eligibility for rolling review of the associated marketing application. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. The receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, not all products designated as breakthrough therapies ultimately will be shown to have the substantial improvement over available therapies suggested by the preliminary clinical evidence at the time of designation. As a result, if a Breakthrough Therapy designation for any future designation we receive is no longer supported by subsequent data, the FDA may rescind the designation. We may seek PRIME designation by EMA or other designations, schemes or tools in the EU for one or more of our product candidates, which we may not receive. Such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing authorization. We may seek EMA PRIME (~~Priority~~ **PRIority** ~~Medicines~~ **MEdicines**) designation or other designations, schemes or tools for one or more of our product candidates. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the Breakthrough Therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the European Medicines Agency' s, or EMA, support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process. Even if we believe one of our product candidates is eligible for PRIME, the EMA may disagree and instead determine not to make such designation. The EMA PRIME scheme or other schemes, designations, or tools, even if obtained or used for any of our product candidates may not lead to a faster development, regulatory review or approval process compared to therapies considered for approval under conventional procedures and do not assure ultimate approval. In addition, even if one or more of our product candidates is eligible to the PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened. Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed. The competent regulatory authorities in the EU have broad discretion whether to grant such an accelerated assessment, and, even if such assessment is granted, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such an accelerated assessment may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our ~~products and~~ product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations. We may seek orphan drug designation for some of our product candidates but may not be able to obtain it. We ~~previously obtained orphan drug designation from the FDA for SER- 109 for recurrent CDI and SER- 287 for pediatric UC and~~ may seek orphan drug designation ~~and exclusivity~~ for some of our future product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. In the United States, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200, 000 individuals in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application

fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. In addition, if a product with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or other regulatory authorities from approving another marketing application for the same drug and same disease or condition during that time period, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. The applicable period is seven years in the United States and ten years in the EU. The European exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that a product no longer meets the criteria for orphan designation, if the product is sufficiently profitable so that market exclusivity is no longer justified, or the prevalence of the condition has increased above the orphan designation threshold. Orphan drug exclusivity may be lost if the FDA or other regulatory authorities determine that the request for designation was materially defective or if the manufacturer is unable to assure a sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective. ~~In connection with VOWST' s approval, we received a seven year period of exclusivity to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, which period began on April 26, 2023.~~ Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity for a product may not effectively protect the product from competition because different drugs and biologics can be approved for the same disease or condition. Even after an orphan drug or biologic is approved, the FDA or other regulatory authorities can subsequently approve the same drug or biologic for the same disease or condition if the FDA or other regulatory authorities conclude that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time nor gives the drug any advantage in the regulatory review or approval process. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA and other regulatory authorities to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s and other regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s and other regulatory authorities' ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory authorities, such as the EMA, ~~following its relocation to Amsterdam and resulting staff changes,~~ may also slow the time necessary for new drugs and biologics to be reviewed and / or approved by necessary regulatory authorities, which would adversely affect our business. For example, **in recent** ~~over the last several~~ years, the U. S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. ~~Even though the FDA has since resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays.~~ If a prolonged government shutdown occurs, or if **renewed** global health concerns ~~continue to~~ delay or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Risks Related to our Dependence on Third Parties and Manufacturing ~~The collaboration and license agreements with Société des Produits Nestlé S. A. and NHSc Rx License GmbH (collectively, and together with their affiliates and subsidiaries, Nestlé) are important to our business. If we or Nestlé fail to adequately perform under these agreements, or if we or Nestlé terminate the agreements, the development and commercialization of our CDI and IBD product candidates and / or VOWST could be adversely affected, delayed or terminated and our business would be adversely affected. In January 2016, we entered into a Collaboration and License Agreement with Nestlé, or the 2016 License Agreement. The 2016 License Agreement may be terminated: • by Nestlé in the event of serious safety issues related to VOWST, SER- 287, SER- 301 or other specific products added under the 2016 License Agreement, or, collectively, the 2016 Collaboration Products; • by us if Nestlé challenges the validity or enforceability of any of our licensed patents; and • by either Nestlé or us in the event of the other party' s uncured material breach or insolvency. Upon termination of the 2016 License Agreement, all licenses granted to Nestlé by us will terminate, and all rights in and to the 2016 Collaboration Products held by Nestlé will revert to us. If we commit a material breach of the 2016 License Agreement, Nestlé may elect not to terminate the 2016 License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the 2016 License Agreement. If Nestlé were to make such adjustments, the funding from and benefits of the 2016 License Agreement could be diminished, which could adversely affect our financial condition. Unless the 2016 License Agreement is terminated by us for Nestlé' s uncured material breach, upon termination of the 2016 License Agreement, Nestlé will be eligible to receive post- termination royalties from us until Nestlé has recouped certain development costs related to the 2016 Collaboration Products and specified percentages of any milestone payments paid to us under the 2016 License Agreement prior to termination, which could have a material adverse effect on our business. In July 2021, we entered into a License Agreement with Nestlé, or the 2021 License Agreement. The 2021 License Agreement may be terminated: • by Nestlé with~~

twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of VOWST and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement, or the 2021 Collaboration Products; Upon termination of the 2021 License Agreement, all licenses granted to Nestlé by us will terminate. If we commit a material breach of the 2021 License Agreement, Nestlé may elect not to terminate the 2021 License Agreement but instead apply specified adjustments to the payment terms and other terms and conditions of the agreement. If Nestlé were to make such adjustments, the funding from and benefits of the 2021 License Agreement could be diminished, which could adversely affect our financial condition. In the event we materially breach the 2021 License Agreement or file for bankruptcy, the share of profits and milestones due to us will be reduced by a specified percentage until Nestlé has recouped twice the losses caused by our material breach or bankruptcy. Termination of these agreements could cause significant delays in our product development and commercialization efforts that could prevent us from commercializing our CDI and IBD products and product candidates without first expanding our internal capabilities or entering into another agreement with a third party. Any alternative collaboration or license could also be on less favorable terms to us. In addition, under the agreements, Nestlé agreed to provide funding for certain clinical development activities. If either of the agreements were terminated, we may need to refund those payments and seek additional financing to support the research and development or commercialization of any terminated products or discontinue any terminated products or product candidates, which could have a material adverse effect on our business. Under the collaboration and license agreements, we are dependent upon Nestlé to successfully commercialize any applicable collaboration products both outside and within the United States and Canada, as applicable. For example, we must work closely with Nestlé to supply VOWST to them and coordinate scientific messaging. To optimize the commercial potential of VOWST, we must execute these plans effectively and collaboratively. We cannot directly control Nestlé' s commercialization activities or the resources it allocates to our product candidates. Our interests and Nestlé' s interests may differ or conflict from time to time, or we may disagree with Nestlé' s level of effort or resource allocation. Nestlé may internally prioritize our product candidates differently than we do or it may not allocate sufficient resources to effectively or optimally commercialize them. If these events were to occur, our business would be adversely affected. We rely on Nestlé to provide information related to the commercialization of VOWST so that we can make strategic decisions and projections, and we may provide this data, or statements based upon this data, to investors. If the data Nestlé provides us is inaccurate or incomplete, it may adversely affect our financial statements, business operations, the commercial success of VOWST or our stock price. Under the 2021 License Agreement, VOWST net sales are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. We rely on Nestlé to provide reporting related to net sales of VOWST in accordance with U. S. generally accepted accounting principles in order to calculate and record collaboration profit or loss. We also rely on Nestlé to provide timely, accurate and complete information related to the commercialization of VOWST, including data on prescribers, prescriptions and new patient starts. We use the information provided to us by Nestlé to report our results of operations, to plan for our future operations, and to make strategic decisions and projections, which may prove to be inaccurate or suboptimal. We base some of our strategic decisions and projections on the data Nestlé provides and we may provide this information to investors and analysts who may make their own predictions and estimates, all of which may prove to be inaccurate. Any failure by Nestlé to provide accurate and complete information related to the commercialization of VOWST, or to provide it on a timely basis, could adversely impact our financial statements, business operations, the commercial success of VOWST or our stock price. We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials. Our reliance on these third parties for research and development activities will reduce our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable 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. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations or similar regulatory requirements outside the United States. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or data privacy and security laws. Other countries' regulatory authorities also have requirements for clinical trials with which we must comply. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed, or terminated or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and may

