Risk Factors Comparison 2025-03-31 to 2024-03-28 Form: 10-K

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

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. We urge investors to carefully review and consider the additional discussion of the risks summarized in this risk factor summary, and other risks that we face, which can be found below under the heading " Risk Factors, " together with other information in this report, before making investment decisions regarding our securities. • We will need to raise substantial additional capital to continue our operations, execute our business strategy and remain a going concern, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all. Raising additional capital may cause substantial dilution to our stockholders, restrict our operations or require us to relinquish rights in our technologies or product candidates and their future revenue streams. • **If we fail to regain and maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. •** We have a limited operating history, ~~have incurred~~ **a history of** significant losses ~~since our inception~~ **from operations,** and expect **significant losses from operations, net losses and negative cash flows from operations** to continue ~~to incur losses~~ for the foreseeable future, which, together with our limited financial resources ~~and substantial capital requirements~~, make it difficult to assess our prospects **. • We plan to generate revenue from sales of our proprietary Sildenafil Cream formulation produced under Section 503B of the FDCA. We have no experience in this line of business and may not succeed in our efforts. We will rely on third parties for the compounding and distribution of our proprietary Sildenafil Cream formulation, and the failure of such third parties to perform as expected could harm our reputation and negatively impact our ability to succeed. In addition, this line of business subjects us to new regulations and potential liability** . • Our business depends on obtaining the approval of regulatory authorities, and in particular, FDA approval, to market products that we develop. All of our product candidates are investigational, require the conduct and successful completion of clinical studies and nonclinical work, and may never complete development or be submitted for or receive regulatory approval. The FDA' s approval of XACIATO is not predictive of favorable development or marketing approval outcomes for our product candidates. • Clinical development is a lengthy and expensive process with an inherently uncertain outcome. Failure to successfully complete clinical trials and nonclinical activities and obtain regulatory approval to market and sell our product candidates on our anticipated timelines at reasonable costs to us, or at all, particularly Ovaprene and Sildenafil Cream, could have a material adverse effect on our business, operating results and financial condition. • The regulatory approval processes of the FDA and comparable foreign authorities are expensive, lengthy, time- consuming, and inherently unpredictable. If we are not able to obtain regulatory approvals for our product candidates, our ability to generate product revenue will be materially impaired. • **We rely on** ~~Drug products and drug / device combination products are complex to manufacture and we face significant challenges~~ in ~~scaling up manufacturing of~~ **- license agreements with third parties for rights to develop and commercialize XACIATO and** our product candidates **. The loss** ~~for~~ **or impairment of our rights under these agreements** ~~larger clinical trials and commercial production. Manufacturing and supply delays and disruptions~~ could **disrupt** ~~postpone the initiation of or interrupt our~~ **or require us to discontinue** ~~clinical studies, extend the timeframe and cost of~~ development ~~of our~~ **or** ~~product candidates, delay potential regulatory approvals and adversely impact the~~ commercialization ~~of any approved products~~ **activities, or impair our rights to receive payments from our sublicensees, which could have a material adverse effect on our operations and business prospects and viability** . • Strategic collaborations are a key part of our strategy and our existing strategic collaborations are important to our business. If we are unable to maintain existing strategic collaborations or establish new ones, or if they are not successful, we may require substantial additional capital to develop and commercialize our products and product candidates and our business and prospects may be materially harmed. • ~~Unless~~ **Delays** and ~~until one~~ **disruptions in the supply and manufacturing** of our product candidates ~~receives~~ **could postpone the initiation of or interrupt our clinical studies, extend the timeframe and cost of development of our product candidates, delay potential** regulatory ~~approval~~ **approvals** ~~, payments under our license agreement with Organon based on net sales of XACIATO represent our only potential source of ongoing revenue~~ and **adversely impact** ~~the amount of those~~ **the commercialization** ~~net sales is largely outside~~ of ~~our control~~ **any approved products** . • We have no manufacturing, sales, marketing or distribution infrastructure. We depend heavily on, and expect to continue to rely on, the performance of third parties, including our strategic collaborators, contract manufacturers and suppliers, CROs, medical institutions, and scientific, medical, regulatory and other consultants and advisors, to develop our product candidates and commercialize any approved products. Failure of these third parties to perform as expected could result in substantial delays, increased costs or failures of our product development programs, delayed or unsuccessful commercialization of any approved products, and the need for significant additional capital. • Due in part to our limited financial and human resources, we may fail to effectively execute our product development, regulatory submission and commercialization plans in accordance with communicated timelines, or at all. • The ~~loss or impairment of our rights under our license agreements for XACIATO or any of our product candidates could prevent us from developing or commercializing them, which could have a material adverse effect on our business prospects, operations and viability. • The~~ commercial success of XACIATO **is outside of our control and** will depend on Organon' s efforts and capabilities and a variety of factors, many of which currently are unknown or uncertain, and if commercialization of XACIATO is not successful, our reputation, business and prospects may suffer. • **Our** ~~XACIATO and any future products~~ **product candidates, if approved for commercial sale,**

will face intense competition ~~, including from generic products,~~ and may fail to achieve the degree of market acceptance necessary for commercial success. Our business, operating results and financial condition will suffer if we, or our commercial collaborators, fail to compete effectively ~~and fail to achieve market acceptance~~ . • Failure to successfully obtain coverage and adequate reimbursement for XACIATO and any future products from government health care programs and other third- party payors would diminish our ability, or that of a commercial collaborator, to generate net product revenue or net sales. If out- of- pocket costs for products we develop are deemed by women to be unaffordable, a commercial market may never develop. • We have a relatively small number of employees ~~,~~ and if we fail to attract and retain key personnel ~~or effectively manage our personnel costs,~~ our business may materially suffer. • We may not be successful in our efforts to identify and acquire or in- license additional product candidates or technologies, which may limit our growth potential. • **If we and** ~~Our failure to adequately protect or~~ **our** ~~enforce our~~ **licensors are unable to obtain and maintain sufficient** intellectual property ~~rights~~ **protection** , **competitors** ~~and those of our licensors,~~ could **develop and commercialize or make available products similar or identical to ours, which could significantly limit the commercial potential of our products and product candidates and** materially harm our **business, financial condition, results of operations, and prospects. • Most of the products we are developing utilize active pharmaceutical ingredients that are not** proprietary **to us or** ~~position in the marketplace or~~ **our** ~~prevent~~ **licensors and the patents and patent applications owned by us and** ~~or~~ **our licensors intended to protect our** ~~impede the commercialization of XACIATO and any future~~ products ~~. • Lack~~ **and product candidates relate to specific formulations, processes, methods** of ~~patent~~ **delivery, and / or uses, which may not afford sufficient** protection **against** ~~for the active ingredients in certain of our product candidates, including Sildenafil Cream and DARE- HRT1, may limit the commercial opportunity for those products if~~ competitors ~~are able to develop and commercialize safe and effective alternative formulations or methods of delivery of the active ingredients~~ . • Volatility in the financial markets, geopolitical conflicts and events **, natural disasters** , public health emergencies **, international trade policies,** ~~such as the COVID- 19 pandemic~~ and other macroeconomic factors may negatively impact our business, financial condition and results and our stock price, including by increasing the cost and timelines for our clinical development programs or making it more difficult or costly to raise additional capital when needed. • Product liability lawsuits against us could cause us to incur substantial liabilities and divert management attention from our business. • The price of our common stock has been and may continue to be highly volatile and such volatility may be related or unrelated to our performance and operating results. Volatility in our stock price may subject us to increased risk of securities litigation, including class- action lawsuits, which could be expensive and divert management attention. • ~~If we fail to regain and maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. •~~ Future dilution to our existing stockholders from sales and issuances of our common stock **to raise additional capital** ~~through at- the- market, or ATM, offerings, other types of public or private offerings of equity or equity- linked securities and upon the exercise of stock options~~ , or the market' s expectation that such sales **may occur,** could adversely affect our stock price ~~,~~ even if our business is doing well. • We have been subject to a cyber- related crime and our controls and security measures may not be successful in preventing other cybersecurity incidents in the future. Cyber- attacks, security breaches, loss of data and other disruptions to our information technology systems or those of our strategic collaborators or third- party service providers could compromise sensitive **or confidential** information related to our business, delay or prevent us from accessing critical information, subject us to significant financial loss, or expose us to liability, any of which could adversely affect our business and our reputation. Investment in our securities involves a high degree of risk and uncertainty. Our business, operating results, growth prospects and financial condition are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge investors to consider carefully the risks described below, together with all of the information in this report and our other public filings, before making investment decisions regarding our securities. Each of these risk factors, as well as additional risks not presently known to us or that we currently deem immaterial, could adversely affect our business, operating results, growth prospects or financial condition, as well as the trading price of our common stock, in which case you may lose all or part of your investment. Risks Related to Our Financial Position and Capital Needs We will need to raise substantial additional capital to continue our operations and execute our business strategy, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all. We have a history of losses from operations, we expect **significant losses from operations, net losses and** negative cash flows from ~~our~~ operations ~~to continue~~ for **at least** the ~~foreseeable future, and we expect that our net~~ **next several years** ~~losses will continue for the foreseeable future~~ as we develop and seek to bring to market our existing product candidates and as we seek to potentially acquire or license and develop additional product candidates **. At December 31, 2024, we had an accumulated deficit of approximately $ 175. 3 million, cash and cash equivalents of approximately $ 15. 7 million, and a working capital deficit of approximately $ 3. 2 million. We will need additional capital to fund our operating needs into the third quarter of 2025 and to meet our current obligations as they become due. All of our cash and cash equivalents at December 31, 2024 represented funds received under grant agreements that generally may be applied solely toward direct costs of carrying out the respective projects under those grant agreements. We have a history of losses from operations and we expect significant losses from operations, net losses, and negative cash flows from operations for at least the next several years as we continue to develop and seek to bring to market our product candidates. We are dependent on securing substantial additional capital from one or more third- party sources to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying consolidated financial statements** . These circumstances raise substantial doubt about our ability to continue as a going concern. ~~Our~~ **The consolidated** financial statements **included in this report** ~~as of December 31, 2023~~ were prepared under the assumption that we will continue as a going concern and do not include any adjustments that might result

from the outcome of this uncertainty. ~~At December 31, 2023, our accumulated deficit was approximately $ 171. 2 million, our cash and cash equivalents were approximately $ 10. 5 million, our deferred grant funding liability under our grant agreements related to DARE- LARC1 and DARE- LBT was approximately $ 13. 7 million, and our working capital deficit was approximately $ 2. 9 million. Our cash and cash equivalents at December 31, 2023 represented funds received under such grant agreements and such funds may be applied solely toward direct costs for the development of DARE- LARC1 and DARE- LBT, other than approximately 10 % of such funds, which may be applied toward general overhead and administration expenses that support our entire operations. We will require additional capital to fund our operating needs into the third quarter of 2024. and to meet our current obligations as they become due.~~ Advancing our investigational ~~women' s health~~ products through clinical development and pursuing regulatory approval and commercialization will require substantial additional investment. We will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. The amount and timing of our capital needs have and will continue to depend highly on many factors, as discussed further below ~~as well as under" ITEM 7. MANAGEMENT' S DISCUSSION OF AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS — Liquidity and Capital Resources — Plan of Operations and Future Funding Requirements."~~ Our management may devote significant time and we may incur substantial costs in pursuing, evaluating and negotiating potential capital- raising transactions and those efforts may not prove successful on a timely basis, or at all. If we cannot raise adequate additional capital when needed, we may be forced to reduce, or even terminate our operations. We may delay, scale back or eliminate one or more of our product development programs; relinquish rights under our license agreements with third parties relating to our product candidates; forgo opportunities to expand our product portfolio; take other measures to reduce our expenses; reorganize or merge with another entity; or file for bankruptcy or cease operations. **For example, in recent years, due to our limited capital resources, we have focused our resources primarily on the advancement of Ovaprene and Sildenafil Cream, unless a program has been supported by grant or other non- dilutive funding, and we have delayed R & D activities for other programs.** If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and our stockholders may lose all or part of their investment in our common stock. Our capital needs have depended on, and will continue to depend on, many factors that are highly variable and difficult to predict, including: • the product development programs we choose to pursue; • the **initiation, type, number, scope, progress, expansions, results,** ~~cost~~ **costs ,** and ~~pace~~ **timing** of **clinical trials and** preclinical ~~and clinical development~~ **studies of our product candidates that we are pursuing or may choose to pursue in the future** ; • the **cost** ~~results of preclinical activities~~ and **timing of manufacturing for** clinical ~~trials~~ **supplies of product candidates and, if applicable, commercial product at sufficient scale** ; • the cost and timing of ~~obtaining clinical supplies of product candidates; • the cost and timing of~~ regulatory submissions **to** and **the timing and outcome of** decisions by the FDA and other regulatory authorities on our applications to commence and advance clinical development of and to market our product candidates; • the amount and timing of payments to third parties required under acquisition, in- license and other agreements relating our rights to develop and commercialize our product and product candidates; • the cost and timing of commercialization activities we undertake or engage third parties to undertake for any ~~approved~~ product; • the amount and timing of future royalty, milestone or other payments, if any, we receive under our **licensing** ~~commercial collaboration agreements~~ **agreement with Bayer, any future out- licensing agreement,** ~~for~~ **or** ~~XACIATO and Ovaprene~~ **the Royalty Purchase Agreements** ; • our ability to maintain, and establish new, strategic collaborations relating to the development and / or commercialization of our product and product candidates **, and the terms and timing of such arrangements** ; • the extent to which we acquire, in- license, or otherwise invest in new product candidates or technologies and the terms of any such transaction; and • the cost and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property- related claims, including any claims by third parties that we are infringing upon their intellectual property rights. Should we add product candidates to our portfolio, should our existing product candidates require testing or other capital- intensive development activities that we do not anticipate, should the duration of our clinical trials be longer than anticipated, should manufacturing and supply be disrupted, or should regulatory approvals be delayed, our cash resources will be further strained. Should our product development efforts succeed, we will need to develop **and implement** a commercialization plan for each product, which may also require significant resources to create and implement. In addition, the terms of any collaboration agreements for development and / or commercialization of our product and product candidates may significantly impact our need for additional capital. Because of these uncertainties and the other risks and uncertainties discussed in this ~~“~~Risk Factors ~~”~~ section, we cannot reasonably estimate the amount funding necessary to successfully complete development of and seek regulatory approval for our product candidates or to commercialize any approved products. 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 planned operations. We may seek to raise additional capital through a variety of means, including equity, equity- linked or debt securities offerings, government or other grant funding, strategic collaborations or alliances, debt, royalty monetization or other structured financings, or other similar types of arrangements. Our past success in raising capital through equity offerings, grant funding, collaboration agreements, and ~~a~~ royalty monetization ~~financing~~ **transactions** should not be viewed as ~~an~~ **any** indication we will be successful in raising capital through those or any other means in the future. We expect that our ability to raise additional capital and the amount of capital available to us will depend not only on progress we and our collaborators make toward successfully developing, obtaining regulatory approval for and commercializing our product and product candidates, but also on factors outside of our control, such as macroeconomic and financial market conditions. To the extent we seek to obtain additional capital before achieving clinical, regulatory and / or sales milestones or when our stock price or trading volume or both are low, or when the general market for biopharmaceutical or women’ s health companies is weak, additional capital may not be available to us on favorable terms, or at all. Unstable and unfavorable market and economic conditions may harm our ability to raise additional capital. The occurrence or continued occurrence of macroeconomic factors or

events similar to those experienced in recent years, such as a U. S. economic crisis or recession or recessionary concerns, inflation, **rising interest rates,** public health emergencies (such as the COVID- 19 pandemic), geopolitical conflict (such as the wars in Ukraine and the Middle East), natural / environmental disasters, supply- chain disruptions, terrorist attacks, strained **trade and other** relations between the U. S. and a number of other countries, social and political discord and unrest in the U. S. and other countries, and government shutdowns, among others, increase market volatility and have long- term adverse effects on the U. S. and global economies and financial markets. Volatility and deterioration in the financial markets and liquidity constraints or other adverse developments affecting financial institutions may make equity or debt financings more difficult, more costly or more dilutive and may increase competition for, or limit the availability of, funding from other third- party sources, such as from strategic collaborations and government and other grants. As discussed above, we may seek to raise additional capital through a variety of means. Raising capital through the issuance of shares of our common stock, or securities convertible into or exercisable for our common stock, may depress our stock price and substantially dilute our existing stockholders. The terms of securities issued may include liquidation or other preferences that may materially adversely affect the rights of our existing stockholders. Debt and other structured financings, if available, would increase our fixed payment obligations and may involve covenants requiring us to maintain specified financial ratios or a specified cash balance, or limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, and making capital expenditures, or impose other operating restrictions that could adversely impact our ability to operate our business and pursue our strategic objectives. We could also be required to meet certain milestones in connection with a debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies, product candidates or products, or otherwise agree to terms unfavorable to us. In addition, we may ~~be required to relinquish~~ **forego part or all of potentially** valuable ~~rights to~~ **streams of** future **payments (e. g., milestone and / or royalty** revenue ~~streams~~ **) to raise immediate capital to fund our operations and advance our development programs** , such as in the case of ~~the~~ **our** royalty interest financing agreement **and the Royalty Purchase Agreements** ~~we entered into in December 2023~~ . Moreover, the lower our cash balance when we seek to raise additional capital, the more difficult, costly or dilutive to our existing stockholders it may be for us to raise additional capital. We may be required to seek additional capital through arrangements with collaborators at an earlier stage of development or commercialization of our technologies, product candidates or products than otherwise would be desirable, in which case we may grant rights to our technologies, product candidates or products on terms that may not be as favorable to us or grant rights that we would otherwise prefer to retain. If we raise capital through new collaborations, strategic alliances or other similar types of arrangements, we may relinquish valuable rights to future revenue streams. Licensing agreements likely would significantly reduce our control over the development or commercialization of the licensed technology, product candidates or products, and our collaborators may become unable or unwilling to devote adequate resources to realize their full potential value. If we obtain funding through grants from governmental entities or private organizations, such parties may impose restrictions on our rights to technologies, product candidates or products developed with such funding, obtain rights to license such technologies, product candidates or products to third parties (e. g., if we are unable or unwilling to commercialize a product or make it available to certain patient populations in a timely manner or at certain prices), or require future royalty or other payments if such technologies, product candidates or products are commercialized. We have a limited operating history upon which to evaluate our business and prospects. The development of drug and drug / device combination products in order to obtain regulatory approval is a highly speculative, lengthy and expensive undertaking and involves substantial risk. We cannot accurately determine the duration and completion costs of our development programs, or if, when and to what extent we will generate revenue from ~~the commercialization of~~ any ~~of our product~~ **products** ~~candidates~~ **we develop** . Other than XACIATO ~~, which was recently commercially launched by our collaborator Organon~~ , we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any product revenue ~~. We do not expect the potential milestone and royalty payments to us under our exclusive license agreement for XACIATO will be sufficient to cover our operating expenses~~ . We have not been profitable since we commenced operations and may never achieve profitability. We devote significant resources to licensing or otherwise acquiring the rights to our product candidates and to research and development, or R & D, activities for them. **We** ~~Since inception, we~~ have ~~incurred~~ **a history of** significant operating losses. As discussed above, we must raise additional capital to finance our operations and remain a going concern and adequate additional capital may not be available to us on a timely basis, or at all. ~~If~~ **The Revenue Sharing Threshold may never be achieved and, as a result, we may not realize any future income based** ~~one~~ **on sales** of **XACIATO** ~~our commercial collaborators terminates its exclusive license agreement with us, our need for additional capital may significantly increase~~ . We have ~~entered into~~ **sold our right, title** ~~an~~ **and** ~~exclusive~~ **interest in 100 % of the royalties and potential milestone payments we would otherwise have the right to receive under our** license agreement with Organon ~~for the commercialization~~ **based on net sales** of XACIATO ~~and an exclusive license agreement with Bayer for the commercialization of Ovaprene~~ , **net** ~~if approved. Each~~ of ~~these license agreements may be terminated by the licensee for convenience upon the completion of a specified notice period, subject to limited restrictions. Furthermore, under our agreement with Bayer, Bayer has no payment~~ **payments** ~~obligations~~ to **upstream third- party** ~~us, unless, after reviewing the results of our pivotal clinical trial of Ovaprene, it elects, in its sole discretion, to make the license~~ **licensors and UiE** ~~grant under our agreement effective by making a $ 20~~ . **Whether** ~~0 million payment to us. If~~ we ~~do not successfully complete a pivotal clinical trial of Ovaprene in a timely manner, the license grant may never become effective, and we may not~~ receive any ~~additional payments from Bayer. Bayer~~ **future income based on net sales of XACIATO will depend on whether the Revenue Sharing Threshold is reached, which** may ~~elect~~ not **occur** ~~to make the license grant effective regardless of the outcome of the pivotal clinical trial~~ . ~~If an exclusive license agreement~~ **Whether the Revenue Sharing Threshold** is ~~terminated early~~ **reached will depend** , **in part, on Organon' s future commercial success with XACIATO, which is outside of** ~~or~~ **our** ~~in~~ **control, and the successful development and commercialization of** Ovaprene ~~' s~~ **and / or Sildenafil Cream, which are**

subject to significant risks and uncertainties, some of which are outside of our control, as discussed elsewhere in this Risk Factors section. To the extent we enter into licensing agreements for third- party commercialization of products we develop, as is the case **with XACIATO and Ovaprene** ~~, does not become fully effective~~ , we **expect** ~~may realize only a small fraction of the potential value of the agreement to us, and we would need to raise significant additional capital to pursue further development and commercialization of XACIATO or~~ **our revenue streams related to those products will** ~~Ovaprene, as applicable, or establish another commercial collaboration, which we may not~~ be ~~able to do on a timely basis, on favorable terms, or at all. The royalties we may receive under our license agreements with our commercial collaborators are~~ based **primarily** on net sales, which will be largely outside of our control. **In a typical biopharmaceutical licensing** ~~We expect XACIATO' s and Ovaprene' s value to us under our~~ - **or " partnering " deal, the biopharmaceutical company out-** ~~license~~ **licenses technology** ~~agreements with Organon~~ and ~~Bayer, assuming the~~ **other assets** ~~license grant~~ to ~~Bayer becomes effective~~ **a third party in exchange for future payments** , ~~to be generated primarily through~~ **the bulk of which (e. g.,** royalties and ~~potential commercial milestone~~ **milestones** ~~payments, in each case,~~ **) are conditional on the licensee successfully developing and / or commercializing the licensed assets and determined** based on net sales. ~~The~~ **To the extent we enter into such licensing agreements, the** amount of net sales our products may generate, if ~~any~~ **approved for commercial sale** , ~~is~~ **will be** largely outside of our control because marketing and sales activities will be conducted by the licensee and ~~the~~ product pricing **and costs that impact net sales** will be determined by the licensee. Gross sales can be greatly reduced by sales discounts and allowances, which will ~~also~~ be determined by ~~the~~ **our** licensee (or mandated by governmental entities) ~~and outside of our control~~ . Sales discounts may be particularly substantial for new products compared to established products to incentivize purchases and promote customer loyalty. These factors would serve to reduce ~~our~~ **the** royalties **payable to us** and delay potential achievement of commercial milestones **and the corresponding milestone payments to us** . If a **licensee** ~~commercial collaborator~~ has no or limited commercialization success, or net sales are otherwise minimal due to pricing and discount structures, our **financial condition and** operating results ~~would~~ **could** be negatively impacted and our need for additional capital could significantly increase or be accelerated **. Due to our exclusive license agreements with Organon and Bayer, assuming the license grant to Bayer becomes effective, our royalty interest financing agreement, and the Royalty Purchase Agreements, XACIATO' s and Ovaprene' s value to us will be based primarily on net sales, as determined under those agreements** . In the future, we may rely on revenues received from third- party licensees to fund our operations, and failure to receive such revenues, or receipt of only minimal revenue, may cause us to, among other things: • pursue raising additional funds through equity ~~or~~ **,** debt **or other structured** financings that could be dilutive to our stockholders or involve restrictive covenants, operational restrictions ~~and~~ **,** security interests in our assets **, and / or relinquishing part or all of our rights to potentially valuable future revenue streams** ; • enter into new strategic collaborations that may be less favorable than those we would have obtained under different circumstances; • delay, reduce or terminate one or more development programs; • reduce headcount; • forgo opportunities to expand our product portfolio; or • take other measures to reduce our expenses, pursue strategic transactions, such as a merger or other business combination or sale of assets, file for bankruptcy, or cease operations. **If one of our commercial collaborators terminates its exclusive license agreement with us, our need for additional capital may significantly increase. We have entered into an exclusive license agreement with Organon for the commercialization of XACIATO and an exclusive license agreement with Bayer for the commercialization of Ovaprene, if approved for commercial sale. Each of these license agreements may be terminated by the licensee for convenience upon the completion of a specified notice period, subject to limited restrictions. Furthermore, under our agreement with Bayer, Bayer has no payment obligations to us, unless, after reviewing the results of our pivotal clinical trial of Ovaprene, it elects, in its sole discretion, to make the license grant under our agreement effective by making a $ 20. 0 million payment to us. If we do not successfully complete a pivotal clinical trial of Ovaprene in a timely manner, the license grant may never become effective, and we may not receive any additional payments from Bayer. Bayer may elect not to make the license grant effective regardless of the outcome of the pivotal clinical trial. If an exclusive license agreement is terminated early, or in Ovaprene' s case, does not become fully effective, we may realize only a small fraction of the potential value of the agreement to us, and we would need to raise significant additional capital to pursue further development and commercialization of XACIATO or Ovaprene, as applicable, or establish another commercial collaboration, which we may not be able to do on a timely basis, on favorable terms, or at all.** We have relied heavily on sales of our common stock to fund our operations, and our ~~future~~ ability to obtain additional capital through stock sales or other securities offerings may be more costly or dilutive to our stockholders than in the past, or may not be available to us at all. Our ability to raise additional capital may be limited by a low trading volume, stock price and market capitalization, as well as by laws, regulations and market conditions. We have relied heavily on our ability to raise capital by selling shares of our common stock. For example, we raised an aggregate of approximately $ 79. 1 million in gross proceeds in fiscal years 2021 and 2022 through the sale of shares of our common stock in offerings made under a Form S- 3 " shelf " registration statement. Our ability to raise additional capital through sales of our common stock or other securities offerings will depend on several factors, many of which may not be in our favor, including the trading volume and volatile trading price of our common stock, our relatively low public float and market capitalization, our potential inability to regain and maintain compliance with the listing requirements of the Nasdaq Capital Market, unfavorable financial market conditions, and the other risks and uncertainties described in this " Risk Factors " section. If we are unable to raise additional capital through the offering and sale of shares of our common stock, or securities convertible into or exercisable for our common stock, on a timely basis or acceptable terms, or at all, we may seek additional capital through other third- party sources that require us to relinquish valuable rights in our intellectual property, technologies, product candidates or future revenue streams, or that subject us to restrictive covenants, operational restrictions or security interests in our assets, or we may need to delay, scale back or eliminate some or all of our development programs, reduce other expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. Using a shelf registration statement to conduct an equity offering to

raise capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S- 1 registration statement. We currently have a shelf registration statement effective, however, our ability to raise capital under a shelf registration statement is, and may continue to be, limited by, among other things, current and future SEC rules and regulations impacting the eligibility of smaller companies to use Form S- 3 for primary offerings of securities. For example, we currently are subject to the" baby shelf rule" because the market value of our outstanding shares of common stock held by non- affiliates, or our public float, was less than $ 75. 0 million at the time of filing this annual report on Form 10- K, calculated in accordance with SEC rules. This means that we may use our shelf registration statement to raise additional funds only to the extent that the aggregate market value of securities sold by us or on our behalf pursuant to Instruction I. B. 6. of Form S- 3 during the 12 calendar months immediately prior to, and including, the intended sale does not exceed one- third of the aggregate market value of our public float, calculated in accordance with the instructions to Form S- 3. ~~As an example, as of March 27, 2024, we could not offer or sell more than approximately $ 19. 0 million of new securities under our shelf registration statement.~~ If our ability to offer securities under an effective shelf registration statement is limited, including by the baby shelf rule, we may choose to conduct an offering of our securities under an exemption from registration under the Securities Act or under a Form S- 1 registration statement. We would expect either of these alternatives to take more time and be a more expensive method of raising additional capital relative to using our shelf registration statement. In addition, under SEC rules and regulations, our common stock must be listed and registered on a national securities exchange in order to use a Form S- 3 registration statement (1) for a primary offering, if our public float is not at least $ 75. 0 million as of a date within 60 days prior to the date of filing the Form S- 3 or a re- evaluation date, whichever is later, and (2) to register the resale of our securities by persons other than us (i. e., a resale offering). While our common stock is currently listed on the Nasdaq Capital Market, there can be no assurance that we can maintain such listing. See, " Risks Related to **Ownership of** Our ~~Securities~~ **Common Stock** — If we fail to regain and maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock, " below. Our ability to raise capital on a timely basis through the issuance and sale of equity securities may also be limited by Nasdaq' s stockholder approval requirement for any transaction that is not a public offering (as defined in Nasdaq listing rules). For transactions other than public offerings, Nasdaq requires stockholder approval prior to the issuance or potential issuance of common stock (or securities convertible into or exercisable for common stock) at a price per share that is less than the" Minimum Price" if the issuance (together with sales by our officers, directors and substantial shareholders (as defined in Nasdaq listing rules)) would equal 20 % or more of our common stock outstanding before the issuance. Under Nasdaq rules, the" Minimum Price" means a price that is the lower of (i) the Nasdaq official closing price immediately preceding the signing of the binding agreement; or (ii) the average Nasdaq official closing price of the common stock for the five trading days immediately preceding the signing of the binding agreement. In addition, certain prior sales of securities by us may be aggregated with any offering we may propose at a price that is less than the Minimum Price and which is not considered a public offering by Nasdaq, further limiting the amount we could raise in the offering. Under Nasdaq rules, stockholder approval is also required prior to the issuance of securities when the issuance or potential issuance will result in a change of control of our company. Even if a public offering under Nasdaq rules is not subject to the 20 % limitation described above, it may involve publicly announcing the proposed transaction ~~before it is completed~~, which often has the effect of depressing **the market price of** a company' s stock **and could result in a reduced offering** price. Accordingly, our existing investors may suffer greater dilution if we seek to raise additional capital through such a public offering of our securities. Obtaining stockholder approval is a costly and time- consuming process. If we must obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our business plan, and there is no guarantee our stockholders ultimately would approve a proposed transaction. Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates, we may be unable to pursue and complete the clinical trials we would like to pursue and complete, and we may be unable to commence or complete clinical trials and pursue regulatory approvals in accordance with our current timeline expectations. Our current financial and ~~technical~~ **other** resources are limited and not sufficient to develop all of the product candidates to which we hold licenses or options to license. This may affect our efforts to develop and bring to market the product candidates currently in our portfolio and any candidates we may add to our portfolio in the future. Due to our limited resources, we have curtailed, and may be required to further curtail, **certain of** our development programs and clinical and nonclinical development activities that might otherwise have led, or lead, to more rapid progress in the development of our product candidates, or product candidates that we may in the future choose to develop. We may make determinations with regard to the indications and clinical trials on which to focus our resources that result in our realization of less than the full potential value of a product candidate. The decisions to allocate our research, management, personnel and financial resources toward particular indications may not lead to positive clinical milestones or to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate development programs may also cause us to miss valuable opportunities, including the potential for some of our product candidates to be first- in- category products. As a result of financial and other resource constraints, we may be unable to commence or complete our planned clinical trials or prepare and submit applications for marketing approval of our product candidates in accordance with our currently anticipated timelines. See also " Risks Related to Product Research & Development ~~,~~ and Regulatory Approval – Delays in the commencement or completion of clinical testing of **our** product candidates ~~we are developing or may develop in the future~~ may occur due to any of a number of factors and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable " below ~~. Women' s health has historically~~

