Risk Factors Comparison 2024-03-29 to 2023-04-07 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, together with all of the information included in this ~~2022~~ **2023** 10- K Report and our other filings with the SEC, before you decide to purchase shares of our common stock. We believe the risks and uncertainties described below are the most significant we face. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition, or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Our business is subject to a number of risks and uncertainties. The following is a summary of the principal risk factors described in this section: ● We currently derive all of our revenues from royalties related to sales of our products, and the failure of our licensees to maintain or increase sales of these products could have an adverse effect on our business, financial condition, results of operations, and growth prospects. ● We have incurred net losses in the past and there are no assurances we will be able to maintain or increase profitability in the future. ● There is substantial doubt about our ability to continue as a going concern. ● We could be affected by transitions in our senior management team. ● The dependence upon third parties for the manufacture and supply of our women' s healthcare products may cause delays in, or prevent our licensees from, successfully commercializing and marketing our products. ● The commercial success of our products will depend upon gaining and retaining significant market acceptance of these products among physicians and payers. ● Coverage and reimbursement may not be available for our products, which could make it difficult for our licensees to sell our products profitably. ● Time and costs associated with winding down our general and administrative, commercial, and research and development activities may be significant. ● ~~• Our future success depends on our ability to attract and retain qualified personnel. • Our financial condition and results of operations for 2021 and 2022 were, and our financial condition and results of operations for 2023 and beyond may be, adversely affected by the ongoing COVID- 19 (coronavirus) pandemic and any future pandemics or epidemics. •~~ Licensing of intellectual property involves complex legal, business and scientific issues, and disputes could jeopardize our rights under such agreements. ● Our products and our licensees are subject to extensive government regulation. ● We must rely on Mayne Pharma to prosecute, file lawsuits **,** or take other actions to protect or enforce our intellectual property and there can be no assurance they will ~~be~~ take such actions or be successful. ● If ~~our~~ efforts to protect the proprietary nature of the intellectual property covering our hormone therapy pharmaceutical products and other products are not adequate, ~~we~~ **our licensees** may not be able to compete effectively in ~~our~~ **the** market **, which would adversely affect our royalties** . ● Our products face significant competition from branded and generic products, and our operating results will suffer if ~~we~~ **our products** fail to compete effectively. ● Our success is tied to the distribution channels of our licensees. ● Any failure of our licensees to adequately maintain a sales force **or effectively implement sales strategies** will impede our growth. ● **Our future success depends on our ability to attract and retain qualified personnel.** ● Our failure to maintain compliance with Nasdaq' s continued listing requirements could result in the delisting of our common stock. Risks related to our business We currently derive all revenue from royalties related to sales of our **licensed** women' s healthcare products, and the failure of our licensees to maintain or increase sales of these products could have an adverse effect on our business, financial condition, results of operations, and growth prospects. Following the Mayne Transaction, we derive all revenue from royalties related to sales of our women' s healthcare products, including patient- controlled, long- acting contraceptive, hormone therapy pharmaceutical products, prenatal and women' s multi- vitamins, and iron supplements. We cannot assure you that our licensees will be able to sustain such sales or that such sales will grow. In addition to other risks described herein, the ability of our licensees to maintain or increase existing product sales is subject to several risks and uncertainties, including the following: ● the presence of new or existing competing products, including non- authorized generic copies of our products; ● supply or distribution problems arising with any of their manufacturing and distribution partners; ● changed or increased regulatory restrictions or regulatory actions by the FDA; ● changes in healthcare laws and policy, including changes in requirements for drug pricing, rebates, reimbursement, and coverage by federal healthcare programs and commercial payers; ● the impact or efficacy of any price increases our licensees may implement in the future; ● changes to the licensed products' labels and labeling, including new safety warnings or changes to boxed warnings, that further restrict how our licensees market and sell our products; and ● acceptance of our products as safe and effective by physicians and patients. If revenue from royalties related to sales of our products does not increase, we may be required to seek to raise additional funds, which could have an adverse effect on our business, financial condition, results of operations, and growth prospects. In ~~2022~~ **addition** , **our revenue from royalties is based on information compiled by, and received from, our licensees. If the sales information provided by our licensees is erroneous, it could have an adverse effect on our business, financial condition and results of operations. We have incurred net losses in the past and there are no assurances** we **will be able** ~~recognized a net income of $ 112. 0 million due~~ to **maintain** ~~the net proceeds from the Mayne Pharma Transaction and vitaCare divestiture exceeding our~~ **or increase profitability in the future** ~~costs and expenses. We utilized a significant portion of net proceeds to repay borrowings and redeem our preferred stock~~ . In the past, we have incurred recurring net losses, including net losses of $ **10. 3 million and $** 172. 4 million **for 2023** and **2021, respectively. In 2022, we recognized net income of** $ ~~183~~ **112** . ~~5~~ **0** million ~~for 2021~~ **due to the net proceeds from the Mayne Transaction** and ~~2020, respectively~~ **vitaCare divestiture exceeding our costs and expenses. We utilized most of the net proceeds to repay borrowings and redeem our preferred stock** . As of December 31, ~~2022~~ **2023** , our stockholders' equity was $ ~~35~~ **29** . ~~1~~ **3** million. We have funded our operations to date primarily from public and private

sales of equity and private sales of debt securities. We may incur substantial additional losses over the next few years because of costs associated with the **winddown** ~~wind down~~ of our historical business as well as the ongoing costs of being a public company. As a result, we may not maintain or increase profitability. If we continue to incur substantial losses **, because the royalties of our products are insufficient or otherwise,** and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us. **There is substantial doubt about our ability to continue as a going concern.** Our current liquidity position raises substantial doubt about our ability to continue as a going concern and **Berkowitz Pollack** ~~Grant~~ **Brant** ~~Thornton LLP~~ **, Advisors CPAs** , our independent registered public accounting firm for the fiscal year ended December 31, ~~2022~~ **2023** , has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, ~~2022~~ **2023** , indicating such **. If Mayne Pharma' s sales of IMVEXXY, BIJUVA, or ANNOVERA grow more slowly than expected or decline, if the net working capital settlement with Mayne Pharma under the Transaction Agreement is greater than our current estimates, if we are unsuccessful with future financings or if the supply chains related to the third- party contract manufacturers are worse than we anticipate, our existing cash reserves may be insufficient to satisfy our liquidity requirements** . Our ability to continue as a going concern may depend on our ability to obtain additional capital as well as our ability to minimize operational expenses, including any potential net working capital adjustments relating to the Mayne Transaction. As substantial doubt about our ability to continue as a going concern exists, our ability to finance our operations through the sale and issuance of debt or equity securities or through bank or other financing could be impaired. Our ability to obtain financing on reasonable terms is subject to factors beyond the Company' s control, including general economic, political, and financial market conditions. The capital markets have in the past experienced, are currently experiencing, and may in the future experience, periods of upheaval that could impact the availability and cost of equity and debt financing and there can be no assurance that such financing will be available on terms commercially