not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or **potential** commercialization of our products **, if and when approved** , producing additional losses and depriving us of potential product revenue. We rely on third parties for certain aspects of the manufacture of our product ~~and product~~ candidates, and we expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product ~~and product~~ candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or **potential future** commercialization efforts. We rely, and expect to continue to rely, on third parties ~~, including GenIbet and Baethera,~~ for certain aspects of materials supply for our product candidates in preclinical and clinical testing, as well as for commercial manufacture ~~of VOWST and~~ if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates on a timely basis or at all, or that such quantities will be available at an acceptable cost or quality, which could delay, prevent or impair our development or **potential future** commercialization efforts ~~. For example, VOWST and certain of our product candidates rely on human stool from third- party donors. If we do not obtain an adequate supply of donor- derived material to meet clinical or commercial demand, our ability to manufacture VOWST and our product candidates may be delayed or adversely impacted~~ . We rely on third- party manufacturers, which entails additional risks, including: • failure of third- party manufacturers to comply with regulatory requirements and maintain quality assurance; • failure of third- party manufacturers to perform the manufacturing process adequately; • breach of supply agreements by the third- party manufacturers; • failure to supply components, intermediates, services, or product according to our specifications; • failure to supply components, intermediates, services, or product according to our schedule or at all; • misappropriation or disclosure of our proprietary information, including our trade secrets and know- how; and • termination or nonrenewal of agreements by third- party manufacturers at times that are costly or inconvenient for us. Third- party manufacturers may not be able to comply with current good manufacturing processes, or cGMP, regulations or similar regulatory requirements inside or outside the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products **, if and when** ~~. Some of the contract manufacturers we rely on to produce VOWST or our product candidates have never produced any other FDA-~~ approved ~~therapeutic. One of the contract manufacturers on which we rely is constructing a building, which is substantially complete but remains under construction, to manufacture VOWST and our product candidates, however, upon completion, it may not be approved by the FDA for the manufacture of VOWST~~ . If our manufacturers are unable to comply with cGMP regulation or similar regulatory requirements outside the United States or if the FDA or other regulatory authorities do not approve their facility upon a pre- approval inspection, our therapeutic candidates may not be approved or may be delayed in obtaining approval. In addition, there are a limited number of manufacturers that operate under cGMP regulations and similar regulatory requirements outside the United States that might be capable of manufacturing our products **, if and when approved** . Therefore, our product candidates and any future products that we may develop may compete with other products for access to manufacturing facilities. Any failure to gain access to these limited manufacturing facilities could severely impact the clinical development, marketing approval and **potential future** commercialization of our product candidates. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval **. Furthermore, if we breach or are perceived to breach our contractual obligations or otherwise default under our agreements with third parties, or if we otherwise have contractual disputes with such third parties, it may lead to adverse outcomes, including potential delays, unforeseen expenses, or the termination of those contracts** . We do not currently have a second source for certain required materials used for the manufacture of finished product. If our current manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products could delay, prevent or impair our development and **potential future** commercialization efforts. **We** ~~Other than the manufacture of VOWST after its recent FDA approval, we~~ have **limited** ~~very little~~ experience manufacturing our product candidates commercially, and we cannot assure you that we can manufacture our product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable. We have manufacturing facilities at our Cambridge ~~and Waltham~~ , Massachusetts locations where we conduct process development, scale- up activities **,** ~~and a portion of~~ the manufacture of ~~microbiome~~ **active components for our** ~~therapeutics~~ **biotherapeutic candidates, and** ~~as well as conduct~~ quality control **testing** ~~. The FDA and other comparable foreign regulatory authorities must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product meet cGMP or similar regulatory requirements outside the United States. The FDA inspected our Cambridge and Waltham facilities in December 2022 and closed the inspections without issue~~ . We **additionally utilize** ~~currently intend to rely in part on~~ third- party **contract** manufacturers **and test labs to perform product packaging and additional quality control testing. We may or may not utilize existing facilities and third- party vendors** for **future** ~~portions of the commercial manufacturing of VOWST and may establish a manufacturing facility for VOWST or any of our product candidates for~~ production ~~at a~~ **, including to support** commercial scale **supply** . We have no experience in manufacturing ~~, without reliance on third- party manufacturers, sufficient volume of~~ our product candidates to meet potential market demands ~~. We~~ **and we** may not be able to develop commercial- scale manufacturing facilities that are adequate to produce materials for commercial use. The **FDA and other comparable foreign regulatory authorities must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product meet cGMP or similar regulatory requirements outside the United States. We**

have not yet had our manufacturing facilities inspected for our product candidates. The equipment and facilities employed in the manufacture of pharmaceuticals are subject to stringent qualification requirements by regulatory agencies, including validation of facility, equipment, systems, processes and analytics. We may be subject to lengthy delays and expense in conducting validation studies, if we can meet the requirements at all. ~~In addition, some of our product candidates require donor material, of which we may not be able to collect sufficient quantities for commercial- scale or other manufacturing.~~ Risks Related to ~~Commercialization of~~ Our ~~Products,~~ Product Candidates and Other Legal Matters ~~We depend heavily on the commercial success of VOWST, which was approved for marketing by the FDA in April 2023 and launched in the United States in June 2023. There is no assurance that our commercialization efforts, or those of our collaborators, in the United States with respect to VOWST will be successful or that we will be able to generate collaboration profit at the levels or within the timing we expect, or at the levels or within the timing necessary to support our goals for VOWST.~~ Our ~~business currently depends heavily on our ability to successfully commercialize VOWST in the United States in its approved indication with our collaborator, Nestlé. We may never be able to successfully commercialize VOWST or meet our expectations with respect to collaboration profit. There is no guarantee that the infrastructure, systems, processes, policies, personnel, relationships and materials we have built in preparation for the launch and commercialization of VOWST in the United States will be sufficient for us to achieve success at the levels we expect. Additionally, healthcare providers may not accept a new treatment paradigm for patients with recurrent CDI. We may also encounter challenges related to reimbursement of VOWST, even if we have positive early indications from payors, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering VOWST. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable. Our results may also be negatively impacted if we encounter deficiencies or inefficiencies in our infrastructure or processes. Any of these issues could impair our ability to successfully commercialize VOWST or to generate substantial collaboration profit or to meet our expectations with respect to the amount or timing of collaboration profit. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition and prospects. There is no guarantee that we will be successful in our commercialization efforts with respect to VOWST, or that we will generate significant collaboration profit from VOWST or any product candidate or become profitable. Even though VOWST has received FDA approval and even if any of our product candidates receive marketing approval, VOWST and such~~ product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third- party payors and others in the medical community necessary for commercial success. Even ~~though VOWST has received FDA approval to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, and even~~ if any of our product candidates receive marketing approval, ~~VOWST or~~ our product candidates may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. ~~For example, current CDI treatment involves the use of antibiotics alone, which are well established in the medical community or the use of FMT, and physicians may continue to rely on these treatments or the treatments of our competitors.~~ If ~~VOWST or~~ our product candidates (if and when they are approved) do not achieve an adequate level of acceptance, we ~~or our collaborators may not generate significant collaboration profit and we~~ may not become profitable. The degree of market acceptance of ~~VOWST or~~ any of our product candidates, if approved, will depend on a number of factors, including: • their efficacy, safety and other potential advantages compared to alternative treatments; • the clinical indications for which such products are approved; • our ability to offer them for sale at competitive prices; • their convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the strength of marketing and distribution support; • the availability of third- party coverage and adequate reimbursement for our product candidates; • the prevalence and severity of their side effects and their overall safety profiles; • any restrictions on the use of our products **, if and when approved,** together with other medications; • interactions of our products **, if and when approved,** with other medicines patients are taking; and • the ability of patients to take our products **, if and when approved** . If we ~~or our collaborators~~ are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties with such capabilities, we ~~or our collaborators~~ may not be successful in commercializing ~~VOWST or~~ any of our product candidates if and when they are approved. We have employees with experience in sales and marketing, but we have limited sales or marketing infrastructure and, as a company, have little experience in the sale, marketing, and distribution of pharmaceutical products. To achieve commercial success ~~for VOWST or~~ for any other product for which we obtain marketing approval, we will need to establish a sales and marketing organization and ~~/ or~~ we ~~will need our collaborator Nestlé to perform sales and marketing functions and they~~ may not be successful in doing so. In ~~July 2021, we entered into the 2021 License Agreement with Nestlé, pursuant to which we granted Nestlé, under certain of our patent rights and know- how, a co- exclusive, sublicensable (under certain conditions) license to develop, commercialize and conduct medical affairs activities for the 2021 Collaboration Products, including VOWST, in the United States and Canada. Under the 2021 License Agreement, Nestlé has the sole right to commercialize VOWST in the 2021 Licensed Territory in accordance with a commercialization plan, subject to our right to elect to provide up to a specified percentage of all promotional details for a certain target audience. Each party will use commercially reasonable efforts to commercialize VOWST in the 2021 Licensed Territory in accordance with the commercialization plan. Both parties will perform medical affairs activities for VOWST in the 2021 Licensed Territory in accordance with a medical affairs plan. We were responsible for commercialization and medical affairs activities costs incurred by the parties until first commercial sale of the first 2021 Collaboration Product, or VOWST, in the 2021 Licensed Territory and in accordance with a pre- launch plan, up to a specified cap. Since the first commercial sale of VOWST in June 2023, we are entitled to share equally in its commercial profits and losses. In~~ the future, we expect to build a focused sales and marketing infrastructure, or certain components of such infrastructure, if we were to market ~~or co- promote VOWST and~~ our product candidates, if and when they are approved in the United States and potentially elsewhere. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example,