~~been an underfunded sector.In recent years,~~ a number of public companies focused in women' s health **have** failed to achieve expected commercial success and struggled to access sufficient capital.We are solely focused in women' s health and may be unfavorably impacted by weak investor sentiment and a lack of interest in the category.Our ability to access capital and to advance our candidates could be adversely impacted.We are solely focused in women' s health,and primarily in the areas of contraception, **vaginal health,reproductive health,menopause,** sexual health **and** ~~,pelvic pain,~~ fertility ~~,infectious disease and menopause~~ .The sector has historically been underfunded,with only about one percent of healthcare research and innovation in the U.S.invested in female- specific conditions beyond oncology according to market research. ~~Non- oncologic women' s health therapeutics product launches in recent years have not been perceived as successful.Those~~ -- **The** ~~perceived commercial failures and the~~ failure of the women' s health sector to receive consistent and committed investment fuels investor sentiment that market opportunities for new products in women' s health are limited. **Our stock price** ~~While women' s health recently has received more attention,~~ and ~~investment in the~~ **our ability to access additional capital on acceptable terms when needed may be adversely impacted by unfavorable investor perception of market opportunities for** women ~~'~~ **' s health products,and our business,operating results,financial condition and prospects could suffer.Risks Related to Product Research & Development and Regulatory Approval** . Our cash could be adversely impacted if a financial institution with which we have deposit or other accounts fails. Our cash and cash equivalents we use to satisfy our working capital and operating expense needs are held in accounts at various financial institutions. The balance held in deposit accounts often exceeds the Federal Deposit Insurance Corporation (" FDIC ") deposit insurance limit or similar government deposit insurance schemes. Our cash and cash equivalents could be adversely impacted, including the loss of uninsured deposits and other uninsured financial assets, if one or more of the financial institutions in which we hold our cash or cash equivalents fails or is subject to other adverse conditions in the financial or credit markets. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation and taken into receivership by the FDIC. At that time, substantially all of our cash and cash equivalents were held in accounts with Silicon Valley Bank and we could not access such accounts. While we were afforded full access to our accounts on March 13, 2023 as a result of action taken by the U. S. Department of the Treasury, the Federal Reserve and the FDIC under the systemic risk exception, there is no guarantee that the systemic risk exception will be relied upon to provide access to uninsured deposits and other assets in the future in the event of the closure of a financial institution, or that such access would be afforded in a timely fashion. Any loss of our cash or cash equivalents or any delay in our access thereto could, among other risks, adversely impact our ability to pay our operating expenses, result in breaches of our contractual obligations, or result in violations of federal or state wage and hour laws if we are unable to pay our employees on a timely basis. **To date** ~~Women' s health has historically been an underfunded sector. Recently~~ , a number of public companies focused in..... Product Research & Development and Regulatory Approval XACIATO is **the** ~~our first and~~ only FDA- approved product **to emerge from our portfolio** . The FDA' s approval of XACIATO does not provide any assurance or predict that we will be successful in developing or achieving regulatory approval ~~of~~ **to market** any other product candidate. If we are unable to successfully conduct and complete development of and obtain regulatory approvals for our investigational products, which may never occur, our business may fail and you could lose all or part of your investment. Historical success in clinical development of and obtaining regulatory approval for a product candidate does not guarantee or predict future successful outcomes for other investigational products. Each of our development programs is unique and subject to substantial uncertainty of success inherent in pharmaceutical and biopharmaceutical development. Our **current** pipeline consists entirely of investigational products, which we also refer to as product candidates, which means that they must successfully complete one or more clinical studies to be considered for marketing approval and undergo a submission and review process with the FDA to obtain approval to be marketed in the U. S., or a similar process with comparable regulatory authorities in other jurisdictions to be marketed anywhere outside of the U. S. FDA or other regulatory authority approval may never be obtained **. See also ITEM 1. " BUSINESS – Government Regulation – U. S. Government Regulation – FDA Review and Approval Process for Prescription Drugs, FDA Review and Approval of Medical Devices, and FDA Review and Approval Process for Combination Products " and " – Government Regulation Outside the U. S. " above** . If we are unable to successfully complete development of and obtain regulatory approvals for our product candidates, our business may fail and you could lose all or part of your investment. Clinical development is a lengthy and expensive process with an inherently uncertain outcome. Failure to successfully develop and obtain regulatory approval to market and sell our product candidates, and in particular, Ovaprene and Sildenafil Cream, would likely adversely affect our business. Our business depends on the successful clinical development and regulatory approval of our product candidates, and in particular, our lead product candidates, which may never occur. The product candidates we develop require substantial clinical testing to demonstrate that they are safe and effective for their proposed uses. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its outcome is inherently uncertain. A failure of one or more clinical trials could occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial. Accordingly, while some of our product candidates have undergone clinical trials and demonstrated positive results, including Ovaprene and Sildenafil Cream, there is no guarantee of successful outcomes in current or future clinical studies of these product candidates or of obtaining marketing approval for any of them. For example, while PCT clinical trials have been used as a surrogate marker for contraceptive effectiveness and our PCT clinical trial of Ovaprene met its primary endpoint, there is no guarantee Ovaprene will demonstrate contraceptive effectiveness in its ongoing pivotal Phase 3 clinical study **or demonstrate a level of contraceptive effectiveness that will enable it to compete effectively in the contraceptive market** . As another example, while **data from** ~~we believe the objectives of~~ our exploratory Phase 2b RESPOND study of Sildenafil Cream **allows us to advance Sildenafil Cream into** ~~were met and enabled successful completion of an end- of- Phase 2 meeting with the FDA and alignment on key elements of the~~ Phase 3 **development** ~~program for Sildenafil Cream~~ , the co- primary efficacy endpoints of the Phase 2b study were not met and there is no guarantee that **our planned** Phase 3 clinical

studies **, which will have the same co- primary efficacy endpoints used in the Phase 2b study,** will be successful. The fact that the active pharmaceutical ingredients in certain of our product candidates, including Sildenafil Cream, received regulatory approval in other formulations and / or for other indications does not guarantee successful development of our product candidates for their proposed intended uses. Clinical trials may never demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for our product candidates. ~~Even if we conduct and complete clinical trials for our product candidates, we may not obtain regulatory approval to market and sell any of them on the timelines we anticipate, or at all, which would have a material adverse effect on our business and operations.~~ Outcomes of our clinical trials, particularly later- stage clinical trials, **including our ongoing Phase 3 study of Ovaprene,** may significantly impact our stock price **and our business prospects** . If ~~the~~ **interim, preliminary or final** results ~~of~~ **from** our ~~pivotal Phase 3~~ clinical **studies** ~~study of Ovaprene~~ are not positive, ~~our stock price could decline and our business and prospects may be adversely affected. Ovaprene is one of our lead product candidates. If the results of our pivotal Phase 3 clinical study of Ovaprene are not positive~~ or are perceived by third parties, including ~~financial market participants, as not positive, our business, prospects and stock price could suffer significantly. If Ovaprene fails to demonstrate adequate safety or contraceptive effectiveness in~~ the **medical community** ~~Phase 3 study~~ , **current** ~~we may determine to delay, scale back or terminate the program,~~ and **potential collaborators** ~~we may not realize any return on our investment in the program. In addition~~ , **and** ~~if we,~~ the investment community, ~~potential collaborators or the FDA view the topline or complete results of the study~~ as not positive, our stock price could decline significantly, our reputation may suffer, and our ability to raise additional capital to continue to operate as a going concern and execute our business strategy could be adversely impacted. **If a product candidate fails to demonstrate adequate safety or effectiveness in a clinical study, we may determine to delay, scale back or terminate the program, and we may not realize any return on our investment in the program. Even if we conduct and complete clinical trials for our product candidates, we may not obtain regulatory approval to market and sell any of them on the timelines we anticipate, or at all, which would have a material adverse effect on our business and operations.** Delays in the commencement or completion of clinical testing of our product candidates may occur due to any of a number of factors and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable. Clinical trials of our product candidates may not commence, progress or be completed as expected. Delays could significantly impact our product development costs and timelines, as well as a product candidate' s market potential, if ultimately approved. The timing of initiation, conduct and completion of clinical trials and other development activities for our product candidates may vary dramatically due to factors within and outside of our control and is difficult to predict accurately. We may make statements regarding anticipated timing ~~for~~ **of clinical development milestones, such as** commencement, completion of enrollment, and / or availability of results from our clinical studies, but those statements are predictions based on significant assumptions and the actual timing of achievement of development milestones may differ materially from our predictions for a variety of reasons. The commencement of clinical trials of our product candidates can be delayed for many reasons, including: • lack of adequate capital and the need to obtain additional funding; • delays in obtaining guidance or authorizations from the FDA or foreign regulatory authorities; • delays in obtaining approval from the institutional review boards, or IRBs, of prospective clinical study sites; • delays in finalizing the trial design as a result of discussions with the FDA, foreign regulatory authorities, prospective clinical trial investigators or IRBs; • delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites; or • inability to obtain sufficient quantities of clinical product supplies from our contract manufacturers and suppliers. Once a clinical trial has begun, it may be delayed, suspended or terminated by us, an IRB, the FDA or other regulatory authorities as a result of the occurrence of any of a number of events or circumstances, including: • failure to conduct the clinical trial in accordance with **its protocol or** regulatory or IRB requirements; • slower than expected rates of participant recruitment and enrollment; • higher than anticipated participant drop- out rates; • failure of participants to use the investigational product as directed or to report data as per trial protocols; • inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; • failure to achieve certain efficacy and / or safety standards; • participants experiencing severe undesirable side effects or other unexpected adverse events ~~related to the investigational product~~ ; • disruptions in or insufficient supply of clinical trial material or inadequate quality of such materials; • failure of our CROs or other third- party service providers to meet their contractual obligations to us in a timely manner, or at all; or • delays in quality control / quality assurance procedures necessary for study database lock and analysis of unblinded data. Unexpected **SAEs** ~~serious adverse events~~ or other undesirable side effects could arise during clinical development and interrupt, delay, or cause the termination of clinical trials, and require us to conduct additional clinical and nonclinical studies that were not part of our development plan, which could significantly increase the development costs and timeline for a program and adversely impact its value and our ability to continue product development. These events may also cause our reputation to suffer and subject us to lawsuits. As discussed elsewhere in this Risk Factors section, macroeconomic factors and events also have the potential to cause or contribute to significant delays in commencement and completion of our clinical trials. Global supply chain disruptions and the subsequent effects thereof may adversely affect the ability of contract manufacturers to manufacture and supply our clinical trial material. Our prospective or contracted clinical trial sites may experience resource constraints, including staffing shortages, stemming from global or regional issues, such as a ~~pandemic or other~~ public health emergency **, natural disaster, or worker strike** , and become unable to allocate adequate resources to reach agreements necessary to commence our clinical trials at their facilities or, even if agreements are in place, to conduct our clinical trials. For ongoing clinical trials, macroeconomic factors or events, such as a global pandemic, may result in lower than anticipated subject enrollment and completion rates, including because clinical trial sites may temporarily close or reallocate resources away from clinical research, or study participants may withdraw prior to receiving study treatment or discontinue their treatment or follow up visits to avoid medical settings or because they become sick or must care for a sick family member. Significant clinical trial delays could have a material adverse impact on our financial condition and results of operations by substantially increasing the costs of our development programs. Significant

clinical trial delays also could jeopardize our ability to meet obligations under agreements under which we license our rights to our product candidates, allow other companies to bring competitive products to market before we do, shorten any period of market exclusivity we may otherwise have under our patent rights, and weaken our negotiating position in discussions with potential collaborators, any of which could impair our ability to successfully complete development of or commercialize our product candidates, if ultimately approved. Any significant delays in commencement or completion of clinical trials of our product candidates, or the suspension or termination of a clinical trial, could materially harm our business, financial condition and results of operations. Delays in the manufacture of our clinical supplies as well as other supply chain disruptions could postpone the initiation of or interrupt clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and impact the commercialization of any approved products. The manufacture of our product candidates is ~~complex and~~ subject to compliance with extensive regulatory requirements **, in some cases is complex** , and in most cases we rely on single source contract manufacturers and suppliers. As a result, we face significant risks of manufacturing and supply delays and disruptions that may be difficult and expensive to resolve and may cause substantial delays in the development and regulatory approval of our product candidates or the commercialization of any approved product. To date, our clinical- stage product candidates have been tested in a relatively small number of clinical study participants. Significant scale- up of manufacturing will be required to provide adequate supplies of our product candidates for larger Phase 2 and Phase 3 clinical trials and may take longer and be more expensive than anticipated **. For example** , ~~potentially having For example,~~ the ongoing pivotal clinical study of Ovaprene will require far more clinical product supplies than were manufactured for prior clinical and nonclinical studies combined.A substantial scale up in production **of Ovaprene clinical supplies** was necessary to ~~meet~~ **support** the **ongoing Phase 3 clinical** study ~~' s requirements~~ **of Ovaprene,which took longer** and ~~required~~ **was** more ~~time and expense~~ **expensive** than anticipated **,impacting** ~~.Additional clinical supplies must be produced to complete the study and manufacturing disruptions may occur~~ -- **our development** ~~that extend the overall~~ timeline ~~and cost to complete the study~~ .Under our agreement with ADVA- Tec,we are dependent on ADVA- Tec and its contract manufacturer,Poly-Med,Inc.,for all Ovaprene clinical and commercial product supplies,and we do not control these third parties and have limited influence the efforts and resources they expend to meet our supply requirements. ~~Furthermore,~~ **Disruptions and delays in scaling up manufacturing of our product candidates for later stage clinical studies may have** a significant negative impact on our development costs and timelines. We have, and we expect we will continue to, face multiple challenges as our contract manufacturers scale their processes to provide supplies for larger clinical trials or commercial production including, among others, potential difficulties with process scale- up, process reproducibility, stability and purity issues, compliance with cGMP, lot consistency, and timely availability of acceptable raw materials. For example, the ongoing pivotal clinical..... pivotal clinical study' s requirements. The manufacture of our product candidates is subject to extensive regulation. The finished products (and their APIs) used in clinical trials or approved for commercial sale must be manufactured in accordance with cGMP requirements in the U. S. that are enforced by the FDA and must comply with applicable requirements of foreign regulatory authorities for sales outside of the U. S. These regulations govern manufacturing processes and procedures, including record keeping and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of a product that may result in closure of the manufacturing facility for an extended period of time to investigate and remedy the contamination or inadvertent change. In addition, deviations anywhere in the manufacturing process could cause our product candidates to perform differently and affect the results of clinical trials. Further, even minor deviations in the manufacturing process, including filling labeling, packaging, storage and shipping, and quality control and testing, may result in shipment delays, lot failures, recalls or spoilage, and delay or disrupt our clinical studies or commercial supply of any approved product. **See also ITEM 1. " BUSINESS – Government Regulation – U. S. Government Regulation – FDA Review and Approval Process for Prescription Drugs, FDA Review and Approval of Medical Devices, and FDA Review and Approval Process for Combination Products " and " – Government Regulation Outside the U. S. " above.** If our contract manufacturers are unable to produce sufficient quantities of our product candidates (or their APIs) for clinical trials or, if approved **for commercial sale** , for commercialization at acceptable quality levels, our development and commercialization efforts would be impaired, which could have a material adverse effect on our business, financial condition and results of operations. As product candidates progress through the development process, it is not uncommon that manufacturing methods are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs, achieve consistent quality and results, or to comply with regulatory authority requirements. Any such changes carry risk that they will not achieve the intended objectives. If and when changes are made to the manufacturing process of our product candidates (or their APIs), we may be required by the FDA or foreign regulatory authorities to conduct bridging clinical or nonclinical studies or repeat one or more clinical trials to demonstrate comparable identity, strength, quality and purity of the product candidate before and after such changes, which could significantly increase development costs and delay regulatory approval or disrupt commercial supply. These manufacturing and supply risks are similarly applicable to any product or product candidate we license to a commercial collaborator and could adversely impact the timing or amount of potential milestone and royalty payments to us. In addition, our cost of goods for our product candidates is at an early stage of development. The cost to manufacture our product candidates at commercial scale is difficult to predict currently. We may need to alter the materials, equipment or processes for making our product candidates in order to yield commercially viable products. As discussed above, manufacturing changes could increase development costs and timing **, delay regulatory approval or disrupt commercial supply** and may not achieve the intended objectives. Manufacturing costs may negatively impact the commercial viability of our product candidates, if approved **for commercial sale** . See also " Risks Related to Our Dependence on Third Parties- We do not have, and we do not have plans to establish, our own manufacturing capabilities and instead rely on third- party suppliers and manufacturers for clinical study materials, including multiple single source suppliers and manufacturers. If these third parties do not perform as we expect, do

not maintain their regulatory approvals or become subject to negative circumstances, it could delay, prevent or impair our product development or commercialization efforts, or those of our collaborators, and harm our business, ” and “- In some cases, we may be contractually required to obtain clinical or commercial product supplies from specific third parties or there may be a limited number of third- party suppliers of raw materials and other components of our product candidates or future products, which may heighten our dependence on those third parties ~~and~~ **, increase** the risk of manufacturing disruptions **, and result in higher development costs or costs of goods sold** ” below. **The factors contributing to female sexual dysfunction disorders, including FSAD, are complex and there is limited clinical trial precedent from which to draw experience, making the design and execution of a clinical trial that demonstrates effectiveness of Sildenafil Cream in treating FSAD more inherently challenging and uncertain compared with investigational products for** ~~Many~~ **many other conditions. There are currently no FDA- approved pharmacologic treatments for FSAD and there is no precedent program to reference in the design** of our **clinical trials for Sildenafil Cream. Female sexual dysfunction disorders in women vary in nature and may be the result of a variety of physiological and psychological factors. Given the variability of factors contributing to the underlying condition, and the** product candidates ~~below.The factors contributing~~ **' attributes,clinical studies** to **evaluate effectiveness in any subset of the conditions under the umbrella of** female sexual dysfunction ~~disorders,including FSAD,are complex and there is limited clinical trial precedent from which to draw experience,making the design and execution of a clinical trial that demonstrates effectiveness of Sildenafil Cream in treating FSAD more inherently challenging and uncertain compared with investigational products for many other conditions.There are currently no FDA- approved pharmacologic treatments for female sexual arousal disorder,or FSAD,and there is no precedent program to reference in the design of our clinical trials for Sildenafil Cream.Female sexual dysfunction disorders in women vary in nature and may be the result of a variety of physiological and psychological factors.Given the variability of factors contributing to the underlying condition,and the product candidates' attributes,clinical studies to evaluate effectiveness in any subset of the conditions under the umbrella of Sexual Dysfunction~~ ,such as FSAD,are complex.While we worked with experts to **select existing as well as** develop novel patient reported outcome (PRO) instruments for our exploratory Phase 2b RESPOND study of Sildenafil Cream,tested the potential PRO instruments in a content validity study,reviewed the results of that study with the FDA and aligned with the FDA on the Phase 2b study design, **there is no precedent program that has utilized these same endpoints in a Phase 3 study and there is no assurance they will be adequate to detect a treatment effect.In addition,** the Phase 2b RESPOND study proved more difficult to enroll than anticipated given the enrollment criteria for the study,particularly the requirement that the partner be enrolled in the study.Moreover,the Phase 2b RESPOND study did not demonstrate statistical significance for the co- primary or secondary efficacy endpoints ~~,although we determined that topline~~ **.While post- hoc analyses of** data **from** ~~supported continued clinical development of Sildenafil Cream and further analysis of~~ the **Phase 2b RESPOND** study ~~data~~ identified ~~certain~~ **a subsets** ~~-~~ **subset** of participants that achieved ~~clinically meaningful and~~ statistically significant improvement in **one of** ~~certain items relating to~~ the co- primary efficacy endpoints **of the study** and ~~data from~~ **the planned Phase 3 study will be in that subset of patients,** ~~the there RESPOND study enabled~~ **can be no assurance that Sildenafil Cream will be** successful **in** ~~completion of an end- of- Phase 2 meeting with~~ the **planned** ~~FDA and ongoing feedback from the FDA to align on key elements of the~~ Phase 3 **study** ~~program for Sildenafil Cream~~ .Sildenafil Cream is designed to work primarily by increasing blood flow to the genital tissue.Therefore,identifying and enrolling patients in our clinical trials of Sildenafil Cream for whom inadequate blood flow to the genital tissue is the primary contributor to their arousal disorder is critical.If we fail to screen **study participants** properly ~~,and instead enroll patients with different contributing factors~~ ,the results of our clinical trials are unlikely to demonstrate effectiveness of Sildenafil Cream.Conversely, ~~trying to screen~~ **screening procedures** ~~out patients with different contributing factors~~ may slow enrollment in a study,delay its completion and increase its costs.In our exploratory Phase 2b RESPOND study,we experienced a slower than anticipated pace of enrollment given the enrollment criteria for the study,which lengthened our original estimated timeline for the study.We may experience delays in future clinical studies of Sildenafil Cream relative to our communicated expectations due to the novel nature of the studies and the complexities of the condition it is intended to treat,which may significantly lengthen clinical study timelines,increase overall costs,and may lead to unfavorable results.With respect to any clinical study of Sildenafil Cream,even if we can identify and enroll a sufficient number of women for whom inadequate blood flow to the genital tissue is the primary contributing factor to their arousal disorder,there is no ~~guaranty~~ **guarantee** that the use of Sildenafil Cream will **meaningfully** improve their **sensations** ~~general feelings~~ of arousal or **demonstrate statistically significant improvement** ~~that the PRO instruments we utilize to measure the effectiveness of Sildenafil Cream~~ in ~~the study will adequately capture their~~ -- **the** ~~genital arousal response~~ **primary or secondary efficacy endpoints of the study** .We expect to conduct two Phase 3 studies to support an NDA for Sildenafil Cream.Given the multiple factors contributing to arousal disorders **and the novelty of the clinical endpoints that will be utilized to measure effectiveness of Sildenafil Cream in treating FSAD,we may be required to conduct multiple clinical trials in large patient populations,extending the timeline and increasing the cost of development for Sildenafil Cream,without any guarantee of positive results.If we are unable to efficiently and successfully advance Sildenafil Cream through clinical development,our business,operating results and financial conditional,as well as our stock price,could suffer.Interim,topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data,and others** , including ~~Ovaprene~~ **regulatory authorities** , **may** not agree with our interpretation of study data.From time to time,we may publicly disclose interim,preliminary or topline data from our clinical studies,which are based on a preliminary analysis of then- available data,and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial.We also make assumptions,estimations,calculations and conclusions as part of our analysis of data,and we may not have received or had the opportunity to fully and carefully evaluate all data.As a result,the topline results of clinical trials we report may differ from final