acceptable to the Company, or at all. If we **sell equity securities, convertible securities or other securities current investors may be materially diluted by subsequent sales. If we** are unable to improve our liquidity position, we may not be able to continue as a going concern. We have experienced significant turnover in our top executives, and our business could be adversely affected by these and other transitions in our senior management team. We have experienced turnover in our top executives and the replacement of these positions with new officers. In December 2022, following the Mayne Transaction, all ~~of~~ our top executives, except for our former General Counsel, were terminated, and our former General Counsel was appointed as Chief Executive Officer. Management transition is often difficult and inherently causes some loss of institutional knowledge, which could negatively affect ~~our~~ **the** results of operations and financial condition. Our ability to execute our business strategies may be adversely affected by the uncertainty associated with these transitions and the time and attention of the board and management dedicated to management transitions could disrupt our business. Further, we cannot guarantee that we will not face similar turnover in the future. Although we generally enter into employment agreements with our executives, our executive officers may terminate their employment relationship with us at any time, and we cannot ensure that we will be able to retain the services of any of them. Our senior management' s knowledge of our business and industry could be difficult to replace, and management turnover could negatively affect our business, growth, financial conditions, results of operations and cash flows. Our dependence upon third parties for the manufacture and supply of our existing women' s healthcare products may cause delays in ~~,~~ or prevent our licensees from ~~,~~ successfully commercializing and marketing our products. We do not currently have, nor do we currently plan to build or acquire, the infrastructure or capability to internally manufacture our existing women' s healthcare products, IMVEXXY, BIJUVA, and ANNOVERA. We have relied, and will continue to rely, on third parties to manufacture these products in accordance with specifications and in compliance with applicable regulatory requirements, including the FDA' s current Good Manufacturing Practice (" cGMPs "). We entered into long- term supply agreements with Catalent Pharma Solutions, LLC for the commercial supply of IMVEXXY and BIJUVA which have been assigned to Mayne Pharma. We also entered into a long- term supply contract with QPharma AB, now known as Sever Pharma Solutions, for ANNOVERA, which contract was also assigned to Mayne Pharma. We depended on Lang, a full- service, private label and corporate brand manufacturer, to supply our vitaMedMD and BocaGreen products. We do not have long- term contracts for the commercial supply of our vitaMedMD and BocaGreen products **. We believe that our licensees evolved these relationships based on the products they licensed from us. We continue to provide support for the third party manufacturers and our licensees as needed** . Regulatory requirements could pose barriers to the manufacture of our women' s healthcare products. All of our existing products are manufactured by third- party contract manufacturing organizations (" CMOs "). These CMOs are required to manufacture our products in compliance with the applicable regulatory requirements. The CMO that manufactures IMVEXXY and BIJUVA has previously been inspected by the FDA and received Form 483 observations with respect to its softgel manufacturing plant that is used for the manufacture of the commercial supply of IMVEXXY and BIJUVA. The CMO that manufactures ANNOVERA has previously been inspected by the FDA and received Form 483 observations with respect to its facility that is used for the commercial supply of ANNOVERA. We believe that corrective actions to address the compliance issues identified in the referenced Forms 483 have been implemented by the CMOs **and that** ~~; however, the FDA has not yet reinspected~~ the CMOs **continue** to **have** ~~confirm that~~ the **right** ~~corrective actions were implemented as described~~ to **manufacture under current regulations** ~~the agency in the respective Form 483 responses~~ . If the manufacturers of our ~~product~~ **products** cannot successfully manufacture material that conforms to specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, regulatory submissions related to our products may be delayed or disapproved, and our marketed products may be affected. If these facilities are not in compliance for the manufacture of our products, our licensees may need to find alternative manufacturing facilities, which would result in substantial disruptions of sales of our products. In addition, manufacturers of our products will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for

compliance with cGMPs and similar regulatory requirements ~~. After generally suspending in- person inspections due to COVID- 19, the FDA announced it would resume domestic facility inspections, although the agency continues its general suspension of foreign facility inspections (although " mission- critical " inspections may be considered on a case- by- case basis). Because of the global pandemic, decision- making around facility inspections by the FDA (including preapproval inspections) continues to evolve~~ . Failure by any of the manufacturers of our products to comply with applicable cGMP regulations or other applicable requirements could result in sanctions being imposed on us or our licensees, including fines, injunctions, civil penalties, violation letters, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts, and criminal prosecutions, any of which could have an adverse impact on our business, financial condition, results of operations, and prospects. Our licensees may **seek** ~~be able~~ to enter into long- term agreements with alternative manufacturers ~~, or do so~~ on commercially reasonable terms, and if they do enter into agreements with alternative manufacturers, those alternative manufacturers may not be approved by the FDA **or subsequently lose FDA approval to manufacture our drugs** , any of which could have an adverse impact on our business. We also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products to the delay or other detriment of our products, or otherwise do not satisfactorily perform according to the terms of their agreements ~~. Finally, we could experience manufacturing delays or interruptions because of the ongoing COVID- 19 pandemic~~ . We have also experienced a greater than expected amount of raw materials for ANNOVERA being out of specification. If any of the third- party CMOs of our products or any suppliers of raw materials or API experience further difficulties, do not comply with the terms of their agreements, or do not devote sufficient time, energy, and care to providing our manufacturing needs, or if any manufacturing specification modifications that we or Mayne Pharma have requested are not approved by the FDA, we could experience additional interruptions in the supply of our products, which may have a material adverse impact on our revenue, results of operations **,** and financial position. Our licensees also do not have long- term contracts for the supply of all the API used in BIJUVA, and ANNOVERA. If any supplier of the API or other products used in our products experiences any significant difficulties in its respective manufacturing processes, **chooses to cease supplying** ~~does not comply with the terms of their agreement between~~ , or does not devote sufficient time, energy, and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our products, which could impair our licensee' s ability to supply our products at the levels required for commercialization and prevent or delay their successful commercialization. The commercial success of our existing products will depend upon gaining and retaining significant market acceptance of these products among physicians and payers. Physicians may not prescribe our products, which would prevent us from generating revenue or becoming profitable. Market acceptance of our products, including our hormone therapy pharmaceutical products and patient- controlled, long- acting contraceptive, by physicians, patients, and payers, will depend on a number of factors, many of which are beyond our control, including the following: ~~•~~ ● the clinical indications for which our hormone therapy pharmaceutical products and patient- controlled, long- acting contraceptive are approved; ~~•~~ ● acceptance by physicians and payers of each product as a safe and effective treatment; ~~•~~ ● the cost of treatment in relation to alternative treatments, including numerous generic pharmaceutical products; ~~•~~ ● the relative convenience and ease of administration of our products in the treatment of the symptoms for which they are intended; ~~•~~ ● the availability and efficacy of competitive drugs and devices; ~~•~~ ● the effectiveness of our licensee' s sales force and marketing efforts; ~~•~~ ● the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations, including any access barriers such as