recruiting and training a sales force is expensive and time- consuming and could delay **the launch of** any **approved** product ~~launch~~ . If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we or ~~our~~ **any** collaborators cannot retain or reposition sales and marketing personnel. Factors that may inhibit efforts to commercialize our ~~products~~ **product candidates, if and when approved,** include: • inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to or educate physicians on the benefits of our products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; • unforeseen costs and expenses associated with creating an independent sales and marketing organization; and • inability to obtain sufficient coverage and reimbursement from third- party payors and governmental agencies. Outside the United States, we intend to rely and may increasingly rely on third parties ~~, including Nestlé,~~ to sell, market and distribute ~~VOWST and~~ our product candidates, if and when approved. We may not be successful in entering into arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, ~~our product revenue or collaboration profit and~~ our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our ~~products~~ **product candidates, if and when they are approved,** effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do. The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We ~~and our collaborators~~ face competition with respect to ~~VOWST and~~ our ~~other~~ current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early- stage companies, that are pursuing the development or commercialization of products, including ~~microbiome~~ **live** ~~therapeutics~~ **biotherapeutics** , for ~~reducing CDI and other~~ disease indications we are targeting. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others may be based on entirely different approaches ~~. For example, FMT is a procedure that has resulted in reports of high success rates for recurrent CDI~~ . Potential competitors also include academic institutions, government agencies, not- for- profits, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we have or may in the future develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a ~~microbiome~~ **live** ~~therapeutic~~ **biotherapeutic** which will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of generic or biosimilar products. Even if we are able to commercialize ~~VOWST or~~ any of our product candidates, if approved, the products may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, any of which would harm our business. Our ability to ~~continue to~~ commercialize ~~VOWST or~~ any of our product candidates successfully will depend, in part, on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and impact reimbursement levels. Obtaining and maintaining adequate reimbursement for our ~~products~~ **product candidates** may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our ~~products~~ **product candidates** by third- party payors. Even if we do obtain adequate levels of reimbursement, third- party payors, such as government or private healthcare insurers, carefully review, and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize ~~VOWST or~~ any product candidate for which we obtain marketing approval, and ~~the~~ **potential** royalties resulting from the sales of those products may

also be adversely impacted. 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 similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost treatment approaches and may be incorporated into existing payments for other services. 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. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be reimbursed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, 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. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically necessary for a specific indication or cost- effective, or that coverage or an adequate level of reimbursement will be available. Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of ~~VOWST or~~ any ~~other~~ products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and an even greater risk with the commercial sale of ~~VOWST or~~ any ~~other~~ products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions; • decreased demand for ~~any~~ product candidates or products **, if any** ; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards to trial participants or patients; • loss of revenue; • reduced resources of our management to pursue our business strategy; and • the inability to commercialize ~~any~~ products that we develop **, if any** . We currently hold $ 10. 0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of $ 10. 0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials, ~~increase commercialization of VOWST,~~ or if we commence commercialization of our product candidates **, if and when approved** . 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. We may face competition from biosimilars, which may have a material adverse impact on the future commercial prospects of ~~VOWST or~~ our product candidates. **If** ~~Because we have received FDA approval of VOWST to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, and if~~ we obtain approval or any of our product candidates, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act, or BPCIA, enacted in 2010 as part of the Patient Protection and Affordable Care Act, created an abbreviated approval pathway for biological products that are demonstrated to be " highly similar, " or biosimilar, to or " interchangeable " with an FDA-approved biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until four years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of their product. This pathway could allow competitors to reference data from innovative biological products 12 years after the time of approval of the innovative biological product, though the FDA may not approve an application relying on such data for a further eight years. This data exclusivity does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator' s application to support the biosimilar product' s approval. **We** ~~VOWST qualified, and we~~ believe that any of our product candidates approved as a biological product under a BLA should also qualify ~~,~~ for the 12- year period of reference product exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. In the EU, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class- specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product but will not be able to get on the market until 10 years after the time of approval of the innovative product. This 10- year marketing exclusivity period can be extended to 11 years if, during the first eight of those 10 years, the marketing authorization

holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our ~~products~~ **product candidates**. If competitors are able to obtain marketing approval for biosimilars referencing our ~~products~~ **product candidates**, our ~~products~~ **product candidates** may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad. In order to market and sell our ~~products~~ **product candidates** in the EU and many other jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We ~~or our collaborators~~ may not obtain approvals for ~~VOWST or~~ our product candidates from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our ~~products~~ **product candidates** in any market. **Any** ~~VOWST and any~~ product candidate for which we obtain marketing approval will remain subject to significant post- marketing regulatory requirements and oversight. **Any** ~~VOWST and any~~ product candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, advertising and promotional activities for such product, will be subject to the continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP and similar foreign 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. We and our contract manufacturers will also be subject to continual review and periodic inspections to assess compliance with cGMP and similar foreign requirements. Accordingly, we, and ~~our~~ **any** ~~collaborators~~ **collaborator** and others with whom we work, must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control ~~. For example, the FDA- approved label for VOWST includes certain warnings and precautions regarding transmissible infectious agents and the potential presence of food allergens~~. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to specific conditions of approval, including a requirement to implement a risk evaluation and mitigation strategy, which could include requirements for a medication guide, communication plan, or restricted distribution system. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product ~~. For example, the FDA- approved label for VOWST includes a limitation of use that VOWST is not indicated for the treatment of CDI~~. The FDA or other regulatory authorities may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA or other regulatory authorities closely regulates the post- approval marketing and promotion of drugs and biologics to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the FDA' s and other regulatory authorities' restrictions relating to the promotion of prescription drugs by us or ~~our~~ **any** collaborators may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. In addition, if a regulatory authority, we or ~~our~~ **any** collaborators later discover previously unknown problems with our ~~products~~ **product candidates**, such as adverse events of unanticipated severity or frequency, problems with manufacturers or manufacturing processes, or failure to comply with regulatory requirements, the regulatory authority may impose restrictions on the products or us and ~~our~~ **any** collaborators, including requiring withdrawal of the product from the market. Any failure by us or ~~our~~ **any** collaborators to comply with applicable regulatory requirements may yield various results, including: • litigation involving patients taking our products **, if and when they are approved**; • restrictions on such products, manufacturers or manufacturing processes; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning letters; • withdrawal of products from the market; • suspension or termination of ongoing clinical trials; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • damage to relationships with potential collaborators; • unfavorable press coverage and damage to our reputation; • refusal to permit the import or export of our products **, if and when they are approved**; • product seizure or detention; • injunctions; or • imposition of civil or criminal penalties. Noncompliance with similar EU requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with U. S. and foreign regulatory requirements regarding the development of products for pediatric populations and the protection of personal health information can also lead to significant penalties and sanctions. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not