results reported for those studies,or different conclusions or considerations may qualify such results,once additional data have been received and fully evaluated.Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published.As a result,topline data should be viewed with caution until the final,complete data are available.Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available.Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.There can be no guarantee that a favorable interim analysis ~~will~~ will **result in a favorable final result at the completion of the clinical trial. Further, others, including regulatory authorities, may not accept or agree with** ~~or~~ **our assumptions, estimates, calculations, conclusions or analyses or** may interpret or weigh the importance of study data differently than we do,which could impact the value of the particular program,the approvability or commercialization of the particular product candidate or product and our company in general.In addition,the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically an extensive set of data and analyses,and investors and others may disagree with the information we determine is the material or otherwise appropriate information to include in our public disclosure.Information we determine not to publicly disclose may ultimately be ~~considered combination~~ **deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular** ~~products~~ **product candidate,product or our business.If the topline data that we report differ from complete results,or if others,including regulatory authorities,disagree with the conclusions reached,our ability to obtain approval for,and commercialize,our product candidates may be harmed,which could harm our business,operating results,prospects or financial condition.Our business depends on obtaining regulatory approval to market our product candidates in a timely manner,in particular,FDA approval** .The regulatory approval processes of the FDA and comparable foreign authorities are expensive,lengthy,time- consuming,and inherently unpredictable.If we are not able to obtain regulatory approvals for our product candidates,our ability to generate product revenue will be materially impaired.Our product candidates and the activities associated with their development and commercialization,including their design,testing,manufacture,release,safety,efficacy,regulatory filings,recordkeeping,labeling,storage,approval,advertising,promotion,sale and distribution,are subject to comprehensive regulation ~~by the FDA,other regulatory authorities in the U.S.,and comparable authorities in other countries or jurisdictions where we seek to test or market our product candidates.The process of obtaining marketing approvals in the U.S.and elsewhere is expensive,may take many years and can vary substantially based upon a variety of factors,including the type,complexity and novelty of the product candidates involved.In addition,requirements for approval may change over~~ by the FDA ~~and~~ **,** other regulatory authorities ~~similar to ours,any of which may~~ have implications for our proposed regulatory authorization pathways,could impact how investors and potential strategic collaborators view the development risks associated with our product candidates.Changing testing or manufacturing requirements for our product candidates or for product candidates deemed to be comparable to ours may adversely impact our financial resources,our development timelines and may harm the perception held by others of our business. ~~A change in the regulatory approval pathway we anticipate for a product candidate could significantly increase development cost and timeline and heighten the risk of failure.~~ We expect to utilize the FDA' s Section 505 (b) (2) pathway for most of our current product candidates ~~,including all of our clinical- stage candidates other than Ovaprene,~~ and if that pathway is not available,the development of our product candidates will likely take significantly longer,cost significantly more and entail significantly greater complexity and risk than currently anticipated,and,in any case,may not be successful. ~~Section~~ **We intend to develop and seek approval for many of our product candidates,including Sildenafil Cream,pursuant to the FDA' s** 505 (b) (2) ~~of~~ **pathway.If** the ~~FDCA~~ **FDA** ~~permits~~ **determines that we may not use this regulatory pathway,** ~~the~~ **then we would need to seek regulatory approval via a " full "** ~~filing of an NDA in which the applicant relies,at least in part,on the FDA' s prior findings of safety and efficacy data for an existing product,~~ or ~~" published literature,in support of its NDA,potentially eliminating or reducing the need to conduct certain nonclinical testing or clinical studies and~~ **stand - alone "** ~~expediting development timelines relative to the traditional or" full"~~ NDA under Section 505 (b) (1) of the FDCA. ~~See ITEM 1~~ **This would require us to conduct additional clinical trials and nonclinical testing,provide additional safety and efficacy data and other information,and meet additional standards for regulatory approval . If this were to occur,the time and financial resources required to obtain FDA approval,as well as the development complexity and risk associated with these programs,would likely substantially increase,which could** , which could ~~increase the complexity, cost~~ **have a material adverse effect on our business** and ~~timeline~~ **financial condition. In addition, Section 505 (b) (2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs referenced in a Section 505 (b) (2) NDA, and the filing of a patent infringement lawsuit against us following our submission of a 505 (b) (2) NDA could significantly delay any potential FDA approval of the NDA. Even if we are able to utilize the Section 505 (b) (2) regulatory pathway for one** ~~for~~ **or more of our candidates,** ~~their~~ **there is no guarantee this would ultimately lead to faster product** development ~~and regulatory~~ **or earlier** ~~approvals~~ **approval or commercial launch** . ~~A~~ **In regard to Ovaprene, a** change in the FDA' s prior determination that CDRH would lead the review of a marketing application for Ovaprene would adversely impact Ovaprene' s development timeline and significantly raise our costs to complete clinical development and obtain regulatory approval for Ovaprene. To the extent our..... Process for Combination Products, " above . Ovaprene is composed of both device and drug components and is considered a combination product by the FDA. The process for obtaining FDA approval of Ovaprene will require compliance with complex procedures because concordance between two centers of the FDA (CDRH and CDER) is necessary. **See ITEM 1." BUSINESS – Government Regulation – U. S. Government Regulation – FDA Review and Approval Process for Combination Products, " above for more information about the FDA review and approval process for combination products.** Ovaprene previously underwent a request for designation, or RFD, process with the FDA that determined that CDRH would lead the review of a PMA for

potential marketing approval of this product candidate. If the designation were to be changed to CDER, or if either center were to institute additional requirements for the approval of Ovaprene, we could be required to complete clinical studies with more patients and over longer periods of time than is currently anticipated. This would significantly increase the anticipated cost and timeline to completion of Ovaprene' s development and require us to raise additional funds. Based on discussions with the FDA, we believe that if our ongoing pivotal clinical study of Ovaprene is successful, the FDA will not require additional clinical studies to support the PMA for Ovaprene. However, the FDA may determine that the results of the study are not sufficiently robust or convincing and require additional clinical and / or nonclinical studies prior to approval of Ovaprene. Because Ovaprene is one of our lead product candidates, the impact of either a change in the lead FDA review center or the imposition of additional, currently unplanned requirements for approval could be significant to us and have a material adverse effect on the prospects for developing Ovaprene, as well as on our business and our financial condition. See also " The commercial success of..... without any guarantee of positive results. If we are unable to **pursue** efficiently and successfully advance Sildenafil Cream through..... a timely manner, in particular, FDA approval **via** . The regulatory approval processes of the..... from the FDA by another company pursuing the FDA' s 505 (b) (2) pathway ~~for -~~ **or, in the case of Ovaprene, through review of a PMA by CDRH, new competitive products may reach the market more quickly than our** product candidates ~~identical to or similar to ours~~ , ~~any of~~ which may have implications for our proposed regulatory authorization..... would likely substantially increase, which could have a material adverse ~~effect~~ **impact** on our ~~business and financial condition. The Drug Price Competition and Patent Term Restoration Act of 1984, informally known as the Hatch- Waxman Act, added Section 505 (b) (2) to the FDCA. Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies and information that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505 (b) (2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA' s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite our development programs relative to seeking approval under the 505 (b) (1) regulatory pathway. If the FDA changes its 505 (b) (2) policies and practices or if Congress were to amend the statute to alter the currently available regulatory pathway, it could delay or even prevent the FDA from approving any NDA we submit under Section 505 (b) (2). In addition, the pharmaceutical industry is highly~~ competitive ~~,~~ **position** and ~~Section 505 (b) (2) NDAs are subject to special requirements designed to protect~~ **prospects** ~~the patent rights of sponsors of previously approved drugs referenced in a Section 505 (b) (2) NDA~~ . Even if we are **allowed** ~~able to utilize the Section 505 (b) (2) regulatory pathway for one or more of our candidates, there is no guarantee this would ultimately lead to faster product development or earlier approval. Moreover, any delay resulting from our inability~~ to pursue the FDA' s 505 (b) (2) pathway ~~could result in new competitive products reaching the market more quickly than our product candidates~~ , ~~which may have a material adverse impact on our competitive position~~ and **in** ~~prospects. Even if we are allowed to pursue~~ the **case of Ovaprene, review of a PMA by CDRH** ~~FDA' s 505 (b) (2) pathway~~ , we cannot assure you that our product candidates will receive the requisite approvals for commercialization ~~candidates may be considered combination products by the FDA and other regulatory authorities,which could increase the complexity,cost and timeline~~ for **Ovaprene** ~~their development and regulatory approval~~ .To the extent our product candidates meet the FDA' s or any other regulatory authority' s definition of a combination product,the regulatory approval requirements can be more complex and costly because ~~,~~ in addition to the individual regulatory requirements for each component,e.g.,a drug and a medical device,additional combination product regulatory requirements may apply. **The cost and timeline for development of product candidates determined to be combination products may be substantially greater than product candidates that are not considered combination products.** See **also** ITEM 1." BUSINESS – Government Regulation – U.S.Government Regulation – FDA Review and Approval Process for Combination Products," above ~~.~~ . Our clinical- stage product candidates have only been tested in a small number of women over short periods of use and no data exists regarding a potential increase in fetal abnormalities in pregnant women. If our clinical- stage product candidates, including Ovaprene and Sildenafil Cream, are successful in their clinical development, we expect that women of child- bearing age will use them, and potentially for many months or years. To date, human clinical studies of these product candidates have been for relatively short periods of time and these product candidates lack safety data over longer periods of use. For example, while we believe the risk of adverse fetal development from using these product candidates is low, the impact of these product candidates on fetal development has not been studied and there are no adequate or well- controlled studies of these product candidates in pregnant women. Thus, the risk of adverse fetal development from any one or more of these product candidates may be greater than expected. Should any of these product candidates be shown to increase the risk of adverse fetal development, our ability to develop those or other product candidates would be substantially impaired, our business prospects and operations ~~would~~ **could** be materially harmed, and we could also be subject to potential claims and lawsuits. Pre- clinical product candidates may ~~not~~ be ~~valued~~ **undervalued** by investors and may be difficult to fund. Given their early stage of development and the lack of data, many pre- clinical assets are often perceived as having low valuations by investors and potential strategic collaborators, such as pharmaceutical companies. Our investment of time and resources in such assets may not be appreciated or valued. As a result, it may be difficult for us to fund such programs. Additionally, past receipt of grant funding may not be predictive of our ability to secure additional grants to fund further development of a program. Our portfolio includes several pre- clinical stage programs and if they fail to be adequately valued by investors or potential strategic collaborators, our business, financial condition and stock price may be adversely affected. Several of our product candidates are in pre- clinical stages of development and may never advance to clinical development. Pre- clinical studies refer to a stage of research that begins before clinical trials (testing in humans) can begin, and during which important feasibility, iterative testing and drug safety data are collected. Because of their early nature, pre- clinical product candidates tend to carry a higher risk of failure as compared with clinical- stage assets. Pre- clinical candidates must generate sufficient safety and efficacy data through in vitro studies, animal studies and a variety of tests before they can be considered appropriate for testing in humans. The development risks, timeline and cost of pre- clinical

assets can be high because of the unknowns and absence of data. It can be difficult to identify relevant tests and animal models for pre- clinical studies. Even if the results from our pre- clinical studies are favorable, we still may not be able to advance the candidates into clinical trials. If pre- clinical studies of product candidates do not generate strong data, our pre- clinical stage programs may never progress to clinical development and may prove to be worthless. The grants **and other non- dilutive funding awards** supporting **several of our development** ~~the DARE- LARC1 and DARE- LBT~~ programs do not guarantee that **the** pre- clinical **or clinical** development **work being funded** will be successful or that we will be able **or will choose** to fund ~~their~~ -- **the** ~~clinical~~ **additional** development **work that will be required** in the future **to advance the product candidates toward regulatory approval** . The grants ~~supporting pre- clinical development of DARE- LARC1~~ and ~~DARE- LBT, including the~~ **other** ~~grant agreement under which we were awarded up to $ 48. 95 million in~~ non- dilutive funding ~~for pre~~ **supporting development of several of our programs, including Ovaprene, DARE** - ~~clinical development of~~ **HPV, DARE- PTB1,** DARE- LARC1, ~~do~~ **DARE- LBT, and activities to aid in the identification and development a novel non- hormonal intravaginal contraceptive candidate, should** not ~~guarantee~~ **provide any assurance** that pre- clinical **or clinical** development **supported by that funding** will be successful, or, even if we are successful with all specified **development** ~~pre- clinical~~ activities, that we will be able **or will choose** to fund ~~their~~ -- **the additional** ~~future clinical~~ development **work that will be required to continue to advance the product candidates toward commercialization** . Further, ~~while we received aggregate~~ **the grant agreements or other non- dilutive funding award agreements supporting these development programs generally feature milestone- based** payments **or, in** ~~of approximately $ 28. 4 million under~~ the **case of NIH** ~~2021 DARE- LARC1 grant~~ **grants** ~~agreement as of December 31~~ , ~~2023, additional~~ payments are **received in reimbursement** ~~contingent upon the DARE- LARC1 program' s achievement~~ of specified **activities** ~~development and reporting milestones during the grant period and our compliance with other obligations under the agreement~~ , and there is no assurance ~~those milestones will be achieved or~~ that we will **be able to achieve or otherwise demonstrate satisfaction of the specified development and reporting milestones required to** receive ~~additional~~ **future** payments **under the agreements. Additionally, the counterparties to these agreements may modify, suspend, discontinue payment of funds** or **terminate the agreements in certain circumstances largely in their discretion. Accordingly, we may never receive future payments under these agreements or realize** the full potential amount of the grant **or other funding award** . Our existing product development and commercialization collaborations are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, if these collaborations are not successful, or if we are unable to establish additional strategic collaborations, our business and prospects may be materially harmed. We have limited resources and no internal sales, marketing or distribution capabilities. A key aspect of our strategy is to establish collaborations with third parties, such as large and mid- size pharmaceutical companies and other third parties with the relevant R & D and / or commercial expertise and infrastructure **,** to help bring our product candidates to market. We currently do not expect to directly market, sell or distribute any of our products that receive regulatory approval, and instead intend to enter into agreements with third parties to market, sell and distribute and provide related support services for those products. For example, we have entered into out- license agreements with third parties for the commercialization of XACIATO and, if approved **for commercial sale** , Ovaprene ~~. We also have a CRADA for the conduct of a pivotal clinical study of Ovaprene with NICHD~~ . We intend to seek additional strategic collaborations. However, **such strategic collaboration opportunities may not be available to us for a variety of reasons. For example, certain potential pharmaceutical company collaborators have announced discontinuation or significant reduction in their research and development efforts in women' s health therapeutics. To** ~~these~~ -- **the extent we do enter into strategic** collaborations ~~make~~ **similar to our agreements for the commercialization of XACIATO and Ovaprene,** the successful development and commercialization of our products and product candidates **may become partially or entirely** dependent upon the performance of third parties. By entering into strategic collaborations, we may relinquish control over important elements of product development and commercialization, and the collaborator may fail to develop or effectively commercialize the applicable products or product candidates. In addition, in the case of commercial collaborations, our product revenues ~~,~~ may be lower than if we were to sell and distribute products that we develop ourselves. Our existing collaborations, and any future strategic collaborations we establish, involve significant risks to the success of the product, including that: • collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may not pursue development or commercialization of a product or product candidate or elect not to continue or renew a collaboration based on clinical or nonclinical study results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, a public health emergency, or macroeconomic events or conditions, that cause them to divert resources to other initiatives or create competing priorities; • collaborators may refuse to perform clinical studies or other development work required for approval in a particular jurisdiction outside the U. S.; • collaborators may delay or stop clinical studies, provide insufficient funding for or abandon a clinical program, repeat or conduct new clinical studies or require a new formulation of a product or product candidate for clinical testing; • collaborators could independently, or together with third parties, develop and commercialize products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • collaborators with marketing and distribution rights to one or more of our products may not commit sufficient resources to the marketing and distribution of such product or products; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or product development or commercialization strategy, might cause delays or termination of the research, development or commercialization of our products or product candidates, might lead to additional responsibilities for us with respect to products or product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or

invalidate our intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • collaborators may violate, or be investigated for potentially violating, health care compliance and related laws and regulations, which may expose us to litigation, enforcement actions or inquiries, or other potential liability; and • collaborations may be terminated for the convenience of the collaborator and, if terminated, could significantly delay product development and commercial launch and increase the cost to us to pursue further development or commercialization of the applicable product or product candidate. For example, our out- license agreements for XACIATO and Ovaprene and the CRADA with NICHD may be terminated by the counterparty for convenience upon the completion of a specified notice period, subject to limited restrictions. If a collaborator terminates its agreement with us or if a collaboration does not result in the successful development of any product candidates and / or commercialization of any approved products, we may not receive any future royalty revenue, commercial milestones or other revenues under the collaboration, our development programs may not be funded as we expect, and our ability to establish another collaboration for the applicable product or product candidate may be negatively impacted. We may be unable to replace any commercial collaborator with an alternate third party on a timely or commercially reasonable basis, or at all. See also, " Risks Related to Our Financial Position and Capital Needs- If one of our commercial collaborators terminates its exclusive license agreement with us or fails to perform as expected, our need for additional capital may significantly increase, " above and " We rely on, and intend to continue to rely on, third parties for the execution of significant aspects of our product development programs. Failure of these third parties to successfully carry out their contractual duties, comply with regulatory requirements and applicable law, or meet expected deadlines may cause significant delays in our development timelines and / or failure of our programs, " below. Moreover, the risks relating to product development, regulatory approval and commercialization and compliance with health care related laws and regulations described in this report also apply to the activities of our collaborators. ~~Except~~ **Organon has global commercial rights** to **XACIATO** ~~the extent of any license fees or milestone payments under our current and any future collaboration agreements, because we currently have only one FDA- approved product, our ability to generate revenue over the next several years will largely be dependent on royalties and net sales- based milestones~~ under our exclusive license agreement ~~with Organon. Accordingly, our revenues may be dependent on Organon' s ability to successfully market, sell and distribute XACIATO and to perform its contractual obligations~~. There is no assurance that commercialization of XACIATO in the U. S. will be successful, or that Organon will pursue development and commercialization of XACIATO outside of the U. S. ~~The amount~~ **As discussed elsewhere in this Risk Factors section, as a result** of **the traditional** royalty **purchase agreement** ~~and milestone payments~~ we **entered into with XOMA, whether we receive any future income based on net sales of XACIATO** will ~~receive under~~ **depend on whether** the ~~license agreement~~ **Revenue Sharing Threshold** is ~~uncertain~~ **reached, which will depend, in part, on Organon' s future commercial success with XACIATO, which is outside of our control** . Apart from Organon' s diligence obligation under our license agreement, we have no control over the efforts and resources Organon devotes to the marketing and sale of XACIATO. The occurrence of any of the risks described above could negatively impact the commercial success of XACIATO and have a material adverse effect on our business, financial condition and results of operations . Termination of the CRADA by NICHD..... price of our common stock to decline . We face significant competition in seeking strategic collaborations. Collaborations can also be complex and time- consuming arrangements to negotiate and document. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product or product candidate, reduce or delay one or more of our other development programs, delay or reduce the scope of any commercial readiness activities, delay commercialization, or increase our expenditures and undertake development or commercialization activities at our own expense. Our success in entering into a definitive agreement for any collaboration will depend upon, among other things, our assessment of the prospective collaborator' s resources and expertise, the terms of the proposed collaboration and the proposed collaborator' s evaluation of several factors. Those factors may include the design and outcomes of our clinical studies, the likelihood of approval by regulatory authorities, the potential market for the product, the costs and complexities of manufacturing and delivering such product to customers, the potential of competing products, the strength of the intellectual property and other potential sources of market exclusivity for such product, the market performance of other products we developed, and industry and market conditions generally. The prospective collaborator may also have opportunities to collaborate with third parties on products or technologies that would compete with our products or product candidates and will evaluate whether those opportunities are more attractive than a collaboration with us. We face competition in our search for collaborators from other biotechnology and pharmaceutical companies worldwide, many of which are larger and able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support. Inadequate capitalization of our company, or the perception thereof, could negatively affect our negotiating leverage in transactions. We may also be restricted under existing collaboration agreements from entering into other collaborations on certain terms with other potential collaborators. For example, the terms of our exclusive license agreement also provide Organon exclusive worldwide rights of first negotiation for specified potential future products of ours, which may increase the complexity and time required, or otherwise inhibit our ability to transfer, license, sublicense, assign, grant or otherwise dispose of any rights in those potential future products to a third party, and lead to delays in their development and commercialization. If we are not successful in attracting collaborators, entering into collaborations on acceptable terms and maintaining our collaborations for the products we develop, we may not complete development of or obtain regulatory approval for such products and product candidates, or if we obtain regulatory approval, commercial launch may be delayed and market penetration could be limited. In such event, our ability to generate revenues from such products and achieve or sustain profitability would be significantly hindered which would materially harm our business and financial condition. **.Termination of** ~~study follow- up visits with existing participants are completed or before the study is completed,we may determine to contract directly with those sites to enable them~~ **the** ~~to restart recruitment and enrollment of new participants~~

CRADA by NICHD or by us could significantly delay the conduct and / or ~~ensure~~ **completion of** ~~they~~ **the Phase 3 study of Ovaprene and significantly** ~~remain active sites to continue follow- up with existing participants,which could~~ increase the ~~time~~ **overall timeline** and ~~cost~~ **costs** ~~to us to complete the study.In addition,if CCTN sites are closed,some participants may drop out of the study,which could adversely affect completion or~~ **for** ~~results~~ **development** of **Ovaprene** ~~the study~~ .Though the CRADA has a five- year term ~~ending in 2026~~ ,either party may terminate it for any reason or for no reason upon 30 days' prior written notice to the other party. ~~Termination of the CRADA by NICHD or by us could significantly delay the conduct and / or completion of the Phase 3 study and significantly increase the overall timeline and costs for development of Ovaprene.~~ If the CRADA is terminated before completion of the Phase 3 study **of Ovaprene** ,NICHD will cooperate with us to transfer the data and the conduct of the study to us or our designee and will continue to conduct the study for so long as necessary to enable such transfer to be completed without interrupting the study.If we terminate the CRADA before the completion of any active study protocol,we generally will be responsible for providing sufficient clinical supplies of Ovaprene to NICHD in order to complete the study.NICHD may retain and use the cash payments we have made under the CRADA for up to one year after expiration or termination to cover costs associated with the conduct of activities described under the research plan in the CRADA that were initiated prior to expiration or termination **.If we fail to make any scheduled payment to NICHD under the CRADA,NICHD is not obligated to carry out R & D activities until it receives the funds.We have paid NICHD $ 5.0 million under the CRADA to date.Under the terms of the CRADA,a final payment of $ 0.5 million was due in the second quarter of 2023.Pursuant to our discussions with NICHD,we expect to make the final payment in the third quarter of 2024** .Suspension by NICHD of activities under the CRADA or termination by NICHD or by us of the CRADA could have a material adverse effect on the Phase 3 study **of Ovaprene** and on our business,results of operations and financial condition,and may cause the market price of our common stock to **decline** We do not have, and we do not have plans to establish, our own manufacturing capabilities and instead rely on third- party suppliers and manufacturers for our clinical study supplies, including multiple single source suppliers and manufacturers. If these third parties do not perform as we expect, fail to maintain their regulatory approvals or become subject to negative circumstances, it could delay, prevent or impair our product development or commercialization efforts, or those of our collaborators, and harm our business. We do not own or operate, and we currently have no plans to establish, facilities for manufacturing, storage and distribution, or testing of product candidates. We rely and expect to continue to rely on third parties to supply and manufacture our product candidates and other materials necessary to commence and complete pre- clinical testing, clinical trials and other activities required for regulatory approval of our product candidates, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials, and conducting stability testing. In addition, we expect to continue to rely on third parties for commercial production and supplies of any future products. This reliance on third- party manufacturers and suppliers subjects us to inherent uncertainties related to product safety, availability, quality and cost. Our product candidates (including their component materials) must be manufactured, packaged, tested, and labeled in accordance with our specifications and in conformity with cGMP and other applicable regulatory requirements, which requires dedication of substantial resources to specialized personnel, facilities and equipment and sophisticated quality assurance, quality control, recordkeeping procedures. While our employees and consultants monitor and audit our CMOs' manufacturing processes and systems, we have limited control over our CMOs and they may fail to perform as expected. The facilities and quality systems of CMOs who produce our product candidates and their APIs must pass a pre- approval inspection for compliance with applicable regulations as a condition of FDA approval. Failure to pass inspections, or to timely remediate any compliance issues identified by the FDA, could substantially delay marketing approval. As long as we are the product candidate sponsor or the holder of the product approval or manufacturer of record with the FDA or other regulatory authority, we are ultimately responsible for compliance with regulatory requirements for manufacturing and distribution of our product candidates and any future approved products, regardless of our lack of control over our third- party manufacturers and suppliers. Failure of those third parties to comply with cGMP and other applicable regulatory requirements may result in fines and civil penalties on us, suspension of production, delay or failure to obtain product approval, product seizure or recall, or withdrawal of product approval. Our CMOs and component suppliers may experience delays in producing and supplying, or may become unable or unwilling to produce and supply, our clinical trial material or commercial supply material due to financial or personnel constraints, their obligations to, or their decision to prioritize the production and supply of products for, other customers, partial or full loss of their facilities, or supply chain disruptions, including as a result of geopolitical conflicts, macroeconomic events or conditions, natural or **manmade** ~~man- made~~ disasters, or public health emergencies such as the COVID- 19 pandemic. For example, our single source CMO for Ovaprene is located in an area of the U. S. that is vulnerable to tropical storms, hurricanes, flooding and tornadoes, which have potential to render its facilities inoperative for protracted periods. One or more of our CMOs may fail or be unable to perform at a time that is costly or inconvenient for us. We may not have adequate or any recourse against a CMO or supplier who does not perform or terminates its agreement with us if such non- performance or termination is excused under the applicable agreement. We do not have long- term supply agreements with any of our CMOs **or raw materials suppliers** . We generally enter into manufacturing agreements on a project- by- project basis based on our development needs, which may heighten the risk of timely availability of sufficient quantities of our product candidates at acceptable costs for clinical trials. **For example, we do not have any long- term manufacturing or supply agreements with the CMO from which we plan to obtain clinical supplies for our first Phase 3 clinical study of Sildenafil Cream or with the current supplier of the API for Sildenafil Cream. Future supplies of Sildenafil Cream or the raw materials required to produce it may be more difficult and costly to obtain because we do not have long- term supply contracts, which could make us more vulnerable to significant price increases.** As we advance development of our product candidates, we will need to negotiate agreements for commercial supply and we may not be able to reach agreement on a timely basis or acceptable terms, or at all. In addition, the FDA or regulatory authorities outside of the U. S. may require that we have an alternate manufacturer of a product before

approving it for marketing and sale in the U. S. or other jurisdiction, and securing such alternate manufacturer before approval of a marketing application could result in considerable additional time and cost prior to product approval. Currently, we do not have alternative CMOs or API suppliers to back up our primary vendors of clinical trial material. Identification of and discussions with other vendors may be protracted and / or unsuccessful, or new vendors may not be successful in producing the same results as our current vendors on a timely basis at the appropriate volumes, at an acceptable cost, or at all. Therefore, if the current vendors become unable or unwilling to perform their required activities, we could experience protracted delays or interruptions in the supply of clinical trial material or any future approved product for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results, and financial condition. Any new CMO or API supplier would be required to qualify under applicable regulatory requirements. In some cases, the technical skills or technology required to manufacture our clinical trial material or commercial material may be unique or proprietary to the original CMO or supplier and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such CMOs and suppliers or require us to obtain a license from them in order to have another third party manufacture our product candidates or any future approved product. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. In some cases, the FDA or a foreign regulatory authority may require us to conduct additional clinical or nonclinical studies, collect additional stability data, and provide additional information concerning any new CMO or supplier, or change in a validated manufacturing process, including scaling- up production, before we could distribute products from that manufacturer or supplier or revised process. The process of identifying, verifying and transitioning to a new CMO or supplier could significantly delay development or regulatory approval of our product candidates or delay or disrupt commercialization of any approved product and substantially increase costs or result in significant loss of product sales and associated revenue. If our CMOs encounter difficulties or otherwise fail to comply with their contractual obligations or there are delays entering commercial supply agreements, we may have insufficient quantities of material to support ongoing or planned clinical trials or to meet commercial demand for any approved product in the future. In addition, any delay or interruption in the supply of materials necessary or useful to manufacture our product candidates could delay the completion of our clinical trials, increase the costs associated with our development programs, and depending upon the period of delay, require us to terminate the clinical trials completely and commence new clinical trials at significant additional expense. Delays or interruptions in the supply of commercial product could result in increased cost of goods sold and lost sales. Manufacturing or quality control problems may arise in connection with the manufacture of our clinical trial material or future approved product and CMOs may not be able to maintain the necessary governmental licenses and approvals to continue their manufacturing services for us. In addition, with respect to any finished product or key components manufactured outside the U. S., such as the API for Sildenafil Cream, **which is sourced from a supplier located in India,** we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Furthermore, **future** ~~changes in~~ currency fluctuations, **increased** shipping costs, or ~~import~~ **new or increased U. S.** tariffs **and trade disputes with other countries could increase our clinical development costs, and ultimately, our cost of goods sold, which** could adversely ~~affect cost of goods sold~~ **impact our operating results and financial condition** . Any of the above factors could cause us to delay or suspend anticipated or ongoing clinical trials, regulatory submissions or commercialization of a product candidate, entail higher costs, or result in being unable to effectively commercialize an approved product. Our dependence on third parties for the manufacture of our product candidates or future approved products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Similarly, while Organon **assumed manufacturing responsibility for** ~~now holds the FDA marketing approval and we have transferred~~ XACIATO ~~manufacturing responsibilities to Organon~~ **from us in December 2023** , commercial production and supply of XACIATO remains subject to comparable manufacturing risks as described herein, and any interruption in the commercial supply of XACIATO that directly or indirectly results in significant loss of product sales could have a material adverse effect on ~~the~~ **future** payments we **may** receive under ~~our license~~ **the traditional royalty purchase** agreement **we entered into with XOMA** . In some cases, we may be contractually required to obtain clinical or commercial product supplies from specific third parties or there may be a limited number of third-party suppliers of raw materials and other components of our product candidates or future products, which may heighten our dependence on those third parties ~~and~~ **, increase** the risk of manufacturing disruptions **, and result in higher development costs or costs of goods sold** . Our agreement with ADVA- Tec restricts our ability to engage a manufacturing source for Ovaprene other than ADVA- Tec during Ovaprene' s development period as well as following regulatory approval, subject to limited exceptions. If ADVA- Tec fails to provide sufficient clinical supply of Ovaprene on anticipated timelines, our ability to complete clinical development and seek regulatory approval of Ovaprene could be significantly delayed. A substantial scale up in production of Ovaprene clinical supplies was necessary to support the ongoing Phase 3 clinical study of Ovaprene, which took longer and was more expensive than anticipated, and if Ovaprene receives marketing approval, further substantial manufacturing scale up will be necessary. If Ovaprene receives marketing approval, failure by ADVA- Tec to provide sufficient commercial product quantities at reasonable costs could have a significant adverse effect on our revenue and ability to become profitable. Furthermore, for some key raw materials and components of Ovaprene, there currently is only a single source of supply, and alternate sources of supply may not be readily available. ~~Under the terms of the SST license agreement, SST was responsible for obtaining supplies of Sildenafil Cream for Phase 2 clinical trials conducted in the U. S., and we are responsible for providing supplies of Sildenafil Cream for Phase 3 clinical development and, if approved, for marketing and sale. We do not have any long- term manufacturing or supply agreements with the CMO from which we plan to obtain Sildenafil Cream for our first Phase 3 clinical study of Sildenafil Cream or with any supplier of the raw materials required to produce Sildenafil Cream. Future supplies of Sildenafil Cream or the raw materials required to produce Sildenafil Cream may be more difficult and costly~~

