Risk Factors Comparison 2024-02-22 to 2023-02-23 Form: 10-K

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Investing in our common stock involves a high degree of risk. Before deciding to invest in our company or deciding to maintain or increase your investment, you should consider carefully the risks and uncertainties described below. The risks and uncertainties described below and in our other filings with the SEC are not the only risks we face. If one or more of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the market price for our common stock could decline, and you may lose your entire investment. Risk Factor Summary The following is a summary of certain important factors that may make an investment in our Company speculative or risky. You should carefully consider the fuller risk factor disclosure set forth in this Annual Report, in addition to the other information herein, including the section of this report titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our financial statements and related notes. • **Our** ~~The coronavirus pandemic has caused interruptions or delays of our~~ business ~~plan~~ **could be materially** and ~~may continue to have a significant adverse~~ **adversely affected in the future by the** ~~effect~~ **effects** ~~on our business~~ **of disease outbreaks, epidemics and pandemics** . • Continued inflation and uncertainty in global economic conditions could negatively affect our business, results of operations and financial condition. • Our clinical trials have been delayed as a result of the ongoing military action by Russia in Ukraine and the continuation of this conflict could have further adverse effects on our business. • We have a limited operating history with our current business plan, have incurred significant losses since 2016, anticipate that we will continue to incur significant and increasing losses for the foreseeable future and may never achieve or maintain profitability. The absence of any commercial sales and our limited operating history make it difficult to assess our future viability. • We currently have no source of product sales revenue and may never earn product revenue or be profitable. • We will require substantial additional funding, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or future commercialization efforts. • Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. • The marketing approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed. • Clinical drug development involves a lengthy and expensive process with an uncertain outcome. • Clinical failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive marketing approval. The effect of failure or results different than expectations can result in significant market value decline and possible negative financial results or asset related impairment. • Our product candidates may cause undesirable adverse effects or have other properties that could delay or prevent their marketing approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if obtained. • We are heavily dependent on the success of our product candidates, which are in the early **to late** stages of clinical development. We may not be able to generate data for any of our product candidates sufficient to receive regulatory approval in our planned indications, which will be required before they can be commercialized. • Due to our limited resources and access to capital, we must decide to prioritize development of our current product candidates for certain indications and at certain doses. These decisions may prove to have been wrong and may materially adversely affect our business, financial condition, results of operations and prospects. • If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates. • Even if we obtain the required regulatory approvals in the United States and other territories, the commercial success of our product candidates will depend on market awareness and acceptance of our product candidates. • We currently have limited marketing and sales experience. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, if and when regulatory approval is received, we may be unable to generate any revenue. • If we fail to enter into strategic relationships or collaborations, our business, financial condition, commercialization prospects and results of operations may be materially adversely affected. • Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably. • We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do. • The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates. • We may be unable to realize the potential benefits of any collaboration. • Our proprietary rights may not adequately protect our technologies and product candidates. • We may not be able to protect our intellectual property rights throughout the world. • Intellectual property rights do not protect against all potential threats to our competitive advantage. • We incur significant costs and demands upon management as a result of complying with the laws and regulations affecting public companies. • **Our failure to meet the $ 1. 00 minimum bid price or other continued listing requirements of Nasdaq could result in a delisting of our common stock, which could negatively impact the market price and liquidity of our common stock and our ability to access the capital markets. •** The market price of our common stock has been and is expected to continue to be volatile. • We do not anticipate that we will pay any cash dividends in the foreseeable future. Macroeconomic Risks **Disease outbreaks, epidemics** ~~COVID- 19 has had~~ and ~~continues to~~ **pandemics, in regions where we** have ~~a~~ **concentrations of clinical trial sites and other business operations, could adversely affect our business, including by causing** significant **disruptions in our operations and / or in the**

operations of manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and to maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of our product candidates, if at all. Additionally, general supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact ~~around the world. In an effort to contain and mitigate the spread of COVID- 19, many countries imposed unprecedented restrictions on travel, quarantines, vaccine mandates and other~~ -- **the ability** ~~public health safety measures. Although some~~ of ~~these restrictions have been loosened or~~ **our** ~~lifted~~ **clinical trial sites to obtain basic medical supplies used** in ~~the United States and~~ **our trials in a timely fashion, if at all. Moreover,** ~~other~~ -- **the extent** ~~countries, new variants continue~~ to **which disease** ~~emerge, new~~ outbreaks **, epidemics** ~~are periodically reported~~ and ~~significant uncertainty and concern remain. The extent to which the pandemic~~ **pandemics** may ~~continue to~~ impact our business **, results of operations and financial position** will depend on future developments, which are highly uncertain and cannot be predicted ~~, but~~ **with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. To** the ~~development~~ **extent any future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results** of ~~clinical supply materials~~ **operations and growth prospects, it** could **also** ~~be delayed and enrollment of patients in our ongoing studies may be delayed or suspended, if hospitals and clinics in areas where we are conducting trials~~ have ~~to shift resources to cope with~~ the **effect of heightening** ~~COVID- 19 pandemic and may~~ **many** ~~limit access or close clinical facilities due to the COVID- 19 pandemic. Additionally, if our trial participants are unable to travel to our clinical study sites as a result~~ of **the** ~~quarantines, vaccine mandates, travel bans or~~ other **risks** ~~restrictions resulting from the COVID- 19 pandemic, we may experience higher discontinuation rates or delays in our clinical studies, as occurred in our investigator- sponsored trial of vidofludimus calcium in PSC that was conducted at the Mayo Clinic. Government- imposed quarantines and restrictions may also require us to temporarily terminate our clinical sites. Furthermore, if we determine that our trial participants may suffer from exposure to COVID- 19 as a result of their participation in our clinical trials, we may voluntarily terminate certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected development timelines for our product candidates may be negatively impacted. We cannot predict the continuing impact of the COVID- 19 pandemic, as consequences of such an~~ **and** ~~event are highly uncertain~~ **uncertainties described** ~~and subject to change. We do not yet know the full extent of potential delays or impacts that have affected and may continue to affect our business, or our clinical studies~~ in **this " Risk Factors " section** ~~general. The COVID- 19 pandemic has already adversely affected our operations and may further materially disrupt or delay our business operations, further divert the attention and efforts of the medical community to coping with COVID- 19, disrupt the marketplace in which we operate, and / or have continuing material adverse effects on our operations. The COVID- 19 pandemic could further disrupt our business and operations, interrupt our sources of supply, hamper our ability to raise additional funds or sell our securities, continue to slow down the overall economy or curtail consumer spending~~ . Adverse macroeconomic conditions, including inflation, slower growth or recession, higher interest rates, currency fluctuations, supply chain delays or shortages, high unemployment or personnel shortages could hurt our business. We have already seen a general increase in many of our costs as a result of inflation, although inflation has not yet had a material impact on our results of operations. However, the economies of Germany, the United States, Australia and other countries in which we do business have experienced high rates of inflation during 2022 **and 2023** and, if inflation were to continue for a prolonged period of time or the rate of inflation in our markets were to increase, or if a global recession were to occur, our expenses could increase substantially, resulting in increased losses from operations and net loss. A downturn in the economic environment can also lead to limitations on our ability to obtain financing, reduced liquidity and declines in our stock price. Our clinical trials have been delayed as a result of the ongoing military action by Russia in Ukraine and the continuation of this conflict could have further adverse effects on our business. Our clinical trials of vidofludimus calcium were originally planned to be conducted at more than 60 sites in Ukraine and Russia, but most had to be relocated to other countries because of the invasion of Ukraine by Russia in February 2022 and resulting sanctions imposed on Russia by the United States and other countries. These disruptions delayed our clinical development program, increased our costs and may disrupt future planned clinical development activities in these two countries. This military action has continued for more than ~~a~~ **two** ~~year~~ **years** and its future course and effects on our Company are highly unpredictable. We currently have ~~19~~ **35** active sites in western Ukraine and the ongoing conflict could put the data associated with these patients in jeopardy as well as extend patient recruitment timelines. We anticipate that Ukraine will make up approximately ~~15 %~~ 20 % of our ENSURE- 1 and ENSURE- 2 phase 3 patient population. ~~In addition, no clinical sites in Russia have been activated or are intended to be used in the future.~~ Alternative sites to fully and timely compensate for our clinical trial activities in Ukraine may not continue to be available. If our clinical trials are further interrupted, our clinical development program could experience further delays and increased costs and we may have insufficient data to support regulatory approvals of vidofludimus calcium, and any commercialization may be delayed or not approved, which could limit our potential revenue and hurt the competitive position of our potential products. Risks Related to Our Business and Financial Condition We are a development- stage pharmaceutical company with a limited operating history with our current business plan. Our net losses were $ **93. 6 million and $** 120. 4 ~~million and $ 92. 9~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~317~~ **410** . ~~3~~ **9** million and to date and have not generated any revenue from our current product candidates. Moreover, Immunic AG, the company' s operating subsidiary, has only a limited operating history upon which stockholders can evaluate our business and prospects, is not profitable and has incurred losses in each year since its inception in 2016. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. We have devoted substantially all of our financial resources to identify, acquire and develop our product candidates, including providing general and administrative support for our