able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. The FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we or ~~our~~ **any** collaborators are found to have improperly promoted off- label uses of approved products, including ~~VOWST or~~ any of our product candidates that may be approved in the future, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as ~~VOWST and~~ our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product' s approved labeling. ~~The current FDA- approved indication for VOWST is limited to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI.~~ Physicians may nevertheless prescribe ~~VOWST or~~ a product candidate that is approved in future, if any, to their patients in a manner that is inconsistent with the approved label. If we or ~~our~~ **any** collaborators are found to have promoted such off- label uses, we may become subject to significant liability. The U. S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of ~~VOWST or of~~ our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Our relationships and any collaborators' relationships with customers, physicians and third- party payors are and will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us or ~~our~~ **any** collaborators to criminal sanctions, civil penalties, exclusion from governmental healthcare programs, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of ~~VOWST and~~ any product candidates for which we obtain marketing approval. Our and ~~our~~ **any** collaborators' current and future arrangements with third- party payors, physicians and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may restrict the business or financial arrangements and relationships through which we market, sell and distribute ~~VOWST and~~ any other products for which we may in the future obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following: • the federal Anti- Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; • the False Claims Act, imposes, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act; • the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary' s decision to order or receive items or services reimbursable by the government from a particular provider or supplier. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties; • HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation; • the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; manufacturers are required to submit reports to the government by the 90th day of each calendar year; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, may apply to our business practices, including but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government (or foreign governments) and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, pricing information or marketing expenditures. The risk of **us** ~~our~~ **or any** ~~or our~~ collaborators being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us or ~~our~~ **any** collaborators for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that we may violate one or more of the requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes,

regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement, and the curtailment or restructuring of our operations. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our ~~products and~~ product candidates and affect the prices we may obtain. 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 prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, is a sweeping law intended 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 the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to ~~VOWST and~~ our other potential product candidates are the following: • establishment of a new pathway for approval of lower- cost biosimilars to compete with biologic products, such as those we are developing or commercializing; • an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents; • an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program ~~; • a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point- of- sale discounts off negotiated prices~~ ; • extension of manufacturers' Medicaid rebate liability; • expansion of eligibility criteria for Medicaid programs; • expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; • a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and • a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. 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 ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, enacted in August 2011, required sequestration that included aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will increase in future years of the sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Drug manufacturers' Medicaid Drug Rebate Program rebate liability was previously capped at 100 % of the average manufacturer price for a covered outpatient drug. We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to price our ~~products~~ **product candidates, if and when they are approved,** at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize ~~VOWST or~~ our product candidates, if approved. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (~~beginning~~ **which began** in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. ~~On August 29~~ **The Centers for Medicare & Medicaid Services** , **or CMS, has published the negotiated prices for the initial ten drugs, which will first be effective in** ~~2023~~ **2026** , ~~HHS announced~~ **and has published** the list of the ~~first ten~~ **subsequent 15** drugs that will be subject to ~~price negotiations~~ **negotiation** , although the Medicare drug price negotiation program is currently subject to legal challenges. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our ability to price our ~~products~~ **product candidates, if and when they are approved,** appropriately, which could negatively impact our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for ~~VOWST or~~ our product candidates,

if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any. In some countries, particularly the EU member states, the pricing of certain pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various EU member states and parallel distribution or arbitrage between low- priced and high- priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. If coverage and reimbursement of our ~~products~~ **product candidates, if and when they are approved,** are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels that impacts our ability to compete with other products or our ability to recoup our costs of developing our ~~products~~ **product candidates** , our business could be harmed, possibly materially. Risks Related to Our Intellectual Property If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and ~~products~~ **product candidates** . We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. 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, in a timely manner, or in all jurisdictions. Prosecution of our patent portfolio is at various stages. We have successfully obtained multiple patents (both U. S. and foreign) in some patent families. In others, prosecution is at an early stage (e. g., provisional or PCT stage). For many patent applications in our portfolio, we have filed national stage applications based on our Patent Cooperation Treaty, or PCT, applications, thereby limiting the jurisdictions in which we can pursue patent protection for the various inventions claimed in those applications. 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. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results. We have obtained ~~licenses and options to obtain~~ licenses from third parties and may obtain additional licenses and options in the future. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business. We have had in the past, and may have in the future, certain funding arrangements. Such funding arrangements impose various obligations on us, including reporting obligations, and may subject certain of our intellectual property, such as intellectual property made using the applicable funding, to the rights of the U. S. government under the Bayh- Dole Act. Any failure to comply with our obligations under a funding arrangement may have an adverse effect on our rights under the applicable agreement or our rights in the applicable intellectual property. Compliance with our obligations or the exercise by the government or other funder of its rights, may limit certain opportunities or otherwise have an adverse effect on our business. Our patent portfolio currently includes 21 active patent application families (which includes exclusive licenses to certain IP from Memorial Sloan Kettering Cancer Center). Of these, ~~20~~ **19** applications have been nationalized ~~and~~ **,** one is at the PCT stage **, and one is at the provisional stage** . ~~While~~ **To date,** we have obtained ~~30~~ **issuance of 31 U. S. patents (which includes three as licensee). Of the** issued U. S. patents, ~~we~~ **13 U. S. patents (including one as licensee) have been assigned to Nestlé Health Science as part of its purchase of VOWST. We** cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents or our current patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. For example, we are pursuing claims to therapeutic, binary compositions of certain bacterial populations. Any claims that may issue may provide coverage for such binary compositions and / or their use. However, there can be no assurance that an alternative composition that may fall outside the scope of such claims will not be equally effective.

Further, **while our product candidates are made up of specific cultivated bacteria** ~~given that VOWST is a complex composition with some variation from lot- to- lot and that, likewise~~ , third- party compositions may have ~~similar~~ **greater** complexity and variability **(e. g.** , **lot to lot variations), and** it is possible that a patent claim may provide coverage for some but not all ~~lots of a product, product candidate or~~ third- party ~~product~~ **compositions** . These and other factors may provide opportunities for our competitors to design around our patents, should they issue. Moreover, other parties have developed technologies that may be related or competitive to our approach and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming similar methods or by claiming subject matter that could dominate our patent position or cover one or more of our ~~products or~~ product candidates. In addition, given the on- going prosecution of our portfolio, we continue development of our understanding of how patent offices react to our patent claims and whether they identify prior art of relevance that we have not already considered. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued which protect our technology or ~~products~~ **product candidates** , in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. 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. We may be subject to third- party preissuance submissions of prior art to the United States Patent and Trademark Office, or USPTO, or in a foreign jurisdiction in which our applications are filed, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, on April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo. See " — Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. " The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Opposition Division' s decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or ~~products~~ **product candidates** and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize ~~products~~ **product candidates** 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 current or future product candidates. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty. 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. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering biotechnological and pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if issued, a patent' s validity, inventorship, ownership or enforceability is not conclusive. Accordingly, rights under any existing patent or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that: • any of our pending patent applications, if issued, will include claims having a scope sufficient to protect any products or product candidates; • any of our pending patent applications will issue as patents at all; • we will be able to successfully commercialize ~~VOWST or~~ any of our product candidates, if approved, before our relevant patents expire; • we were the first to make the inventions covered by any existing patent and pending patent applications; • we were the first to file patent applications for these inventions; • others will not develop similar or alternative technologies that do not infringe or design around our patents; • others will not use pre- existing technology to effectively compete against us; • any of our patents, if issued, will be found to ultimately be valid and enforceable; • third parties will not compete with us in jurisdictions where we do not pursue and obtain patent protection; • we will be able to obtain and / or maintain necessary or useful licenses on reasonable terms or at all; • any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; • we will develop additional proprietary technologies or product candidates that are separately patentable; or • our commercial activities or products will not infringe upon the patents or proprietary rights of others. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time- consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings, may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent

misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed. If we are unable to protect the confidentiality of our trade secrets and know- how, our business and competitive position may be harmed. In addition to seeking patents for some of our technology and product candidates, we also utilize our trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our ~~products~~ **product candidates**. 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. In addition, patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, in particular the first to file provisions, became effective on March 16, 2013. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Thus, for our U. S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. Moreover, some of the patent applications in our portfolio will be subject to examination under the pre- Leahy- Smith Act law and regulations, while other patent applications in our portfolio will be subject to examination under the law and regulations, as amended by the Leahy- Smith Act. This introduces additional complexities into the prosecution and management of our portfolio. In addition, the Leahy- Smith Act limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. These provisions apply to all of our U. S. patents, even those filed before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a federal court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims because it may be easier for them to do so relative to challenging the patent in a federal court action. It is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. From time to time, the Supreme Court, other federal courts, Congress, or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business. A number of cases decided by the Supreme Court have involved questions of when claims reciting abstract ideas, laws of nature, natural phenomena and / or natural products are eligible for a patent, regardless of whether the claimed subject matter is otherwise novel and inventive. These cases include Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U. S. 12- 398 (2013); Alice Corp. v. CLS Bank International, 573 U. S. 13- 298 (2014); and Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U. S. 10- 1150 (2012). In response to these cases, the USPTO has issued guidance to the examining corps. The USPTO first issued a memorandum reflecting the USPTO' s interpretation of the cases related to patent eligibility of natural products on March 4, 2014, which it subsequently revised and expanded upon in several additional updates now incorporated into its Manual of Patent Examination Procedure. The USPTO' s interpretation of the case law and new guidelines for examination may influence, possibly adversely, prosecution and defense of certain types of claims in our portfolio. In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on these and other decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change or be interpreted in unpredictable ways that would weaken our ability to obtain new

patents or to enforce any patents that may issue to us in the future. In addition, these events may adversely affect our ability to defend any patents that may issue in procedures in the USPTO or in courts. Our commercial success depends upon our ability, and the ability of ~~our~~ **any** collaborators, to develop, manufacture, market and sell ~~VOWST and~~ our product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. ~~While no such litigation has been brought~~ **For example, on August 20, 2024, Vedanta Biosciences, Inc. and The University of Tokyo filed a complaint** against us and **Nestlé S. A., Nestlé Health Science S. A., Nestlé Health Science US Holdings, Inc. and SPN in the United States District Court for the District of Delaware alleging that the making, sale and use of VOWST infringes on U. S. Patent Nos. 9, 433, 652, 9, 662, 381, 9, 808, 519, 10, 555, 978, and 11, 090, 343. The complaint seeks unspecified damages, fees, expenses and injunctive relief. We believe the complaint is without merit and intend to defend ourself vigorously against the claims. While** we have not been held by any court to have infringed a third party' s intellectual property rights, we cannot guarantee that our technology ~~, VOWST~~ or our product candidates, or use of ~~VOWST or~~ our product candidates do not infringe third- party patents. We are aware of numerous patents and pending applications owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third- party patent rights that may be relevant to ~~VOWST or~~ our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology ~~, VOWST~~ or our product candidates. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of ~~VOWST or~~ our product candidates, or we may incorrectly conclude that a third- party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies ~~, VOWST~~ or our product candidates or the use of ~~VOWST or~~ our product candidates. We are aware of several pending patent applications containing one or more claims that could be construed to cover ~~VOWST,~~ some of our product candidates or technology, should those claims issue in their original form or in the form presently being pursued. In addition, we are aware of third- party patent families that include issued and allowed patents, including in the United States, including claims that, if valid and enforceable, could be construed to cover ~~VOWST,~~ some of our product candidates or their methods of use. On April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo and requesting that it be revoked in its entirety for the reasons set forth in our opposition. The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Oppositions Division' s decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that ~~VOWST,~~ our product candidates, or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to ~~VOWST,~~ our product candidates and technology, including interference or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. If we were to challenge the validity of an issued U. S. patent in court, such as an issued U. S. patent of potential relevance to some of ~~VOWST,~~ our product candidates or methods of use, we would need to overcome a statutory presumption of validity that attaches to every U. S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent' s claims. There is no assurance that a court would find in our favor on questions of infringement or validity. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found or believe there is a risk we may be found, to infringe a third party' s intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing ~~VOWST,~~ our product candidates and technology. However, we may not be able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing ~~VOWST or~~ our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign ~~VOWST or~~ our product candidates. Patent litigation is costly and time- consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following: • cease developing, selling or otherwise commercializing ~~VOWST or~~ our product candidates; • pay

substantial damages for past use of the asserted intellectual property; • obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and • in the case of trademark claims, redesign, or rename, some or all of our product candidates or other brands to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time- consuming. Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects. Issued patents covering ~~VOWST or~~ our product candidates could be found invalid or unenforceable or could be interpreted narrowly if challenged in court. Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third- party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time- consuming. If we initiated legal proceedings against a third party to enforce a patent, if and when issued, covering ~~VOWST or~~ one of our product candidates, the defendant could counterclaim that the patent covering ~~VOWST or~~ our product candidate is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement, or failure to claim patent eligible subject matter. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on ~~VOWST or~~ our product candidates. Moreover, even if not found invalid or unenforceable, the claims of our patents could be construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and, in some jurisdictions, during the pendency of a patent application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, contractors and advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, advisors or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party' s former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. In addition, while it is our policy to require our employees, consultants, advisors and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that

conflicts with that person' s obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection. Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For each of the patent families that we believe provide coverage for our product candidates, we decide whether and where to pursue protection outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, even if we do elect to pursue patent rights outside the United States, we may not be able to obtain relevant claims and / or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Additionally, Europe' s Unified Patent Court, or UPC, may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Although this new court has been implemented to provide more certainty and efficiency to patent enforcement throughout Europe, it will also provide our competitors with a new forum to use to centrally challenge our patents if opted into the UPC, rather than having to seek invalidity or non- infringement decisions on a country- by- country basis. It will be several years before the scope of patent rights that will be recognized and the strength of patent remedies that will be provided is known. Competitors may use our technologies in jurisdictions where we do not pursue and obtain 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 United States. These products may compete with our ~~products~~ **product candidates** and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. If our ability to obtain and, if obtained, enforce our patents to stop infringing activities is inadequate, third parties may compete with our ~~products~~ **product candidates**, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Accordingly, our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license. Risks Related to Our Operations ~~We may be unable to realize the expected benefits from our Restructuring Plan and our business might be adversely affected. In November 2023, we announced that, based on a challenging macro environment and financial backdrop, a Restructuring Plan to focus our business operations to prioritize the commercialization of VOWST and the completion of the SER- 155 Phase 1b study, while significantly reducing costs and supporting longer- term business sustainability. Under the Restructuring Plan, we reduced our workforce by approximately 41 % and significantly scaled back all non- partnered research and development activities other than the completion of the SER- 155 Phase 1b study. The Restructuring Plan has been substantially implemented. These types of restructuring and cost reduction activities are complex and may result in unintended consequences and costs, such as unforeseen delays in the implementation of our strategic initiatives, business and operational disruptions, decreased employee morale and retention, loss of institutional knowledge and expertise, and potential impacts on financial~~