~~to obtain. For example, the current supplier of sildenafil is located in India. Should this supplier slow production, shut down its factory or increase its prices for any reason, including due to factors outside of its control such as a public health emergency or geopolitical conflicts or events, we may not be able to obtain adequate supplies of sildenafil to satisfy our clinical supply requirements.~~ We rely on, and intend to continue to rely on, third parties ~~for the~~ **to conduct our clinical and nonclinical studies and** ~~execution~~ **execute** ~~of~~ **other** significant aspects of our product development programs. Failure of these third parties to successfully carry out their contractual duties, comply with **our clinical protocols or** regulatory requirements and applicable law, or meet expected deadlines may cause significant delays in our development timelines and / or failure of our programs. Our business model relies on the outsourcing of important product development functions, tests and services to **third parties. We rely on** CROs, medical institutions ~~and other specialist providers~~ **, clinical investigators, laboratories** , vendors and consultants **to conduct all of our clinical trials and perform nonclinical testing. These third parties play a significant role in the conduct and timing of our clinical and nonclinical studies and the collection, management and analysis of study data, which are critical to our business. In addition, we have relied, and expect in the future to rely, on third parties to assist us in preparing, submitting and supporting the applications necessary to gain marketing approvals for our product candidates** . We ~~rely~~ **enter into agreements with these third parties governing their work for us, but we do not control them and have limited influence over their actual performance. They may not devote sufficient time and resources to our projects, or their performance may be substandard, resulting in clinical trial delays, suspensions or terminations, delays in submission of our marketing applications, failure of a regulatory authority to accept our applications for filing or receipt of a CRL. The performance of these third parties may also be negatively impacted by macroeconomic factors, geopolitical conflicts or events, natural or manmade disasters, public health emergencies, information system and cybersecurity incidents, and workforce challenges. In addition, these third parties may have relationships with companies developing competitive products and prioritize a competitor' s clinical or nonclinical studies or regulatory affairs activities over their work for us, which could harm our competitive position. Because of our dependence** on these third parties ~~to conduct our clinical trials and perform related activities~~ , ~~including quality assurance, clinical monitoring and clinical data management, as well as to assist us in preparing, submitting and supporting the applications necessary to gain marketing approvals for our product candidates. For example, we engaged CROs to run all aspects of the pivotal Phase 3 clinical trial of XACIATO, the exploratory Phase 2b RESPOND clinical trial of Sildenafil Cream, the PCT clinical trial for Ovaprene, and our respective Phase 1 / 2 clinical studies of DARE- HRT1 and DARE- VVA1. In addition, our ongoing pivotal Phase 3 clinical trial of Ovaprene is being conducted by third parties under our CRADA with NICHD. We similarly expect to rely on CROs and other third parties to perform all clinical and nonclinical testing and many other important development and regulatory affairs activities needed to support applications for regulatory approvals of all product candidates we develop. We do not control these third parties and they may not devote sufficient time and resources to our projects, or their performance may be substandard, resulting in clinical trial delays or suspensions, delays in submission of our marketing applications or failure of a regulatory authority to accept our applications for filing. There is no assurance that the third parties we or our strategic collaborators engage will be able to provide the functions, tests, activities or services as agreed upon, or provide them at the agreed upon price and timeline or to our requisite quality standards, including due to macroeconomic factors, geopolitical conflicts or events, natural or manmade disasters, public health emergencies or pandemics or poor workforce relations or human capital management. We rely on the efforts of these third parties and~~ if they fail to **meet expected deadlines, adhere to our study protocols, meet regulatory and legal requirements, or otherwise** perform ~~as expected~~ **in a substandard manner** , we could suffer significant delays and additional costs in, and potentially failure of, the development of one or more of our product candidates. ~~There is also no assurance~~ **Our CROs, study sites and other consultants generally have the right to terminate their agreements with us without cause upon the completion of a specified notice period, subject to limited restrictions. If any of our relationships with** these third parties **terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner, or at all. Switching or adding additional CROs, study sites, and other third party service providers due to substandard or inadequate performance or termination of a relationship involves additional cost and requires our management' s time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our communicated clinical development timelines. Though we work to carefully manage our relationships with our CROs, study sites, and other third parties, we have encountered challenges and delays in our clinical and nonclinical studies as a result of performance issues in the past, and there can be no assurance that we** will not **encounter challenges** ~~make errors in the design, management or retention of our~~ **or** ~~data or data systems. Any failures by such third parties could lead to a loss of data, which in turn could lead to~~ delays in **the future or that these delays or challenges will** ~~clinical development and obtaining regulatory approval. Third parties may~~ not ~~pass FDA or other regulatory audits, which could delay or prohibit regulatory approval. In addition, the cost of such services could significantly increase over time. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, regulatory approval of current and future product candidates may be delayed, prevented or cost significantly more than expected, all of which could~~ have a material adverse ~~effect~~ **impact** on our business, financial condition, ~~results of operations~~ and prospects ~~. In particular, as a result of the CRADA, we are highly dependent on NICHD and the third parties it engages for the conduct and completion of our ongoing pivotal Phase 3 clinical trial of Ovaprene. Pursuant to the terms of the CRADA, the study is being conducted within NICHD' s Contraceptive Clinical Trial Network, or the CCTN, with NICHD' s selected CRO providing clinical coordination and data collection and management services for the study. NICHD is responsible for selecting participating clinical sites from the pool of CCTN sites and, together with its selected CRO, overseeing the clinical investigators in the conduct of the study, providing clinical site monitoring and quality assurance along with establishing the electronic data capture database for the study and performing data analysis, which are key factors to the successful completion of a clinical trial. We do not control these third~~

~~parties and, accordingly, our control over the conduct and completion of the study is limited. If NICHD or the third parties it engages for the study prioritize other projects over the study or otherwise do not devote adequate time and resources to the study, or their performance is substandard, completion of the study may be delayed or suspended or the study may be unsuccessful, which could significantly harm our business, operating results and financial condition, as well as our relationship with Bayer, and cause the price of our common stock to decline~~ . Our ability to develop and commercialize our product candidates depends upon maintaining rights granted to us under license agreements with third parties. The loss or impairment of our rights under our in- license agreements relating to XACIATO or our product candidates could have a material adverse effect on our business prospects, operations and viability. We have rights to develop and commercialize XACIATO and our product candidates under license agreements between us and third- party licensors. The loss or impairment of these rights, including as a result of our inability or other failure (or that of our licensors, in the case of sublicenses) to meet our obligations under any one of such license agreements, including, without limitation, our payment obligations, could have a substantial negative effect on our business and prospects. In December 2018, we entered into definitive agreements with Hammock Pharmaceuticals, Inc., TriLogic Pharma LLC and MilanaPharm LLC under which we acquired exclusive global rights to XACIATO for the treatment of bacterial vaginosis, as well as the rights to utilize the underlying proprietary hydrogel drug delivery technology for any vaginal or urological application in humans. Under the license agreement with TriLogic Pharma and MilanaPharm, we must use commercially reasonable efforts and resources consistent with those we undertake in pursuing development and commercialization of other pharmaceutical products, taking into account program- specific factors, (a) to develop and commercialize at least one licensed product or process in the United States and at least one licensed product or process in at least one of Canada, the United Kingdom, France, Germany, Italy or Spain, and (b) following the first commercial sale of a licensed product or process in any jurisdiction, to continue to commercialize that product or process in that jurisdiction. In addition to customary termination rights, MilanaPharm may terminate our license with respect to a licensed product or process in a country if, after having launched such product or process in such country, we, or our affiliates or sublicensees, as applicable, discontinue the sale of, or commercially reasonable marketing efforts to sell, such product or process in such country, and fail to resume such efforts or to reasonably demonstrate a strategic justification for the discontinuation and failure. See ITEM 1." BUSINESS- Strategic Agreements for Pipeline Development- Hammock / MilanaPharm Assignment and License Agreement, " above. We entered into a license agreement with ADVA- Tec for the exclusive worldwide rights to develop and commercialize Ovaprene that became effective in July 2017. In addition to standard termination rights, ADVA- Tec may terminate the license agreement if we (1) fail to make significant scheduled investments in product development activities over the course of the agreement, (2) fail to commercialize Ovaprene within six months of obtaining a pre- market approval from the FDA, (3) with respect to the license in any particular country, fail to commercialize Ovaprene in that particular country within three years of the first commercial sale, (4) develop or commercialize a non- hormonal ring- based vaginal contraceptive device other than Ovaprene, (5) fail to conduct certain clinical trials, or (6) fail to make certain milestone, sublicense and / or royalty payments to ADVA-Tec. See ITEM 1." BUSINESS- Strategic Agreements for Pipeline Development- ADVA- Tec License Agreement," above. In February 2018, we entered into a world- wide license and collaboration agreement with SST for the exclusive worldwide rights to develop and commercialize Sildenafil Cream for all indications for women related to female sexual dysfunction and / or female reproductive health, including treatment of FSAD. The SST license agreement provides that each party will have customary rights to terminate the agreement in the event of material uncured breach by the other party and under certain other circumstances. The SST license agreement provides SST with the right to terminate it with respect to the applicable SST licensed products in specified countries upon 30 days' notice if we fail to use commercially reasonable efforts to perform development activities in substantial accordance with the development plan contained in the SST license agreement, or any updated development plan approved by the joint development committee, and do not cure such failure within 60 days of receipt of SST' s notice thereof. See ITEM 1." BUSINESS- Strategic Agreements for Pipeline Development- SST License and Collaboration Agreement, " above. In April 2018, we entered into the Catalent license agreement under which we acquired exclusive global rights to Catalent' s IVR technology platform, including the product candidates we now call DARE- HRT1, DARE- FRT1, and DARE- PTB1. Under this agreement, we must use commercially reasonable efforts to develop and make at least one product or process available to the public, which efforts include achieving specific diligence requirements by ~~specific~~ dates specified in the agreement, and Catalent may terminate the agreement upon 60 days' notice for any uncured material breach by us of any of our other obligations under the agreement. See ITEM 1." BUSINESS- Strategic Agreements for Pipeline Development- Catalent JNP License Agreement **, " above. In May 2018, we completed our acquisition of Pear Tree and obtained exclusive global rights to certain patents and know- how to develop and commercialize a proprietary formulation of tamoxifen for vaginal administration, which led to our DARE- VVA1 program. Under the applicable license agreements, as amended, we are required to use commercially reasonable efforts or reasonable best efforts to bring licensed products and processes to market, which include achieving specified milestones. The licensors may terminate the agreements for failure to make certain payments due to the licensors and any uncured material breach or default, including breach of our diligence obligations. See ITEM 1." BUSINESS- Strategic Agreements for Pipeline Development — Pear Tree Acquisition and License Agreements, " above. In August 2023, we entered into a license agreement with Douglas for exclusive rights to develop and commercialize a lopinavir and ritonavir combination soft gel vaginal insert for the treatment of CIN and other HPV- related pathologies, and commenced our DARE- HPV program. Under this agreement, we must use commercially reasonable efforts to develop and introduce to market at least one product or process, which efforts include achieving specific diligence requirements by dates specified in the agreement. Douglas may terminate the agreement for any uncured failure to make certain payments, any uncured material failure to fulfill our diligence obligations, or any other uncured material breach of our other obligations under the agreement. See ITEM 1." BUSINESS- Strategic Agreements for Pipeline Development — Douglas License Agreement / The**

University of Manchester Stand- by Direct License Arrangement , " above. If we do not meet our obligations under our license agreements in a timely manner, some of which require the expenditure or payment to the licensor of significant amounts of cash, or if we are unable to obtain an extension of deadlines for satisfying our obligations, we could lose our rights under these agreements. Moreover, because some of our rights to XACIATO and our product candidates are sublicensed to us, our license agreements may be terminated or we may otherwise lose rights to intellectual property underlying our product or product candidates in the event of termination or loss of rights by our licensors, which may be outside of our control. There is no assurance that we would be able to renew or renegotiate license agreements on acceptable terms, or at all, if our existing license agreements (or the underlying agreements in the case of sublicenses) are terminated. Furthermore, we cannot guarantee that any license agreement will be enforceable. The termination of these license agreements or our inability to enforce our rights under these license agreements could result in the loss of our ability, or that of our sublicensees, to develop, manufacture, market or sell XACIATO or the product candidate covered by the agreement, as well as our ability to grant rights to other third parties to collaborate with us in the development and commercialization of our product candidates **and our ability to receive milestone and royalty payments from third- party sublicensees** , which could have a material adverse effect on our business **, financial condition, results of operations and** prospects ~~and operations~~ . Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our technology and processes infringe, misappropriate or violate the intellectual property of the licensor that is not subject to the license agreement; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations **; • the timing and amount of milestone or royalty payments due to the licensor** ; • the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and • the priority of invention of patented technology. In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize, or maintain third- party collaborations to commercialize, the affected product or product candidate. We may seek to license the product and technology rights to additional product candidates in accordance with our business strategy, but there can be no assurance we will be able to do so on favorable terms or at all. There are risks, uncertainties and costs associated with identifying, licensing and advancing product candidates through successful clinical development. Even if we obtained the rights to additional product candidates, there can be no assurance those candidates would ever be advanced successfully through clinical development. Risks Related to Commercialization of ~~XACIATO and Our Product~~ **Products We Develop** ~~Candidates The commercial success of XACIATO is outside of our control and will depend on Organon' s efforts and capabilities, as well as a variety of factors, many of which currently are unknown or uncertain, and if commercialization of XACIATO is not successful, our business and prospects may suffer. If commercialization of XACIATO is not successful, or is perceived to be unsuccessful, our business, financial condition, results of operations and prospects may suffer, particularly because XACIATO is the first and only product for which we have received regulatory approval. XACIATO' s commercial success will depend on many factors, including: • the capabilities of Organon and its commitment of sufficient resources to market, distribute and sell the product; • timely and adequate commercial supply of the finished product and its components; • perceived superiority of its cure rates compared to other available treatments; • the extent to which the approved product labeling contains features or expected benefits that differentiate it from other available treatments; • preferences by health care providers and women for a vaginally administered therapy; • the prevalence and severity of any adverse side effects; • patient satisfaction and willingness to use it again and refer it to others; • price pressure given the high level of generic treatments and changes in health care laws and regulations, including the Inflation Reduction Act of 2022; • adequate coverage, pricing and reimbursement from third- party payors; • the willingness of patients, without third- party insurance coverage or adequate reimbursement, to pay for the product; • the success or failure of other branded therapies; • market exclusivity provided by our intellectual property rights or conferred by regulatory authorities; and • approval of new entrants, including alternative, non- antibiotic treatment options. There is no assurance that Organon' s efforts with respect to XACIATO will be successful or that product sales will be able to generate revenue to us at the levels or within the timing we expect or at the levels or within the timing necessary to support our goals. See also the risks and uncertainties described under " Risks Related to Our Dependence on Third Parties, " above.** We have no internal sales, marketing or distribution capabilities **, and we may need to invest significant resources to establish those capabilities** . If we are unable to **timely** establish those capabilities on our own or through **arrangements with** third parties, **product launch may be delayed, commercialization may be adversely impacted, and** we ~~will~~ **may not** be ~~unable~~ **able** to ~~successfully commercialize our product candidates, if approved, or~~ generate product sales revenue. We **currently** do not have ~~a~~ **, and have never had,** product marketing, sales or distribution infrastructure. In order to commercialize any of our product candidates **,** if approved for commercial sale, we must either establish a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third- parties that have sales and marketing experience. As we move our product candidates through development toward, and in some cases, through regulatory approval, we evaluate several options for each product candidate' s commercialization strategy. These options include building our own sales force and other commercial infrastructure, **or collaborating** ~~entering into strategic marketing partnerships~~ with third parties **that have established sales forces and distribution systems** , ~~including~~ **either to augment our own sales force and** commercial

infrastructure or in lieu of establishing our own sales **force** ~~organizations or other pharmaceutical or biotechnology companies, out- licensing the product to other pharmaceutical or biotechnology companies,~~ and **commercial infrastructure** ~~combinations of these strategies~~. We currently have no commercialization agreements with third parties other than our license agreements with Organon for XACIATO and Bayer for Ovaprene. We may not be able to maintain our existing commercial collaborations or establish and maintain other commercial collaborations on favorable terms, on a timely basis, or at all. **In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties to commercialize products we develop than if we were to do it ourselves.** To generate revenue from our product candidates, if approved **for commercial sale**, we may need to establish ~~a~~ **our own sales forces and** commercial infrastructure. There are significant **challenges and** risks involved with ~~establishing our own~~ **building and managing a sales organization and other** commercial infrastructure ~~. For example~~, **even if we collaborate with third parties that have established sales forces and distribution systems to augment our own capabilities, including: • difficulties in** recruiting **and retaining adequate numbers of qualified individuals; • providing adequate training for sales and marketing and support personnel; • effectively managing a geographically dispersed sales force; • difficulties generating sales leads; • potential lack of complementary products our sales personnel may be able to offer compared with sales personnel for competitive products; and • unforeseen costs and expenses associated with establishing a new corporate function and the rapid growth of our company. Recruiting, incentivizing** and training a sales force is expensive and **requires substantial management** time ~~- consuming~~ and **focus** ~~could delay product launch~~. If we recruit and train a sales force and the commercial launch of the product is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred significant ~~commercialization~~ expenses ~~. This may be costly~~, and our investment would be lost if we could not retain or reposition our sales and marketing personnel. **On the other hand, if we do not timely establish a sales force and other commercial infrastructure, a product launch may be significantly delayed, adversely impacting the potential commercial success of the product, as well as our operating results and financial condition.** Both the launch and ongoing commercial support of our products would require significant capital, which may not be available to us when needed or on acceptable terms or at all. All of these factors could strain our cash resources and require us to raise additional capital. **Failure** ~~In addition, there is no guarantee that our~~ **or delay in** ~~efforts to generate product revenue would be successful. Factors that may hinder efforts to commercialize our products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our products; • the lack of complementary products our sales personnel could offer, which may put us at a competitive disadvantage compared to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. The risks described above may also apply if our commercial collaborations do not involve an exclusive license of substantially all commercialization rights to a third party and we instead enter~~ **entering** into **and maintaining** ~~co- promotion~~ arrangements with ~~a~~ third **parties** ~~party. Failure~~ to ~~timely enter into~~ **market and sell, or assist us in marketing and selling,** ~~or~~ **our product candidates, if approved** ~~maintain a commercialization arrangement with a third party or~~ **for commercial sale, or in** ~~establish~~ **establishing** ~~our own commercialization~~ capabilities **to independently commercialize our product candidates** could significantly delay commercial launch **and negatively impact** ~~of our products or require us to reduce the~~ **their potential commercial success** ~~scope of any sales and marketing activities~~, which could have a material adverse effect on our business, financial condition and results of operations. Our product candidates, if approved **for commercial sale**, ~~and XACIATO~~ will face intense competition and our business and operating results will suffer if we, or our commercial collaborators, fail to compete effectively. The ~~biopharmaceutical~~ --- **pharmaceutical** industry is intensely competitive and characterized by rapid technological developments. ~~Our~~ **Moreover, the women' s health sector is very fragmented and highly competitive. We anticipate that our product candidates may compete not only with FDA-approved, prescription and over- the- counter, branded and generic drug products, but also compounded drugs, medical devices, dietary supplements, and cosmetics. We face and will continue to face intense** ~~competitors~~ **competition** ~~and potential competitors~~ **from a variety of businesses,** ~~include~~ **including** large **, fully integrated**, well- established pharmaceutical ~~and biotechnology~~ companies ~~, many of which have~~ **and specialty pharmaceutical companies that already possess** robust product portfolios and strong franchises in women' s health **in areas in which we plan to compete, as well as generics manufacturers, compounding pharmacies and other drug compounding facilities, and dietary supplements manufacturers. In addition, academic and other research institutions are and could be engaged in research and development efforts for products in the therapeutic areas targeted by our product candidates**. Many of our competitors or potential competitors, either alone or with strategic collaborators, have: • much greater financial, research, technical and human resources than we have at every stage of the product development and commercialization life cycle; • more extensive experience in designing and conducting clinical trials, nonclinical studies, obtaining regulatory approvals, and in manufacturing, marketing and selling prescription medical products; and • approved products or product candidates in late stages of development for one or more of our target indications. Competitive products may be equally safe and as effective as our products, but sold at a substantially lower price. Alternatively, competitive products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than our products. ~~Our~~ **Many of our** product candidates, if approved **for commercial sale**, will compete with products that have already been accepted by the medical community and patients. If our product candidates fail to generate compelling clinical results or if patients and health care providers fail to adopt our products for their respective indications, their commercial potential could be adversely impacted or severely diminished. It is possible that the potential advantages of our product candidates do not materialize or that the approved prescribing information for our products does not describe expected features or benefits. We also expect to face competition from new products that enter the market over time. We are aware of products currently under development intended for the same indications as our product candidates. These competitive product candidates may prove safer, more tolerable, more

effective, and less expensive, and may be introduced to market earlier, or produced, marketed and sold more effectively or on a more cost- effective basis, than our product candidates. The success of competitive products may render our product candidates noncompetitive or obsolete, even prior to completion of their development. With respect to XACIATO, there are ~~many FDA-~~ **multiple generic and branded prescription drug products currently** approved ~~products~~ **in the U. S.** for ~~treating~~ **the treatment of** bacterial vaginosis, **including** ~~and many are generic. XACIATO will compete with those products. Current therapies for the treatment of bacterial vaginosis primarily consist of~~ oral and vaginal **gel** formulations of **metronidazole and vaginal cream formulations of clindamycin** ~~antibiotics delivered as a single dose or through multiple doses over consecutive days~~. If health care providers do not view the prescribing information for XACIATO as compelling compared with other products available for the treatment of bacterial vaginosis, or if competitive products have better insurance coverage or reimbursement levels than XACIATO, health care providers may opt to ~~continue to~~ prescribe ~~existing treatments~~ **a competitive product** rather than recommend or prescribe XACIATO to their patients. In addition, women may prefer orally delivered options to vaginally administered XACIATO unless they view XACIATO as providing significantly superior efficacy, safety and / or convenience. **If** ~~Failure of~~ our commercial collaborator **fails** to generate significant net sales of XACIATO **which exceed** ~~would negatively effect~~ the ~~payments~~ **Revenue Sharing Threshold,** we ~~receive under our license agreement~~ **will not have any future revenue stream relating to XACIATO** . The women' s health market includes many generic **FDA- approved drug** products **, compounded drugs, as well as dietary supplements and consumer health products,** and growth in ~~generics~~ **these categories** is expected to continue, which could make the successful introduction of our ~~branded~~ products difficult and expensive. The proportion of the U. S. **drug** market made up of generic products has been increasing. ~~If this trend continues~~ **In addition, compounded drugs and dietary supplements in women' s health are multi- billion dollar markets. As a result, even if our product candidates are approved** , it may be more difficult for us or a commercial collaborator to introduce a new **product, particularly a** branded ~~medical~~ **prescription** product ~~, if approved~~ , at a price that will allow us to achieve acceptable levels of revenue and net income from product sales. Generic competition is particularly strong in contraception and hormone therapy, which are areas in which ~~our~~ **we seek to compete. Our** product candidates **for menopause symptoms** ~~, if approved,~~ will **additionally have to** compete **with compounded hormones supplied by compounding pharmacies and other drug compounding facilities, as well as dietary supplements marketed for relief of menopause symptoms. Compounded sildenafil cream medications are also currently being supplied by compounding pharmacies and other drug compounding facilities** . In order for our branded products to develop commercial markets and for third- party payors to cover these higher cost products, our products must demonstrate better patient compliance and clinical benefit **as** ~~in their clinical trials~~ compared to **what** other available products **have demonstrated** . Additional marketing and educational efforts may be required to introduce a new branded prescription medical product in order to overcome **use of** ~~the trend towards generics~~ **generic products, compounded drugs and dietary supplements** and gain access to reimbursement by payors. If we or a commercial collaborator cannot introduce a product at the desired price or gain reimbursement from payors for the product, or if patients opt for a lower cost generic product **, compounded drug, or dietary supplement** rather than pay out- of- pocket or a higher co- pay for our product, our **sales** revenues or royalties and other license fees, as applicable, will be limited ~~. XACIATO~~ and ~~any of our future approved~~ **we may never become profitable. Our** ~~products~~ **product candidates** may fail to achieve the degree of market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success, which would negatively impact our business. ~~XACIATO and~~ **The commercial success of** any ~~future products~~ **product** ~~may fail~~ **we develop and bring** to ~~gain sufficient~~ market **, or is marketed by a licensee, will depend significantly on the broad** acceptance **of the product** by physicians, patients **, and others in the medical community, as well as, in many cases** , third- party payors ~~and others in the medical community~~ . **The degree** ~~If XACIATO and any future products do not achieve an adequate level~~ of market acceptance **of** ~~, they may not generate significant net product revenue or~~ **our** ~~net sales or result in significant payments to us from our commercial collaborators, we may suffer reputational harm and we may never become profitable. The degree of market acceptance of XACIATO and any future~~ products will depend on several factors, including: • the **indication for** ~~timing of our receipt of any marketing approvals and the jurisdictions in~~ which ~~marketing approvals are obtained~~ **the product is approved** ; • the **timing of market introduction of the product and availability of alternative treatments and products for the same indication; • the demonstrated clinical efficacy and safety of the product, including as compared to alternative products; • the** terms of ~~any~~ **regulatory** ~~approvals~~ **approval** , such as any restrictions on the use of ~~our~~ **the** product together with other medications **, ;** ~~• the indications for~~ **or** ~~which~~ **required warnings in** the ~~product is approved; • demonstrated evidence of efficacy and safety; • the approval and availability of alternative treatments and products~~ **product labeling** ~~for the same indications as our product~~ ; • the prevalence and severity of any adverse side effects associated with ~~our~~ **the product, including as compared to alternative treatments and** ~~product~~ **products** ; • **the** convenience and ease of administration for patients **, including as** compared to alternative treatments and products ~~, or other potential advantages and disadvantages compared to the alternatives~~ ; • ~~adverse~~ **the willingness of the target patient population and prescribing physicians to try a new product; • the effectiveness of the sales and marketing strategy and efforts for the product, including the success of efforts to educate the medical community and third- party payors regarding the benefits of the product; • the pricing and cost- effectiveness of the product, including as compared to alternative treatments and products; • the availability and extent of third- party coverage and reimbursement for the product; • the willingness of patients to pay all, or a portion of, the out- of- pocket cost for the product in the absence or insufficiency of third- party payor coverage and reimbursement; • unfavorable** publicity ~~about~~ **relating to the product** ~~our~~ - **or** ~~product~~ **products with the same or similar APIs,** or favorable publicity about competing **therapies or** products; **and** • ~~our ability to offer our product for sale at competitive prices; •~~ the **existence** ~~willingness of the target patient population to try a new product and of physicians to prescribe a new product; • the success of any physician education programs for our product; • the availability~~ and extent of **pending** ~~third- party coverage and reimbursement for~~ - **or** ~~our~~ **potential** product **liability claims** ~~and~~