prior authorizations and step- edits; ● ~~• the potential inclusion of a new category for one- year multi- cycle hormonal birth control methods in the FDA Birth Control Guide, which payers may rely upon as guidance for coverage; •~~ the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other healthcare payers, or by government healthcare programs, including Medicare and Medicaid; ~~•~~ ● limitations or warnings contained in a product' s FDA- approved labeling; and ~~•~~ ● prevalence and severity of adverse side effects. Even if the medical community accepts that our products are safe and effective for their approved indications, physicians may not immediately be receptive to their use or may be slow to adopt our products as an accepted treatment for the symptoms for which they are intended. Labeling approved by the FDA may not permit our licensees to promote our products as being superior to competing products, because the FDA applies a heightened level of scrutiny to comparative claims when applying its statutory standards for advertising and promotion, including with regard to its requirements for supporting data and that promotional labeling be truthful and not misleading, and there is potential for differing interpretations of whether certain communications are consistent with a product' s FDA- required labeling. If our products do not achieve an adequate level of acceptance by physicians and payers, we may not generate sufficient or any revenue from royalties related to sales of these products. In addition, the efforts of our licensees to educate the medical community and third- party payers on the benefits of our products may require significant resources and may never be successful. **Coverage and reimbursement may not be available for our products, which could make it difficult for our licensees to sell our products profitably.** Market acceptance and sales of our products, including IMVEXXY, BIJUVA, and ANNOVERA, and our prescription vitamins, will depend on coverage and reimbursement policies and may be affected by healthcare reform measures. Government healthcare programs and third- party payers decide which prescription pharmaceutical products they will pay for and establish reimbursement levels. Payers generally do not cover OTC products, and coverage for prescription vitamins and dietary supplements varies. Many private third- party payers, such as managed care plans, manage access to pharmaceutical products' coverage partly to control costs to their plans, and may use drug formularies and medical policies to limit their exposure. Factors considered by these payers include product efficacy, cost effectiveness, and safety, as well as the availability of other treatments including generic prescription drugs. The ability to commercialize IMVEXXY, BIJUVA, and ANNOVERA successfully depends on coverage and reimbursement levels set by government healthcare programs and third- party private payers. Obtaining and maintaining favorable reimbursement can be a time- consuming and expensive process, and our licensees may not be able to negotiate or continue to negotiate reimbursement or pricing terms for our products with payers at levels that are

profitable to them, or at all. In both the U. S. and some foreign jurisdictions, there have been several legislative and regulatory proposals to change the healthcare system in ways that could affect our licensees' ability to sell our products profitably. Payment or reimbursement of prescription drugs by Medicaid or Medicare requires manufacturers of the drugs to submit pricing information to CMS. The Medicaid Drug Rebate statute requires manufacturers to calculate and report price points, which are used to determine Medicaid rebate payments shared between the states and the federal government and Medicaid payment rates for the drug. For drugs paid under Medicare Part B, manufacturers must also calculate and report their Average Sales Price (" ASP "), which is used to determine the Medicare Part B payment rate for the drug. The federal government sets general guidelines for Medicaid and requires rebates on outpatient drugs. Each state creates specific regulations that govern its individual program, including supplemental rebate programs that prioritize coverage for drugs on the state Preferred Drug List. In the United States, private health insurers and other third- party ~~payors~~ **payers** often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services. In addition, government programs like Medicaid include substantial penalties for increasing commercial prices over the rate of inflation which can affect realization and return on investment. The cost of pharmaceuticals continues to generate substantial governmental and third- party ~~payor~~ **payer** interest and states have begun to take action to increase transparency in drug pricing through mandatory reporting requirements. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations, and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms. While we cannot predict whether any proposed cost- containment measures will be adopted or otherwise implemented in the future, any such cost- reduction initiatives could decrease the coverage and price that our licensees receive for our products from Medicare, if any, including IMVEXXY, BIJUVA, and ANNOVERA, and could significantly harm our business. It was historically unclear whether products approved to treat moderate- to- severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause, such as IMVEXXY, were excluded under Medicare Part D, which resulted in limited Medicare coverage for such products. A clarification issued by CMS in May 2018 indicated that drugs, such as IMVEXXY, that are approved for the treatment of moderate- to- severe dyspareunia (as well as drugs approved for the treatment of moderate- to- severe symptoms of vulvar and vaginal atrophy associated with menopause) are not excluded from Medicare Part D coverage. CMS' s clarification, however, is no guarantee that such coverage will be obtained or maintained for IMVEXXY and obtaining Medicare or other government healthcare program reimbursement for any new pharmaceutical products may take up to several years following FDA approval. The ability of our licensees to commercialize ANNOVERA depends on coverage and reimbursement levels set by government healthcare programs and third- party private payers. **Despite our licensees** ~~The ACA mandates that private health plans provide~~ coverage ~~for women' s preventative services, without imposing patient cost- sharing requirements, as recommended by HRSA. HRSA Guidelines require private health plans to cover,~~ with **commercial payers** ~~no patient out- of- pocket costs, at least one form of treatment (e. g., one product) in each of the methods (e. g., classes of contraception) identified by the FDA for women in its Birth Control Guide. To the extent ANNOVERA is deemed a new class of contraception by the FDA, such a designation could allow for coverage by private health plans with no patient out- of- pocket costs. However~~ , there is no guarantee that ~~such coverage will be obtained, and it is possible that other FDA- approved products could also be included in this new class. For instance, the FDA may find that ANNOVERA fits into the vaginal contraceptive ring class, which it would share with NuvaRing and its generic equivalents, and potentially others. Pursuant to HRSA Guidelines, private payers need only provide no- cost coverage for one product in each class and may use reasonable medical management to determine whether and to what extent to cover other products in the class. Private payers may interpret the statute and its associated rules in ways in which they decline to cover ANNOVERA, even if we believe ANNOVERA should be covered without cost sharing under the ACA framework. To the extent ANNOVERA is not the only FDA- approved product in a designated class of contraception, private payers may choose not to cover our one- year vaginal contraceptive system or may require patient cost- sharing obligations. Some states have amended and expanded requirements to match the standard set in the ACA mandate, specifically requiring coverage for the full range of contraceptive methods, counseling and services used by women and eliminating out- of- pocket costs and limiting other health plan restrictions. The prior administration implemented policies that permit certain employers to claim a religious or moral objection to the birth control coverage mandate under the ACA. In July 2020, the Supreme Court held in Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania, et. al. that health plans sponsored by certain exempt religious employers and non- profit religious organizations that certify they have religious objections do not need to offer contraception coverage through their health benefit plans. This exemption could be overturned by the Biden administration through an Executive Order or other policy or regulatory action. Further, despite our progress with commercial payers, there is no guarantee that~~ our licensees will be able to retain ~~our~~ **ours or their** agreements or obtain new agreements **,** or that they will be able to negotiate favorable reimbursement or pricing terms for our products in the future. Healthcare reform implementation, additional legislation or regulations, and other changes in government policy or regulation may affect our licensees' reimbursement or impose additional coverage limitations and / or cost- sharing obligations on patients, any of which could have an adverse effect on coverage and reimbursement of our products, and our business, financial condition, results of operations, and prospects could be harmed. We expect that our licensees will experience pricing pressures in connection with the sale of our products generally due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, the scrutiny of pharmaceutical pricing, the ongoing debates on reducing government spending and additional legislative proposals. We cannot predict whether new proposals will be made or adopted, when they may be adopted, or what impact they may have on us if they are adopted. The availability of generic products at lower prices than branded products may substantially reduce the likelihood of reimbursement for branded products, such as IMVEXXY, BIJUVA, and ANNOVERA. If our licensees fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, they could have difficulty achieving market acceptance