~~reporting. The significant reduction in our workforce under the Restructuring Plan could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. In addition, the decision to significantly scale back all non- partnered research and development activities other than the completion of the SER- 155 Phase 1b study may negatively impact our growth, competitive positioning, business and results of operations. If we do not successfully manage the impact of the Restructuring Plan or any other similar activities that we may undertake in the future, we may not achieve the expected costs savings and other expected benefits in the expected timeframe or at all, and our business, financial condition, and results of operations may be materially adversely affected.~~ Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on Eric Shaff, our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and **potential future** commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions ~~. Our Restructuring Plan may make it more difficult for us to hire qualified personnel~~ . In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy and execution. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. A variety of risks associated with operating internationally could materially adversely affect our business. We currently have limited international operations, but our business strategy incorporates potentially expanding internationally ~~with respect to VOWST and~~ if any of our product candidates receive regulatory approval. We have conducted clinical studies in Australia and New Zealand in the past, and ~~may~~ **will likely** in the future conduct clinical studies in other countries as well. ~~We currently plan to rely on collaborators, including Nestlé, to commercialize certain approved products outside of North America. Also, for certain manufacturing services for VOWST, we rely on GenIbet in Portugal, and Bacthera, which has substantially completed a dedicated full- scale production suite for us in Switzerland.~~ Doing business internationally involves a number of risks, including but not limited to: • multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions **, including tariffs** , employment laws, regulatory requirements and other governmental approvals, permits and licenses; • failure by us to obtain and maintain regulatory approvals for the use of our ~~products~~ **product candidates** in various countries; • additional potentially relevant third- party patent rights; • complexities and difficulties in obtaining protection and enforcing our intellectual property; • difficulties in staffing and managing foreign operations; • complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; • limits in our ability to penetrate international markets; • global macroeconomic conditions, including a continued increase in inflation rates or interest rates, labor shortages, supply chain shortages, disruptions and instability in the banking industry and other parts of the financial services sector, or other economic, political or legal uncertainties or adverse developments; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our ~~products~~ **product candidates** and exposure to foreign currency exchange rate fluctuations; • terrorism and / or political instability, unrest and wars, such as the conflicts involving Ukraine and Russia or Israel and its surrounding regions, which could delay or disrupt our business, and if such political unrest escalates or spills over to or otherwise impacts additional regions it could heighten many of the other risk factors included in this Item 1A; • natural disasters (including as a result of **severe weather events,** climate change **or otherwise**), which could cause significant damage to the infrastructure upon which our business operations rely, and the timing, nature or severity of which we may be unable to prepare for; • economic instability, outbreak of disease or epidemics ~~such as the COVID- 19 pandemic~~ , boycotts, curtailment of trade and other business restrictions; • certain expenses including, among others, expenses for travel, translation and insurance; and • regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U. S. Foreign Corrupt Practices Act, its books and records provisions, or its anti- bribery provisions. Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations. Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity. In the ordinary course of our business, we collect and store sensitive data, including personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or our employees ~~, customers~~ and other third ~~-~~ parties. We manage and maintain our applications and data utilizing a combination of on- site systems and cloud- based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers, and as a result a number of third- party vendors may or could have access to our confidential information. These applications and data encompass a wide variety of business- critical information, including research and development information, customer information, commercial information and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate or unauthorized access, use, modification or disclosure, and the risk of our being unable to

adequately monitor and audit and modify our controls over our confidential information. This risk extends to the third- party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take reasonable measures to protect sensitive data from unauthorized access, use or disclosure, our information technology systems and those of our third- party service providers, strategic partners and other contractors or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e. g., ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation- state and nation- state- supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who continue to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We and certain of our service providers are from time to time subject to cyberattacks and security **attempts or** incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. If we or our third- party vendors were to experience a significant cybersecurity breach of our or their information technology systems or data, the costs associated with the investigation and remediation could be material. Any such real or perceived unauthorized access or use, breach, or other loss of confidential information could also result in regulatory scrutiny, reputational harm, legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, and regulatory enforcement, including penalties or fines. Notice of breaches may be required to affected individuals or state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such notifications could be costly, harm our reputation and our ability to compete. Although we have implemented security measures to prevent unauthorized access, such data is currently accessible through multiple channels, and there is no guarantee that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and data from breach. Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition. The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U. S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our results of operations, financial performance and business. In the U. S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, or collectively HIPAA, imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. Most healthcare providers, including research institutions from which we obtain clinical trial information, are subject to privacy and security regulations promulgated under HIPAA. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not regulated under HIPAA. However, any person may be prosecuted under HIPAA' s criminal provisions either directly or under aiding- and- abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA- covered healthcare provider or research institution that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health- related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act or collectively, **the** CCPA, requires ~~certain~~ **covered** businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business' s collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information,

or to opt- out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business' s behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in other states, and continue to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Furthermore, the Federal Trade Commission, or FTC, and many State Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the European Union General Data Protection Regulation, or the GDPR, went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area, or EEA, or in the context of our activities within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million or 4 % of the annual global revenues of the noncompliant undertaking, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease / change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and / or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the EU states that reliance on the standard contractual clauses, or SCCs- a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism- alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case- by- case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU- U. S. Data Privacy Framework, or DPF, rendering the DPF effective as a GDPR transfer mechanism to U. S. entities self- certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. **In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.** As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and / or start taking enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Since the beginning of 2021, after the end of the transition period following the UK' s departure from the European Union, we are also subject to the UK General Data Protection Regulation and Data Protection Act 2018, or collectively, the UK GDPR, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £ 17. 5 million or 4 % of a noncompliant undertaking' s global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U. S. entities self- certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations. Acquisitions **, dispositions,** or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business. We may **from time to time** acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses ~~or~~ **,** investments in complementary businesses **, or dispose of assets** . We have not made any acquisitions to date, and our ability to do so successfully is unproven. **On September 30, 2024, we completed the sale of our VOWST Business to SPN, which included all inventory and equipment, certain patents and patent applications, know- how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of VOWST.** Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including: • disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction; • unanticipated liabilities related to acquired companies **or disposed assets or businesses** ; • additional exposure to cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure; • difficulties **retaining or** integrating acquired personnel, technologies and

operations ~~into our existing business~~ ; • diversion of management time and focus from operating our business to **transaction,** acquisition integration **, or disposition- related** challenges; • increases in our expenses and reductions in our cash available for operations and other uses; • possible write- offs or impairment charges relating to acquired **or disposed** businesses; and • inability to develop a sales force for any additional product candidates. Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. Also, the anticipated benefit of any acquisition **or disposition** may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write- offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions **or dispositions** , or the effect that any such transactions might have on our operating results. We have in the past been subject to securities class action litigation and may be subject to similar or other litigation in the future, which may harm our business. Securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. On September 28, 2016, a purported stockholder filed a putative class action lawsuit in the U. S. District Court for the District of Massachusetts against us entitled Mariusz Mazurek v. Seres Therapeutics, Inc., et. al. alleging false and misleading statements and omissions about our clinical trials for our then product candidate SER- 109 in our public disclosures between June 25, 2015 and July 29, 2016. Although this lawsuit has been dismissed by the court, should we face similar or other litigation again, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. In addition, the uncertainty of a pending lawsuit or potential filing of additional lawsuits could lead to more volatility and a reduction in our stock price. **We are subject to complex and changing laws and regulations, which exposes us to potential liabilities, increased costs and other adverse effects on our business. We are subject to complex and changing laws, regulations, and executive orders, and compliance with these laws and regulations and executive orders is onerous and expensive. New and changing laws, regulations, and executive orders can adversely affect our business by increasing our costs, limiting the Company' s ability to pursue or offer a product candidate or product, and requiring changes to our business. New and changing laws, regulations, and executive orders can also create uncertainty about how such laws and regulations will be interpreted and applied. Regulatory changes and other actions that materially adversely affect our business may be announced with little or no advance notice we may not be able to effectively mitigate all adverse impacts from such measures. Differing interpretations of such legal obligations can expose us to significant fines, government investigations, litigation and reputational harm. If we are found to have violated laws, regulations, or executive orders, it could materially adversely affect our business, reputation, results of operations and financial condition.** If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials such as human stool. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury ~~, including from the novel coronavirus SARS- CoV- 2, which causes the COVID- 19 disease,~~ from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Our ability to use our net operating loss carryforwards and research and development credits to offset future taxable income or income tax liabilities may be subject to certain limitations. As of December 31, ~~2023~~ **2024** , we had net operating loss carryforwards, or NOLs, of $ ~~527~~ **580** . 1 million for federal income tax purposes and $ ~~504~~ **543** . ~~2~~ **6** million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal NOLs subject to expiration begin to expire in various amounts in 2035. Our federal NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration, but may generally only be used to offset 80 % of taxable income in years beginning after December 31, 2020. Our state NOLs also begin to expire in various amounts in 2035. As of December 31, ~~2023~~ **2024** , we also had federal and state research and development and other tax credit carryforwards of approximately $ ~~45~~ **46. 5 million and $ 8** . 1 ~~million and $ 7. 7~~ million, respectively, net of uncertain tax position reserves, available to reduce future income tax liabilities, if any. Our federal and state tax credit carryforwards begin to expire in various amounts in 2031 and 2028, respectively. The federal research and development tax credit carryforwards include an orphan drug credit carryforward of $ 25. 9 million. These NOLs and tax credit carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future taxable income or income tax liabilities. In addition, in general, under Sections 382 and 383 of the U. S. Internal Revenue Code of 1986, as amended ~~(the" Code")~~ , a corporation that undergoes an " ownership change " is subject to limitations on its ability to use its pre- change NOLs and tax credit carryforwards to offset future taxable income and income taxes. For these purposes, an ownership change generally occurs where the aggregate change in stock ownership of one or more stockholders or groups of stockholders owning at least 5 % of a corporation' s stock exceeds 50 percentage points over a rolling three- year period. Similar