~~amount of out- of- pocket cost to patients; • the willingness of uninsured patients to pay for the product; • the willingness of pharmacy chains to stock the product; and • effectiveness of our or our collaborators' sales and marketing strategy and efforts~~ . If XACIATO or any future product does not achieve an adequate level of market acceptance, ~~it~~ **the product may not generate significant revenue or may generate substantially less revenue than anticipated, which** could have a material and adverse effect on our business, financial condition, results of operation and prospects. **We may suffer reputational harm and we may never become profitable.** The commercial success of ~~Ovaprene, if approved,~~ **XACIATO is outside of our control and** will depend on **Organon' s efforts and capabilities, as well as a variety of factors, many of which currently are unknown or uncertain, and if commercialization of XACIATO is not successful, our business and prospects may suffer. If commercialization of XACIATO is not successful, or is perceived to be unsuccessful, our business, financial condition, results of operations and prospects may suffer, particularly because XACIATO is the first and only product for which we have received regulatory approval. XACIATO' s commercial success will depend on many factors, including those discussed elsewhere in these " Risks Related to Commercialization of Products We Develop " and " Risks Related to Our Intellectual Property " below, as well as the capabilities of Organon and its commitment of sufficient resources to market, distribute and sell the product, preferences by health care providers and women for a vaginally administered therapy, and regulatory approval and market introduction of alternative therapies, including non- antibiotic treatment options. We have limited control over Organon' s efforts with respect to XACIATO and there is no assurance they will be successful or that the Revenue Sharing Threshold will be reached. As discussed elsewhere in this Risk Factors section, we will not receive any payments based on product sales until after the Revenue Sharing Threshold is reached. We may suffer reputational harm if XACIATO is not commercially successful and our ability to raise additional capital or enter into other commercial collaborations could be impaired. See also the risks and uncertainties described under " Risks Related to Our Dependence on Third Parties, " above. The commercial success of Ovaprene, if approved for commercial sale, will depend on the degree of** market acceptance of a hormone- free, monthly intravaginal product, ~~availability~~ **clinical efficacy** and ~~effectiveness~~ **safety** of **the product, including as compared to** alternative contraceptive **methods, pricing of the** ~~products~~ **product,** and ~~women' s preferences~~ **the availability and extent of third- party coverage and reimbursement for the product** , as well as ~~the~~ **other** ~~success of~~ **factors including** Bayer' s marketing and sales efforts. Today, there ~~are~~ **is** a ~~variety~~ **wide range** of ~~hormonal~~ **prescription** and ~~non~~ **over** - ~~hormonal~~ **the- counter** contraceptive options ~~available to women~~ , including ~~oral contraceptive~~ **hormone- free options such as condoms, diaphragms, cervical caps, sponges, copper IUDs, spermicides and vaginal gels, as well as hormonal products such as** pills ~~and intrauterine devices~~ , **patches** ~~newer hormonal contraceptive products including implants, injectables~~ , vaginal rings, ~~patches~~ **IUDs** , **implantable rods** and ~~hormonal intrauterine systems~~ **injectables. In addition** , **multiple** ~~and non- hormonal methods such as female condoms, novel diaphragms, and~~ new methods of ~~female sterilization~~ **pregnancy prevention are in development, including hormone- free options, and some may be marketed in the U. S. before Ovaprene, potentially adding to the level of market competition Ovaprene will face, if approved** . In surveys, women have said that the features they consider most important when selecting a contraceptive method are efficacy, ease- of- use and side effects. To have significant revenue potential as a new contraceptive product option, Ovaprene may need to **demonstrate** ~~have a~~ typical use efficacy ~~outcome~~ (**or** ~~which is~~ the expected rate of pregnancy protection once the product is used widely under everyday circumstances) ~~comparable to~~ **that approaches the approximately 93 % typical use efficacy at 12 months of** current **FDA- approved** non- implanted **, non- injected** hormonal contraceptive methods (pills, patches and vaginal rings) ~~, which is approximately 86 %- 91 % typical use efficacy~~ . Clinical testing will also need to demonstrate that the product can be safely worn for multiple weeks. If ~~we~~ **Ovaprene** ~~receive~~ **receives** regulatory approval ~~to market Ovaprene~~ , its commercial success, or the success of any other future contraceptive product ~~candidate~~ we ~~may seek to~~ develop, including our current **early clinical- stage and** pre- clinical stage candidates, will depend upon the contraceptive market and market acceptance of an alternative method. ~~Risks related~~ **Factors expected** to **impact broad** market acceptance **of a new contraceptive product** include **those discussed above under" Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success, which would negatively impact our business," as well as** : • **demonstration of** minimum acceptable contraceptive efficacy rates; • perceived safety differences of hormonal and / or non- hormonal contraceptive options; • competition from new lower dose hormonal contraceptives with more favorable side effect profiles **compared with higher dose hormonal contraceptives** ; • ~~new~~ **preference for a monthly format product over contraceptive products to be taken daily or used in the moment; • preference for an intravaginal product over other formats such as pills, patches, injectables and condoms; •** generic contraceptive options **,** including ~~a~~ generic ~~version~~ **versions** of the hormone- containing intravaginal product NuvaRing ®; **and** • the effects of changes in health care laws and regulations on third- party payor coverage (including the birth control coverage mandate) and reimbursement and out- of- pocket costs to patients ~~; and • the availability and extent of third- party coverage and reimbursement for our product, the amount of out- of- pocket cost to patients and the effects of any changes in health care laws and regulations, including the birth control mandate, on product pricing and coverage and out- of- pocket costs to patients~~ . If one or more of these risks occur, it could reduce the market potential for Ovaprene, or any ~~future~~ **other** contraceptive product we ~~may seek to~~ develop, and place pressure on our business, financial condition, results of operations and prospects. Under our license agreement with Bayer, provided the license grant becomes effective, Bayer will have exclusive rights to market and sell Ovaprene in the U. S. Accordingly, the potential value of Ovaprene to our company ~~is~~ **may be** highly dependent on the efforts and activities of Bayer. Should Ovaprene fail to generate compelling clinical safety and efficacy data, the license grant under our agreement with Bayer may never become effective. Even if Bayer elects to make the license agreement effective, Bayer has significant discretion in determining the resources that it will allocate to commercialization of Ovaprene and Ovaprene' s commercial success may be limited, in which case our business, financial condition, results of operations and prospects could suffer significantly. The commercial success of **an FDA-**

approved Sildenafil Cream **product** ~~, if approved,~~ will depend on the availability of alternative **treatments and** products ~~for female sexual dysfunction disorders~~, the **effectiveness of the sales** ~~age group for which our product is indicated~~ and **marketing strategy and efforts for the product, including the success of efforts to educate** women **and** ~~' s preferences, in addition to the~~ **their** ~~market' s acceptance~~ **health care providers about FSAD, and the availability and extent** of ~~our topical cream~~ **third-party coverage and reimbursement for the product, among other factors**. Today, there are no FDA- approved products to treat FSAD. While our goal is for Sildenafil Cream to be the first product to receive such approval, one or more competitive products may be approved before our product. **In addition, an FDA- approved Sildenafil Cream product may also have to compete with compounded drugs. Some compounding entities currently supply topical cream formulations of sildenafil. In addition, some compounding entities have partnered with telemedicine providers, enabling them to expand the potential market for their compounded drugs. The availability of cream formulations of sildenafil through compounding entities, could make it more challenging for Sildenafil Cream to build and maintain market share.** Even if we achieve our goal of being first- to- market for FSAD, the costs associated with introducing a new **branded prescription** product into the **female** sexual ~~dysfunctions~~ **dysfunction** market would likely be significant, and regardless of the amount spent, there is no guarantee that our new product will be broadly adopted. **Broad market adoption of Sildenafil Cream will depend not only on Sildenafil Cream' s ability to demonstrate safety and effectiveness in treating FSAD in Phase 3 clinical trials, but a variety of factors, as discussed above under " Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success, which would negatively impact our business. " If we or a commercial collaborator are not successful in increasing awareness and understanding about FSAD and Sildenafil Cream, the market potential of Sildenafil Cream will not be realized.** Women **who experience low or no genital arousal may be hesitant to seek treatment due to stigma and embarrassment associated with sexual health issues, lack of understanding of normal versus abnormal sexual functioning, or lack of awareness that FSAD may be treated with medication. Health care providers may be hesitant to prescribe Sildenafil Cream for** ~~may~~ **many reasons, including lack of understanding or experience with female sexual dysfunction in general and FSAD in particular, lack of experience with any product approved to treat FSAD, or perceived lack of clinical evidence of the safety and efficacy of Sildenafil Cream. Women may also** be hesitant to use Sildenafil Cream for many reasons, including the lack of experience with any product designed to treat FSAD, **concern over potential side effects** ~~the lack or perceived lack of clinical evidence supporting its benefits~~, and the out- of- pocket cost of Sildenafil Cream, particularly if it is not covered by insurance. **Currently, third- party payors such as government health care programs and private insurance companies often do not cover products prescribed to treat female sexual dysfunction disorders. If Sildenafil Cream is not an affordable option for a significant segment of potential users, the ability to build a commercial market for Sildenafil Cream will be significantly impaired.** In addition, FSAD is a condition that impacts women of many ages, including older and elderly populations. We have not yet thoroughly studied the topical or clinical pharmacology of Sildenafil Cream in different patient populations, and sildenafil, the active ingredient in our drug candidate, has not been tested over long periods of time in older or elderly women. Older or elderly women may react differently and adversely to Sildenafil Cream than younger populations. **We** ~~Based on our end- of- Phase 2 meeting with the FDA, we~~ expect our pivotal Phase 3 clinical trials of Sildenafil Cream will be conducted in a premenopausal population. Therefore, we expect initial FDA approval of Sildenafil Cream, if received, ~~would~~ **to** be limited to premenopausal women. Should Sildenafil Cream not be studied in older or elderly women, or, if studied in those populations, should it show increased risk of adverse reactions, or signs thereof, in older or elderly women during clinical development, the potential market for Sildenafil Cream could be significantly limited, which could have a material adverse impact on the value of this program. ~~If we receive marketing approval in the future, our commercial success with Sildenafil Cream will depend, in large part, on the ability of the product candidate to demonstrate safety and effectiveness in treating FSAD in clinical trials, as well as our ability, or that of a commercial collaborator, to educate doctors and women about the need to diagnose and treat FSAD and the potential benefits of using of Sildenafil Cream, which may not prove successful. Sexual arousal can be influenced by many emotional and physiological factors. To be successful, our clinical trials of Sildenafil Cream must anticipate such factors. Sildenafil Cream is designed to increase local blood flow to the genital tissue. Even if Sildenafil Cream demonstrates success in increasing blood flow, the product candidate may not demonstrate a significant, or any, increase in arousal or improvement in the overall sexual experience in some women in our clinical trials. If we fail to generate compelling clinical results, we may not receive regulatory approval to market Sildenafil Cream, or, if approved, many physicians may not prescribe and / or many women diagnosed with sexual arousal disorder may opt not to try Sildenafil Cream. If we fail to produce strong clinical outcomes, our ability to build a commercial market for Sildenafil Cream will be materially adversely impacted.~~ The commercial success of DARE- HRT1, if approved **for commercial sale**, will depend on the availability of alternative products for managing **menopause** ~~the vasomotor and vaginal~~ symptoms **, concerns about the safety** of ~~menopause~~ **hormone therapy,** and women' s preferences, ~~in addition~~ **among other factors. DARE- HRT1, if approved as a treatment for moderate** to **severe VMS due to menopause, will compete with the many options on** the market **targeted to** ~~' s acceptance of our~~ **or** ~~IVR.~~ **FDA- approved for the** ~~Treatments~~ **treatment of menopausal** ~~to address the~~ symptoms ~~associated with menopause~~, including **VMS. Such options** ~~the vasomotor symptoms, also known as hot flashes,~~ include ~~combinations of prescription hormones~~ **hormone therapies in the form of pills, patches and creams**, some of which are FDA- approved **products** and others which are ~~prepared in~~ **supplied by** compounding ~~pharmacies~~ **entities, as well as non- hormonal options, including an FDA- approved product (Veozah ® (fezolinetant)), and dietary supplements**. ~~Numerous~~ **Both the supplement and the compounded hormone therapy markets are very significant. A considerable segment of the compounded hormone therapy market is comprised of compounded hormones in pellet form that are implanted under the skin as a non- daily alternative, which could be directly competitive with DARE- HRT. In addition, we are aware of non- hormonal drug** products ~~already exist~~ **in development for the treatment of**

VMS , **including elinzanetant, a dual neurokinin- 1 and 3 (NK- 1 and NK- 3) receptor antagonist, for which Bayer submitted** ~~and~~ **an** ~~this number~~ **NDA in August 2024, and** is ~~likely~~ **anticipated to launch in the second half of 2025. We expect the options for hormone therapy to continue** to expand with time ~~. In addition, there has been an emerging preference among some women and providers for bio- identical hormones that are chemically identical to those the body produces~~ . DARE- HRT1 is designed to offer a convenient vaginal ring that continuously delivers a combination of ~~bio- identical~~ **bioidentical** estradiol and progesterone over 28 days. **Bioidentical hormones refer to compounds that are chemically** ~~Until relatively recently, no FDA- approved bio-~~ identical ~~hormone treatments existed. In 2018, Bijuva ® estradiol and progesterone capsules, which are~~ to ~~be taken daily, received the~~ **those** ~~first such approval~~ **produced naturally in the human body** . Studies have **not** ~~failed to demonstrate~~ **demonstrated** that ~~bio- identical~~ **bioidentical** hormones are safer than ~~other~~ **synthetic** hormones, so DARE- HRT1 will need to compete with many types of hormone therapy options in terms of convenience, safety and efficacy in managing symptoms of menopause. Risks related to market acceptance of DARE- HRT1 ~~, if approved for hormone therapy,~~ include: • **women' s** preference for ~~a~~ vaginal ring delivery of hormone therapy over pills, patches and creams ~~by menopausal~~ **; •** women **' s preference for a monthly product format over products to be taken or applied daily** ; • data regarding symptom relief of DARE- HRT1 ~~over~~ **compared with** other ~~hormonal~~ treatments **and products** for **VMS** ~~vasomotor symptoms associated with menopause~~ ; • preference for ~~bio- identical~~ **bioidentical** hormones by women and health care providers; • positive or negative news and research regarding ~~bio-~~ **hormone therapy in general and** ~~identicals~~ **bioidentical hormone therapy in particular** ; • preference for an FDA- approved product by women and health care providers over treatments prepared in compounding ~~pharmacies~~ **entities** ; • the success or failure of ~~Bijuva ®, the~~ **other** ~~first~~ FDA- approved ~~bio~~ **bioidentical hormone products and FDA** - ~~identical~~ **approved non- hormonal** ~~product~~ **products for VMS** ; • new information supportive or against the use of hormones in menopause; and • availability and extent of third- party payor coverage and reimbursement for DARE- HRT1 and out- of- pocket cost for patients. Depending upon the direction of the factors above, a commercial market for DARE- HRT1 may develop more slowly than expected, or not at all, and our business, financial condition, results of operation and prospects could be hurt as a result. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses for prescription medical products. If we or any commercial collaborator is found or alleged to have improperly promoted any of our products for off- label uses, we may become subject to significant liability, including fines, penalties or injunctions, and reputational harm. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription medical products. In particular, a product may not be promoted for uses that are not approved by the FDA (i. e., off- label uses), as reflected in the product' s approved or cleared labeling. Promotional labeling and advertising for any of our drug product candidates that receive marketing approval, must be submitted to FDA at the time of first use and the agency actively solicits reports from health care professionals about improper promotional claims or activities by the drug manufacturer or distributor. Medical device promotion and advertising are subject to similar off- label restrictions, although without the same requirement to submit promotional materials to FDA at the time of first use. Both prescription drug and medical device promotional materials must present a fair balance between the product' s effectiveness and the risks associated with its use, and must be truthful and not misleading. If we or a commercial collaborator is alleged or found to have promoted a product for any off- label use, we may become subject to significant liability and reputational harm. The federal government has levied large civil and criminal fines against companies for alleged improper medical product promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Other enforcement authorities may also take action against a company for promoting an off- label use of a prescription medical product, which could result in penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. See also " Risks Related to Our Business Operations and Industry- The pharmaceutical and medical device industries are highly regulated and subject to various fraud and abuse laws, including, without limitation, the U. S. federal Anti- Kickback Statute, the U. S. federal False Claims Act and the U. S. Foreign Corrupt Practices Act " below. If we or our commercial collaborators, as applicable, cannot successfully manage the product promotion to ensure compliance with these legal and regulatory requirements, we could become subject to significant liability, our reputation could be damaged, and adoption of our products could be considerably impaired. Unexpected safety, efficacy or quality concerns relating to XACIATO could develop, which could have significant negative consequences for us. XACIATO was approved by the FDA based on prior findings of safety or effectiveness of previously approved clindamycin products and on clinical data from the Phase 3 DARE- BVFREE clinical trial, in which 307 patients were randomized and treated once. In light of its commercial launch, XACIATO will be used by larger numbers of patients, and some patients may use multiple regimens over the course of a year. New data may emerge from market surveillance or future clinical trials of XACIATO that give rise to safety, efficacy or quality concerns and result in negative consequences, including: • modification to the product' s prescribing information, such as the addition of boxed or other warnings, contraindications, or limitations of use; • restrictions on the promotion or marketing of the product; • issuance of " Dear Doctor Letters " or similar communications to health care professionals or the public regarding safety or efficacy concerns; • imposition of post- marketing clinical trial requirements or other post- marketing studies; • product distribution restrictions or other risk management measures, such as a risk evaluation and mitigation strategy, or REMS, which could include elements to assure safe use; • warning or untitled letters; • suspension or withdrawal of marketing approvals; • suspension or termination of ongoing clinical trials, if any; • refusal by regulators to approve pending marketing applications or supplements to approved applications that we submit; • suspension of, or imposition of restrictions on, the operations of our commercial collaborator or any CMO producing commercial supplies of XACIATO, including costly new manufacturing requirements; • costly and time- consuming corrective actions; • voluntary or mandatory product recalls or withdrawals from the market; • significant reputational harm; and • product liability claims and lawsuits. Furthermore, the discovery of significant problems with another intravaginally administered or clindamycin- containing product perceived as comparable to XACIATO,

could have an adverse impact on commercialization of XACIATO, including as a result of occurrence of the events described above. For example, XACIATO has not been studied in pregnant or breastfeeding women. Should increased risk of miscarriage or other adverse effects on maternal or fetal outcomes or breastfed infants be observed in future data from market surveillance or clinical trials of XACIATO or other clindamycin products, XACIATO' s commercial potential may be limited and we could become subject to product liability claims and lawsuits. The occurrence of any of the circumstances described above could reduce XACIATO' s market acceptance ~~, inhibit or delay its commercialization within or outside of the U. S.~~ and adversely affect sales of XACIATO **in the U. S. and inhibit or delay its development, approval or commercialization outside of the U. S.** , which could, in turn, have a significant negative impact on ~~the~~ **potential** payments **to us under the traditional royalty purchase agreement** we **entered into** ~~receive under our license agreement~~ with **XOMA** ~~our commercial collaborator for XACIATO~~ , as well as our stock price. If we suffer negative publicity concerning the safety or efficacy of XACIATO or the product candidates we develop, our reputation could be harmed, product sales could be adversely affected or we may be forced to cease or curtail product development efforts. If concerns should arise about the actual or anticipated clinical outcomes regarding the safety of **any of our product candidates, or about adverse event reports on** XACIATO ~~or any of our product candidates~~ , including as a result of safety concerns related to third- party products containing the same or similar active or excipient substances, such concerns could adversely affect the market' s perception of XACIATO and our product candidates. Negative publicity could be time consuming and expensive to address and could adversely affect potential opportunities with strategic partners or collaborators, lead to a decline in product sales, and negatively impact investor sentiment toward a product or product candidate or our company as a whole, which could lead to a decline in ~~the~~ **our stock** price ~~of our common stock~~ . We are and will remain subject to ongoing regulatory requirements even after obtaining regulatory approval for a product candidate. Even if any of the product candidates we develop are approved by the FDA or a comparable regulatory authority outside of the U. S., as long as we are the holder of the product approval or manufacturer of record with the FDA or other regulatory authority, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing clinical trials and submission of safety, efficacy and other post- approval information, including both federal and state requirements in the U. S. and requirements of comparable foreign regulatory authorities. In addition, manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring quality control and manufacturing procedures conform to cGMP regulations and corresponding foreign regulatory manufacturing requirements. Accordingly, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in our NDA or PMA submissions to the FDA. Any marketing approvals we receive for our product candidates in the future may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. In addition, we will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities (when products are approved in foreign markets). Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If a regulatory agency discovers previously unknown problems with a product, such as problems with the facility where the product is manufactured, or it disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or on us or our commercial collaborator, including requiring withdrawal of the product from the market. If we or our commercial collaborators are unable to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things: • issue warning letters; • impose civil or criminal penalties; • suspend or withdraw regulatory approval; • suspend any of our ongoing clinical trials; • refuse to approve pending applications or supplements to approved applications submitted by us; • impose restrictions on our operations, including closing our contract manufacturers' facilities; or • require a product recall. Any government investigation of alleged violations of law would require us and / or our commercial collaborators to expend significant time and resources in response and could generate adverse publicity. Any inability to comply with ongoing regulatory requirements may significantly and adversely affect our ability, or that of our collaborators, to develop and commercialize our products and the value of our business, and our operating results would be adversely affected. Failure to successfully obtain coverage and reimbursement for XACIATO and any future products in the United States, or the availability of coverage only at limited levels, would diminish our ability, or that of a commercial collaborator, to generate net product revenue or net sales. Coverage from government health care programs and private commercial health insurance companies is critical to the commercial success of XACIATO and any future products. Market acceptance and sales of XACIATO and any future products that we or a commercial collaborator may seek to commercialize will depend in part on the extent to which reimbursement for these products will be available from third- party payors. Third- party payors, such as government health care programs, private health insurers, managed health care providers, and other organizations, are increasingly challenging medical product prices and examining the medical necessity and cost- effectiveness of medical products, in addition to their safety and efficacy. If these third- party payors do not consider XACIATO or any future product to be **medically necessary or** cost- effective compared to other available therapies and medical products, they may not cover the product as a benefit under their plans or, even if they do, the level of payment may not be sufficient to allow us, or a commercial collaborator, to sell the product on a profitable basis. Coverage decisions can depend upon clinical and economic standards that disfavor new prescription medical products when more established or lower cost alternatives are already available or subsequently become available. Third- party payor coverage may not be available to patients for XACIATO or any future product. If third- party payors do not provide adequate coverage and reimbursement, health care providers may not prescribe our products or patients may ask their health care providers to prescribe competing products with more favorable reimbursement. Significant uncertainty exists as to the reimbursement status for newly approved prescription medical products, including coverage and payment. There is no uniform policy requirement for

coverage and reimbursement for prescription medical products among third- party payors in the U. S.; therefore, coverage and reimbursement for our products could differ significantly from payor to payor. In the U. S., the principal decisions about reimbursement for new medical products are typically made by the Centers for Medicare and Medicaid Services, or CMS, as CMS decides whether and to what extent a new medical product will be covered and reimbursed under Medicare. Third- party payors often rely upon Medicare coverage policy and payment limitations to a substantial degree in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. It is difficult to predict what CMS will decide with respect to reimbursement. Decisions regarding the extent of coverage and amount of reimbursement to be provided for XACIATO and any future products will be made on a payor- by- payor basis. Accordingly, one third- party payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. Moreover, reimbursement agencies in Europe may be more conservative than CMS, should XACIATO or any of our product candidates be approved for marketing in Europe. In addition to CMS and private payors, professional organizations can influence decisions about reimbursement for new medical products by determining standards of care. In addition, many private payors contract with commercial vendors who sell software that provides guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit as compared to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of any of our commercialized products. To secure coverage and reimbursement for XACIATO and any future product, we or a commercial collaborator may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of the product to third- party payors, which costs would be in addition to those required to obtain FDA or other comparable regulatory approvals. A payor' s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Third- party payors increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for XACIATO or any future product, or obtaining such pricing or placement at unfavorable pricing levels, could materially adversely affect our business, financial conditions, results of operations and prospects. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, or those of a commercial collaborator. Interim payments for new products, if applicable, also may not be sufficient to cover our costs, or those of a commercial collaborator, and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third- party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U. S. Accordingly, the coverage determination process is often a time- consuming and costly process that will require us or our commercial collaborator to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payor will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be cost prohibitive for health care providers or their patients, or less profitable than alternative treatments or products, or if administrative burdens make our products less desirable to use. Our inability, or that of our commercial collaborator, to obtain coverage and profitable payment rates from both government- funded and private payors for XACIATO or any future product could have a material adverse effect on our operating results, our ability to raise capital needed to execute our business strategy and our overall financial condition. Failure by us or a commercial collaborator to obtain timely and adequate coverage and pricing for **a** ~~XACIATO and any future products~~ **product**, or obtaining such coverage and pricing at unfavorable levels, could materially adversely affect our business, financial condition, results of operations and prospects. Legislation and legislative and regulatory proposals intended to contain health care costs may adversely affect our business. The containment of health care costs has become a priority of federal and state governments and the prices of drug products have been a focus of this effort. For example, there have been several recent U. S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect that federal, state and local governments in the U. S. will continue to consider legislation directed at lowering the total cost of health care and prescription drugs. Individual states in the U. S. have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U. S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Biden Administration has also indicated that lowering prescription drug prices is a priority, and on August 16, 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U. S. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product' s price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment

year 2026, the Centers for Medicare and Medicaid Services, or CMS, will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA' s impact on the pharmaceutical industry in the U. S. remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e. g., the U. S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing. Further, in December 2023, the Biden Administration announced an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act of 1980 (the" Bayh- Dole Act"), and the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights, which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. It is uncertain whether and how future legislation or regulatory changes could affect prospects for XACIATO or our product candidates or what actions third- party payors may take in response to any such health care reform proposals or legislation. Adoption of price controls and cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures reforms, may prevent or limit our ability, or the ability of a commercial collaborator, to commercialize any future products as well as our ability to generate revenue and attain profitability. Even seemingly small copayments or other cost-sharing requirements could dramatically reduce the market potential for XACIATO and our product candidates. If the out- of-pocket costs for XACIATO or any of our product candidates, if approved **for commercial sale** , are deemed by women to be unaffordable, or if less expensive alternatives exist, a commercial market may never develop or the market potential for that product may be significantly reduced, which could have a material adverse effect on our business, financial condition, and prospects. With regard to contraceptive products, the ACA and subsequent regulations enacted by DHHS, require health plans to provide coverage for women' s preventive care, including all forms of FDA- cleared or approved contraception, without imposing any cost sharing on the plan beneficiary. These regulations ensure that women in the U. S. who wish to use an approved form of contraception may request it from their doctors and their health insurance plan must cover all costs associated with such contraceptive products. In January and July of 2022, the DHHS, Department of Labor, and Treasury Department jointly issued guidance on implementation of this ACA mandate, among other things. The federal guidance makes clear that all FDA- approved or cleared contraceptive products that are determined by an individual' s medical provider to be medically appropriate for such individual must be covered without cost sharing, regardless of whether the product is specifically identified in a Birth Control Guide published by the FDA. Any future repeal or elimination of the ACA' s preventive care coverage rules would mean that women seeking to use prescribed forms of contraceptives may have to pay some portion of the cost for such products out- of- pocket, which could deter some women from using prescription contraceptive products or branded prescription contraceptive products, including Ovaprene and our other investigational contraceptive products, if and when approved by the FDA. As no FDA- approved treatments for FSAD currently exist, there is little precedent to help assess whether health insurance plans will cover Sildenafil Cream, if approved **for commercial sale** . Sildenafil Cream is being developed for female sexual arousal disorder, a life altering, but not a life threatening, condition. Hence, there is no assurance that third- party reimbursement will be available for Sildenafil Cream, if approved **for commercial sale** . Even if reimbursement becomes available, the amount of such reimbursement may not make our product affordable to women and profitable to us. Insurers may deem Sildenafil Cream to be a lifestyle drug and decide not to provide reimbursement. Today, many health insurance plans provide reimbursement for male sexual arousal medications. However, we cannot predict whether they will continue to do so or whether they will do so for FSAD treatments as well. The safety and efficacy data from our clinical trials may impact whether Sildenafil Cream will become eligible for insurance coverage, and if it does, the level of such reimbursement. In an environment of rapidly rising health care costs, insurers have been looking for ways to reduce costs, which could make it difficult for new therapies to gain coverage if they are not deemed medically critical or essential. If Sildenafil Cream fails to obtain insurance coverage, or if the patient' s share of the cost is deemed to be expensive, a market may never develop for Sildenafil Cream, which would have a material adverse effect on our financial condition and prospects. The commercial success of products we develop, if approved **for commercial sale** , will be impacted by the prescribing information approved by the FDA and comparable regulatory authorities outside the U. S. The commercial success of any products we develop will significantly depend upon our ability, or that of our commercial collaborator, to obtain approval from the FDA and other regulatory authorities of prescribing information for the product that adequately describes expected features or benefits. Failure to achieve such approval will prevent or substantially limit our or our collaborators' ability to advertise and promote such features and benefits in order to differentiate our products from competing products. This failure could have a material adverse effect on our business, financial condition, results of operations and prospects. **Manufacturing disruptions could cause significant delays and disruption in the commercial launch and / or supply shortages of any product we develop. The manufacture of** ~~Drug~~ **drug** products and drug / device combination products ~~are~~ **can be** complex ~~to manufacture,~~ and ~~manufacturing disruptions may occur that could cause significant delays and disruption in the commercial supply of any product we develop, if approved. The manufacture of our product candidates~~ is ~~complex,~~ subject to compliance with extensive regulatory requirements and we are dependent on, and expect to continue to rely on, contract manufacturers and other third parties to supply our products and their components. Manufacturing disruptions may occur, including as a result of scaling up production to meet commercial requirements or due to global supply chain disruptions. Such problems may prevent the production of lots that meet the specifications required for sale of a product and may be difficult and expensive to resolve. To the extent we or our commercial collaborators rely on single source contract manufacturers and suppliers, if disruptions occur in the operations of any one of

those third parties, there may be immediate shortages of our products. If any such issues were to arise, we could lose sales and associated revenue, incur additional costs, delay commercial launch of new products or suffer harm to our reputation. See above: " Risks Related to Product Research & Development and Regulatory Approval- Delays in the manufacture of our clinical supplies as well as other supply chain disruptions could postpone the initiation of or interrupt clinical studies, extend the timeframe and cost of development of our product candidates, delay potential regulatory approvals and impact the commercialization of any approved products. "; " Risks Related to Our Dependence on Third Parties- We do not have, and we do not have plans to establish, our own manufacturing capabilities and instead rely on third- party suppliers and manufacturers for clinical study materials, including multiple single source suppliers and manufacturers. If these third parties do not perform as we expect, do not maintain their regulatory approvals or become subject to negative circumstances, it could delay, prevent or impair our product development or commercialization efforts, or those of our collaborators, and harm our business; " and " Risks Related to Our Dependence on Third Parties- In some cases, we may be contractually required to obtain clinical or commercial product supplies from specific third parties or there may be a limited number of third- party suppliers of raw materials and other components of our product candidates or future products, which may heighten our dependence on those third parties ~~and~~ **, increase** the risk of manufacturing disruptions **, and result in higher development costs or costs of goods sold** . " If competitors obtain approval for generic versions of **our products, our business may suffer.** XACIATO ~~or~~ **and** any future ~~products~~ **product we develop** ~~, our business may suffer. XACIATO and any future product~~ may face direct competition from generic products earlier or more aggressively than anticipated, depending upon the product' s success in the market. In addition to creating the 505 (b) (2) NDA pathway, the Hatch- Waxman Act amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to abbreviated new drug applications, or ANDAs. An ANDA relies on the nonclinical and clinical testing conducted for a previously approved reference listed drug, or RLD, and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is " bioequivalent " to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD. If a third party is able to demonstrate bioequivalence without infringing our patents or if a data exclusivity period granted to a product under the FDCA is successfully challenged, a third party may be able to introduce a competing generic product onto the market before the expiration of the applicable patents or exclusivity period under the FDCA. Reduction or loss of periods of market exclusivity for our products could negatively affect our business, operating results and financial condition. We will need to obtain FDA approval of any proposed prescription medical product name, and any failure or delay associated with such approval may adversely affect our business. Any name we intend to use for our current or future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U. S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed new prescription medical product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a proposed product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose any goodwill or brand recognition developed for previously used names and marks, such as Ovaprene, as well as the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. We or a commercial collaborator may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our or our collaborator' s ability to commercialize our product candidates. Even if we receive marketing approval from the FDA, we may fail to receive similar approvals outside the U. S., which could substantially limit the value of our products. To market any ~~future~~ product outside the U. S., we, or our commercial collaborators, must obtain separate marketing approvals from comparable regulatory authorities for each jurisdiction and comply with numerous and varying regulatory requirements of other countries, including clinical trials, commercial sales, pricing, manufacturing, distribution and safety requirements. The time required to obtain approval in other countries might differ from, and be longer than, that required to obtain FDA approval. Approval by the FDA or a comparable foreign authority does not ensure approval by regulatory authorities in any other countries or jurisdictions, but a failure to obtain marketing approval in one jurisdiction may adversely impact the likelihood of approval in other jurisdictions. The marketing approval process in other countries may include all of the risks associated with obtaining FDA approval in the U. S., as well as other risks. Further, for approval in foreign jurisdictions, we may not have rights to reference the necessary clinical and nonclinical data that we do not own or have licensed rights to use, as we anticipate doing under the 505 (b) (2) regulatory pathway in the U. S., and we, or our commercial collaborator, may have to conduct further nonclinical studies or clinical trials or develop other additional data to seek approvals in other jurisdictions. In addition, in many countries outside the U. S., a new product must receive pricing and reimbursement approval prior to commercialization. This can result in substantial delays in these countries. Additionally, the product labeling requirements outside the U. S. may be different and inconsistent with the U. S. labeling requirements, negatively affecting our ability to market our products in countries outside the U. S. In addition, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we, or our commercial collaborator, fail to comply with applicable foreign regulatory requirements. In such an event, our ability, or our commercial collaborator' s ability, to market to the full target market for our products will be reduced and the full market potential of our products may not be realized, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Risks Related to **Section 503B Compounding We plan to generate revenue from sales of our proprietary Sildenafil Cream formulation produced by Section 503B- registered outsourcing facilities, but we have no experience in this line of business and may not be successful in our efforts. One aspect of our**

business strategy is to enter into licensing arrangements with outsourcing facilities through which we can generate revenue from sales of our proprietary Sildenafil Cream formulation produced by those outsourcing facilities under Section 503B. We have no experience in the compounded drugs market and we have never entered into arrangements with outsourcing facilities. We will be required to successfully identify and enter into satisfactory arrangements with one or more outsourcing facilities, and no assurances can be given that we will be successful in doing so on commercially reasonable terms or at all. Even if we are successful in this regard, we may not generate sufficient revenue to recover our costs. Establishing such arrangements could be expensive and time consuming, disrupt our other operations, require significant capital expenditures and distract management and our other employees from other aspects of our business. We will be reliant on Section 503B- registered outsourcing facilities to produce our proprietary Sildenafil Cream formulation, and their failure to adequately perform their obligations could harm our reputation, business and financial condition. If we are able to enter into arrangements with one or more outsourcing facilities, we will be reliant on them to compound and distribute our proprietary Sildenafil Cream formulation and to comply with applicable statutory and regulatory requirements, including FDA' s cGMP regulations and related FDA guidance for drugs compounded at outsourcing facilities. We will also be reliant on suppliers that supply sildenafil citrate to the outsourcing facilities. We will not control or direct the compounding or distribution process used by these parties, and we will have no control over their ability to maintain adequate quality control, quality assurance and qualified personnel. These arrangements also involve other risks, including: • the inability of third parties to consistently meet product specifications and quality requirements; • delay or inability to procure or expand sufficient manufacturing capacity; • issues related to scale- up of manufacturing; • costs and validation of new equipment and facilities required for scale- up; • third parties may not be able to appropriately execute necessary manufacturing procedures and other logistical support requirements; • third parties may fail to comply with cGMP requirements and other FDA or other comparable regulatory requirements; • breach, termination or non- renewal of agreements in a manner or at a time that is costly or damaging to us; • inability to procure or maintain state licenses in those states into which our proprietary Sildenafil Cream formulations are shipped; • third parties may not devote sufficient resources to our needs; • the operations of third parties could be disrupted by conditions unrelated to our business or operations; and • logistics carrier disruptions or increased costs that are beyond our control. Adverse developments affecting the supply of sildenafil citrate or the compounding or distribution operations of parties involved in the compounding and distribution of our proprietary Sildenafil Cream formulation may result in lot failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in the availability of our proprietary Sildenafil Cream formulation. We may also have to undertake costly remediation efforts, or seek more costly supply, compounding and distribution alternatives. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, total or partial suspension of production, or issuance of a Form 483 or Warning Letter. Our plan to bring our proprietary Sildenafil Cream formulation to market under Section 503B will subject us to a variety of new regulations and related potential liability. We plan to enter into arrangements with one or more outsourcing facility (ies) to produce and distribute our proprietary Sildenafil Cream formulation under Section 503B. An outsourcing facility must meet certain conditions under Section 503B, including registering with the FDA, operating in compliance with the FDA' s cGMP regulations and guidance, and is subject to FDA inspection. Outsourcing facilities have been subject to increased scrutiny of their compounding activities by the FDA and state governmental agencies. Governmental inquiries or actions or litigation brought against us or any of our suppliers or outsourcing facilities relating to our proprietary Sildenafil Cream formulation, whether or not such inquiry, action or litigation ultimately results in penalties, changes to our business practices or other consequences, could have an adverse effect on our reputation, business and financial condition. We or any outsourcing facility with which we have a business relationship may also face allegations, litigation, and regulatory investigations under federal or state laws related to the promotion, advertising, fulfillment, distribution, and / or sale of our proprietary Sildenafil Cream formulation under Section 503B. Litigation and regulatory proceedings, and particularly the healthcare, pharmaceutical- related, consumer protection, data privacy and / or class action matters we could face, may be protracted and expensive, and the results are difficult to predict. Such litigation or regulatory proceedings and investigations, unexpected side effects or safety or efficacy concerns with our proprietary Sildenafil Cream formulation or related negative publicity could have an adverse effect on our reputation, business and financial condition. Achieving and maintaining market acceptance of our proprietary Sildenafil Cream formulation produced and distributed under Section 503B could be negatively impacted by perceived risks associated with compounded drugs. Compounded drugs are not FDA- approved products; lawfully compounded drugs are specifically exempt from FDA approval pursuant to Section 503B (a). Some physicians may be hesitant to prescribe, and some patients may be hesitant to purchase and use, a compounded drug for a variety of reasons, including because it is not required to be, and has not been, approved for marketing and sale by the FDA. In addition, certain outsourcing facilities have experienced both facility and product quality issues and been the subject of negative media coverage and litigation, and the actions of these facilities have resulted in increased scrutiny of compounding activities. Our ability to generate revenue from sales of our proprietary Sildenafil Cream formulation produced and distributed under Section 503B will be adversely impacted if we are unable to achieve and maintain market acceptance for it. Sildenafil citrate must remain on the list of bulk substances that may be used in compounding under Section 503B, and if it were to be removed, we would be unable to offer our proprietary Sildenafil Cream formulation under Section 503B. Sildenafil citrate is currently listed among those nominated substances for which bulk drug substance may be used in compounding by Section 503B- registered outsourcing facilities; the so- called" Category 1" list pending FDA' s evaluation. However, we have no control over whether sildenafil citrate will remain on the list of bulk drug substance that may be used in compounding by outsourcing facilities

or for how long. If sildenafil citrate is removed from the list, we would be unable to offer our proprietary Sildenafil Cream formulation via a Section 503B- registered outsourcing facility, and it could harm our reputation, business and financial condition. In addition, a third party could request that the FDA remove sildenafil citrate from the list of bulk substances that may be used in compounding by Section 503B- registered outsourcing facilities. If removed from such list, outsourcing facilities would be prohibited from producing any compounded drug that includes sildenafil citrate, including our proprietary Sildenafil Cream formulation. For information regarding how the FDA intends to evaluate whether there exists a clinical need for compounding with a bulk drug substance, see" Regulation of Compounded Drugs," below. If a compounded drug formulation provided by an outsourcing facility leads to patient injury or death, or results in a product recall, we may be exposed to significant liability and reputational harm. The success of our proprietary Sildenafil Cream formulation produced and distributed under Section 503B will depend to a significant extent upon perceptions of product quality. We could be adversely affected if the formulation is subject to negative publicity. We could also be adversely affected if it or similar products sold by other companies, or any products sold by outsourcing facilities that produce our proprietary Sildenafil Cream formulation, prove to be, or are alleged or asserted to be, harmful to patients. There are a number of factors that could result in the injury or death of a patient who takes a compounded drug, including quality issues, manufacturing or labeling flaws, improper packaging or unanticipated or improper distribution or other uses of the compounded drug, any of which could result from human or other error. Any of these situations could lead to a recall of, or safety alert relating to, the compounded drug. Similarly, to the extent any of the ingredients used to produce a compounded drug have quality or other problems that adversely affect the finished compounded drug, its sales could be adversely affected. Because of our dependence upon perceptions of prescribing physicians and their patients, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our proprietary Sildenafil Cream formulation produced and distributed under Section 503B, any similar product sold by other companies, or related to compounded formulations generally, could have a material adverse impact on our reputation, business, and financial condition. Risks Related to Employee Matters and Managing Our Growth We have a relatively small number of employees to manage and operate our business. As of March ~~27~~ **28** , ~~2024~~ **2025** , we had ~~26~~ **23** employees, of which ~~24~~ **21** were full- time and ~~five~~ **two** were part- time. Our focus on ~~limiting~~ **controlling our** cash utilization requires us to manage and operate our business in a highly efficient manner, relying on consultants and other third- party service providers for product development and operational expertise we require, and to limit full- time personnel resources. With a small number of employees, our ability to supervise the service providers we engage, including our CMOs and CROs, may be constrained, which may impact the timing and quality of services we receive. No assurance can be given that we will be able to run our operations or accomplish all of the objectives we otherwise would seek to accomplish with the limited personnel resources we currently have ~~. We generally allow for a hybrid work model. We instituted remote work policies in March 2020 in response to the COVID- 19 pandemic and resulting government stay- at- home orders, which have evolved into our current policies generally permitting a hybrid work schedule. In addition, many consultants, collaborators and other third- party service providers on which we rely currently have a remote or hybrid workforce model. The long- term impact of less frequent in- person meetings on our productivity and creativity is difficult to assess. Remote working arrangements for our personnel and that of third parties on which we rely may weaken our ability to effectively manage and operate our business and lead to delays in our anticipated development program timelines~~ . In addition, due to our small workforce, if multiple employees were to become unable to work for a protracted period for any reason, or if they were to resign at roughly the same time, our business could suffer. Our ability to effectively manage and operate our business could become significantly impaired and our expenses could increase materially, including as a result of expenditures related to recruiting, hiring and training qualified new employees and engaging additional consultants and service providers to perform the job responsibilities of the employees on leave or who resign. If we or our collaborators or service providers experience staffing shortages, it may result in significant delays in our anticipated development program timelines. If we fail to attract and retain management and other key personnel, we may not successfully complete development of, obtain regulatory approval for or commercialize our product candidates, or otherwise implement our business plan. Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified managerial and key personnel. We depend highly on our senior management. Losing the services of our senior management, and our chief executive officer in particular, could impede, delay or prevent the development and commercialization of our product candidates, harm our ability to raise additional funds and negatively impact our ability to implement our business plan. If we lose the services of any of our senior management team, we might not find suitable replacements on a timely basis or at all, and our business could be materially harmed. We do not maintain " key man " insurance policies on the lives of any of our senior management employees. We might not attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biopharmaceutical companies and other life sciences R & D organizations, particularly in the San Diego area where we are headquartered. In addition, our limited personnel and financial resources may result in greater workloads for our employees compared to those at companies with which we compete for personnel, which may lead to higher levels of employee burnout and turnover. Many of the other companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better opportunities for career advancement. If we cannot attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives. New legal precedent, laws and regulations **and increased levels of lawsuits by public company stockholders** could make it costlier or more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more

difficult for us to attract or retain qualified persons to serve as our senior management or on our board of directors. Our business development strategy involves identifying and acquiring or in- licensing potential product candidates or technologies. We assembled our current portfolio of product candidates through the acquisition of companies and assets and in- licensing transactions beginning in 2017. We may engage in strategic transactions that could cause us to incur additional liabilities, commitments or significant expense. These efforts may not be successful, including for reasons discussed in elsewhere in this Risk Factors section and also: • we may fail to appropriately evaluate the potential risks and uncertainties associated with a transaction; • there may be intense competition to acquire or in- license promising product candidates and technologies and many of our competitors have considerably more financial, development and commercialization resources than we have; • we may not effectively integrate the acquired or in- licensed assets, businesses, personnel, intellectual property or business relationships; • we may underestimate the development and regulatory approval challenges, costs and timelines and overestimate the market opportunity for the potential product candidates and technologies; and • during development, the acquired or in- licensed product candidates may not prove to be safe or effective in their targeted indications. We may fail to realize the anticipated value of any strategic transaction and the costs of a transaction may outweigh the benefits we realize from it. In addition, we have used shares of our common stock as consideration in strategic transactions and we may do so in the future, which may result in significant dilution to our stockholders. Any strategic transaction we pursue may not produce the outcomes and benefits we originally anticipated and may adversely impact our operating results and financial condition and be detrimental to our company in general. ~~Risks Related to Our Intellectual Property Our failure to adequately protect or enforce our and our licensors' intellectual property rights could materially harm our proprietary position in the marketplace or prevent or impede the commercialization of our current and potential future products.~~ Our success depends in part on our ability, and the ability of our licensors, to obtain ~~and~~ **,** maintain ~~protection~~ **, enforce, and defend patent rights, proprietary know- how, and trademarks of sufficient scope** in the U. S. and other countries ~~for the~~ **with respect to our products, product candidates and proprietary technologies. If we are unable to obtain, maintain, enforce and defend sufficient** intellectual property ~~covering~~ **protection,** ~~or~~ **our business, financial condition, results** ~~incorporated into our technologies and products. Many~~ of **operations** ~~the patents~~ and **prospects could be materially harmed. We depend heavily on** patent ~~applications relied upon by~~ **rights and other intellectual property in- licensed to** us **from** ~~are licensed to us by~~ third parties **to protect most of the products and technologies we develop** . ~~Our ability, or~~ **For** ~~the ability of~~ **some such rights,** our **third- party** licensors **control patent strategy and prosecution and we have little** , ~~to protect~~ **if any, influence** ~~our~~ **or control over** ~~product candidates from unauthorized use or infringement by third parties depends substantially on our abilities and the abilities of~~ such **patent strategy and prosecution, and our** licensors ~~to obtain and maintain,~~ **may not always act in** ~~or~~ **our best interest** ~~license, valid and enforceable patents~~ . Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability, and that of our licensors, to obtain or enforce patents is uncertain and involves complex legal and factual questions for which important legal principles are 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 may not have been the first to file patent applications for these inventions. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. We cannot be certain if any of the patents that cover our product candidates will be eligible to be listed in the Orange Book following a drug product marketing approval. The advantage of being listed in the Orange Book is that, under the Hatch- Waxman Act, any future generic applicant for any of our approved products needs to include a patent certification in their generic application with respect to each patent listed in the Orange Book for an approved product (referred to as the " listed drug ") for which they are seeking approval. If the generic applicant believes that any of the patents in the Orange Book on the listed drug is invalid, unenforceable, or not infringed by their product, the generic applicant usually will file a " Paragraph IV " certification on that patent if they plan to challenge the patent. When a generic applicant files a Paragraph IV certification, they must provide the listed drug applicant (and the patent owner if different) a notice that they filed a generic application with the Paragraph IV certification. If, in reply to that notice, the listed drug holder files a patent lawsuit against the generic applicant within 45 days of the Paragraph IV notice, a 30- month automatic stay is imposed by the Hatch- Waxman Act on FDA during which FDA may not approve the generic application (unless the patent litigation is resolved in the generic applicant' s favor). These 30- month stays are major protection available in the Hatch- Waxman Act for innovative drug makers. However, if our products are approved, but one or more of our patents are not listed in the Orange Book, generic firms that might seek approval of a generic version of our product would not have to " certify " in their generic drug applications as to any such unlisted patent. This could result in the absence of a 30- month stay and thus faster approval of some generic applications for our products. Other companies or individuals may independently develop similar or alternative technologies or duplicate our technologies. This could enable our competitors to develop a competing product that avoids infringing our patents. In such an event, our competitors might be able to enter the market, which could significantly harm the commercial opportunity for our product candidates. The laws of some foreign countries 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 countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, products and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. As an example, the complexity and uncertainty of European laws have increased in recent years. In Europe, a new unitary patent system was launched on June 1, 2023, which significantly impacted European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications now have the option, upon grant of a patent, of becoming a Unitary Patent which are subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes ~~. Our patent strategy for protecting Ovaprene includes in- licensing several patent families from ADVA- Tec. Patent prosecution for the intellectual property incorporated into Ovaprene is entirely controlled by ADVA- Tec and we have little, if any, influence or control over such patent prosecution. Our patent strategy for protecting Sildenafil Cream includes in- licensing a patent family from SST, whose last U. S. claim expires in June 2029, but which could be eligible for three- year market exclusivity under the Hatch- Waxman Act in the U. S. However, if granted 3- year exclusivity, generic applicants can still submit an abbreviated application during the 3- year period and the FDA is required to review the application, but will defer any approval until the end of the 3- year period. Three- year exclusivity differs from 5- year exclusivity under the Hatch- Waxman Act, which bars the submission of a generic application during the 5- year period, with the exception that a generic application can be filed after 4 years if it contains a Paragraph IV certification challenging an Orange Book- listed patent for the brand drug. With respect to patents related to Sildenafil Cream, SST has the sole right, but not the obligation, to prepare, file, prosecute and maintain such patents. We will be responsible for the costs incurred to maintain and prosecute all such patents and we will be kept informed of all strategies. However, we will have little if any, influence or control over implementing the patent strategy. With respect to patent rights related to our IVR product candidates, including DARE- HRT1 and DARE- FRT1, The General Hospital Corporation (also known as Massachusetts General Hospital or MGH) has the sole right to prosecute and maintain its patent rights, and we have the right to prosecute and maintain Catalent' s patent rights. We will be responsible for the costs incurred by MGH to maintain and prosecute such patents and we will be kept informed of all strategies. However, we will have little, if any, influence or control over MGH' s implementation of the patent strategy. With respect to patents related to DARE- VVA1, we have the right and obligation, at our expense, to prosecute and maintain the in- licensed patent rights in certain major markets, if possible. With respect to patents rights related to our DARE- GML program, the University of Minnesota (UMN) has the sole right to prosecute and maintain its patent rights, and we have the right to prosecute and maintain patents licensed from Hennepin Life Sciences. We will be responsible for the costs incurred by UMN to maintain and prosecute such patents and we will be kept informed of all strategies. However, we will have little, if any, influence or control over UMN' s implementation of the patent strategy. With respect to patent rights licensed from Douglas and underlying patent rights from University of Manchester, Douglas has the sole right to prosecute and maintain those patent rights. We will be responsible for the costs incurred by Douglas to maintain and prosecute such patents and we will be kept informed of all strategies. However, we will have little, if any, influence or control over Douglas' s implementation of the patent strategy~~ . There is a substantial backlog of patent applications at the USPTO that may lead to delays in having patent applications examined by the USPTO. There can be no assurance that any patent applications relating to our products or methods will be issued as patents or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide a competitive advantage. We and our licensors may not obtain patent rights on products, treatment methods or manufacturing processes that we may develop or to which we may obtain license or other rights. Even if patents are issued to us and our licensors, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against our competitors or their competitive products or processes. It is possible that no patents will be issued from any pending or future patent applications owned by us or licensed to us. Others may challenge, seek to invalidate, infringe or circumvent any patents we own or license, including the patents we have licensed to date and any other patents we may license in the future. Conversely, in the future we may have to initiate litigation against third parties to enforce our intellectual property rights. The defense and enforcement of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to us. Any adverse outcome could subject us to significant liabilities, require us to license disputed rights from others or require us to cease selling our future products. In addition, many other organizations are engaged in research and product development efforts that may overlap with our products. Such organizations may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods we are developing or considering for development. These rights may prevent us from commercializing technology, or they may require us to obtain a license from the organizations to use the technology. We may not obtain any such licenses that may be required on reasonable financial terms, if at all, and there can be no assurance that the patents underlying any such licenses will be valid or enforceable. As with other companies in the pharmaceutical industry, we are subject to the risks that persons located in other countries will engage in development, marketing or sales activities of products that would infringe our intellectual property rights if such activities were conducted in the U. S. and enforcing our intellectual property rights against such persons may be difficult or not possible. Our patents and other intellectual property also may not afford protection against competitors with similar technology. We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our products or by covering the same or similar technologies that may affect our ability to market or license our product candidates. Many companies have encountered difficulties in protecting and defending