of our products and our business, financial condition, results of operations, and prospects could be harmed. **Time and costs associated with winding down our general and administrative, commercial, and research and development activities may be significant.** There are significant costs associated with winding down our normal historic operations, such as separation of employees, termination of contracts and engagement of external consultants, all of which have and ~~may~~ in the future **will** reduce our cash resources and take up large portions of our employees' and consultants' time. We have **received certain invoices related to our historic operations that we are currently disputing. Our accruals related to such invoices reflect the amount we believe we will be responsible for based** ~~one~~ **on** ~~employee and use~~ **the current information we have. Any litigation related to such disputes or to the winding down of our operations, as well as any unforeseen liabilities related to the same, could have** a ~~limited number~~ **material impact on our business, growth, financial conditions, results** of ~~external consultants for the operation~~ **operations** ~~of~~ **and cash flows. There is no guarantee that** our **cash and cash equivalents on hand** ~~company, any of whom may terminate their consultancy with us~~ at any **given** time **will** ~~. We may not~~ be ~~able~~ **enough** to **cover** ~~attract and retain consultants on acceptable terms given the competition for similar personnel. Some of our consultants and advisors may be employed by employers other than us and may have commitments under consulting or~~ **our** ~~advisory contracts~~ **liabilities associated** with **winding down** ~~other entities that may limit their availability to us. We do not maintain " key person " insurance. If we are unable to continue to use our current consultants, or~~ **our historic** ~~if we are unable to recruit new consultants, then our ability to operate our business will be negatively impacted and it could interfere with our ability to receive any potential royalties. Our financial condition and results of~~ operations for 2021 and 2022 were, and..... the near- term and beyond 2023 . Unfavorable global economic conditions could harm our business, financial condition or results of operations. Our results of operations could be harmed by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, including the impact of increased interest rates and inflation ~~(such as the recent rise in inflation in the United States)~~ , could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. The foregoing could harm our business and we cannot anticipate all ~~of~~ the ways in which unfavorable economic conditions and financial market conditions could harm our business ~~our products~~ .Licensing of intellectual property involves complex legal,business,and scientific issues,and disputes could jeopardize our rights under such agreements.We are currently and may in the future be a party to license agreements of importance to our business and to our products.Disputes may arise between us and any of these counterparties regarding intellectual property subject to and each parties' obligations under such agreements,including: ~~•~~ ● the scope of rights granted under the agreement and other interpretation- related issues; ~~•~~ ● our or our licensees' obligations to make milestone,royalty,or other payments under those agreements **,or the amount of any such payments** ; ~~•~~ ● our or our licensees' obligations to prosecute existing and new patent applications; ~~•~~ ● our or our licensees' obligations to enforce infringement of our intellectual property; ~~•~~ ● whether and the extent to which the ANNOVERA technology and processes infringe on intellectual property of the Population Council that is not subject to the ANNOVERA license agreement; ~~•~~ ● the ownership of inventions and know- how arising under the agreement or resulting from the joint creation or use of intellectual property by our licensees and us and our partners; ~~•~~ ● our right,or the right of our licensees,to transfer or assign the license;and ~~•~~ ● the effects of termination.These or other disputes over our obligations,our licensees' obligations,or intellectual property that we have licensed may prevent or impair our ability to maintain our current arrangements on acceptable terms,or may impair the value of the arrangement to us.Any such dispute could have an adverse effect on our business ~~.If we,or,with respect to the ANNOVERA license agreement that we have assigned to Mayne Pharma,Mayne Pharma,fail to meet obligations under that license agreement in a material respect,the respective licensor could have the right to terminate the respective agreement and upon the effective date of such termination,have the right to re- obtain the related technology as well as,potentially,aspects of any intellectual property controlled by us or Mayne Pharma and developed during the period the agreement was in force that relate to the applicable technology.This means that the licensor to each of these agreements could effectively take control of the development and commercialization of the applicable product after an uncured,material breach of the agreement by us.Any uncured,material breach under a license agreement could result in our loss of exclusive rights and may lead to a complete termination of any commercialization efforts for the applicable product~~ .In July 2018,we entered into the Population Council License Agreement to obtain exclusive U.S.rights to commercialize ANNOVERA.The agreement required us to commercialize this product and enter into certain manufacturing agreements,make timely milestone and other payments,provide certain information regarding our activities under the agreement,and indemnify the other party with respect to our development and commercialization activities under the terms of the agreements.The Company' s license under the Population Council License Agreement was sold to Mayne Pharma as part of the Mayne Transaction **.If Mayne Pharma,with respect to the ANNOVERA license agreement that we have assigned to Mayne Pharma,fails to meet obligations under that license agreement in a material respect,the Population Council could have the right to terminate the agreement and upon the effective date of such termination,have the right to re- obtain the related technology as well as,potentially,aspects of any intellectual property controlled by Mayne Pharma and developed during the period the agreement was in force that relate to the applicable technology.This means that Population Council could effectively take control of the development and commercialization of ANNOVERA after an uncured,material breach of the agreement by us or Mayne Pharma.Any uncured,material breach under a license agreement could result in our loss of exclusive rights and may lead to a complete termination of any commercialization efforts for the applicable product** .In connection with the Mayne Transaction,we granted a license to Mayne Pharma (i) to research,develop,register,manufacture,have manufactured,market,sell,use,and commercialize the Licensed Products in the United States and its possessions and territories and (ii) to manufacture,have manufactured,import and have imported the Licensed Products outside the United States for commercialization in the United States and its possessions and territories.Any disputes arising under the agreements governing the Mayne Transaction may have a material adverse impact on our revenue,results of operations and financial position.We have also entered into licensing and supply agreements with Knight pursuant to which we granted Knight an exclusive license to