rules may apply under state tax laws. We have experienced ownership changes in the past, per a Section 382 study performed through December 31, 2020. We believe that none of our existing tax assets will expire unused as a result of the calculated limitations resulting from such ownership changes. However, we may have experienced additional ownership changes since December 31, 2020, and we may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we have undergone additional ownership changes, or if we undergo ownership changes in the future, our ability to use our NOLs and tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets. **Risks Related to Our Common Stock We have received a notice of the failure to satisfy a continued listing rule from Nasdaq. Nasdaq maintains several requirements for continued listing of our common stock, one of which is the maintenance of a minimum closing bid price of $ 1. 00. On November 7, 2024, we received written notice from Nasdaq notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the $ 1. 00 Bid Price Requirement for continued inclusion on** The ~~terms of the Oaktree Credit Agreement place restrictions~~ **Nasdaq Global Select Market. The notice had no immediate effect** on **the listing of our common stock, which continues to trade on The Nasdaq Global Select Market under the symbol" MCRB". Pursuant to the Nasdaq listing rules, we were provided a period of 180 calendar days,** ~~our~~ **or** ~~operating and financial flexibility~~ **until May 6, 2025 to regain compliance with the Bid Price Requirement** . If we ~~raise~~ **do not regain compliance with this requirement by May 6, 2025, we may be eligible for an** additional **180- calendar day compliance period by transferring the listing of our common stock to The Nasdaq** ~~capital~~ **Capital** ~~through debt financing~~ **Market and satisfying certain requirements. To qualify for the additional grace period , we would be required to submit a transfer application for transfer between Nasdaq market tiers and pay an application fee. In addition, we would be required to meet the continued listing requirement for the market value of our publicly held shares and all other applicable initial listing standards for The Nasdaq Capital Market, with the exception of the Bid Price Requirement, and would need to provide written notice of our intention to cure the deficiency during the second grace period. If we fail to regain compliance during the compliance period (including a second compliance period provided by a transfer to The Nasdaq Capital Market, if applicable),** ~~the~~ **then** ~~terms of any new debt could further restrict our ability to operate our business. On April 27, 2023,~~ we ~~entered into the Oaktree Credit Agreement~~ **expect that Nasdaq will notify us of its determination to delist our common stock , at** which ~~establishes~~ **point we may appeal Nasdaq' s delisting determination to** a ~~term loan facility of $ 250~~ **Nasdaq hearing panel or pursue other available options to regain compliance** . ~~0 million~~ **If we fail to regain compliance during a second 180- day compliance period** , ~~consisting~~ **and we appeal a Nasdaq delisting determination to a Nasdaq hearing panel, our common stock will be immediately suspended from trading on Nasdaq during the pendency** of **the hearings panel review and would trade in over- the- counter** (~~i) the Tranche A Loan, funded on the Oaktree Closing Date, (ii) the Tranche B Loan, that we may borrow subject to certain conditions, (iii) the Tranche C Loan, that we may borrow subject to certain conditions, and (iv) the Tranche D Loan, available in Oaktree' s sole discretion (collectively with the Tranche A Loan, the Tranche B Loan, the Tranche C Loan, and the Tranche D Loan, the~~ " **OTC** ~~Oaktree Term Loan~~ ") **market while that appeal is pending** . We ~~may draw~~ **have and intend to continue to actively monitor** the ~~Tranche B Loan until September 30~~ **closing bid price of our common stock. After considering all available options to regain compliance with the Bid Price Requirement , our board of directors intends to recommend that our stockholders approve amendments to our restated certificate of incorporation to effect a reverse stock split of our common stock at our** ~~2024~~ **2025 Annual Meeting of Stockholders. However, there can be no assurance that any such reverse stock split** , if ~~VOWST net sales~~ **approved by the stockholders and implemented, would increase the market price of our common stock in proportion to the reverse split ratio or result in a sustained increase in the market price of our common stock. In addition, it is possible that the reduced number of issued shares of common stock resulting from such a reverse stock split could adversely affect the liquidity of our common stock. Furthermore, if, in the future, our common stock fails to meet the Bid Price Requirement and we have effected a reverse stock split within the prior one- year period, we will not be eligible** for **any compliance period to address** the **bid price deficiency** ~~trailing six consecutive months are at least $ 35. 0 million~~ and ~~at least 4. 5 %~~ **would be issued a delisting determination** ~~greater~~ -- **rather** ~~in~~ **than be granted a compliance period. Under** ~~the~~ **these** ~~calendar quarter prior~~ **circumstances, we could appeal the delisting determination** to **a Nasdaq hearing panel, during which time any suspension or delisting action will be stayed. There can also be no assurance that we will regain compliance with the Bid Price Requirement during the 180- day compliance period, secure a second 180- day period to regain compliance, maintain compliance with the** ~~the~~ **other** ~~Applicable Funding Date (as defined~~ **Nasdaq listing requirements, or be successful** in **appealing any delisting determination. If our common stock is delisted in** the **future,** ~~Oaktree Credit Agreement) over the calendar quarter immediately preceding~~ it **is unlikely that we** ~~. We may draw the Tranche C Loan until September 30, 2025, if VOWST net sales for the trailing 12 consecutive months are at least $ 120. 0 million and at least 4. 5 % greater in each of the two calendar quarters prior to the Applicable Funding Date relative, in each case, to the calendar quarter immediately preceding it. The Oaktree Term Loan has a maturity date of April 27, 2029 (the " Oaktree Maturity Date "). Our obligations under the Oaktree Credit Agreement and the other Loan Documents (as defined in the Oaktree Credit Agreement)~~ will be **able** ~~guaranteed by any of our domestic subsidiaries that become Guarantors (as defined in the Oaktree Credit Agreement), subject~~ to **list** ~~certain exceptions. Our and~~ our **common stock on** ~~Guarantors' (collectively, the " Loan Parties ") respective obligations under the Oaktree Credit Agreement and the other~~ **another national** ~~Loan Documents are secured by first priority security~~ **securities exchange on** ~~interests in substantially all assets of the Loan Parties, including intellectual property, subject to certain customary thresholds and exceptions. As of December 31, 2023, there are no Guarantors. The Oaktree Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including~~ a **timely basis or** ~~financial covenant~~