operations. We expect our losses to increase as we continue to conduct clinical trials and continue to develop our lead product candidates. We expect to invest significant funds into the research and development of our current product candidates to determine the potential to advance these product candidates to seek regulatory approval. To date, we have financed our operations primarily through the sale of equity securities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or grants. We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for, and successfully commercialize, any current or future product candidate. However pharmaceutical product development is an extremely costly and highly speculative undertaking and involves a substantial degree of risk. In addition, if we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive regulatory approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third- party payors, and adequate market share for our product candidates. Even if we eventually obtain adequate market share for our product candidates, to the extent they receive regulatory and market approval **and authorization for reimbursement** , the potential markets for our product candidates may not be large enough for us to become profitable. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our expenses will increase substantially if and as we: • continue the clinical development of our product candidates; • continue efforts to discover, develop and / or acquire new product candidates; • undertake the manufacturing of our product candidates for clinical development and, potentially, commercialization, or increase volumes manufactured by third parties; • advance our programs into larger, more expensive clinical trials; • initiate additional preclinical, clinical, or other trials or studies for our product candidates; • seek regulatory and marketing approvals and reimbursement for our product candidates; • experience any delays or encounter issues with the development and process for regulatory approval of our product candidates such as safety issues, clinical trial accrual delays, longer follow- up for planned studies, additional major studies or supportive studies necessary to support marketing approval; • establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for our self; • make milestone, royalty or other payments under any third- party license agreements; • seek to maintain, protect and expand our intellectual property portfolio; • seek to retain current skilled personnel and attract additional personnel; and • add operational, financial and management, and information systems personnel, including personnel to support our product development and commercialization efforts. Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. Failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, expand our pipeline of product candidates or continue our operations. We have not generated any revenues from commercial sales of any of our current product candidates. Our ability to generate product revenue depends upon our ability to successfully commercialize these product candidates or other product candidates that we may develop, in- license or acquire in the future. We do not anticipate generating revenue from the sale of products for the foreseeable future. Our ability to generate revenue from our current or future product candidates also depends on a number of additional factors, including our ability to: • successfully complete research and clinical development of current and future product candidates; • establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of product candidates; • obtain regulatory approval from relevant regulatory authorities in jurisdictions where we intend to market our product candidates; • launch and commercialize any product candidates for which we obtain marketing approval, and if launched independently, successfully establish a sales force and marketing and distribution infrastructure; • obtain coverage and adequate product reimbursement from insurance companies and other third- party payors, including government payors; • achieve market acceptance for any approved products; • establish, maintain and protect our intellectual property rights; and • attract, hire and retain qualified personnel. In addition, because of the numerous risks and uncertainties associated with clinical product development, including that our product candidates may not advance through development or achieve regulatory approval, we are unable to predict the timing or amount of any potential future product sale revenues. Our expenses also could increase beyond expectations if we decide to, or are required by the FDA or comparable foreign regulatory authorities to, perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing any product candidates that may be approved. Since the inception of Immunic AG, substantially all of our resources have been dedicated to the clinical development of our product candidates. Developing pharmaceutical products, including conducting preclinical and non- clinical studies and clinical trials, is a very time- consuming, expensive and uncertain process that takes years to complete. We have consumed substantial amounts of cash since our inception. For example, in the years ended December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** , we used net cash of $ **70. 8 million and $** 65. 1 ~~million and $ 83. 8~~ million, respectively, in our operating activities, substantially all of which related to development of our current product candidates. We believe that we will continue to expend substantial resources for the foreseeable future toward the completion of clinical development and regulatory preparedness of our product candidates, preparations for a commercial launch of any approved product candidates, and development of any other current or future product candidates we may choose to further develop. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, seeking marketing approvals, and manufacturing and supply as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any drug development process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any current or future product candidates that may be approved for marketing. Our operating plan may change as a result of factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to our stockholders, imposition of debt

covenants and repayment obligations, or other restrictions that may adversely affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the ~~fourth~~ **third** quarter of ~~2024~~ **2025**. Our estimate as to how long we expect our existing cash and cash equivalents to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume cash and cash equivalents significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future capital requirements depend on many factors, including: • the scope, progress, results and costs of researching and developing our current product candidates, future product candidates and related preclinical and clinical trials; • the cost of commercialization activities if our current product candidates and future product candidates are approved for sale, including marketing, sales and distribution costs and preparedness of our corporate infrastructure; • the cost of manufacturing current product candidates and future product candidates that we may obtain approval for and successfully commercialize; • our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements; • the number and characteristics of any additional product candidates we may develop or acquire; • any product liability or other lawsuits related to our products or otherwise commenced against us; • the expenses needed to attract and retain skilled personnel; • the costs associated with being a public company; • the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of any such litigation; and • the timing, receipt and amount of sales of, or royalties on, any future approved products. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate: • preclinical studies, clinical trials or other development activities for our current product candidates or any future product candidates; • our research and development activities; or • our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our future product candidates. We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of such equity or convertible debt securities may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, acquire or license intellectual property rights, redeem stock or declare dividends, and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic collaborations and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us. Risks Related to the Clinical Development and Marketing Approval of Our Product Candidates None of our current product candidates have ~~gained~~ **yet advanced to the point when we could seek** marketing approval for sale in the United States or any other country, and we cannot guarantee that we will ever have marketable products. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize, our product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining approval from the FDA to market each product candidate. Similarly, we cannot commercialize our product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Our product candidates could fail to receive marketing approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • the FDA or comparable foreign regulatory authorities may find the human subject protections for our clinical trials inadequate and place a clinical hold on (i) an investigational new drug (“ IND ”) application at the time of its submission, precluding commencement of any trials, or (ii) one or more clinical trials at any time during the conduct of such trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a product candidate’ s clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application “ NDA ”) to obtain marketing approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities may find inadequate the manufacturing processes or facilities of manufacturers with which we contract for clinical and commercial supplies of our product candidates; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner that would delay marketing approval. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. We cannot be certain that any NDA submissions we may make will be accepted for filing and reviewed by the FDA, or ultimately be approved. If an application is not accepted for review, the FDA may require that we conduct additional clinical studies or preclinical testing, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional information to be complete or sufficient to support the filing or approval of the NDA. Regulatory authorities outside of the United States, such as in Europe and Japan and in emerging markets, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those jurisdictions. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates into the relevant markets. Clinical trials conducted in one country may not be accepted or the results may not be found adequate by

regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on our ability to obtain approval in ~~a~~ different ~~jurisdiction~~ **jurisdictions** . Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non- clinical studies or clinical trials, which could be costly and time- consuming. Foreign regulatory approval may be subject to all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. The process to develop, obtain marketing approval for, and commercialize product candidates both inside and outside of the United States is long, complex and costly, and approval is never guaranteed. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary between jurisdictions. Even if our product candidates were to successfully obtain approval from regulatory authorities, any such approval might significantly limit the approved indications for use, including conditioning approval on the requirement of (i) more limited patient populations, (ii) precautions, warnings or contraindications on the product labeling, including " black box " warnings of serious risks, (iii) expensive and time- consuming post- approval clinical studies, risk evaluation and mitigation strategies (" REMS"), or surveillance, or (iv) limiting the claims that the product label may make, any of which may impede the successful commercialization of our product candidates. Following any approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, may require costly new studies and will be subject to additional FDA notification, or review and approval. Also, marketing approval for any of our product candidates may be withdrawn. If we are unable to obtain and maintain marketing approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, our ability to market our product candidates to our full target market will be reduced and our ability to realize the full market potential of our product candidates will be impaired. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue or complete the development of any of our current or future product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. The FDA and comparable foreign regulatory authorities have substantial discretion when and if to grant approval to our product candidates. Even if we believe the data collected from clinical trials of our current product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. Our future clinical trial results also may not be successful. It is impossible to predict the extent to which the clinical trial process may be affected by existing or prospective legislative and regulatory developments. Due to these and other factors, our current or future product candidates could take significantly longer than expected to gain marketing approval, if at all. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our current product candidates. Our clinical trials are conducted at multiple sites, including some sites in countries outside the United States and the European Union, which may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of foreign and non- European Union contract research organizations (" CROs"), as well as expose us to risks associated with clinical investigators who are unknown to the FDA or European regulatory authorities, and with different standards of diagnosis, screening and medical care. Most of our clinical trials of vidofludimus calcium planned at sites in Ukraine and Russia had to be delayed, suspended or relocated because of the invasion of Ukraine by Russia in February 2022, which caused disruptions to our clinical development program and increased our costs. To date, we have not completed all clinical trials required for the approval of any of our current product candidates. The commencement and completion of clinical trials for our current product candidates may be delayed, suspended or terminated as a result of many factors, including but not limited to: • the delay or refusal of regulators or institutional review boards (" IRBs ") at the medical institutions where the clinical trials are conducted. to authorize us to commence a clinical trial at a prospective trial site; • changes in regulatory requirements, policies and guidelines; • the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials; • failure to reach agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • delays in patient enrollment and variability in the number and types of patients available for clinical trials; • the inability to enroll a sufficient number of patients in trials to ensure adequate statistical power to detect statistically significant treatment effects; • lower than anticipated retention rates of patients and volunteers in clinical trials; • clinical sites deviating from trial protocols or dropping out of a trial; • adding new clinical trial sites or relocating planned or existing clinical trial sites; • negative or inconclusive results, which may require us to conduct additional preclinical or clinical trials or to abandon projects that we expect to be promising; • safety or tolerability concerns, which could cause us to suspend or terminate a trial if we find that participants are exposed to unacceptable health risks; • regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; • our third- party research and manufacturing contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • third- party researchers becoming debarred or otherwise penalized by the FDA or other regulatory authorities for violations of regulatory requirements, which could call into question data collected by such researcher and potentially affecting our ability rely on some or all of the data in support of our marketing applications; • difficulty in maintaining contact with patients after treatment, resulting in incomplete data; • delays in establishing the appropriate dosage levels; • the quality or stability of our current product candidates falling below acceptable standards; • the inability to produce or obtain sufficient quantities of our current product candidates to complete clinical trials; and • exceeding budgeted costs due to difficulty in accurately predicting the costs associated with clinical trials. Patient enrollment is a significant factor in the timing