their intellectual property rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in either the U. S. or foreign jurisdictions, our business prospects could be substantially harmed. In addition, because of funding limitations and our limited cash resources, we may not be able to devote the resources that we might otherwise desire to prepare or pursue patent applications, either at all or in all jurisdictions in which we might desire to obtain patents, or to maintain already- issued patents. The **APIs in XACIATO,** ~~patents and the patent applications covering~~ Sildenafil Cream **, DARE- HRT1, DARE- VVA1, DARE- HPV,** and ~~XACIATO~~ **other products we are developing are not proprietary to us or our licensors. There are generic drugs available with the same APIs. The patent protection we and our licensors may obtain and maintain for such product candidates** are limited to specific formulations, processes **, methods of delivery,** and **/ or** uses ~~of sildenafil and clindamycin~~ , **which** ~~and our market opportunity~~ may **not afford us sufficient** ~~be limited by the lack of patent~~ protection **against** ~~for the active ingredient itself and other formulations and delivery technology and systems that may be developed by~~ competitors. **For example** ~~The active ingredient in our product candidate for FSAD~~ , ~~Sildenafil Cream, is sildenafil and the active ingredient in our FDA- approved product for the treatment of bacterial vaginosis, XACIATO, is clindamycin. Patent protection for these ingredients has expired and generic products are available. As a result, a competitor~~ **competitors** ~~that obtains the requisite regulatory approvals~~ could offer products with the same ~~active ingredient~~ **API as our products** in a different formulation **or delivery system or for** ~~so long as the competitor does not infringe any~~ - **an** ~~process~~ **indication that is outside the scope of our patented formulation** , **system or** use ~~or formulation patents that we have developed, or that may not be barred by any three- year Waxman- Hatch Act exclusivity, or any GAIN Act extension thereof, we might enjoy upon approval of our products. Competitors may seek to develop and market competing formulations that may not be covered by our patents and patent applications~~ . The commercial opportunity for **our products** ~~Sildenafil Cream and XACIATO~~ could be significantly harmed if competitors are able to develop ~~and commercialize~~ **or make available** alternative formulations ~~using these ingredients. The patents and the patent applications covering our IVR product candidates cover the method of delivery and the device and our market opportunity may be limited by the lack of patent protection for the active ingredients themselves and other formulations, delivery technology and systems that may be developed by competitors. The active ingredients in our IVR product candidates include bio- identical progesterone, estrogen and oxybutynin, and none of those ingredients are proprietary to us. As a result, we must compete~~ with **the** ~~currently available products and any future products developed by competitors using~~ same **APIs** ~~active ingredients in a different formulation or via a different delivery system. The commercial opportunity for our IVR product candidates, including DARE- HRT1 for hormone therapy, could be significantly harmed if competitors develop and commercialize alternative formulations~~ or better delivery approaches **compared with** ~~. The patents and the patent applications covering the use and delivery of DARE- VVA1 and our market opportunity may be limited by the lack of patent protection for the active ingredient itself and other~~ -- **the products** ~~formulations, delivery technology and systems that may be developed by competitors. The active ingredient in DARE- VVA1, tamoxifen, is not proprietary to us. As a result,~~ we ~~must compete with currently available products and any future products developed by competitors using the same active ingredient in a different formulation or via a different delivery system. The commercial opportunity for our product candidate for the treatment of vulvar and vaginal atrophy could be significantly harmed if competitors~~ develop ~~and commercialize alternative formulations or better delivery approaches~~ . We may become involved in patent litigation or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts. The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights. The situations in which we may become party to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights, or that one of our trademarks or trade names infringes the third party' s trademark rights; in such case, we would need to defend against such proceedings. The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our potential competitors will be able to sustain the cost of such litigation and proceedings more effectively than us because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace, our financial condition and our stock price. Patent litigation and other intellectual property proceedings may also consume significant management time. If a competitor infringes upon our patent or other intellectual property rights, including any rights licensed by us, enforcing those rights may be costly, difficult and time- consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time- consuming and could divert our management' s attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. **Our rights to enforce and defend patents we in-license depend upon the terms of our agreements with our third- party licensors, and in some cases, our licensors have the right to control patent enforcement litigation and defense against patent infringement litigation, and we have indemnification obligations for certain losses arising from third- party claims. We also have indemnification obligations under our out- license agreements for XACIATO and Ovaprene, which could subject us to significant liabilities that may have a material adverse effect on our business, results of operations and financial condition. Our rights to indemnification by our licensors and licensees may not be adequate to compensate us for losses or the potential loss of our ability to manufacture and sell products.** If we were unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business ~~. With respect to XACIATO, we have the initial right to enforce patents we license from TriLogic and MilanaPharm against third parties whose activities infringe such patents in a manner that could affect our exercise of the licenses granted to us, and TriLogic and MilanaPharm must reasonably cooperate in any such suit, including, if necessary, by being joined as a party to any such suit. In some cases, MilanaPharm may assume the defense of a claim initiated by a third- party alleging infringement of a third party' s intellectual property rights as a result of the~~

~~manufacture or sale of a product we develop under our license agreement with TriLogie / MilanaPharm. While our license agreement would require MilanaPharm to indemnify us for certain losses arising from these third- party claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and sell XACIATO. Additionally, our license agreement with Organon requires that we indemnify Organon from and against all liabilities, damages, expenses, fines, penalties and losses as a result of any third- party claim arising out of or relating to the development, manufacture, commercialization or other exploitation of XACIATO or any licensed product by or on behalf of us or any affiliate or licensee of ours, except for in limited circumstances. As a result of our indemnification obligations to Organon and limitations on TriLogie' s and MilanaPharm' s obligations to indemnify us, any patent infringement litigation relating to XACIATO could subject us to significant liabilities that may have a material adverse effect on our business, results of operations and financial condition. With respect to Ovaprene, ADVA- Tec has the right, in certain instances, to control the defense against any infringement litigation arising from the manufacture or development (but not the sale) of Ovaprene. While our license agreement with ADVA- Tec requires ADVA- Tec to indemnify us for certain losses arising from these claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and develop Ovaprene. Additionally, our license agreement with Bayer requires that we indemnify Bayer from and against all liabilities, damages, losses and expenses arising from or occurring as a result of development, manufacture, use or commercialization of Ovaprene by us or any licensee of ours, including without limitation, product liability claims, except in limited circumstances. As a result of our indemnification obligations to Bayer and limitations on ADVA- Tec' s obligations to indemnify us, any patent infringement litigation relating to Ovaprene could subject us to significant liabilities that may have a material adverse effect on our business, results of operations and financial condition. With respect to Sildenafil Cream, we have the initial right to enforce the applicable licensed patents against infringers in the field of use where a third party is exploiting a topically applied pharmaceutical product that contains at least one of the same active pharmaceutical ingredients as a licensed product, and SST will provide us with reasonable assistance (excluding financial assistance), at our expense. We also have the initial right to defend any claim initiated by any third- party alleging that a licensed product developed or commercialized under the SST license agreement has infringed any third- party intellectual property rights. While the SST license agreement requires SST to indemnify us for certain losses arising from these claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and develop Sildenafil Cream. With respect to our IVR product candidates, including DARE- HRT1, DARE- FRT1, and DARE- PTB1 we have the first right to enforce the applicable licensed patents against third party infringers in the fields of pharmaceutical, therapeutic, preventative, diagnostic and palliative uses. With respect to DARE- VVA1, we have the first right to enforce the applicable licensed patents against third- party infringers in all fields~~ . We cannot guarantee that we or any of our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the U. S., Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the U. S., applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the U. S. remain confidential until patents issue. Patent applications in the U. S., EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our future product candidates, or their manufacture or use may currently be unpublished. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our or our licensors' interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We or our licensors may incorrectly determine that our product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our or our licensors' determination of the expiration date of any patent in the U. S., the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our licensors' failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. From time to time, we or our licensors may identify patents or applications in the same general area as our products and product candidates. We or our licensors may determine these third- party patents are irrelevant to our business based on various factors including our or our licensors' interpretation of the scope of the patent claims and our or our licensors' interpretation of when the patent expires. If the patents are asserted against us, however, a court may disagree with our or our licensors' determinations. Further, while we or our licensors may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, our determination may be incorrect, and the issuing patent may be asserted against us or our licensors. We cannot guarantee that we or our licensors will be able to successfully settle or otherwise resolve such infringement claims. If we or our licensors fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We or our licensors might, if possible, also be forced to redesign our product candidates so that we or our licensors no longer infringe on the third- party intellectual property rights. Any of these events, even if we or our licensors were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. We also rely upon trade secrets to protect our technology, product and product candidates, and trade secrets can be difficult to maintain and enforce. In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to derive a competitive advantage for products we develop, especially where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult

to maintain. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, we or any of our collaborators' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors and we may not have adequate remedies in respect of that disclosure. Enforcement of claims that a party illegally disclosed or obtained and is using trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, foreign courts are sometimes less willing than U. S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know- how, we would not be able to assert our trade secrets against them and our business could be harmed. Our competitors may independently develop knowledge, methods and know- how equivalent to our trade secrets. Competitors may be able to legally obtain products of ours and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position could be harmed. Confidentiality agreements with employees and others may not adequately prevent disclosure of our know- how, trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete. We enter into confidentiality and nondisclosure agreements with our employees, CROs, CMOs, consultants, collaborators, sponsored researchers, and scientific and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party on our behalf or made known to the party by us during the course of the party' s relationship with us. We also enter into intellectual property assignment agreements with our employees, consultants and certain other service providers, which generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored or may not effectively assign intellectual property rights to us. We have not entered into any non- compete agreements with any of our employees. We cannot guarantee that the confidential nature of our proprietary information will be maintained by our employees and others in the course of their future employment with or provision of services to a competitor. Enforcing a claim that a party illegally disclosed or obtained and is using our know- how, trade secrets or other proprietary information is difficult, expensive and time consuming and the outcome is unpredictable. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage for the products we develop, which could materially adversely affect our business, operating results and financial condition. Provisions in our agreements with governmental agencies and non- profit organizations may affect our intellectual property rights and the value of our development programs to our company. Certain of our product development activities have been funded, are being funded and may in the future be funded, by the U. S. government and / or not- for- profit organizations. Our agreements for these sources of funding include, and may in the future include, terms and conditions that affect our intellectual property rights. For example, under our CRADA with NICHD for the Phase 3 clinical study of Ovaprene, the U. S. government has a nonexclusive, nontransferable, irrevocable, paid- up right to practice for research or other government purposes any invention of either party conceived or first actually reduced to practice in the party' s performance of the CRADA and both parties will jointly own inventions jointly invented by their employees in performing the research plan. Under the CRADA, we were granted an exclusive option to negotiate an exclusive or nonexclusive development and commercialization license with a field of use that does not exceed the scope of the research plan to rights that the U. S. government may have in inventions jointly or independently invented by NICHD employees for which a patent application is filed **. Under our subaward agreement with VentureWell, the federal government has a nonexclusive license to obtain access to and to share research results and data, as well as certain rights, including " march- in " rights, in intellectual property conceived, made, created, developed or reduced to practice in our performance of the research activities and objectives relating to advancement of our DARE- HPV program specified in the subaward agreement, pursuant to and in accordance with the Bayh- Dole Act of 1980. During the term of the subaward agreement and for three years thereafter, we are subject to certain restrictions on foreign access to the intellectual property and other technology developed by or for us in or for the provision of such services, including restrictions on our sale or other transfer of such technology to a foreign firm or institution (which would include a sale of our company and a sale or licensing of such technology, but not sales of products or components) without the prior approval of the federal agency providing funding for the subaward agreement** . The U. S. federal government retains certain rights in inventions produced with its financial assistance. Under the Bayh- Dole Act, the federal government retains a nonexclusive, nontransferable, irrevocable, paid- up license for its own benefit. The Bayh- Dole Act also provides federal agencies with " march- in " rights. March- in rights allow federal agencies, in specified circumstances, to require the recipient of federal funding (the contractor) or successors in title to the patent to grant a nonexclusive, partially exclusive or exclusive license to a third party if it determines that (i) adequate steps have not been taken to achieve practical application of the invention, (ii) government action is necessary to meet public health or safety needs, (iii) government action is necessary to meet requirements for public use under federal regulations or (iv) unless the requirement has been waived, the contractor has failed to substantially manufacture in the U. S. any product embodying the subject invention that is intended for U. S. commerce. If the contractor or its successor refuses to do so, the government may grant the license itself. The federal government also has the right to take title to these inventions if the contractor or its successor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. To date, no federal agency has ever exercised march- in rights; however, the Biden administration ~~has~~ announced that it ~~views~~ **viewed** march- in rights as a legitimate means for the government to address rising pharmaceutical costs and future use of march- in rights by the government is uncertain. Any exercise by the government of march- in rights could harm our competitive position, business, financial condition, results of operations and prospects. Under ~~the~~ **our** grant agreements **with the**

Foundation ~~supporting development of DARE- LARC1 and DARE- LBT~~, we agreed to make ~~DARE- LARC1, DARE- LBT and any other~~ products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the respective projects funded by the respective grants (referred to as Funded Developments), available and accessible at an affordable price to people most in need within developing countries, and to promptly and broadly disseminate the knowledge and information gained from the project funded by the grant (referred to as the Global Access Commitment). In connection with the Global Access Commitment, under the agreement, we also granted the foundation that awarded the grant a nonexclusive, perpetual, irrevocable, worldwide, royalty- free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform, and display Funded Developments and essential background technology (referred to as the Humanitarian License). We are required to ensure that the Humanitarian License survives the assignment or transfer of Funded Developments and essential background technology. Our obligations under the Global Access Commitment and the Humanitarian License may limit the value to us of **the Funded Developments. Disruptions at the FDA, NIH, SEC and other government agencies, including due to lack of funding, changes in leadership, significant personnel turnover, or diminished staffing, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and hinder our ability to raise additional capital. Twice in the past decade, the previous appropriations legislation deadline was reached and Congress failed to pass a new appropriations bill or continuing resolution to temporarily extend funding, resulting in U. S. government shutdowns that caused federal agencies to halt non- essential operations. The federal government came close to another shutdown several times in recent years. Political polarization among lawmakers may lead to a higher frequency and longer duration of government shutdowns in the future. A federal government shutdown could prevent or delay staff at federal agencies from performing key functions that may adversely affect our business. In addition, considerable uncertainty exists regarding how federal government policy changes and budget decisions will unfold, including the regulatory and spending priorities of the new U. S. presidential administration and Congress, and what challenges potential policy changes and budget reductions will present for us and our industry generally. Measures being implemented by the new U. S. presidential administration are expected to significantly impact federal regulatory agencies, such as by reducing funding to or restructuring such agencies. For example, in the first quarter of 2025, the new U. S. presidential administration began terminating federal government employees and federal agencies were directed to develop plans for large- scale reductions in force and reorganization. As a result, agencies throughout the federal government may experience mass layoffs, as well as a significant number of voluntary departures. The impact of these changes at federal government agencies with which we interact is uncertain at this time, however, mass layoffs and large- scale voluntary departures, in particular at the FDA, NIH, ARPA- H and SEC, could adversely impact our company. For example, if it experiences significant workforce reduction or turnover, the FDA in the future may be unlikely to meet its application review goals or be available for timely interactions regarding our product development plans, which could delay our ability to advance clinical development of our product candidates or obtain marketing approvals. The ability of the FDA to review and approve new product applications or take action with respect to other regulatory matters can be affected by a variety of factors, including funding levels, ability to accept the payment of user fees, ability to hire and retain key personnel, and statutory, regulatory and policy changes. Disruptions at the FDA may delay meetings and other communications with or on- site inspections by agency staff necessary to progress development of our product candidates and may slow the time necessary for acceptance, review and approval of applications to commence clinical studies or to market a new product in the U. S. By way of further example, disruptions at the NIH, including its various institutes and centers, such as NICHD, could delay or prevent providing or processing new grant awards to fund research and development activities and disrupt staff' s work and other activities or funding under active grant / cooperative agreements. As discussed elsewhere in this report, including in this Risk Factors section, changes and disruptions at HHS agencies could result in delays or disruptions to our Phase 3 clinical study of Ovaprene and advancement of our** DARE- ~~LARC1~~ **HPV program. Moreover, reduced funding levels or leadership** and **policy changes at HHS agencies could negatively impact our ability to obtain additional grant awards or** other ~~Funded Developments~~ **non-dilutive federal funding opportunities.Disruptions at the SEC could prevent or delay SEC** staff from performing key functions,including,for example,granting acceleration requests for registration statements,declaring registration statements or amendments thereto effective and providing interpretive guidance or no- action letters. ~~While we currently have an effective shelf registration statement on Form~~ **For example** ~~S- 3~~, **if** ~~a shelf registration statement on Form S- 3 typically can only be used for three years,subject to a limited extension,and that three- year period for our current shelf S- 3 registration statement ends on April 7,2024.If~~ a federal government shutdown halts non- essential SEC operations for an extended period **during which we do not have an effective shelf registration statement** ,it may negatively impact our ability to raise additional capital through registered offerings of our securities ~~in the future~~ .If a prolonged U.S.government shutdown or other event or condition occurs that prevents **or significantly delays** the FDA,NIH,SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities **,or if an agency is restructured or experiences a significant reduction in funding,leadership changes,workforce reduction or employee turnover** ,it could significantly impact the ability of these agencies to timely review and process our regulatory submissions and may impede our access to additional capital needed to maintain or expand our operations or to complete important acquisitions or other transactions,which could **have a material adverse effect on our business** . Business interruptions resulting from public health crises, natural disasters or telecommunication and electrical failures may materially and adversely affect our business, operating results and financial condition. We may experience significant business disruptions as a result of a public health emergency, natural or **manmade** ~~man made~~ disaster, act of terrorism, war, or telecommunications or electrical failure that impacts our facilities or employees, or those of the third parties on which we rely for key business activities. The effects of such events or conditions may materially

and adversely affect our product development activities in the future, including as a result of: • difficulties and delays in clinical study site initiation, including due to diversion of healthcare resources away from conducting clinical studies **or delays in IRB review and approval of clinical study protocols** ; • difficulties and delays in recruiting and enrolling clinical study participants and conducting follow- up visits; • interruption of key clinical study activities, such as study site and data monitoring, due to **operational closures or disruptions at our CROs or study sites or** limitations on travel or in- person gatherings; • staff disruptions and turnover internally or at our CMOs, CROs, clinical study sites, collaborators or other third parties on which we rely, either directly or indirectly as a result of reallocation of resources, illness, ~~vaccine~~ **government** mandates or other changes in terms of employment ~~; • delays in receiving approval from regulatory authorities or IRBs to initiate our clinical studies~~ ; • difficulties and delays in production of clinical trial materials and commercial product, including due to supply chain disruptions or resource constraints or reallocation on the part of our CMOs and raw materials suppliers; • interruptions in U. S. or global shipping that may affect the transport and delivery of raw materials, clinical study materials and commercial product **; • imposition of new or increased tariffs, sanctions, import / export controls or other trade policies that significantly increase the costs of the components and raw materials used in the production of XACIATO or our product candidates** ; • changes in local regulations in response to a public health emergency or other emergency situation that may require changes in the ways our clinical studies are conducted, require us to discontinue a clinical study, or make it more difficult for commercial and medical affairs field teams to call on or otherwise access healthcare providers; • patient delays in seeking or receiving treatment, either due to fear of infection or inaccessibility of healthcare providers; • delays in interactions with the FDA or a foreign regulatory authority necessary to advance clinical development of our product candidates, or delays in their review process and timing of potential approval of our product candidates, including delays in pre- approval manufacturing or clinical study site inspections; • difficulties and delays in establishing or maintaining strategic commercial or development collaborations due to the reallocation of resources or shifting business strategies of collaborators or potential collaborators away from the women' s health market in general or our areas of focus within women' s health in particular; or • disruption and volatility in the financial markets which negatively impacts our access to additional capital or stock price. For example, in March 2020, the COVID- 19 pandemic began to impact the global economy. ~~Because of its size and breadth and the continued emergence of new variants, all of the direct and indirect consequences of the COVID- 19 pandemic are not yet known and may not emerge for some time.~~ The COVID- 19 pandemic disrupted our product development activities and the business activities of third parties on which we rely. The COVID- 19 pandemic contributed to a slower than anticipated pace of enrollment of participants in our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream as a result of operational restrictions or closure of certain study sites due to their adherence to governmental guidelines intended to reduce the spread of COVID- 19. The COVID- 19 pandemic also caused us to prioritize advancement of certain of our development programs over others, or certain development activities within a program over others, due to anticipated or actual difficulties and delays in recruiting clinical study sites and participants and obtaining clinical trial materials and supplies. The strategies we implement designed to mitigate the effects or potential effects on our business of a public health emergency such as the COVID- 19 pandemic, a natural or manmade disaster, act of terrorism, war or telecommunications or electrical failure that impacts our facilities or employees or those of third parties on which we rely may not be effective. The occurrence of such an event or condition could cause significant delays in the timelines for our clinical studies, our regulatory submissions or potential marketing approvals of our product candidates, substantially increase our development costs, and delay or contribute to delays in the commercial launch of any approved product or market acceptance of the product. The longer such an event or condition persists, the greater the potential for significant adverse impacts to our business operations and those of the CROs, CMOs, commercial collaborators, and other third- party service providers and vendors on which we depend to, among other things, conduct our clinical and nonclinical studies, supply our clinical trial materials, assist with regulatory affairs necessary to advance and seek regulatory approval for our programs, and market, sell and distribute our products, if approved **for commercial sale** . Public health emergencies, natural or **manmade** ~~man- made~~ disasters, acts of terrorism, war or telecommunications or electrical failures may also have the effect of heightening many of the other risks and uncertainties described in this ~~"~~ Risk Factors ~~"~~ section. Product liability lawsuits against us could cause us to incur substantial liabilities. We face an inherent risk of product liability exposure as a result of testing of our product candidates in human clinical trials and will face an even greater risk following commercial launch of a product we develop. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we will incur substantial liabilities or be required to limit commercialization of our products. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any marketed product; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • termination of product development or commercial collaborations; • loss of revenue; • withdrawal of clinical study participants and delays in commencement or completion of clinical studies; • injury to our reputation and significant negative media attention; • significant costs to defend the related litigation; • substantial monetary awards to patients or clinical study participants; • diversion of our management' s time and other resources from pursuing our business strategy; and • a decline in our stock price. We carry product liability insurance that we believe to be adequate for our clinical testing and product development programs and in connection with XACIATO. However, insurance coverage is increasingly expensive, and it may be difficult to obtain adequate product liability insurance in the future. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of any of our product candidates, if approved **for commercial sale** . We also have indemnification obligations to our commercial and other collaborators. Although we will endeavor to obtain and maintain such insurance in coverage amounts we deem adequate, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a

settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Our current or future employees, clinical investigators, commercial collaborators or service providers may engage in misconduct or other improper activities, including non- compliance with **laws and** regulatory standards. We may become exposed to the risk of employees, clinical investigators, commercial collaborators, CMOs, CROs, consultants or other vendors engaging in fraud or other misconduct. Misconduct by our employees or third parties on which we rely for the development and commercialization of our products and product candidates could include intentional failures, such as failures to: (1) comply with FDA or other regulators' requirements, (2) provide accurate information to such regulators, (3) comply with clinical and nonclinical research standards and manufacturing standards established by us and / or required by the FDA or other laws and regulations, or (4) comply with SEC rules and regulations. ~~In particular, sales~~ **Sales** , marketing and business arrangements in the health care industry are subject to extensive laws, regulations and industry guidance intended to prevent fraud, misconduct, 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 commission, customer incentive programs and other business arrangements. Misconduct by current or future employees, clinical investigators, commercial collaborators, CROs, consultants or other vendors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory or civil sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, 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 comply with such laws or regulations. 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 adverse effect on our business, including the imposition of significant fines or other sanctions, and ~~our reputation~~ **reputational harm** . The pharmaceutical and medical device industries are highly regulated and subject to various fraud and abuse laws, including, without limitation, the U. S. federal Anti- Kickback Statute, the U. S. federal False Claims Act and the U. S. Foreign Corrupt Practices Act. Health care providers and third- party payors play a primary role in the recommendation and prescription of drug products and medical devices that are granted marketing approval. Our arrangements with health care providers, commercial collaborators, principal investigators, consultants, third- party payors, customers and other organizations may expose us to broadly applicable fraud and abuse and other health care laws and regulations in the U. S. Health care fraud and abuse regulations are complex, and even minor irregularities can give rise to claims that a statute or prohibition has been violated. The laws that may affect our operations include: • the federal Anti- Kickback Statute (and comparable state laws), which prohibits, among other things, any person from knowingly and willfully offering, providing, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs. The federal Anti- Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti- Kickback Statute to reach large settlements with health care companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; • federal and state civil and criminal false claims laws, including the civil False Claims Act which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to the U. S. government, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the U. S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. government. Actions under these laws may be brought by the U. S. Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U. S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices; • federal, civil and criminal statues created under HIPAA (and similar state laws), which prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third- party payors, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the Physician Payments Sunshine Act, enacted as part of the ACA, which, among other things, imposes reporting requirements on manufacturers of FDA- approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report to CMS, on an annual basis, information related to payments and other transfers of value to physicians (defined broadly to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain advanced non- physician health care practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members in such manufacturers; • HIPAA, as amended by HITECH, and their respective implementing regulations, which impose specified requirements relating to the privacy, security and electronic exchange of individually identifiable health information, or" protected health information" when subject to HIPAA. Among other things, HITECH makes some of HIPAA' s privacy and all of HIPAA' s security standards directly applicable to " business associates, " defined as independent contractors or agents of covered entities, that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity." Covered entity" or entities that must comply with HIPAA, include certain health care providers, health plans, and health care clearinghouses. HITECH also increased