commercialize IMVEXXY and BIJUVA in Canada and Israel and with Theramex pursuant to which we granted Theramex an exclusive license to commercialize BIJUVA,and IMVEXXY outside of the U.S.,except for Canada and Israel.Sales of our products in the U.S.and our rights to receive royalties with respect to such sales could be adversely affected if products manufactured outside of the U.S.or for sale outside of the U.S.under the terms of these licensing and supply agreements are reimported and sold in the U.S.In addition,our rights to receive royalties with respect to our products sold outside the U.S.could be adversely affected if our licensees fail to diligently pursue approval of our products,or opt not to sell our products,in certain jurisdictions where they are **not required to do so** . We maintain our cash at financial institutions, often in balances that exceed federally insured limits. The majority of our cash is held in accounts at U. S. banking institutions that we believe are of high quality. Cash held in depository accounts may exceed the $ 250, 000 Federal Deposit Insurance Corporation (" FDIC ") insurance limits. If such banking institutions were to fail, such as Silicon Valley Bank when the FDIC took control in March 2023, we could lose all or a portion of those amounts held in excess of such insurance limitations. In the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. Any material loss that we may experience in the future could have a material adverse effect on our financial condition and could materially impact our ability to pay our operational expenses or make other payments. Our products and our licensees are subject to extensive and costly government regulation. Our products are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services (" CMS "), other divisions of the U. S. Department of Health and Human Services, including its Office of Inspector General (" OIG "), the U. S. Department of Justice (" DOJ "), the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments, and their respective foreign equivalents. The FDA regulates dietary supplements, cosmetics, and drugs under different regulatory schemes. For example, the FDA regulates the processing, formulation, safety, manufacturing, packaging, labeling, and distribution of dietary supplements and cosmetics under its dietary supplement and cosmetic authority, respectively. The FDA also regulates the research, development, pre- clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products under various regulatory provisions. If any of our products are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U. S. regulation. We and our licensees are also subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct our business. Applicable federal and state healthcare laws and regulations include the following: ~~•~~ ● The federal Anti- Kickback Statute (" AKS ") ● ~~is a criminal statute that prohibits anyone from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of, or arrangement for the referral of, an individual for, or the purchase, lease, order, or recommendation of, any good or service reimbursable, in whole or in part, by government healthcare programs, such as Medicare, Medicaid, TRICARE, and the State Children' s Health Insurance Program. This statute has been interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. The term " remuneration " has been broadly interpreted to include anything of value, including, for example, kickbacks, bribes, gifts, discounts, rebates, waivers of payment, ownership interest and providing anything at less than its fair market value. There are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution under the AKS, however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The safe harbors are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. The failure to meet the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case- by- case basis based on a cumulative review of all its facts and circumstances. Our practices may not meet the criteria for safe harbor protection from AKS liability in all cases. Liability under the AKS may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, federal law provides that claims for items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (" FCA "), described below. Violations of the AKS carry potentially significant civil, criminal, and administrative penalties, including imprisonment, fines, civil monetary penalties, and exclusion from participation in government healthcare programs. The compliance and enforcement landscape, and related risk, is informed by government precedent, Advisory Opinions, and OIG Special Fraud Alerts. For example, on November 16, 2020, the OIG published a Special Fraud Alert addressing manufacturer speaker programs, signaling that such programs will be subject to an even higher degree of government scrutiny under the AKS. • The FCA prohibits entities and individuals from knowing and willfully (or with reckless disregard or deliberate ignorance) presenting or causing to be presented false or fraudulent claims or the making of false statements material to a claim for payment by Medicare, Medicaid, and other government healthcare programs, or improperly retaining known overpayments from government healthcare programs; oViolations of the FCA carry penalties of up to three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim. Suits filed under the federal FCA can be brought directly by the government or be brought by an individual (known as a " relator " or, more commonly, as a " whistleblower ") on behalf of the government, known as " qui tam " actions. Relators bringing qui tam actions under the FCA receive a share of any amounts paid by the entity to the government whether through judgment or settlement. Qui tam actions have increased significantly in recent years, causing greater numbers of entities, including manufacturers, to have to defend a false claim action, even before the validity of the claim is established and even if the government decides not to intervene in the lawsuit. Companies may decide to agree to large settlements with the government and / or whistleblowers to avoid the cost and negative publicity associated with litigation. Criminal prosecution is possible for**

knowingly making or presenting a false or fictitious or fraudulent claim to the federal government. In addition to the FCA, many states have enacted their own false claims act statutes that address similar conduct and that may apply to claims for items or services submitted to any payor source, not just government- funded programs. oAlthough we do not submit claims directly to payers, manufacturers can be held liable under the FCA if they are deemed to " cause " the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off- label, marketing products of sub- standard quality, or, as noted above, paying a kickback that results in a claim for items or services. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third- party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under the FCA. For example, several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill government healthcare programs for the product. • The Civil Monetary Penalties Law (" CMPL ") ● imposes substantial civil monetary penalties against an entity that engages in prohibited activities, including but not limited to violations of the AKS, knowing submission of a false or fraudulent claim, employment of an excluded individual and the provision or offer of anything of value to a Medicare or Medicaid beneficiary that the transferring party knows or should know is likely to influence beneficiary selection of a particular provider or supplier for the provision of items or service for which payment may be made in whole or in part by Medicare or Medicaid; o " Remuneration " is defined under the CMPL as any transfer of items or services for free or for less than fair market value. There are certain exceptions to the definition of remuneration for offerings that meet the Financial Need, Preventative Care, or Promoting Access to Care exceptions. Sanctions for violations of the CMPL include civil monetary penalties and administrative penalties up to and including exclusion from participation in government health care programs. • The Health Insurance Portability and Accountability Act of 1996 (" HIPAA ") ● imposes criminal and civil liability for knowingly and willfully executing or attempting to execute a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including third- party private payers, knowingly and willfully falsifying, concealing, or covering up by trick, scheme, or device, a material fact or making any materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH ") ● , and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, also imposes obligations, including mandatory contractual terms, on certain covered entities and their business associates with respect to safeguarding the privacy, security, and transmission of individually identifiable health information. HITECH also gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney' s fees and costs associated with pursuing federal civil actions. The Department of Health and Human Services Office of Civil Rights (the " OCR ") has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. State laws may also govern the privacy and security of health information or other personal information in certain circumstances. • According to the FTC failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or deceptive practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act ● . The FTC expects a company' s data security measures to be reasonable and appropriate considering the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. • Federal