of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating. There are significant requirements imposed on us and on clinical investigators who conduct clinical trials that we sponsor. Although we are responsible for selecting qualified clinical investigators, providing them with the information they need to conduct the clinical trial properly, ensuring proper monitoring of the clinical trial, and ensuring that the clinical trial is conducted in accordance with the general investigational plan and protocols contained in the IND, we cannot ensure that clinical investigators will maintain compliance with all regulatory requirements at all times. The pharmaceutical industry has experienced cases where clinical investigators have been found to incorrectly record, omit, or even falsify data. We cannot ensure that the clinical investigators in our trials will not make mistakes or otherwise compromise the integrity or validity of data, any of which would have a significant negative effect on our ability to obtain marketing approval, our business, and our financial condition. We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs or ethics committees of the institutions in which such trial is being conducted, the independent steering committee, the data safety monitoring board for such trial, or the FDA or comparable foreign regulatory authorities. We or such authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using the drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Delay or termination of clinical trials of our current product candidates will harm their commercial prospects and impair our ability to potentially generate revenues from such product candidates. In addition, any delays in completion of our clinical trials will increase our costs, slow our development and approval process and jeopardize our ability to commence product sales and generate revenues. Moreover, clinical investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. We are required to report certain financial relationships with clinical investigators to the FDA and, where applicable, take steps to minimize the potential for bias resulting from such financial relationships. The FDA may evaluate the reported information and conclude that a financial relationship between us and a clinical investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. The FDA may refuse to accept our marketing applications, and other delays or even denial of marketing approval could result. Preclinical testing or clinical trials of any development candidate may also show new and unexpected findings regarding safety and tolerability. Such findings may harm the ability to conduct further development of product candidates, delay such development, require additional expensive tests, harm our ability to partner these development candidates, or delay or prevent marketing approval by regulatory agencies. Such findings may also harm the ability to compete in the market with other products or to achieve certain pricing thresholds. Any of these occurrences could materially adversely affect our business, financial condition, results of operations, and prospects. In addition, many of the factors that could cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates. Significant clinical trial delays could also allow our competitors to bring products to market before we can, shorten any periods during which we may have the exclusive right to commercialize any approved product candidates, and impair our ability to commercialize any approved product candidates, which may harm our business, financial condition, results of operations and prospects. Use of patient- reported outcomes in our clinical trials may delay the development of our product candidates or increase development costs. In recent years, due to regulatory changes, patient- reported outcomes (" PROs"), may have an important role in the development and regulatory approval of any of our product candidates. PROs involve patients' subjective assessments of efficacy, and this subjectivity increases the uncertainty in determining achievement of clinical endpoints. Such assessments can be influenced by factors outside of our control, and can vary widely from day- to- day for a particular patient, and from patient- to- patient and site- to- site within a clinical trial. Use of PROs may make the outcome of trials more uncertain and may increase our costs and time to finish regulatory approval trials. Clinical failure can occur at any stage of clinical development. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of pharmaceutical companies have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical testing. For example, we announced in October 2022 the analysis of interim group- level data of our Phase 1b clinical trial of IMU- 935 in patients with moderate- to- severe psoriasis did not separate from placebo. Following this announcement, our stock price declined significantly, which caused us to record a full impairment of our goodwill in the quarter ended December 31, 2022. Data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent marketing approval of our product candidates. In addition, the design of a clinical trial can determine whether its results will support approval of a product, or approval of a product for desired indications, and flaws or shortcomings in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to properly design and execute a clinical trial to support marketing approval for our desired indications. Further, clinical trials of product candidates often reveal that it is not practical or feasible to continue development efforts. If one of our product candidates is found to be unsafe or lack efficacy, we will not be able to obtain marketing approval for such product candidate and our business would be harmed. If the results of our clinical trials of

our product candidates do not achieve pre- specified endpoints, we are unable to provide primary or secondary endpoint measurements deemed acceptable by the FDA or comparable foreign regulators, or we are unable to demonstrate an acceptable level of safety relative to the efficacy associated with our proposed indications, the prospects for approval of our product candidates would be materially and adversely affected. For example, we announced in June 2022 that a phase 2 clinical trial of our most advanced drug candidate, vidofludimus calcium, did not achieve its primary endpoint in patients with moderate- to- severe ulcerative colitis. As a result, we do not plan any further drug development activities in ulcerative colitis without a partner. A number of companies in the pharmaceutical industry, including those with greater resources and experience than we, have suffered significant setbacks in Phase 2 and Phase 3 clinical trials, even after seeing promising results in earlier clinical trials. In some instances, there can be significant variability in safety and / or efficacy results between different trials of the same product candidate due to numerous factors, including differences in trial protocols and design, the size and type of the patient population, adherence to the dosing regimen and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent and / or adequate efficacy and safety to obtain marketing approval for our product candidates. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive " approved use " label or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authorities. If any of our current or future product candidates is associated with serious adverse, undesirable or unacceptable side effects, we may need to abandon such candidate' s development or limit development to certain uses or sub- populations in which such side effects are less prevalent, less severe or more acceptable from a risk- benefit perspective. Many drug candidates that initially showed promise in early-stage or clinical testing have later been found to cause side effects that prevented their further development. Results of our trials could reveal a high and unacceptable prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug- related side effects could also adversely affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. If our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approvals of such products; • we may be required to recall a product or change the way such product is administered to patients; • additional restrictions may be imposed on the marketing of the particular product or the manufacturing process for the product or any component thereof; • regulatory authorities may require the addition of labeling statements, such as a precaution, " black box " warning of serious risks or other warnings or a contraindication; • we or our collaborators may be required to implement a REMS or create a medication guide outlining the risks of such side effect for distribution to patients; • we or our collaborators could be sued and held liable for harm caused to patients; • the product may become less competitive and revenues could decline substantially; and • our reputation would suffer. Any of these events could prevent us from achieving or maintaining market acceptance of any approved product candidates, and could materially adversely affect our business, financial condition, results of operations and prospects. We are heavily dependent on the success of our product candidates, most of which are in the early **to late** stages of clinical development. We may not be able to generate data for any product candidates sufficient to receive regulatory approval in its planned indications, which will be required before it can be commercialized. We have invested substantially all of our efforts and financial resources to identify, acquire and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more product candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a product candidate. Our most advanced product candidate, vidofludimus calcium, had the first patient enrolled in a Phase 3 program for relapsing multiple sclerosis (" RMS ") in November 2021 and we do not expect the readout of topline data from this trial until the ~~end~~ **middle** of ~~2025~~ **2026** . We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. We may use our limited financial and operational resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and operational resources, we may forego or delay pursuit of opportunities in some programs, product candidates or indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. We may also enter into strategic collaboration agreements to develop and commercialize some of our programs and potential product candidates in indications with potentially large commercial markets. If we do not accurately evaluate and predict the commercial potential or target market for a particular product candidate, we may (i) relinquish valuable rights to that product candidate through strategic collaborations, licensing or other royalty arrangements when it would have been more advantageous to retain sole development and commercialization rights to such product candidate, or (ii) allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a collaborative arrangement. We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being studied. Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates. Identifying and qualifying sufficient numbers of eligible patients to participate in clinical trials of our product candidates is essential to our success. The timing of our clinical trials depends in part on the rate at

which we can recruit eligible patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. The specific eligibility criteria of our planned clinical trials may further limit the population of available eligible trial participants. We may not be able to identify, recruit, and enroll a sufficient number of eligible patients to initiate or complete our clinical trials in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our product candidates may be delayed. If we experience delays in the completion of, or ~~experiences~~ **experience** termination of, any clinical trials of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from product candidates could be delayed or impaired. We have recently experienced delays in our planned clinical trials of vidofludimus calcium at sites in Ukraine and Russia because of the invasion of Ukraine by Russia **in 2022 and the ongoing conflict** . These and other delays we may encounter in initiating or completing clinical trials would likely increase our overall costs, impair product candidate development and impair our ability to obtain regulatory approval. Any of these occurrences may harm our business, financial condition, and prospects significantly. Even if we receive marketing approval for any of our product candidates, such approved products will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any approved product candidates could be subject to labeling and other restrictions, and we may be subject to penalties and legal sanctions if we fail to comply with regulatory requirements or experience unanticipated problems with any of our approved products. If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, packaging, distribution, adverse event reporting, storage, labeling, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP regulations and GCP for any clinical trials that we conduct post- approval. Any marketing approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or subject to conditions of approval, or contain requirements for potentially costly post- approval studies, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy. The FDA may also require us to implement a Risk Evaluation and Mitigation Strategy drug safety program as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools **.** Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or problems with manufacturing operations or processes, or failure to comply with regulatory requirements, or evidence of acts that raise questions about the integrity of data supporting the product approval, may result in, among other things: • restrictions on product distribution or use, or requirements to conduct post- marketing studies or clinical trials; • restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; • fines, warning letters, untitled letters, or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals; • product seizure or detention, or refusal to permit the import or export of products; and • injunctions or the imposition of civil or criminal penalties. The FDA' s policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval, manufacturing or commercialization of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or other jurisdictions. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. The occurrence of any event described above may limit our ability to commercialize any approved product candidates and harm our business, financial condition, and prospects significantly. If we fail to obtain regulatory approval in jurisdictions outside the United States, we will not be able to market our products in those jurisdictions. We intend to market any approved product candidates in international markets, either ourselves or in conjunction with collaborators. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary from country to country and may require testing in addition to what is required for a marketing application in the United States. Moreover, the time required to obtain approval in other countries may be different than in the United States. In addition, in many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and additional or different risks. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in some or all of the international markets in which we intend to market any approved product candidates, which would significantly harm our business, results of operations and prospects. Agencies like the FDA and national competition regulators in European countries strictly regulate the marketing and promotion of drugs. If we are found to have improperly promoted any of our product candidates for uses beyond those that are approved, we may become subject to significant liability. Regulatory authorities like the FDA and national competition laws in Europe strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign regulatory authorities as reflected in the product' s approved labeling, known as " off- label " use, nor may a product be promoted prior to marketing approval. If we receive marketing approval for a product candidate for its proposed