the civil and criminal penalties that may be imposed against covered entities, business associates and third parties unlawfully in possession of protected health information, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney' s fees and costs associated with pursuing federal civil actions; and • the U. S. Foreign Corrupt Practices Act, which prohibits U. S. organizations and their representatives from offering, promising, authorizing or making corrupt payments, gifts or transfers of value to non- U. S. officials, which in many countries, could include interactions with certain health care professionals. The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. The risk of violation of, and subsequent investigation and prosecution for violations of, the laws described above may be mitigated through the implementation and maintenance of compliance programs by us and our commercial collaborators and other third parties on which we rely for important aspects of development or commercialization of our products and product candidates, but these risks cannot be eliminated entirely. Ensuring that our current and future business operations and arrangements with third parties comply with applicable health care laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other health care laws and regulations. If we or our operations, or those of a commercial collaborator or other third party on which we rely for development or commercialization of our products and product candidates, are found to be in violation of any of the laws described above or any other governmental regulations that apply to us or that third party, we may be subject to significant civil, criminal and administrative penalties, including monetary damages, fines, individual imprisonment, disgorgement, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, health care reimbursement or other government programs, including Medicare and Medicaid, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with any of these laws, and / or the curtailment or restructuring of our operations. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs. If regulatory authorities challenge our activities, or those of a commercial collaborator or other third party on which we rely, under these laws, any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any investigation of us or the third parties with whom we contract, including a commercial collaborator, regardless of the outcome, would be costly and time consuming, and may negatively affect our results of operations and financial condition. Cyber- attacks, security breaches, loss of data and other disruptions to our information technology systems or those of our collaborators or third- party service providers could compromise sensitive information related to our business, delay or prevent us from accessing critical information, subject us to significant financial loss, and expose us to liability, any of which could adversely affect our business and our reputation. We utilize information technology systems and networks in the ordinary course of our business to process, transmit and store sensitive data, including confidential information, intellectual property, and personally identifiable information of our employees, consultants and others. As the use of digital technologies has increased, cyber incidents, including deliberate attacks (such as the deployment of harmful malware and other malicious code, ransomware, denial of service, social engineering, and other attempts to gain unauthorized access to computer systems and networks), have increased in frequency and sophistication, and have become increasingly difficult to detect. These threats pose a risk to the security of our systems and networks and those of our collaborators and third- party service providers, **including our CMOs and CROs for our clinical studies,** which store sensitive **or confidential** data of ours, and could compromise the confidentiality, availability and integrity of **such** information ~~stored there~~ which ~~is~~ **may be** vital to our operations and business strategy. A successful cyber- attack could cause serious negative consequences for us, including, without limitation, the disruption of our operations, the misappropriation or destruction of our confidential information and sensitive data, including clinical trial data, corporate strategic plans and financial information, and the misappropriation of other assets, including our cash. Organizations and governmental bodies with far greater resources than ours dedicated to cybersecurity have proven vulnerable to cyber- attacks. There can be no assurance we will succeed in preventing cybersecurity breaches or successfully mitigate their effects. In March 2023, we became aware that we had been subject to a criminal fraud commonly referred to as " business email compromise fraud. " The incident involved unauthorized access to an employee' s email account by a third- party impersonator and resulted in an electronic payment of approximately $ 0. 4 million intended for a vendor being fraudulently misdirected to unknown parties. We retained a third party to assist in our investigation of the incident and implementation of remedial measures, including enhancements to our controls relating to electronic payments to third parties. Approximately $ 0. 2 million of the fraud loss was covered by insurance. We do not believe this incident had or will have a material impact on our business, financial condition or results of operations. However, cyber- related criminal activities continue to evolve and increase in frequency and sophistication, including as a result of advancements in generative artificial intelligence technology, and our security measures and controls may not be successful in preventing further cyber- related crimes. Despite implementing security measures, any of the information technology systems belonging to us or our collaborators and third- party service providers **, including our CMOs and CROs for our clinical studies,** and the sensitive and confidential information contained within them are vulnerable to damage or interruption from computer viruses and other malware, unauthorized access, including as a result of employee error (e. g., phishing or spoofing scams) or malfeasance, service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failure. We rely on third- party service providers and technologies for our data processing- related activities, including without limitation third- party providers of cloud- based infrastructure, encryption and authentication technology, employee email, and other functions. ~~Our~~ **We rely on these third parties to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. However, our** ability to monitor these third parties' cybersecurity

practices is limited, and these third parties may not have adequate ~~information~~ security measures in place. In addition, we do not have our own information technology department or personnel and rely on third- party ~~consultants and other service providers to establish and maintain our~~ information technology ~~infrastructure and systems~~ **consultants to assist our management in assessing** , **identifying and managing our cybersecurity risks. We do not control these third parties** and they may fail to perform as expected. Moreover, the shift to remote working arrangements and the prevalent use of mobile devices that access sensitive or confidential information increases the risk of data security breaches. Technology security systems and other security measures in employees' homes or other places they may work may not be as robust and more vulnerable to cybersecurity attacks. Any system failure, accident, security breach or data breach that causes interruptions in our own or in third- party collaborators' or service providers' operations could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive or confidential information **, or that of our employees, collaborators, service providers and participants in our clinical studies** . A security incident or other interruption could disrupt our ability (or that of third parties upon which we rely) to conduct our business operations and could divert significant resources to remedy or mitigate the damage caused. For example, if clinical or nonclinical study data is lost or becomes compromised, it could result in delays in our product development and regulatory approval efforts and significantly increase our costs due to additional time and resources necessary to recover and verify, or potentially reproduce, the data. In addition, a security breach or privacy violation that leads to disclosure of personally identifiable information or protected health information could require us to make notifications to the public as well as regulatory authorities, harm our reputation, subject us to audit, investigation, steep fines and administrative penalties and mandatory corrective action. A data breach could also require us to verify the correctness of database contents and subject us to litigation, including class action lawsuits, or other liability under laws and regulations that protect personal data, consumer protection and other laws. Further, our information technology and other internal infrastructure systems, including firewalls, servers, leased lines and connection to the internet, face the risk of systemic failure, which could disrupt our operations. If any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur resulting liability, our product development programs and competitive position may be adversely affected, the further development of our product candidates may be delayed, and the manufacture and sale of any approved products may be impaired. The costs related to significant security breaches or disruptions could be material, and, as was the case with the fraud discovered in March 2023, our insurance coverage may not cover all the losses arising from any such disruption in, or failure or security breach of, our systems or third- party systems where information important to our business operations and product development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Moreover, if the information technology systems of our third- party collaborators, service providers or vendors become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event. Our business may be adversely affected by **general** ~~unfavorable or unanticipated macroeconomic~~ conditions **in the global economy and financial markets** and geopolitical **tensions and** events. Various macroeconomic factors could adversely affect our business, our results of operations and financial condition, including a U. S. government shutdown, delay or failure of the U. S. government to raise the federal debt ceiling, an increased rate of inflation, rising interest rates, adverse developments affecting financial institutions or the financial services industry, recessionary concerns and overall unfavorable economic conditions and uncertainties, including those resulting from geopolitical events, including the wars in Ukraine and the Middle East and strained relations between the U. S. and a number of foreign countries; international economic sanctions, including those imposed on Russia **; new or increased tariffs and other barriers to trade** ; climate change concerns; or public health emergencies, including the COVID- 19 pandemic. U. S. government actions to reduce the federal deficit, or its delay or failure to raise the federal debt ceiling, may result in reduced funding for government- funded or subsidized health programs or require the federal government to stop or delay making payments on its obligations under such programs, which could impact sales of our products covered under such programs, if any, and negatively affect our operating results. Interest rates and the ability to access credit markets could adversely affect the ability of patients, payors and distributors to purchase, pay for and effectively distribute our products, if and when ~~approved~~ **commercially available** . Similarly, unfavorable or uncertain macroeconomic factors could affect the ability of our current or potential future collaborators, third- party service providers or suppliers, including sole source or single source manufacturers or suppliers, licensors or licensees to remain in business, or otherwise manufacture or supply our clinical trial material and products or commercialize our products, if and when approved. Failure by any of them to remain in business or allocate adequate resources to our products and product candidates could have a material adverse effect on our efforts to develop and obtain regulatory approvals for our product candidates and generate revenue from any approved products. We expect to continue to incur substantial costs and demands on management time to comply with laws and regulations affecting public companies. We incur and expect to continue to incur significant legal, accounting and other expenses as a public reporting company. We expect that these expenses will increase if and when we become an " accelerated filer, " as defined in rules adopted by the SEC under the Securities Exchange Act of 1934. Generally, we will become an accelerated filer if our public float as of the last business day of June is $ 75 million or more and we reported annual revenues of $ 100 million or more for our most recently completed fiscal year. Regardless of whether we become an accelerated filer, we may need to hire additional accounting, finance and other personnel in connection with our continuing efforts to comply with the corporate governance, disclosure and other reporting requirements of being a public company, and our management and other personnel, of whom we have a small number, will need to continue to devote substantial time towards compliance matters and initiatives. For example, pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, we must furnish a report annually by our management on the effectiveness of our internal control over financial reporting, and performing the system and process

documentation and evaluation necessary to issue that report requires us to incur substantial expense and expend significant management time. If and when we are an accelerated filer, we will also have to obtain an attestation report on our internal control over financial reporting by our independent registered public accounting firm, which may substantially increase compliance costs. Recent SEC rules and rulemaking initiatives, such as ~~the~~ **those** ~~new~~ **regarding** pay versus performance, **compensation clawback, and** cybersecurity ~~, and climate- related~~ disclosure requirements, may result in significant additional time and expense devoted to compliance initiatives. We are a smaller reporting company and a non- accelerated filer and the reduced disclosure requirements available to us may make our common stock less attractive to investors. The SEC established the smaller reporting company, or SRC, category of companies in 2008, and expanded it in 2018, in an effort to provide general regulatory relief for smaller companies. SRCs may choose to comply with scaled financial and non- financial disclosure requirements in their annual and quarterly reports and registration statements relative to non- SRCs. In addition, companies that are not " accelerated filers " can take advantage of additional regulatory relief. Whether a company is an accelerated filer or a SRC is determined on an annual basis. For so long as we qualify as a non- accelerated filer and / or an SRC, we will be permitted to and we intend to rely on some or all of the accommodations available to such companies. These accommodations include: • not being required to provide an auditor' s attestation of management' s assessment of internal control over financial reporting required by Section 404 (b) of the Sarbanes- Oxley Act of 2002; • reduced financial disclosure obligations, including that SRCs need only provide two years of financial statements rather than three years; a maximum of two years of acquiree financial statements are required rather than three years; fewer circumstances under which pro forma financial statements are required; and less stringent age of financial statements requirements; • reduced non- financial disclosure obligations, including regarding the description of their business, management' s discussion and analysis of financial condition and results of operations, market risk, executive compensation, **policies governing** transactions with related persons, and corporate governance; and • later deadlines for the filing of annual and quarterly reports compared to accelerated filers. We will continue to qualify as a SRC and non- accelerated filer for so long as (a) our public float is less than $ 75 million as of the last day of our most recently completed second fiscal quarter or (b) our public float is $ 75 million or more but less than $ 700 million and we reported annual revenues of less than $ 100 million for our most recently completed fiscal year. We may choose to take advantage of some, but not all, of the available accommodations. We cannot predict whether investors will find our common stock less attractive if we rely on these accommodations. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile. Our ability to use net operating loss carryforwards and other tax attributes to offset taxable income may be limited. We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all. At December 31, ~~2023~~ **2024** , we had substantial federal and state net operating loss, or NOL, carryforwards. However, our federal NOL carryforwards and other tax attributes may not be available to offset future taxable income because of restrictions under U. S. tax law, **including limitations due to ownership changes that occurred previously or that could occur in the future,** and similar limitations may apply under state tax laws. **In addition, under legislation enacted by California in 2024, generally, there is a suspension of the NOL deduction for tax years 2024 through 2026 for taxpayers with net business income or modified adjusted gross income of $ 1 million or more, and a limit of $ 5 million of business credits on the aggregate use of otherwise allowable business tax credits that any taxpayer could claim for tax years beginning 2024 through 2026. For these reasons, we may not be able to realize a tax benefit from the use of our NOL carryforwards and other tax attributes, even if we attain profitability.** We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets. See Note ~~7~~ **8** " Income Taxes " to the accompanying consolidated financial statements for more information about limitations on our ability to use our NOL carryforwards and other tax attributes. Such limitations could result in increased future..... Related to Ownership of Our Common Stock The price of our common stock may rise and fall rapidly, substantial price fluctuations may occur regardless of developments in our business or our operating performance, and you could lose all or part of your investment as a result. The stock market in general, and the market for biopharmaceutical companies in particular, have experienced significant volatility, which has often been unrelated to the operating performance of particular companies. The stocks of small cap and microcap biopharmaceutical companies like ours tend to be highly volatile. Our common stock has experienced extreme trading price and volume fluctuations in the past, including fluctuations that have been unrelated or disproportionate to developments in our business and our operating performance, and we expect that our stock price will continue to experience high volatility. The market price for our common stock may be influenced by a variety of factors, some of which are beyond our control or are related in complex ways, including: • significant developments with our product development programs, such as actual or anticipated changes to development and approval timelines, results from any clinical trial, unanticipated serious safety concerns, suspension or discontinuation of a program, initiation of **a** new ~~programs~~ **program** and communications or decisions from the FDA or other regulatory authorities relating to applications we submit for clinical trials or marketing approval of our ~~product candidates, in each case particularly those related to our clinical- stage~~ product candidates; • announcements of capital raising transactions, including sales of our common stock or securities convertible into or exercisable for shares of our common stock by us, or expectation of additional financing efforts; • the amount of our ~~unrestricted~~ cash; • the level of actual or anticipated expenses related to development of our product candidates, and in particular our clinical- stage development programs; • announcements relating to strategic collaborations or alliances or significant licenses, acquisitions or dispositions of assets **or capital commitments** by us or **our competitors or** companies perceived to be ~~comparable~~ **economically linked** to us; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies ~~; • announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital~~

~~commitments~~ ; • additions or departures of key management or scientific personnel; • significant developments with third- party products or product development programs perceived as competitive to ours, such as results of clinical trials, unanticipated serious safety concerns, suspension or discontinuation of a program, significant communications or decisions from the FDA or other regulatory authorities, introduction of new product candidates or new uses for existing products, commercial launch and product sales; • significant business disruptions, including as a result of cybersecurity incidents, geopolitical events, including military conflicts, war, terrorism or economic conflicts, or natural disasters such as earthquakes, typhoons, floods and fires or public health emergencies such as the COVID- 19 pandemic; • events or conditions that affect the financial markets or U. S. or global economy in general, including geopolitical conflicts, potential or actual U. S. government shutdown or failure to raise the federal debt ceiling, economic slowdown or recession, increased inflation, and rising interest rates; • regulatory or legal developments in the U. S. and other countries; • changes in the structure of health care payment systems; • developments or trends in the biopharmaceutical or women' s health care industries; • period to period fluctuations in our financial results; • recommendations or reports issued by securities research analysts; • increased selling by our stockholders, as well as the overall trading volume of our common stock; and • the other factors described in this ~~"~~ Risk Factors ~~"~~ section. In the past, following periods of volatility in companies' stock prices, securities class- action litigation has often been instituted against such companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management' s attention and resources, which could materially and adversely affect our business and financial condition. If we fail to regain and maintain compliance with the continued listing requirements of ~~the~~ **The** Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. Our common stock is listed on The Nasdaq Capital Market. **In August** ~~As previously reported, on July 19, 2023~~ **2024** , we received a letter from ~~the Listing Qualifications Department (the "~~ Nasdaq ~~Staff ") of the Nasdaq Stock Market (" Nasdaq ")~~ notifying us that ~~, for~~ **we do not meet** the ~~last 30 consecutive business days, the closing bid price for our common stock was below the minimum $ 1. 00 per share~~ requirement **in Nasdaq Listing Rule 5550 (b) (2)** for continued listing on The Nasdaq Capital Market **.** ~~as set forth in~~ Nasdaq Listing Rule 5550 (~~a~~ **b**) (2) ~~(~~ **requires a company listed on Nasdaq to maintain a minimum market value of listed securities of $ 35. 0 million, which we refer to as** the " Minimum ~~Bid Price Requirement~~ **MVLS Rule.** " ~~).~~ We were provided an initial period of 180 calendar days, or until ~~January 16~~ **February 10** , ~~2024~~ **2025** , to regain compliance with the Minimum **MVLS Rule** ~~Bid Price Requirement~~ . On ~~January 17~~ **February 13** , ~~2024~~ **2025** , ~~the~~ Nasdaq ~~Staff~~ **' s Listing Qualifications Department** notified us that because we ~~had~~ **did** not ~~timely regained~~ -- **regain** compliance with the Minimum ~~Bid Price Requirement~~ **MVLS Rule by February 10, 2025** , our common stock ~~was~~ **is** subject to delisting from ~~The~~ Nasdaq ~~Capital Market~~ unless we timely ~~requested~~ -- **request** a hearing before **the** Nasdaq ~~'~~ **s Hearings ~~-~~ Hearing** Panel (the " Panel ") ~~to appeal the Nasdaq Staff' s delisting determination~~ . We ~~submitted a timely request~~ **requested** ~~for~~ a hearing before the Panel, which **request** stayed the ~~suspension and~~ delisting of our common stock pending the decision of the Panel **following the hearing** and the expiration of any extension period **that may be** granted by the Panel. ~~On February 27~~ **The hearing was held on March 25** , ~~2024~~ **2025 . Pursuant to published Nasdaq guidance** , the Panel **typically issues decisions** ~~notified us that, based on its review of the written record, which included our commitment to effect a reverse stock split if necessary to regain compliance with~~ **within 30 days** ~~the Minimum Bid Price Requirement, it determined to grant us a temporary exception until July 15, 2024 (the " Exception Period ") to regain compliance with the Minimum Bid Price Requirement. The Panel granted the temporary exception subject to us obtaining board~~ of ~~directors and stockholder approval for and effecting~~ the **hearing** ~~reverse stock split on or before specified dates that would enable us to demonstrate compliance with the Minimum Bid Price Requirement by evidencing a closing bid price of $ 1~~ . ~~00 or more per share for a minimum of ten consecutive trading sessions on or before July 15, 2024. The Panel advised us that, during the Exception Period, we must provide Nasdaq with prompt notification of any significant events that may affect our compliance with Nasdaq listing requirements, including any event that may call into question our ability to meet the terms of the temporary exception. The Panel also advised us that should we fail to meet any of the terms of the temporary exception, our common stock will immediately be delisted. As of the date of this report, we have not regained compliance with the Minimum Bid Price Requirement. If we seek stockholder approval of a reverse stock split, there~~ **There** can be no assurance that ~~our stockholders~~ **the Panel** will **grant us any extension period within which** ~~approve it or, if approved and implemented, that we would be able~~ to regain compliance with the Minimum **MVLS Rule, or if** ~~Bid Price Requirement. There are many~~ - **any** ~~factors~~ **extension period is granted,** that ~~affect the trading price of our common stock, including those described in this " Risk Factors " section, and many of those factors are outside of our control. Even if~~ we ~~demonstrate~~ **will regain** compliance with the Minimum **MVLS Rule** ~~Bid Price Requirement~~ within ~~the Exception~~ **such extension** ~~Period~~ **period** , ~~a reverse stock split may not result in any sustained increase in the trading price of our~~ -- **or that** ~~common stock and, as a result, we may not be able to maintain compliance with the Minimum Bid Price Requirement longer term. There can be no assurance~~ we will be able to satisfy all other continued listing requirements of ~~the~~ **The** Nasdaq Capital Market and maintain the listing of our common stock on ~~the~~ **The** Nasdaq Capital Market even if we regain compliance with the Minimum **MVLS Rule** ~~Bid Price Requirement~~ . **For example, until we regained compliance on July 18, 2024, we were not in compliance with** ~~Other~~ -- **the** continued listing ~~requirements include that we satisfy the requirements of at least one of the continued listing standards~~ - **standard** commonly referred to as the ~~stockholders' equity~~ **minimum bid price** rule **since July 19** , ~~the market value of listed securities rule and the net income rule. The stockholders' equity rule requires that our stockholders' equity be at least $ 2. 5 million, the market value of listed securities rule requires that the market value of our common stock be at least $ 35 million, and the net income rule requires that we have net income from continuing operations of $ 500, 000 in our most recently completed fiscal year or in two of our three most recently completed fiscal years. Based on our stockholders' equity as of December 31~~ , 2023 ~~and our results of operations for our three most recently completed fiscal years, we do not satisfy the stockholders' equity rule or the net income rule. As of~~

~~March 27, 2024, we did satisfy the market value of listed securities rule~~ . The suspension or delisting of our common stock, for whatever reason, could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management' s time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the suspension or delisting of our common stock, for whatever reason, may materially impair our stockholders' ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. **The sale** ~~A reverse stock split could lead to a decrease in the overall market value~~ of our common stock ~~and adversely affect the liquidity of our common stock. A reverse stock split, if implemented, would reduce the number of outstanding shares of our common stock in proportion to the reverse split ratio and would have the immediate effect of proportionately increasing the per share price of our common stock. A reverse stock split is often viewed negatively by the market and, consequently, could lead to a decrease in our overall market value. If the per share trading price of our common stock does not increase in proportion to the reverse stock split ratio after the reverse stock split is implemented, then our overall market value (measured as the product of our outstanding shares of common stock and the per share trading price) will be less than before the reverse stock split. In some cases, the per share stock price of companies that have effected reverse stock splits subsequently declined back to pre- reverse stock split levels. Accordingly, if we implement a reverse stock split, there can be no assurance that our overall market value will remain the same after the reverse stock split, or that the reverse stock split would not have an adverse effect on the trading price of our common stock due to the reduced number of shares that would be outstanding after the reverse stock split. Liquidity for our stockholders could be adversely affected by the reduced number of shares outstanding after a reverse stock split. A reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for our common stock. In addition, a reverse stock split may result in some stockholders owning " odd lots " of less than 100 shares. Odd lot shares may be more difficult to sell, and brokerage commissions and other costs of transactions in odd lots are generally somewhat higher than the costs of transactions in " round lots " of even multiples of 100 shares. The sale of our common stock~~ in ATM offerings **or under our equity line arrangement** may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our common stock to decline. We have used at- the- market, or ATM, offerings to fund a significant portion of our operations in ~~recent~~ **prior** years, and we may continue to use ATM offerings to raise additional capital in the future. For example, in 2021, we sold an aggregate of approximately ~~36~~ **3** . ~~4~~ **0** million shares of our common stock in ATM offerings. We sold substantially fewer shares in ATM offerings in 2022 and 2023 **and to date in 2024** , however, we may sell significant amounts of shares in ATM offerings again in the future. **In addition, we may sell up to approximately $ 14. 5 million in shares of our common stock under our equity line arrangement. The purchase price for the shares we may sell under our equity line arrangement will vary based on the market price of our common stock at the time we initiate a sale.** While sales of shares of our common stock in ATM offerings **and under our equity line arrangement** may enable us to raise capital at a lower cost compared with other types of equity financing transactions; such sales may result in substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the trading price of our common stock to decline. The exercise of our outstanding warrants and options as well as the issuance of shares pursuant to future equity awards under our stock incentive plan may result in significant dilution to our stockholders. As of December 31, ~~2023~~ **2024** , we had outstanding warrants to purchase up to approximately ~~15~~ **1** . ~~0~~ **3** million shares of our common stock at a weighted average exercise price of $ ~~0~~ **7** . ~~63~~ **49** per share, outstanding options to purchase up to approximately **0.** 9 ~~. 5~~ million shares of our common stock at a weighted average exercise price of $ ~~1~~ **14** . ~~46~~ **58** per share **,** and approximately ~~6~~ **0** . ~~7~~ **5** million shares of our common stock remained available for future issuance under our stock incentive plan. The exercise of a significant portion of our outstanding warrants and options and the issuance of shares of our common stock pursuant to future equity awards under our stock incentive plan may result in significant dilution to our stockholders. Substantial future sales of our shares of common stock, or the perception that such sales could occur, may cause the price of our common stock to decline, even if our business is doing well. Sales of substantial amounts of our common stock in the public market, or the perception that such sales could occur, may adversely affect the trading price of our common stock, and may make it more difficult for existing stockholders to sell their shares of our common stock at a time and price they deem appropriate. We are unable to predict the effect that such sales may have on the trading price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity or equity- linked securities in the future at a time and at a price that we deem appropriate. Shares underlying outstanding warrants represent approximately **14** ~~15. 0~~ % of the outstanding shares of our common stock as of March ~~27~~ **28** , ~~2024~~ **2025** , and the underlying shares generally may be freely sold into the public market following exercise of the warrants by the warrant holders. In addition, ~~pursuant to~~ the ~~terms of the royalty interest financing agreement we entered into in December 2023, we may issue~~ **issuance of all of the approximately** ~~additional warrants to purchase up to an additional 7.~~ 0 ~~million shares of our common stock with an exercise price of $ 0~~ . ~~3467 per share. Further, the issuance of all of the approximately~~ 9 ~~. 5~~ million shares of our common stock underlying outstanding options and the approximately ~~6~~ **0** . ~~7~~ **5** million shares of our common stock that remained available for future issuance under our stock incentive plan as of December 31, ~~2023~~ **2024** have been registered under the Securities Act and such shares if, and when issued, can be freely sold in the public market, except to the extent they are held by an affiliate of ours, in which case such shares will become eligible for sale in the public market as permitted by Rule 144 under the Securities Act. Almost all of our outstanding warrants have exercise periods that extend into December 2028 or March 2029 and, as of December 31, ~~2023~~ **2024** , our outstanding options had a weighted average remaining contractual exercise period of approximately **6.** 7 ~~. 5~~ years. Accordingly, the potential adverse market and price pressures resulting from

these sales, or the perception that such sales could occur, may continue for an extended period of time and continued negative pressure on the trading price of our common stock could have a material adverse effect on our ability to raise additional capital through equity or equity- linked financings **. In addition, our Restated Certificate of Incorporation, as amended, authorizes us to issue up to 240. 0 million shares of our common stock. Subject to limitations imposed by Nasdaq or such other securities exchange on which our securities may be listed, authorized shares of our common stock that are not issued and outstanding or reserved for issuance may be issued without stockholder approval at any time, in the sole discretion of our board of directors, and as of December 31, 2024, only approximately 8. 7 million shares were issued and outstanding or reserved for issuance** . If, in the future, we issue additional shares of common stock, warrants or other equity or equity- linked securities in one or more transactions, at prices and in a manner we determine from time to time, in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise, any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline. We may issue preferred stock with terms that could dilute the voting power or reduce the value of our common stock. Our **Restated** ~~certificate~~ **Certificate** of ~~incorporation~~ **Incorporation , as amended,** authorizes us to issue, without stockholder approval, one or more series of preferred stock having such designation, powers, privileges, preferences, including preferences over our common stock respecting dividends and distributions, terms of redemption and relative participation, optional, or other rights, if any, of the shares of each such series of preferred stock and any qualifications, limitations or restrictions thereof, as our board of directors may determine. The terms of one or more series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future; capital appreciation, if any, will be your sole source of gain as a holder of our shares. We have never declared or paid cash dividends on any shares of our capital stock. We currently plan to retain all of our future earnings, if any, and all cash received from the sale of securities, the sale of assets or a strategic transaction to finance the growth and development of our business. Accordingly, capital appreciation, if any, of our common stock will be the sole source of gain for our common stockholders for the foreseeable future. Provisions in our certificate of incorporation, our by- laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock. Provisions in our Restated Certificate of Incorporation, as amended, our Third Amended and Restated By- Laws or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that our stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions might frustrate or prevent any attempts by our stockholders to replace or remove the current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: • establish a classified board of directors such that all members of the board are not elected at one time; • allow the authorized number of directors to be changed only by resolution of the board of directors; • limit the manner in which stockholders can remove directors from the board; • establish advance notice requirements for nominations for election to the board or for proposing matters that can be acted on at stockholder meetings; • require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by stockholders by written consent; • limit who may call a special meeting of stockholders; • authorize the board to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the board; and • require the approval of the holders of at least 75 % of the votes that all stockholders would be entitled to cast in any annual election of directors or class of directors to amend or repeal our by- laws or certain provisions of our charter. In addition, we are governed by Section 203 of the Delaware General Corporate Law, which prohibits a publicly- held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15 % of its voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring or merging with us, whether or not it is desired by, or beneficial to, our stockholders. Provisions in our by- laws could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our Third Amended and Restated By- Laws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders; provided that, the exclusive forum provision will not apply to actions or suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. If any action that is required under our by- laws to be brought against us in Delaware is filed by a stockholder in a court other than a court located within Delaware, the stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within Delaware in connection with any action brought in any such court to enforce our Delaware forum selection provision and (ii) having service of process made upon the stockholder in any such enforcement action by service upon that stockholder' s counsel, as agent for the stockholder. In addition, our by- laws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and to have consented to these provisions. Under the Securities Act, federal and state courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act. We believe the forum selection

provisions in our by- laws may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, these provisions may have the effect of discouraging lawsuits against us and / or our directors, officers and employees as it may limit any stockholder' s ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers or employees. The enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a future court could find the choice of forum provisions contained in our by- laws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our by- laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations. If we fail to attract or maintain securities analysts to publish research on our business or if they publish or convey negative evaluations of our business, the price of our stock could decline. The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our common stock could decline. As of the date of this report, to our knowledge, five analysts cover our company. If one or more of these analysts cease coverage or fail to regularly publish reports on our business, we could lose visibility in the financial markets, which in turn could cause our common stock price or trading volume to decline.