laws require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under the Medicaid Program or other government healthcare programs. • The Physician Payments Sunshine Act ● imposes annual reporting requirements to CMS for certain manufacturers of drugs, devices, biologies, and medical supplies for which payment is available under certain government healthcare programs (with certain exceptions) of information related to certain payments or other " transfers of value " made or provided to HCPs and teaching hospitals, or to other entities or individuals at the request of, or designated on behalf of, the HCPs and teaching hospitals. Numerous state laws may also require disclosure of transfers of value to HCPs, pharmaceutical pricing information and marketing expenditures. • Analogous state laws and regulations , such as state anti- kickback and false claims laws, and other state laws addressing the pharmaceutical and healthcare industries, may apply to interactions between pharmaceutical manufacturers and healthcare providers, sales or marketing arrangements, and claims involving healthcare items or services reimbursed by commercial third- party payers, including private healthcare insurers and health maintenance organizations, and in some cases that may apply regardless of payer, i. e., payment is made by a private insurer or even a self- paying patient; further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance program guidelines (the PhRMA Code) and the relevant compliance guidance promulgated by the federal government (HHS-OIG) in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to gifts, payments, or other remuneration to physicians and other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information and the use of prescriber- identifiable data in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For example, California enacted legislation – the California Consumer Privacy Act (" CCPA ") – which went into effect January 1, 2020 and, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information, and creates a private right of action

~~with statutory damages for non compliance, including for certain data breaches, thereby potentially increasing risks associated with a data breach. The CCPA was recently amended by the California Privacy Rights Act, expanding certain consumer rights such as the right to know. It remains unclear what, if any, additional modifications will be made to these laws by the California legislature or through ballot referendum, how these laws will be interpreted and enforced. The potential effects of the CCPA and CPRA are significant and may cause us to incur substantial costs and expenses to comply.~~ Many aspects of these laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations that increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Many state laws differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts. Moreover, the number and complexity of both federal and state laws continues to increase, and additional governmental resources are being used to enforce these laws and to prosecute companies and individuals who are believed to be violating them. We anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. For example, federal enforcement agencies recently have shown interest in pharmaceutical companies' product and patient assistance programs, including manufacturer reimbursement support services and relationships with specialty pharmacies. Some of these investigations have resulted in significant civil and criminal settlements. Efforts to ensure that our operations, including our business arrangements with third parties including our licensees, comply with applicable healthcare laws and regulations could be costly. Although effective compliance programs can help mitigate the risk of investigation, regulatory and enforcement actions, and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state fraud, privacy, security, and reporting laws may prove costly. We cannot guarantee that a government agency will agree with our interpretations, and it is possible that an enforcement authority may find **or we may discover** that one or more of our business practices may not comply. If our past or present operations, including activities conducted by our sales team or agents, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, **and** exclusion from government healthcare programs ~~, and the curtailment or restructuring of our operations~~ . Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management' s attention from the operation of our business, and damage our reputation. In addition, even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, and could result in related stockholder suits, any of which could also have an adverse effect on our business, financial condition and results of operations. In addition, from time to time in the future, we **or our licensees** may become subject to additional laws or regulations issued by federal or state agencies, all of which are subject to influence resulting from changes in political party control ~~. For instance, the Biden Administration may propose substantial changes to the U. S. healthcare system, including expanding government- funded health insurance options~~ . We are uncertain of the impact or outcome of new legislation, regulation, Executive Orders, rescission of rules and policy statements, or new agency priorities, especially any relative impact on the healthcare regulatory and policy landscape, or the impact they may have on our business. Such developments could, however, require reformulation of certain products to meet new standards, recalls or discontinuance of certain products not able to be reformulated, additional record- keeping requirements, increased documentation of the properties of certain products, additional or different labeling, additional scientific substantiation, additional personnel, or other new requirements. Any such developments could have an adverse effect on our business. **Recently enacted or** ~~Future~~ **future** legislation or regulations may adversely affect reimbursement from government healthcare programs and third- party payers. There have been efforts by government officials and legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation ~~. For example~~ , ~~President Biden signed the Inflation Reduction Act of 2022 into~~ **which could adversely affect our royalty revenues. Recently enacted federal and state** ~~law~~ **laws have put considerable pressure** on ~~August 16, 2022, which among other~~ -- **the** ~~things, seeks to lower prescription drug costs for Medicare beneficiaries and reduce drug spending by the federal government. Specifically, the prescription drug provisions under the Inflation Reduction Act: • Require that the federal government negotiate prices for certain drugs covered under Medicare Part B and Part D with the highest total spending, beginning in 2026; • Require drug manufacturers to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries, beginning in 2023; • Cap out of pocket spending for Medicare Part D enrollees and make other Part D benefit design changes, beginning in 2024; • Expand eligibility for full benefits under the Medicare Part D Low- Income Subsidy Program, beginning in 2024; and • Delay implementation of the Trump Administration' s drug rebate rule, beginning in 2027. The law that established the Part D benefit included a provision known as the " noninterference clause ", which stipulates that the HHS Secretary " may not interfere with the negotiations between drug manufacturers and pharmacies and PDP prescription drug plan sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs. " Further, the Secretary does not currently negotiate prices for Part B drugs, rather, Medicare reimburses providers based on 106 % of the average sales price (ASP), which is the average price paid to all non- federal buyers in the U. S., inclusive of rebates (other than Medicaid rebates). The Inflation Reduction Act amends the non- interference clause by adding an exception that requires the Secretary of HHS to negotiate prices with drug manufacturers for a small number of single- source brand- name drugs or biologics without generic or biosimilar competitors that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). Under the new Drug Price Negotiation Program, the number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The total number of drugs with negotiated prices will increase over time. Part D drugs with negotiated maximum fair prices are required to be covered by all Part D plans. Additionally, an excise tax will be~~