indication (s), physicians may nevertheless prescribe the product for their patients in a manner that is inconsistent with the approved label if the physicians personally believe in their professional medical judgment it could be used in such manner. Although physicians may prescribe legally available drugs for off- label uses, manufacturers may not market or promote such off- label uses. In addition, the FDA requires that promotional claims not be " false or misleading " as such terms are interpreted by the FDA. For example, the FDA requires substantial evidence, which generally consists of two adequate and well- controlled head- to- head clinical trials, for a company to make a claim that its product is superior to another product in terms of safety or effectiveness. Generally, unless we perform clinical trials meeting that standard comparing our product candidates to competing products and these claims are approved for our product labeling, we will not be able promote our product candidates as superior to competing products. In the United States, regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found to have improperly promoted our product, including for an off- label use, we may become subject to significant liability. Numerous drug manufacturers have been the subject of investigations related to off- label promotion resulting in multi- billion dollar settlements, consent decrees, and on- going monitoring under corporate integrity agreements or deferred prosecution agreements. In addition, the FDA could also seek permanent injunctions under which specified promotional conduct is monitored, changed or curtailed. Our current and future relationships with healthcare professionals, investigators, consultants, collaborators, actual customers, potential customers and third- party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to sanctions. Healthcare providers, physicians and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare professionals, investigators, consultants, collaborators, actual customers, potential customers and third- party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute and the federal False Claims Act (" FCA"), which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any drug candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the U. S. states and foreign jurisdictions in which we conduct business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate 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, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. Remuneration has been interpreted broadly to include anything of value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and those activities may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor. A conviction for violation of the Anti- Kickback Statute results in mandatory exclusion from participation in federal healthcare programs. This statute has been applied to arrangements between pharmaceutical manufacturers and those in a position to purchase products or refer others including prescribers, patients, purchasers and formulary managers. In addition, the Affordable Care Act amended the Social Security Act to provide that the U. S. government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute also constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, the penalties for which are described below. • Federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or for making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties (tied to inflation) of $ ~~12~~ **13**, ~~537~~ **946** to $ ~~25~~ **27**, ~~076~~ **894** (after ~~May 9~~ **January 15**, ~~2022~~ **2024**) per false claim or statement. • The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. • The federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA") imposes criminal and civil penalties for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. • The federal Open Payments program, created under the Physician Payment Sunshine Act, also known as Section 6002 of the Patient Protection and Affordable Care Act (the " Affordable Care Act "), and its implementing regulations, impose annual reporting requirements for certain manufacturers of drugs, devices, biologicals and medical supplies for payments and " transfers of value " provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family

members. The SUPPORT for Patients and Communities Act expanded the scope of reporting such that companies must also report payments and transfers of value provided to other types of healthcare professionals. Failure to submit timely, accurately and completely the required information for all covered payments, transfers of value and ownership or investment interests may result in civil monetary penalties. • There are many analogous state and foreign laws, such as: state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. • The Affordable Care Act, among other things, amended the intent requirement of the federal Anti- Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. Efforts to ensure that our future business arrangements with third parties comply with applicable healthcare laws and regulations may 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. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including current and any future collaborators, are found not to be in compliance with applicable laws, those persons or entities may be subject to criminal, civil or administrative sanctions, including exclusion from participation in government healthcare programs, which could also negatively affect our business. We are subject to the U. S. Foreign Corrupt Practices Act and other anti- corruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties and other remedial measures, and incur legal expenses, which could adversely affect our business, financial condition, results of operations, stock price and prospects. Our operations are subject to anti- corruption laws, including the U. S. Foreign Corrupt Practices Act (" FCPA"), and other anti- corruption laws that apply in countries where we do, or may in the future do, business. The FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We also may participate in collaborations and relationships with third parties whose actions, if non- compliant, could potentially subject us to liability under the FCPA or local anti- corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing or future laws might be administered or interpreted. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States and authorities in the European Union, including applicable import and export control regulations, economic sanctions on countries and persons, anti- money laundering laws, customs requirements and currency exchange regulations, collectively referred to as trade control laws. We may not be effective in ensuring our compliance with all applicable anti- corruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anti- corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and incur substantial legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. Likewise, any investigation of any potential violations of these anti- corruption laws or trade control laws by U. S. or other authorities could also have an adverse impact on our reputation, business, financial condition, results of operations, stock price and prospects. The impact on us of recent and future healthcare reform legislation and other changes in the healthcare industry and healthcare spending is currently unknown, and may adversely affect our business model. In the United States and some foreign jurisdictions, legislative and regulatory changes and proposed changes regarding the healthcare system could prevent or delay marketing approval of our drug candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and other jurisdictions. We operate in a highly regulated industry and new laws, regulations, judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery of, or payment for, healthcare products and services could negatively impact our business, financial condition, results of operations and prospects. There continues to be significant interest in promoting healthcare reform, as evidenced by the enactment in the United States of the Affordable Care Act and efforts to repeal, invalidate or modify portions of the act. Among other things, the Affordable Care Act contains provisions that may reduce the profitability of drug products, including, for example, revising the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, extending Medicaid rebates to individuals enrolled in Medicaid managed care plans, imposing mandatory discounts for certain Medicare Part D beneficiaries who fall into a coverage gap, and subjecting drug manufacturers to payment of an annual fee based on its market share of prior year total sales of branded ~~programs~~ **products** to certain federal healthcare programs. There have been judicial and congressional challenges to the Affordable Care Act, some of which have been successful, as well as efforts to repeal or replace certain aspects of the Affordable Care Act. If a new law is enacted, or if the Affordable Care Act is overturned, repealed or modified, in whole or in part, by judicial or legislative action, many if not all of the provisions of the Affordable Care Act may

no longer apply to prescription drugs. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how any future prescription drug products are paid for and reimbursed by government and private payors, our business could be adversely impacted. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2 % per fiscal year, which started in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, also reduced Medicare payments to several categories of healthcare providers. The Biden administration and Congress may announce initiatives intended to result in lower drug prices. We are not in a position to know at this time whether such initiatives will become law or what impact they may potentially have on our business. We expect that additional healthcare reform measures and drug pricing regulations that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the revenue that we may potentially receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue or commercialize our drug candidates. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect: • the demand for any drug products for which we may obtain marketing approval; • our ability to set a price for our products that we believe is fair; • our ability to obtain coverage and reimbursement approval for a product approved for marketing; • our ability to generate revenues and achieve or maintain profitability; and • the level of taxes that we are required to pay. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition or results of operations. Our research and development activities and the activities of our contract manufacturers and suppliers involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at facilities of ours and our manufacturers, pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, or the risk of environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our contract manufacturers and suppliers for handling and disposing of these materials generally comply with the current standards prescribed by applicable laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In the event of contamination of injury, we may be held liable for any resulting damages, which could exceed our resources or result in government- imposed restrictions on our use of specified materials or interruptions of our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have generally tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Other Risks Related to Our Business Because we have limited resources and access to capital to fund our operations, we must decide which dosages and indications to pursue for the clinical development of our current product candidates and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward dosages or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the market potential of our current product candidates or if we misread trends in the pharmaceutical industry, our business, financial condition, results of operations and prospects could be materially adversely affected. We may not be able to win contracts or grants from governments, academic institutions or non- profits. From time to time, we may apply for contracts or grants from government agencies, non- profit entities and academic institutions. Such contracts or grants can be highly attractive because they provide capital to fund the ongoing development of our product candidates without diluting our stockholders. However, there is often significant competition for these contracts or grants. Entities offering contracts or grants may have requirements to apply for, or to otherwise be eligible for, certain contracts or grants that our competitors may be able to satisfy that we cannot satisfy. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants may or will be awarded and the conditions and size of the contracts or grants to each awardee. Even if we are able to satisfy the award requirements, we may not be able to win any contracts or grants in a timely manner, if at all. In addition, even if we enter into contracts with or ~~receives~~ **receive** grants from government agencies, non- profit entities or academic institutions, we may lose such contracts or grants due to failure to comply with applicable terms, limitations, or government regulations. As a result, our business, results of operations, financial condition and prospects could be harmed. Our success as a biotechnology company depends on our continued ability to attract, retain and motivate highly qualified management and scientific and clinical personnel. The loss of the services of any such personnel could delay or prevent obtaining marketing approval or commercialization of our product candidates. We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among