~~requiring us to maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of the Agent of at least $ 30. 0 million~~ at all ~~times commencing from 30 days after the Oaktree Closing Date~~ **, and, as a result, we expect our securities would be quoted on** ~~and~~ **an OTC market** ~~decreasing to $ 25~~. **If this** ~~0 million of cash and cash equivalents in such controlled accounts after we borrow any Tranche B Loan. As of December 31, 2023, we~~ were ~~in compliance with all financial covenants pursuant~~ to ~~the Oaktree Credit Agreement. In addition, the Oaktree Credit Agreement contains certain events of default that entitle the Agent to cause our~~ **occur** ~~indebtedness under the Oaktree Credit Agreement to become immediately due and payable~~, **we** and **our stockholders could face significant material adverse consequences** ~~to exercise remedies against the Loan Parties and the collateral securing the Oaktree Term Loan~~, including **limited availability of market quotations** ~~cash. Under the Oaktree Credit Agreement, an~~ **and analyst coverage for** ~~event of default will occur~~ -- **our** ~~if~~ **common stock, and reduced liquidity for the trading of our securities. Delisting also could result in** , among other things, ~~we fail to make payments under the Oaktree Credit Agreement (~~ **a loss of investor confidence or interest in strategic transactions or opportunities, us being** subject to **regulation in** ~~specified cure periods with respect to certain payments), we or our subsidiaries breach~~ -- **each state in** ~~any of the covenants under the Oaktree Credit Agreement (subject to specified cure periods with respect to certain breaches), a material adverse change occurs, we, our subsidiaries or our or their respective assets become subject to certain legal proceedings, such as bankruptcy proceedings, we and / or our subsidiaries are unable to pay our or their debts as they become due or default on contracts with third parties~~ which **we offer** ~~would permit the holder of indebtedness in excess of a certain threshold to accelerate the maturity of such indebtedness or~~ **our securities,** ~~that could cause a material adverse change. Upon the occurrence and for the duration of an~~ **and difficulty in recruiting** ~~event of default, an~~ **and retaining personnel through equity incentive awards** ~~additional default interest rate equal to 2~~. ~~0 % per annum may apply to all obligations owed under the Oaktree Credit Agreement. Any declaration by the Oaktree Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. Risks Related to Our Common Stock~~ Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval. Our executive officers, directors and stockholders who owned more than 5 % of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately ~~43~~ **38** % of our outstanding voting stock as of December 31, ~~2023~~ **2024** . As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may: • delay, defer or prevent a change in control; • entrench our management and the board of directors; or • impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire. A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have also registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We are a " smaller reporting company, " and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are a " smaller reporting company " as defined under the rules promulgated under the Exchange Act. We will remain a smaller reporting company until the fiscal year following the determination that both (i) the value of our voting and non- voting common shares held by non- affiliates is more than $ 250 **. 0** million measured on the last business day of our second fiscal quarter and (ii) our annual revenues are more than $ 100 **. 0** million during the most recently completed fiscal year and the value of our voting and non **–** voting common shares held by non- affiliates is $ 700 **. 0** million or more as measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, or supplemental financial information. We have elected to take advantage of certain of the reduced reporting obligations, and may in the future take advantage of these or others. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing: • a classified board of directors with three- year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors; • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • the exclusive right of our board of directors to elect a director to fill a vacancy created

by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors; • the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; • the ability of our board of directors to alter our bylaws without obtaining stockholder approval; • the required approval of the holders of at least two- thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and • advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer' s own slate of directors or otherwise attempting to obtain control of us. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our certificate of incorporation designates the Court of Chancery of the State of Delaware, subject to certain exceptions, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders and our bylaws designate the federal district courts of the United States as the exclusive forum for actions arising under the Securities Act of 1933, as amended, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. In addition, our bylaws provide that the federal district courts of the United States are the exclusive forum for any complaint raising a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation and bylaws described above. We believe these choice of forum provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, ~~the Oaktree Credit Agreement currently prohibits us from paying dividends on our equity securities, and~~ any future debt agreements may ~~likewise~~ preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future. General Risk Factors The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Our stock price is likely to be volatile. Furthermore, the stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their common stock. The market price for our common stock may be influenced by many factors, including: • our ability to **realize the benefits of the Transaction with SPN; • our ability to** execute and realize the benefits of strategic plans **; • our requirement for additional funding** ~~, such as the Restructuring Plan we announced~~ in ~~November~~ **the first quarter of** ~~2023~~ **2026 ; • our continued compliance with stock exchange listing standards** ; • the success of competitive products or technologies; • actual or anticipated changes in our growth rate relative to our competitors; • results of clinical trials of our product candidates or those of our competitors; • the success of ~~our~~ **any potential future** commercialization efforts; • developments related to any future collaborations; • regulatory or legal developments in the United States and other countries; • development of new product candidates that may address our markets and may make our product candidates less attractive; • changes in physician, hospital or healthcare provider practices that may make our product candidates less useful; • announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any of our product candidates or clinical development programs; • failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; • the results of our efforts to discover, develop, acquire or in- license additional product candidates or products; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be

similar to us; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; • general economic, industry and market conditions; and • the other factors described in this " Risk Factors " section. If securities or industry analysts issue an adverse or misleading opinion regarding our business, our common stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. We will continue to incur costs as a result of being a public company, and our management will continue to devote substantial time to compliance initiatives and corporate governance practices. As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and make some activities more time- consuming and costly. For example, we expect that these rules and regulations will continue to make it more difficult and more expensive for us to maintain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is 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. Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. ~~However~~ **Additionally** , ~~while~~ we ~~remain~~ **are no longer** a non- accelerated filer, **so** we **are** ~~will not be~~ required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the Securities and Exchange Commission or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Failure to keep up with evolving **and conflicting** laws, regulations, trends and stakeholder expectations relating to environmental, social and governance, or ESG, practices or reporting could adversely impact our reputation, share price and access to and cost of capital or otherwise adversely impact our business. Certain institutional investors, investor advocacy groups, investment funds, creditors and other influential financial market participants, as well as governments, regulators, customers, patients, employees and other stakeholders or third parties, have become increasingly focused on companies' ESG practices, including the impact of business on the environment ~~and diversity, equity and inclusion matters~~ . Certain organizations also provide ESG ratings, scores and benchmarking studies that assess companies' ESG practices. Although there are no universal standards for such ratings, scores or benchmarking studies, they are used by some investors to inform their investment and voting decisions. It is possible that our future stockholders or organizations that report on, rate or score ESG practices will not be satisfied with our ESG strategy or performance. Unfavorable press about or ratings or assessments of our ESG strategies or practices, regardless of whether or not we comply with applicable legal requirements, may lead to negative investor sentiment toward us, which may hinder the Company' s access to capital. Our reputation could be damaged if we do not, or are perceived not to, meet evolving stakeholder demand with respect to ESG matters, which could adversely affect our business, financial condition, profitability and cash flows. We may be criticized for our lack of ESG initiatives or goals or perceived as not taking sufficient action **or for taking too much action** in connection with any of these matters. In turn, we may take certain **or terminate other** actions ~~, including the establishment of ESG- related goals or targets,~~ to ~~improve our ESG profile and / or~~ respond to **evolving demand by regulators, governmental officials, investors, employees and other** stakeholder ~~demand~~ ; however, such actions may be costly or be subject to numerous conditions that are outside our control, and we cannot guarantee that we will meet these goals or targets or that such actions will have the desired effect even if met **. There has been an increase in litigation claiming that corporate diversity, equity and inclusion programs may inappropriately discriminate against certain groups. Relatedly, both advocates and opponents to certain environmental and social matters are increasingly resorting to a range of activism forms, including media campaigns, shareholder proposals, and litigation, to advance their perspectives. To the extent we are subject to such litigation, activism or pressure, we may be**

require to incur costs or it may otherwise adversely impact our business or reputation . Additionally, we and / or other parties in our value chain are subject to, or are expected to be subject to additional climate and other ESG- related obligations arising from legislation and regulation in the United States, the European Union and other jurisdictions, including new reporting requirements, even as the availability and quality of the information that may be required to comply with such laws and regulations remains limited. We expect for our compliance costs with these laws ~~and~~ **,** regulations **, and reporting requirements** to increase in **the** future, and any failure, or perceived failure, by us to adhere to such laws ~~and~~ **,** regulations **, and reporting requirements** , or meet evolving and varied stakeholder expectations and standards, could harm our business, reputation, financial condition, and operating results.