~~levied on drug manufacturers that do not comply with the negotiation process. The excise tax starts at 65 % of a drug' s sales in the U. S. and increases by 10 % every quarter to a maximum of 95 %. As an alternative to paying the tax, manufacturers can choose to withdraw all of their drugs from coverage under Medicare and Medicaid. In addition, manufacturers that refuse to offer an agreed- upon negotiated price for a selected drug to Medicare beneficiaries enrolled in Part B and / or Part D or to a provider of services to such individuals (such as a physician or hospital) will pay a civil monetary penalty equal to 10 times the difference between the price charged and the maximum fair price of the drug. Following passage of the Inflation Reduction Act, President Biden issued an Executive Order on October 14, 2022 titled " Lowering Prescription Drug Costs for Americans ", calling for additional measures to complement the Inflation Reduction Act and further drive down prescription drug costs. Under the Executive Order, the HHS Secretary is directed to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for Medicare and Medicaid beneficiaries, including cost- sharing models and value- based payments. It is unclear what additional payment and delivery models the Innovation Center may propose and how those models may impact drug~~ pricing **of** ~~, including the pricing and access to our products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control~~ pharmaceutical ~~pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product~~ **products** ~~access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing~~ . We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The Patient Protection and Affordable Care Act (" ACA ") and any further changes in the law or regulatory framework could also have an adverse effect on our business, financial condition, and results of operations. Further, if a federal government shutdown were to occur for a prolonged period, federal government payment obligations, including its obligations under Medicaid and Medicare, may be delayed. Similarly, if state government shutdowns were to occur, state payment obligations may be delayed. If the federal or state governments fail to make payments under these programs on a timely basis, the ability of our licensees to sell our products to government payers may be limited, thereby reducing anticipated revenues and profitability. Even after the approval of IMVEXXY, BIJUVA, and ANNOVERA, the products and the holder of the marketing authorizations will still face extensive, ongoing regulatory requirements and review, and the products may face future development and regulatory difficulties. With respect to IMVEXXY, BIJUVA, and ANNOVERA, the FDA may still impose significant restrictions on a product' s indicated uses or marketing or to the conditions for approval or impose ongoing requirements for potentially costly post- approval studies, including phase 4 clinical trials or post- market surveillance. As a condition to granting marketing approval of a product, the FDA may require ~~a company to conduct~~ additional clinical trials. The results generated in these post- approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. For example, the labeling for IMVEXXY, BIJUVA, and ANNOVERA contains restrictions on use and warnings. The Food and Drug Administration Amendments Act of 2007 gives the FDA enhanced post- market authority, including the imposition of a Risk Evaluation and Mitigation Strategy (" REMS ") as well as explicit authority to require post- market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA- approved REMS programs. IMVEXXY, BIJUVA, and ANNOVERA will also be subject to ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance and reporting, advertising, promotion, record keeping, and reporting of safety and other post- market information. The FDA' s exercise of its authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post- approval regulatory requirements, and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable requirements. As part of the FDA' s approval of IMVEXXY, we committed to conduct a post- approval observational study to evaluate the risk of endometrial cancer in post- menopausal women with a uterus who use a low- dose vaginal estrogen unopposed by a progestogen such as IMVEXXY, which study was assumed by Mayne Pharma as the holder of the new drug application (" NDA "). As part of the FDA' s approval of ANNOVERA, the FDA has required four non- closed post- marketing studies, including both post- marketing reviews and post- marketing commitments. Each study has a timeline for completion and submission of a final report to the FDA. If a post- approval study is not fulfilled according to FDA requirements, the FDA may impose certain further requirements and penalties against the holder of the NDA, which could include withdrawal of the NDA approval and withdrawal of the product from the market. For ANNOVERA, post marketing studies are being performed by the Population Council and Mayne Pharma as the NDA holder. In July 2021, we received a letter from the FDA indicating that the post- marketing commitment study being conducted by the Population Council for ANNOVERA to characterize the in vivo release rate of ANNOVERA was not fulfilled to FDA' s satisfaction. In addition, the final reports for the two post- marketing requirement studies being performed by the Population Council for ANNOVERA were not submitted by the initial listed submission deadline, which deadlines have since been extended by FDA. To the extent that Mayne Pharma or the Population Council, as applicable, does not fulfil these studies to the FDA' s satisfaction, the ability of our licensees to sell the applicable product may be limited and there may be an adverse impact on our revenue and results of operations. Post- marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our pharmaceutical product candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or

recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products. Manufacturers of pharmaceutical products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA' s cGMP regulations and other regulatory requirements, such as adverse event reporting. Facilities for the manufacturer of pharmaceutical products also undergo internal audits as well as external audits by third parties. If our licensees or a regulatory agency discovers problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or our licensees, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the drug, requiring that additional clinical trials be conducted, imposing new monitoring requirements, or requiring the establishment of a REMS program. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws and are subject to review by FDA. If the FDA raises concerns regarding our licensees' promotional materials or messages, they may be required to modify or discontinue using them and may be required to provide corrective information. Commercial products must now meet the requirements of the Drug Supply Chain Security Act (" DSCSA ") which imposes obligations on manufacturers of prescription pharmaceutical products for commercial distribution, regulating the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain (manufacturers and re-packagers, wholesale distributors, third- party logistics providers, and dispensers). The DSCSA preempts previously enacted state pedigree laws and the pedigree requirements of the Prescription Drug Marketing Act (" PDMA ") and its implementing regulations. Trading partners within the drug supply chain must now ensure certain product tracing requirements are met that they are doing business with other authorized trading partners; and they are required to exchange transaction information, transaction history, and transaction statements. Product identifier information (an aspect of the product tracing scheme) is also now required. The DSCSA requirements, development of standards, and the system for product tracing have been and will continue to be phased in over a period of years ~~, with FDA indicating enforcement discretion on certain aspects due to the COVID- 19 pandemic~~ . The distribution of product samples continues to be regulated under the PDMA, and some states also impose regulations on drug sample distribution. Our activities and the activities of our licensees are also potentially subject to federal and state consumer protection and unfair competition laws. If we, our licensees or our third- party suppliers fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions: ~~•~~ ● conduct an investigation into our or our licensees' practices and any alleged violation of law; ~~•~~ ● seek an injunction or impose civil or criminal penalties or monetary fines; ~~•~~ ● suspend or withdraw regulatory approval; ~~•~~ ● suspend or impose restrictions on our licensees' operations, including costly new manufacturing requirements; ~~•~~ ● seize or detain products, refuse to permit the import or export of products, or require our licensees to initiate a product recall; or ~~•~~ ● exclude our licensees from providing our products to those participating in government healthcare programs, such as Medicare and Medicaid, and refuse to allow our licensees to enter into supply contracts, including government contracts. Recent government enforcement has targeted pharmaceutical companies for violations of fraud, abuse and other laws. The federal government has pursued actions against pharmaceutical companies for violations of **fraud, abuse, and** ~~the~~ **other** ~~AKS~~ **laws** , including ~~relating to remuneration paid to physicians for attendance at speaker programs~~ , ~~consulting arrangements, and marketing, among others. As noted above, the OIG released a Special Fraud Alert in 2020 regarding manufacturer speaker programs and announced several settlements with manufacturers relating thereto. As noted above, violations of the AKS are also per se false claims for purposes of the FCA and as a result, have