biotechnology, pharmaceutical and other companies. Our failure to attract, hire, integrate and retain qualified personnel could impair our ability to achieve our business objectives. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of applicable insurance coverage, we could be forced to pay substantial damage awards. The use of any of our product candidates in clinical trials and the sale of any approved products may expose us to product liability claims. We currently maintain a limited amount of product liability insurance. We intend to monitor the amount of coverage we maintain as the size and design of our clinical trials evolve and seek to adjust the amount of coverage we maintain accordingly. However, we may not maintain insurance coverage that adequately protects us against some or all of the claims to which we might become subject. We might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a claim brought against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to divert substantial financial and managerial resources to such defense, and adverse publicity could result, all of which could harm our business. We could have liability if our employees, independent contractors, investigators, CROs, consultants, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk that our employees and other parties with which we do business may engage in fraudulent conduct or other illegal activity. Misconduct by employees and other parties could include intentional, reckless and / or negligent conduct or violation of FDA regulations and laws that require reporting true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee and other third- party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate. Even if we are ultimately successful in defending any such actions, we could be required to divert financial and managerial resources to such action and adverse publicity could result, all of which could harm our business. We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations. We currently have approximately ~~66~~ 77 employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing our growth. As we advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities. As our operations expand, we expect that we will need to manage additional relationships with such third parties, as well as additional collaborators and suppliers. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure and internal controls, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth. Our internal computer systems, or those of our development collaborators, third- party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs. Our internal computer systems and those of our current and any future strategic collaborators, vendors, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, cybersecurity threats, war and telecommunication and electrical failures. We may experience cyber- attacks on our information technology systems by threat actors of all types (including but not limited to nation states, organized crime, other criminal enterprises, individual actors and / or advanced persistent threat groups). In addition, we may experience intrusions on our physical premises by any of these threat actors. If any such cyber- attack or physical intrusion were to cause interruptions in our operations, such as a material disruption of our development programs or our manufacturing operations, whether due to a loss of our trade secrets or other proprietary information, it would have a material and adverse effect on us. For example, the loss of clinical trial data from one or more ongoing or completed or future clinical trials could result in delays in our regulatory approval efforts, significantly increase our costs to recover or reproduce the data and expose us to liability. In addition, any breach of our computer systems or physical premises could result in a loss of data or compromised data integrity across more than one of our programs in different stages of development. Any such breach, loss, or compromise of clinical trial participant personal data may also subject us to civil fines and penalties or claims for damages, either under the General Data Protection Regulation and relevant member state law in the European Union, other foreign laws, and HIPAA, and other relevant state and federal privacy laws in the United States including

the California Consumer Privacy Act. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including but not limited to information related to our vidofludimus calcium product candidate, we could incur liability, our competitive and reputational position could be harmed, and the further development and commercialization of our investigational medicines could be delayed. On July 31, 2020 we discovered that an email account at the Company was subject to attempted unauthorized access for a period of up to 24 hours and we hired an investigator to ascertain what, if any, Company or patient information was impacted. We do not believe any confidential or proprietary information was compromised and have taken steps to prevent unauthorized action in the future such as implementing two factor authentication for our email accounts. **As a result of a new SEC rule on cybersecurity disclosure, we are required to disclose, on a current basis pursuant to new Item 1. 05 of SEC Form 8- K, any cybersecurity incident that we determine to be material and describe the material aspects of the nature, scope, and timing of the incident, as well as the material impact or reasonably likely material impact of the incident on us, including our financial condition and results of operations. We will also be required to describe, on a periodic basis, our processes, if any, for the assessment, identification, and management of material risks from cybersecurity threats, and describe whether any risks from cybersecurity threats have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition, our board' s oversight of risks from cybersecurity threats and management' s role in assessing and managing material risks from cybersecurity threats.** While we believe that our insurance policies include liability coverage for security breaches, we could be subject to **liability,** indemnity claims or other damages that exceed, or are outside the scope of, our insurance coverage. As a result, the ramifications of a potential security breach could have a material adverse effect on our business, financial condition, results of operations and prospects, as well as cause a decline in the trading price of our common stock. Risks Related to Commercialization of Our Product Candidates Even if we obtain marketing approval for our current product candidates or any other product candidates that we may develop or acquire in the future, our products may not gain market acceptance among physicians, key opinion leaders, healthcare payors, patients and the medical community. Market acceptance of any approved products depends on a number of factors, including: • the timing of market introduction; • the efficacy and safety of the product, as demonstrated in clinical trials; • the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any precautions, warnings or contraindications that may be required on the label; • acceptance by physicians, key opinion leaders and patients of the product as a safe and effective treatment; • the cost, safety and efficacy of treatment in relation to alternative treatments; • the availability of coverage and adequate reimbursement and pricing by third- party payors and government authorities; • the number, cost and clinical profile of competing products; • the growth of drug markets in our various indications; • relative convenience and ease of administration; • marketing and distribution support; • the prevalence and severity of adverse side effects; and • the effectiveness of our sales and marketing efforts. Market acceptance is critical to our ability to generate revenue. Any approved and commercialized product candidate may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate sufficient revenue and our business would suffer. We currently have no marketing and sales experience. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, if and when regulatory approval is received, we may be unable to generate any revenue. We have never commercialized a product candidate, and we currently have no marketing and sales organization. To the extent our product candidates are approved for marketing, if we are unable to establish marketing and sales capabilities or enter into agreements with third parties to effectively market and sell our product candidates, we may not be able to successfully market and sell our product candidates or generate product revenue. In addition, we currently do not have marketing, sales or distribution capabilities for our product candidates. In order to commercialize any of our products that receive marketing approval, we would have to build marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development of our product candidates, if we elect to build a targeted specialty sales force, such an effort would be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have their own sales forces and established distribution systems, in lieu of or to augment any sales force and distribution systems we may create. If we are unable to enter into collaborations with third parties for the commercialization of any approved products on acceptable terms or at all, or if any such collaborator does not devote sufficient resources to the commercialization of our product or otherwise fails in commercialization efforts, we may not be able to successfully commercialize our product candidates even if we receive marketing approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future revenue will be materially and adversely impacted. Our product development programs and the potential commercialization of our current product candidates will require substantial additional cash to fund expenses. Therefore, in addition to financing the development of our product candidates through additional equity financings or through debt financings, we may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of our product candidates in the United States or foreign markets. We announced in June 2022 that we do not plan further drug development activities in ulcerative colitis without a partner ~~, following the failure of our phase 2 clinical trial to achieve its primary endpoint~~ . We face significant competition in seeking appropriate collaborators. Collaborations are complex and time- consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. Any of these contingencies may require us to curtail the development of a particular product, reduce or delay one or more of our development programs, delay our potential commercialization or reduce the scope of our sales or marketing activities, or increase our

expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring any approved product candidates to market and generate product revenue. If we do enter into a new collaboration agreement, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition: • we may not be able to control the amount or timing of resources that the collaborator devotes to the product development program; • the collaborator may experience financial difficulties and thus not commit sufficient financial resources or personnel to the product development program; • we may be required to relinquish important rights such as marketing, distribution and intellectual property rights; • a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors; or • business combinations or significant changes in a collaborator' s business strategy may adversely affect our or the collaborator' s willingness to complete our respective obligations under any arrangement. The pricing, coverage, and reimbursement of any of our approved products must be sufficient to support our commercial efforts and other development programs, and the availability and adequacy of coverage and reimbursement by third- party payors, including governmental and private insurers, are essential for most patients to be able to afford expensive treatments. Sales of any of our approved product candidates will depend substantially, both domestically and in other jurisdictions, on the extent to which the costs of any of our approved products will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government payors and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free, which would harm our potential revenues and profits, or we may not be able to successfully commercialize our products. In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services (" CMS"), an agency within the U. S. Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for our novel product candidates and what reimbursement codes our product candidates may receive if approved. There also may be delays in obtaining coverage for newly- approved drugs. Obtaining coverage and reimbursement approval is time- consuming and costly, requiring us to provide payors with scientific, clinical, and cost- effectiveness data. Further, eligibility for coverage does not necessarily signify that a drug will be reimbursed in all cases or at a rate that covers our costs. Thus, even if we succeed in bringing a product to market, it may not be considered medically necessary or cost- effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Outside the United States, international operations are generally subject to extensive governmental price controls and other price- restrictive regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we may be able to charge for any of our products. Accordingly, the potential revenue and profits from markets outside the United States may be commercially inadequate. Moreover, increasing efforts by governmental and private payors in the United States and other jurisdictions to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations, pharmacy benefit management organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs in particular, has and is expected to continue to increase in the future. For instance, government and private payors who reimburse patients or healthcare providers are increasingly seeking greater upfront discounts, additional rebates and other concessions to reduce prices for pharmaceutical products. As a result, it may be difficult for any of our products to achieve profitability, even if they receive regulatory approval. The development and commercialization of new drug products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to our product candidates that we may seek to develop or commercialize in the future. Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. In particular, the field of inflammatory bowel disease, including ulcerative colitis and Crohn' s disease, are highly competitive. Our competitors in the United States and elsewhere include major pharmaceutical, biotechnology and biosimilar manufacturers. Some of these competitors may have more extensive research and development, regulatory compliance, manufacturing, marketing and sales capabilities than we have **, and are already marketing products approved by the FDA for these indications** . Many competitors also have significantly greater financial resources. These companies may succeed in developing products that are more effective or more economical than any of our product candidates and may also be more successful than we in manufacturing, developing and obtaining regulatory approvals and reimbursement for products. In addition, technological advances or different approaches developed by one or more of our competitors may render our products obsolete, less effective or uneconomical. If our competitors obtain marketing approval

from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than we do, they could establish a strong market position before we are able to enter the market. Third- party payors, including governmental and private insurers, also may encourage the use of less expensive generic products. Failure of any approved product candidates of ours to effectively compete against established treatment options or to compete in the future with new products currently in development would harm our business, financial condition, results of operations and prospects. The potential market opportunities for our product candidates are difficult to estimate and will depend on a number of factors beyond our control. Our estimates of potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third- party research reports, and other surveys. Although we believe that our internal assumptions are reasonable based on currently available information, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be substantially smaller than our estimates. Negative developments in the field of oral therapies for chronic inflammatory and autoimmune diseases could damage public perception of our product candidates and negatively affect our business. The commercial success of our product candidates will depend in part on public acceptance of the use of oral therapies for the treatment of chronic inflammatory and autoimmune diseases. Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments that may occur in the future, including in connection with competitors' therapies, could result in a decrease in demand for our product candidates. These events could also result in the suspension, discontinuation, or clinical hold of, or modifications to, our clinical trials. Our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue, or may be delayed in conducting, our development programs. Price controls may be imposed in foreign markets, which may adversely affect our future profitability. In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after 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 reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected. Risks Related to Third Parties We rely on third- party suppliers and other third parties for production of our product candidates, and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product candidates. We do not currently own or operate manufacturing facilities for clinical or commercial production of our product candidates. We lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. Instead, we rely on, and expect to continue to rely on, third parties for the supply of raw materials and manufacture of drug supplies necessary to conduct our preclinical studies and clinical trials. Our reliance on third parties for manufacturing exposes us to additional risks. Delays in production by third parties could delay our clinical trials or have an adverse impact on any commercial activities. In addition, our dependence on third parties for the manufacture of and formulation of our product candidates subjects us to the risk that such product candidates may have manufacturing defects that we ~~has~~ **have** limited ability to prevent or control. Although we oversee these activities to ensure compliance with our quality standards, budgets and timelines, we have, and will continue to have, less control over the manufacturing of our product candidates than if we were to manufacture our product candidates. Further, the third parties we contract with could have staffing difficulties, might undergo changes in priorities or may become financially distressed, any of which would adversely affect the manufacturing and production of our product candidates. In addition, a third party could be acquired by, or enter into an exclusive arrangement with, one of our competitors, which would adversely affect our ability to access the formulations we require for the manufacturing of our product candidates. The facilities used by our current contract manufacturers and any future manufacturers to manufacture our product candidates must be inspected by the FDA after we submit our NDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with the regulatory requirements, known as cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the FDA may refuse to approve our NDA. If the FDA does not approve our NDA because of concerns about the manufacture of our product candidates, or if significant manufacturing issues arise in the future, we may need to find alternative manufacturing facilities, which would significantly delay and adversely impact our ability to develop our product candidates, obtain marketing approval of our NDA or to continue to market any approved product candidates. Although we are ultimately responsible for ensuring compliance with these regulatory requirements, we do not have day- to- day control over a contract manufacturing organization' s (" CMO"), or other third- party manufacturer' s compliance with applicable laws and regulations, including cGMPs and other laws and regulations, such as those related to environmental, health and safety matters. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. In addition, third- party contractors, such as our CMOs, may elect not to continue to work with us due to factors beyond our control. They may also refuse to work with us because of their own financial difficulties,

business priorities or other reasons, at a time that is costly or otherwise inconvenient for us. If we was unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. Problems with the quality of the work performed by third parties may lead us to seek to terminate our working relationships and seek alternative service providers. However, making this change may be costly and may substantially delay clinical trials. In addition, it may be very challenging, and in some cases impossible, to find replacement service providers that can develop and manufacture our drug candidates in an acceptable manner and at an acceptable cost and on a timely basis. The sale of products containing any defects or any delays in the supply of necessary products or services could adversely affect our business, financial condition, results of operations, and prospects. Growth in the costs and expenses of components or raw materials may also adversely affect our business, financial condition, results of operations, and prospects. Supply sources could be interrupted from time to time and, if interrupted, supplies may not be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all. We currently rely on and plan to continue to rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, it may cause delays in commencing and completing clinical trials of our product candidates or we may be unable to obtain marketing approval for or commercialize our product candidates. Clinical trials must meet applicable FDA and foreign regulatory requirements. We do not have the ability to independently conduct clinical trials for any of our product candidates. We rely and expect to continue relying on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories, to conduct all of our clinical trials of our product candidates; however, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with our investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with IND and human subject protection regulations and cGCPs for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. Regulatory authorities enforce eGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third- party contractors fail to comply with applicable eGCPs, 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. Upon inspection by a given regulatory authority, such regulatory authority may determine that one or more of our clinical trials do not comply with eGCPs. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and increase our expenses. The pharmaceutical industry has experienced cases where clinical investigators have been found to incorrectly record data, omit data, or even falsify data. We cannot ensure that the CROs or clinical investigators in our trials will not make mistakes or otherwise compromise the integrity or validity of data, any of which would have a significant negative effect on our ability to obtain marketing approval, our business, and our financial condition. We or the third parties we rely on may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to manufacture sufficient quantities of materials for use in our clinical trials, conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites, or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, the FDA or foreign regulatory agencies may suspend clinical trials of our product candidates at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks, whether as a result of adverse events occurring in our trials or otherwise, or if we or they find deficiencies in the clinical trial process or conduct of the investigation. The FDA or foreign regulatory agencies could also require additional clinical trials before or after granting marketing approval for any products, which would result in increased costs and significant delays in the development and commercialization of such products and could result in the withdrawal of such products from the market even if marketing approval has already been obtained. Our failure to adequately demonstrate the safety and efficacy of a product candidate in clinical development could delay or prevent marketing approval of the product candidate. Even if market approval has already been obtained, adverse data from post- approval studies could result in the product being withdrawn from the market. Any of these occurrences would likely have a material adverse effect on our business. Even if we are successful in entering into a collaboration with respect to the development and / or commercialization of one or more product candidates, the collaboration may not be successful. Collaborations pose a number of risks, including: • collaborators often have significant discretion in determining the extent of efforts and resources that they will apply to the collaboration, and may not commit sufficient attention and financial or other resources to the development, marketing or commercialization of the product or products that are subject to the collaboration; • collaborators may not perform their obligations as expected; • any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to our current product candidates, potential product candidates or proprietary technologies, or to grant licenses on terms that are not favorable to us; • collaborators may cease to devote sufficient resources to the development or commercialization of our product candidates, especially if the collaborators view our product candidates as competitive with their own products or product candidates; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time- consuming, distracting and expensive; • collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from our collaboration; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • the collaborations may not result in our achieving revenues to justify such transactions; and • collaborations may be terminated, which may require us to raise additional capital to pursue further development or commercialization of the applicable product candidate. As a result of any of these factors, a collaboration may not result in the successful development or

commercialization of our product candidates. We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations. In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting **, financial advisory** and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreements. Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected. If our contract manufacturers fail to comply with continuing regulations, resulting enforcement action could adversely affect us. If any of our contract manufacturers fail to comply with regulatory requirements or if previously unknown problems with products, manufacturers or manufacturing processes are discovered, we or the manufacturer could be subject to administrative or judicially imposed sanctions, including restrictions on the products or the manufacturers or manufacturing processes we use, warning letters, untitled letters (which the FDA uses as an initial notification of violations), civil or criminal penalties, fines, injunctions, product seizures or detentions, import bans, voluntary or mandatory product recalls and publicity requirements, suspension or withdrawal of regulatory approvals, total or partial suspension of production, and refusal to approve pending applications for marketing approval of new products. Risks Related to Our Intellectual Property Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent position as well as our ability to maintain adequate protection of other intellectual property for our technologies, product candidates, and any future products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The laws of some foreign countries, in particular China and India, do not protect our proprietary rights to the same extent or in the same manner as U. S. laws, and we may encounter significant problems in protecting and defending our proprietary rights in these and other countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets. We apply for patents covering both our technologies and product candidates as we deem appropriate. However, we may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or developing competing products and technologies. We cannot be certain that our patent applications will be approved or that any patents issued will adequately protect our intellectual property. Moreover, the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles are evolving and remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether: • we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications; • we or our licensors were the first to file patent applications for these inventions; • any of the patents that cover our product candidates will be eligible to be listed in the FDA' s compendium of " Approved Drug Products with Therapeutic Equivalence Evaluations, " sometimes referred to as the FDA' s Orange Book; • others will independently develop similar or alternative technologies or duplicate any of our technologies; • any of our or our licensors' pending patent applications will result in issued patents; • any of our or our licensors' patents will be valid or enforceable; • any patents issued to us or our licensors and collaborators will provide us with any competitive advantages, or will be challenged by third parties; • we will develop additional proprietary technologies that are patentable; • governmental authorities will exercise any of their statutory rights to our intellectual property that was developed with government funding; or • our business may infringe the patents or other proprietary rights of others. The actual protection afforded by a patent varies based on products or processes, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country, the validity and enforceability of the patents and our financial ability to enforce our patents and other intellectual property rights. Our ability to maintain and solidify our proprietary rights to our product candidates and future products will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, narrowed, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. Due to the extensive amount of time required for the development, testing and regulatory review of a product candidate, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. We may also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our or any of our collaborators' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors or others and we may not have adequate remedies in respect of such disclosure. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, foreign courts are sometimes less willing than U. S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods or know- how, we would not be able to assert our rights to trade secrets and our business could be harmed. We are a party to license agreements under which we license

intellectual property and receive commercialization rights relating to certain of our product candidates. If we fail to comply with obligations in such agreements or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business; any termination of such agreements would adversely affect our business. We are a party to license agreements that give us various commercialization rights, the loss of which (whether due to our actions or inactions or those of the respective counterparties) may adversely affect our business. For instance, in November 2018, Immunic AG and Daiichi Sankyo entered into a license and option agreement that grants us an exclusive global option to license IMU- 856 and related molecules. In January 2020, we exercised this option and acquired the rights to commercialization of IMU- 856 in all countries including the U. S., Europe and Japan. The loss of (i) the licenses granted to us under our agreements with Daiichi Sankyo and other licensors, or (ii) the rights provided under such agreements, would prevent us from developing, manufacturing or marketing products covered by the license or subject to supply commitments, and could materially harm our business, financial condition, results of operations and prospects. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our technologies in all countries outside the United States, or from selling or importing products made using our technologies in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection, to develop their own products and further, may export otherwise infringing products to territories where we have patent protection but enforcement rights are weaker than in the United States. These products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual rights may not be effective or sufficient to prevent such competition. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights throughout the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, we may be unable to extend the term of marketing exclusivity for our product candidates and our business may be materially harmed. Depending on the timing, duration and specifics of any FDA marketing approval of any of our product candidates, one of the U. S. patents covering each such approved product or the use thereof may be eligible for up to five years of patent term restoration under the Hatch- Waxman Act. The Hatch- Waxman Act allows extension of a maximum of one patent per FDA- approved product. Patent term extension or special protection certificates also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, among other things, failing to apply prior to applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension afforded as well as the scope of patent protection during any such extension could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we or our collaborators request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following expiration of our patent, and our potential revenue could be materially reduced. We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent issued to others, which could adversely affect our ability to develop and market our product candidates. Our patent searches or analyses (including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents) might not be accurate, complete or thorough, and could fail to identify each and every patent and pending application in the United States and other jurisdictions that is or may potentially be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by legal interpretation, the written disclosure in a patent and the patent' s prosecution history. If our interpretation of the relevance or the scope of a patent or a pending application is not accurate and we incorrectly determine that our product candidates are not covered by a third- party patent, we could be potentially liable for infringement, prevented from marketing our product candidate, or required to seek costly licenses from patent holders. Many patents may cover a marketed product, including but not limited to patents covering the composition, methods of use, formulations, production processes and purification processes of or for the product. The identification of all patents and their expiration dates relevant to the production and sale of a therapeutic product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. Our determination of the expiration date of any patent in the United States or other jurisdictions that we consider relevant may be incorrect, which could negatively impact our ability to develop and market our product candidates. Obtaining and maintaining patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The United States Patent and Trademark Office (" USPTO"), and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patent and / or pending

patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We employ an outside firm and rely on outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market sooner, which would have a material adverse effect on our business. The patent protection for our product candidates may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue. The patents for our product candidates have, and any patents issued in the future will have, varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. In some of the larger potential markets, such as the United States and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product' s development and regulatory review. However, extensions might not be granted or, if granted, the applicable time period or the scope of patent protection afforded during any extension period could be inadequate. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, we may not be able to qualify the product or obtain exclusivity. If we are unable to obtain patent term extension, restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our U. S. and foreign patents. We may become involved in lawsuits or interference proceedings to protect patents held by us or our licensors or other intellectual property rights, which could be expensive, time- consuming and ultimately unsuccessful. Competitors may infringe our patents or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, directly or through our licensors, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of our licensor is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of the patents we own or license at risk of being invalidated or interpreted narrowly and could put our licensors' patent applications at risk of not issuing. Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to patents and patent applications of our licensors or those of our current or future collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries whose laws do not grant the same protections to intellectual property as fully as the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of our common stock. Third- party claims of intellectual property infringement or misappropriation may adversely affect our business and could prevent us from developing or commercializing our product candidates. Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation and other challenges, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex- parte review, inter party review and post- grant review proceedings before the USPTO and foreign patent offices. Numerous U. S. and foreign patents and patent applications exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to third- party claims of patent infringement. Third- party claims that we infringe on their products or technology could present a number of issues, including: • infringement and other intellectual property claims, whether with or without merit, can be extremely expensive and time- consuming to litigate and can divert management' s attention from our core business; • the risk of substantial court- imposed damages for past infringement; • a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do; • even if a license is available from the patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and • we may need to redesign our processes to avoid further infringement, which may not be possible or could require expenditure of substantial funds and time. Third parties may assert that we are employing their proprietary technology without authorization. We may be unaware of third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. 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 issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product candidates may have been filed by others without the knowledge of us or our licensors. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use or manufacture of our product candidates. We may also face misappropriation claims if a third party believes that we inappropriately obtained and used its trade secrets. If the third- party prevails on such claims, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and may be required to

pay damages. If a court of competent jurisdiction held that any third- party patents covers aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we obtain a license. A license may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights could be nonexclusive, which could result in our competitors having access to our licensed intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms or at all. In addition, during the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, programs, or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time- consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible to obtain or require substantial expenditure of time and money. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into collaborative arrangements that would help us bring our product candidates to market. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents and patent rights. Obtaining and enforcing patents and patent rights in the biotechnology industry involves both technological and legal complexity and, therefore, is costly, time- consuming and inherently uncertain. In addition, some patent reform legislation and court rulings in the United States have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents and patent rights, once obtained. For our U. S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy- Smith America Invents Act (" the AIA"), was signed into law. The AIA includes a number of significant changes to U. S. patent law, including provisions that affect the way patent applications will be prosecuted and reviewed after issuance, and may also affect patent litigation. USPTO regulations and procedures govern administration of the AIA and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of patent rights, all of which could have a material adverse effect on our business and financial condition. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a " first-inventor- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date, but before we or our licensor files a patent application, could therefore be awarded a patent covering an invention of ours even if we or our licensor had made the invention before the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patent rights depends on whether the differences between the ~~licensor~~ **licensors** ~~'~~ **'** s ~~~~ or our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain if we (or our licensor) was the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Among other changes, the AIA limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. This applies to all U. S. patents, even those issued before March 16, 2013. Because the evidentiary standard to invalidate a patent claim in USPTO proceedings is lower than for a procedure in U. S. federal court, a challenger may attempt to use the USPTO procedures to invalidate our patent rights that would not have been invalidated in federal court. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties. Because of the expense and uncertainty of litigation, we may conclude that, even if a third party is infringing our patents or our licensors' patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of us or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. Intellectual property rights do not protect against all potential threats to our potential competitive advantage. The degree of future protection afforded by our intellectual property rights is highly uncertain because intellectual property rights have limitations and may not adequately protect our business, or permit us to maintain any competitive advantage we may gain. The following examples are illustrative: • Others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we license from others or may license

or own in the future. • Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights. • Any of our collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we license or may, in the future, own or license. • Any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we license or may, in the future, license. • Issued patents that have been licensed to us may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors. • Our competitors might conduct research and development activities in countries where we do not have license rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets. • Ownership of patents or patent applications licensed to us may be challenged by third parties. • The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business. Confidentiality agreements with employees, consultants and others may not adequately prevent disclosure of trade secrets and protect other proprietary information. Trade secrets and / or confidential know- how can be difficult to maintain as confidential. In an effort to protect this type of information against disclosure or appropriation by competitors, we require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets and / or confidential know- how is challenging, expensive, time- consuming and unpredictable. The extent to which confidentiality agreements may be enforced does vary from jurisdiction to jurisdiction. Failure to obtain or maintain trade secrets and / or trade protection of our confidential know- how could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection of that information. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and / or confidential know- how. We may need to license certain intellectual property from third parties, and such licenses may not be available on commercially reasonable terms, or at all. A third party may hold intellectual property, including patent rights that are important or necessary to the development or commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from such third parties. Such a license may not be available on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed to us or others confidential information of their former employers or other owners of confidential information. Further, we may be subject to ownership disputes in the future arising from, among other things, consultants or third- parties who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to, and use of, confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights to certain intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents and other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who have been involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could be extremely costly and distract our management and other employees. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on third parties to assist with research and development and to manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements are intended to limit the rights of the third parties to use, disclose or publish our confidential information, including our trade secrets. Despite these contractual restrictions, the need to share trade secrets and other confidential information increases the risk that such trade secrets could become known to our competitors, could be inadvertently incorporated into the technology of others, or could be disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development, or publication of information by any of our

third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. 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 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. If we cannot adequately protect our trademarks and trade names, then we may not be able to build name recognition in our markets of interest and our business would be harmed. 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 trademarks or trade names. Over the long term, if we are unable to successfully register and protect our trademarks and trade names and 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. Risks Related to Being a Public Company We incur significant legal, accounting and other expenses that we would not incur as a private company, including costs associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes- Oxley Act of 2002 (the" Sarbanes- Oxley Act"), as well as existing and new rules implemented by the SEC and The Nasdaq Stock Market (" Nasdaq"). These rules and regulations increase the company' s legal and financial compliance costs and make some activities more time- consuming and costly. Not all members of our management have previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers of our company, which may adversely affect investor confidence in us and could cause our business and stock price to suffer. Effective December 31, 2019, we are no longer an " emerging growth company, " and the reduced disclosure requirements applicable to " emerging growth companies " no longer apply, and we are required to report on internal control over financial reporting, which ~~will~~ **has** ~~increase~~ **increased** our costs as a public company and ~~increase~~ **increased** the demands on management. Effective December 31, 2019, the fiscal year- end following the fifth anniversary of the completion of our initial public offering, we are no longer an " emerging growth company " as defined in the Jumpstart Our Business Startups Act. As a result, we are incurring significant additional expenses in complying with certain provisions of the Sarbanes- Oxley Act and rules implemented by the SEC. Moreover, if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of us may suffer if, in the future, material weaknesses are found, and this could cause a decline in the market price of our stock. Any failure of our internal control over financial reporting could have a material adverse effect on the company' s stated operating results and harm our reputation. If we are unable to implement these changes effectively or efficiently, it could harm our operations, financial reporting and financial results and could result in an adverse opinion on internal control from our independent registered public accounting firm. In addition, we are no longer eligible for reduced disclosure requirements applicable to emerging growth companies regarding executive compensation and exemptions from the requirements of holding advisory say- on- pay votes on executive compensation. These increased disclosure requirements require additional attention from management and increased costs to the company, including higher legal fees, accounting fees and fees associated with investor relations activities, among others. Risks Related to Our Common Stock **Any Nasdaq action relating to a delisting could have a negative effect on the price of our common stock, impair the ability to sell or purchase our common stock when persons wish to do so, and any such delisting action may materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from the Nasdaq Global Select Market could also have other negative results, including the potential loss of institutional investor interest, reduced coverage by equity research analysts and fewer business development opportunities. In the event of any delisting or potential delisting, we may attempt to take actions to restore our compliance with Nasdaq' s listing requirements, such as seeking stockholder approval of a reverse stock split, but we can provide no assurance that any such action taken by us would allow our common stock to remain listed or be re- listed, stabilize the market price or improve the liquidity of our common stock, maintain a minimum closing bid price of $ 1. 00 per share for 10 consecutive trading days as required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450 (a) (1) or prevent future non- compliance with Nasdaq' s listing requirements.** The market price of our common stock has been, and is expected to continue to be, subject to significant fluctuations. Market prices for securities of early- stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include: • reports on or the perception of clinical trial progress, or the lack thereof ~~, which we experienced in October 2022 when our stock price and market capitalization decreased significantly after announcing Phase 1b interim analysis of IMU- 935 for the first two dose patient cohorts with moderate- to- severe psoriasis~~ ; • our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals; • failure of any of our approved product candidates to achieve commercial success; • failure to maintain our existing third- party license, supply and manufacturing agreements; • failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights; •

changes in laws or regulations (or their interpretation) applicable to our product candidates; • any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices; • adverse regulatory authority decisions or delays; • introduction of new products, services, or technologies by our competitors; • failure to meet or exceed financial and development projections that we may provide to the public; • failure to meet or exceed the financial and development projections of the investment community; • the perception of the pharmaceutical industry in general, and companies addressing our disease indications in particular, by the public, legislatures, regulators and the investment community; • announcements of significant acquisitions, strategic collaborations, joint ventures, or capital commitments by us or our competitors; • disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; • additions or departures of key personnel; • significant lawsuits, including patent, product liability or stockholder litigation; • if securities or industry analysts do not publish research or reports about our business, or if they issue negative or misleading opinions regarding our business and stock; • changes in the market valuations of similar companies; • general market or macroeconomic conditions; • sales of common stock by the company or our stockholders in the future; • trading volume of our common stock; • announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments; • adverse publicity relating to the markets in which we operate, including with respect to other products and product candidates in such markets; • the introduction of technological innovations or new therapies that compete or might compete with our product candidates; • changes in the structure of healthcare payment systems; and • period- to- period fluctuations in our financial results. Moreover, stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations have had, and can be expected to continue to have, adverse effects on the trading price of our common stock. In the past, following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. ~~Additionally, a~~ **If our stockholders do not approve an** ~~decrease~~ **increase** in ~~our stock price may cause~~ **the number of authorized shares of** our common stock ~~to no longer satisfy the continued listing standards of The Nasdaq Global Select Market. If we are not able to maintain the requirements for listing on The Nasdaq Global Select Market~~ , ~~we could be delisted, which would likely result in an immediate and significant decline in the trading price and liquidity of our stock, and would have a materially adverse effect on~~ our ability to raise additional **capital to** ~~funds~~ **fund our operations and to incentivize our employees will be extremely limited. We currently have 130, 000, 000 shares of common stock authorized for issuance and a total of 89, 929, 016 shares issued and outstanding as of January 31, 2024. We have asked our stockholders to approve an amendment to our certificate of incorporation to increase our authorized shares of common stock to 500, 000, 000 shares, at a Special Meeting of Stockholders to be held on March 4, 2024. The Securities Purchase Agreement with investors in our January 4, 2024 private placement requires us to submit this proposal to our stockholders for approval at the Special Meeting and, if not approved, to resubmit this proposal to stockholders for approval at least semi- annually until approval is obtained. If holders of a majority of the total outstanding shares of our common stock do not vote in favor of this proposal at the Special Meeting on March 4, 2024, our ability to raise additional equity financing will be severely limited, which will impair our ability to fund the future needs of our business, unless and until we are able to generate sufficient revenue from operations** . Anti- takeover provisions in our organizational documents and Delaware law might discourage or delay acquisition attempts for the company that stockholders might consider favorable. Our Amended and Restated Certificate of Incorporation, and Amended and Restated Bylaws, contain provisions that may delay or prevent an acquisition or change in control of the company. Our certificate of incorporation and bylaws include provisions that: • authorize our board of directors to issue without further action by the stockholders, up to 20, 000, 000 shares of undesignated preferred stock; • require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent; • establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors; • provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and • establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms. Further, as a Delaware corporation, we are subject to provisions of Delaware corporations law, which may impair a takeover attempt that our stockholders may find beneficial. These anti- takeover provisions and other provisions under Delaware law could discourage, delay or prevent a transaction involving a change in control of our company, including actions that our stockholders may deem advantageous, or could negatively affect the trading price of our common stock. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing and to cause us to take other corporate actions they desire. We may experience adverse consequences because of required indemnification of officers and directors. Provisions of our certificate of incorporation and bylaws provide that we will indemnify any director and officer as to liabilities incurred in their capacity as a director or officer and on those terms and conditions set forth therein to the fullest extent of Delaware law. Further, we have purchased directors and officers insurance on behalf of any such persons whether or not we would have the power to indemnify such person against the liability insured against. The foregoing could result in substantial expenditures by us and prevent any recovery from our officers, directors, agents and employees for losses incurred by the company as a result of their actions. The current expectation is that we will retain any future earnings to fund the development and growth of our business. As a result, any capital appreciation of the common stock of the company will be stockholders' sole source of any gain for the foreseeable future. General Risk Factors If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and Nasdaq rules and regulations. The Sarbanes- Oxley Act requires, among other things, that we maintain effective

disclosure controls and procedures and internal control over financial reporting. 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. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10- K for each year, as required by Section 404 of the Sarbanes- Oxley Act (" Section 404"). This requires significant management efforts and requires us to incur substantial professional fees and internal costs to expand our accounting and finance functions. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements, or may identify other areas for further attention or improvement. Furthermore, we cannot be certain that our efforts will be sufficient to remediate or prevent future material weaknesses or significant deficiencies from occurring. If we are not able to comply with the requirements of Section 404, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock would likely decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Our business and stock price could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities. Stockholders may, from time to time, engage in proxy solicitations or put forth stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition and divert management' s attention. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or management team arising from a proxy contest or initiatives of activist stockholders could lead to the perception of a change in the direction of our business or instability, which may result in the loss of potential business opportunities, make it more difficult to pursue strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results and the trading price of our stock. If individuals are ultimately elected to our board of directors with a specific agenda, our ability to effectively implement our business strategy and create additional value for our stockholders may be adversely effected. We may choose to initiate, or may become subject to, litigation as a result of a proxy contest or matters arising from a proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant negative or other fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business. An active trading market for our common stock may not be sustained and our stockholders may not be able to resell their shares of common stock for a profit, if at all. An active trading market for our shares of common stock may not be sustained. If an active market for our common stock is not sustained, it may be difficult for stockholders to sell their shares at an attractive price or at all. Future sales of shares by existing stockholders could cause our stock price to decline. If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, whether after legal restrictions on resale lapse or at other times, the trading price of our common stock could decline. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide **, or cease to provide,** research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. If we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could substantially decline immediately if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price and trading volume to decline. If we become profitable, our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income or taxes may be subject to limitations. We have incurred net losses since our inception, and expect to continue to incur operating losses for the foreseeable future. If we become profitable in the future, our ability to use net operating loss carryforwards, or NOLs, and other tax attributes to offset future taxable income or reduce taxes may be subject to limitations. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an " ownership change " (generally defined as a greater than 50 % cumulative change by value in its equity ownership of certain stockholders over a rolling three- year period) is subject to an annual limitation on its ability to utilize its pre- change NOLs and other tax attributes (including any research and development credit carryforwards). Similar provisions of state tax law may also apply to limit the use of our state NOLs and other tax attributes. We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in one or more ownership changes within the meaning of Sections 382 and 383 of the Code. In addition, we may experience an ownership change in the future as a result of subsequent changes in our stock ownership, some of which are outside our control; and we are not intending to take any steps to prohibit any subsequent changes in our stock ownership in order to avoid such an ownership change. If an ownership change has occurred in the past or occurs in the future, we may not be able to use a material portion of our NOLs and other tax attributes to

offset future taxable income or taxes if we attain profitability. In addition to any limitation imposed by Section 382 of Code, the use of NOLs arising after December 31, 2017 generally is limited to a deduction of 80 % of taxable income for the corresponding taxable year. NOLs arising after December 31, 2017, with certain exceptions, may not be carried back to previous taxable years, but may be carried forward indefinitely. **55**