resulted in large settlements between manufacturers and the government. Separately, the government has pursued actions against manufacturers under the FCA for causing the submission of false claims arising from manufacturer off-label marketing. These and other enforcement efforts have resulted in large civil settlements and corporate integrity agreements between manufacturers and the government. We have adopted comprehensive compliance guidance and endeavor to structure our business arrangements and marketing efforts in compliance with all applicable law, including the AKS and the FCA; however, we cannot guarantee that the government, whistleblower or court will agree with our interpretations. Our practices with respect to interactions with HCPs, including~~ but not limited to ~~consultant relationships, speaker programs, advisory boards, and scientific / educational grant programs, as well as our arrangements with pharmacies, may not in all cases meet all~~ the ~~criteria for safe harbor protection from~~ AKS ~~liability. Moreover~~ , **False Claims Act** ~~there are no safe harbors for many common practices~~ , **FDCA** ~~such as certain educational and research grants or patient assistance programs. The safe harbors are subject to change through legislative and regulatory action~~ , **HIPAA** ~~and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. In addition~~ , **HITECH, Ryan Haight Act, and others, including** ~~several states have recently enacted legislation requiring pharmaceutical companies to establish~~ marketing and promotional compliance programs or codes of conduct **,** and ~~/~~ **law** or **rules requiring** ~~to file periodic reports~~ **reporting of commercial** ~~with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other~~ activities ~~. Several states have also adopted laws that prohibit or limit certain marketing- related activities, including the provision of gifts, meals, or other items to certain healthcare providers. The FDA also strictly regulates marketing, labeling, advertising, and promotion of prescription drug products that are placed into interstate commerce in the United States. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product' s labeling and that differ from those tested and approved by the FDA. Pharmaceutical companies, however, are required to promote their pharmaceutical products only for the approved indications and consistent with the FDA- required, approved label. The FDA and other agencies actively monitoring promotional activities and enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and the FCA, exclusion from participation in federal healthcare~~

~~programs, mandatory compliance programs under corporate integrity agreements, debarment, and refusal of government contracts~~. We cannot ensure that ours or our licensee' s compliance controls, policies, and procedures will be sufficient to protect against acts of ours or their employees, business partners, licenses, or vendors that may violate federal or state fraud and abuse laws or other applicable requirements. **The violations of any of these law or rules may result** ~~Federal enforcement agencies and private whistleblowers have shown and continue to show interest~~ in **penalties** ~~pharmaceutical companies' product and patient assistance programs (PAPs), including reimbursement support, co- pay support, nursing, adherence and educational services, referrals to other providers, donations to independent patient assistance charities, and relationships with specialty pharmacies. We believe~~ that ~~Mayne Pharma offers co- pay assistance for our vitamin products and IMVEXXY and BIJUVA, including co- pay assistance and free drug sample packs for IMVEXXY and BIJUVA, and potentially will enter into similar programs for ANNOVERA. Our co- pay assistance programs are intended to assist qualified patients with private insurance with any out- of- pocket financial obligations but exclude any government healthcare program beneficiaries. Several investigations into patient assistance practices have resulted in significant civil and criminal settlements. While the OIG has approved certain independent charitable PAPs that help financially needy beneficiaries, advisory opinions on this issue have primarily focused on charities that provide assistance to patients who cannot afford cost- sharing obligations for prescription drugs. A key element for the OIG has been whether the charities are sufficiently independent from drug manufacturer donors. In May 2014, the OIG issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs, or the 2014 Special Advisory Bulletin, which updated its 2005 Special Advisory Bulletin relating to PAPs. In the 2014 Special Advisory Bulletin, the OIG stated that although PAPs provide important safety net assistance to financially needy patients, these programs also present a risk of fraud, waste, and abuse with respect to federal health care programs. One of the three factors set forth in the revised guidance was that the PAP could not limit assistance to a single product. In September of 2014, the OIG also released a Special Advisory Bulletin on pharmaceutical manufacturer copayment coupons, specifically stating that manufacturers that did not comply with the law may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including, but not limited to, drugs paid for by Medicare Part D. Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violations of the AKS. PAPs have also been the subject of Congressional review. If patient assistance programs are structure incorrectly or support programs fail to comply with applicable law, Mayne Pharma risks becoming subject to government investigations, and potentially, facing penalties or other consequences for violations under fraud and abuse laws, which may inhibit revenues through royalties due to reduced sales volume. Although we believe that ours and our licensees business practices are structured to be compliant with applicable laws, it is possible that governmental authorities will conclude that ours or our licensees business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our past operations and our licensees current operations, including activities conducted by our former sales team or agents or our licensees current sales team or agents, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we or our licensees may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of ours or their operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management' s attention from the operation of our business, and damage our reputation. In addition, even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition, and results of operations. In addition, to the extent we, our licensees, or our other contractors or agents receive or obtain individually identifiable health information from patients, healthcare professionals, pharmacies, or other individuals or entities, we or they could be subject to criminal penalties if we mishandle individually identifiable health information in a manner that is not authorized or permitted by HIPAA or other applicable privacy and security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. The occurrence of any of the foregoing events or penalties~~ may force us to expend significant amounts of time and money and may significantly inhibit our licensee' s ability to continue to market our products and generate revenue. Following the closing of the vitaCare Divestiture, we may still be required to indemnify the buyer of vitaCare in the event any enforcement related to activities prior to the vitaCare Divestiture. Similar regulations apply in foreign jurisdictions . Some of our products can be..... they are not required to do so . If our dietary supplement, hormone therapy pharmaceutical products or patient- controlled, long- acting contraceptive products do not have the effects intended or cause undesirable side effects, our business may suffer. Although many of the ingredients in our dietary supplement products are vitamins, minerals, and other substances for which there is a long history of human consumption, they also contain innovative ingredients or combinations of ingredients. Furthermore, our hormone therapy or patient- controlled, long- acting contraceptive pharmaceutical products have been approved by the FDA based on its assessment of the safety and efficacy of these products. While we believe that all of these products and the combinations of ingredients in them are safe when taken as directed, the products could have certain undesirable side effects if not taken as directed or if taken by a consumer who has certain medical conditions. In addition, these products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary or other labeling restrictions. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or on an unforeseen cohort. If any of our are shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations, and prospects could be harmed significantly. **Our products face significant competition from branded and generic products, and our operating results will suffer if we fail to compete effectively.** Development and awareness of our products will depend largely upon our licensee' s success in increasing the

consumer base for our products. The pharmaceutical and dietary supplement industries are intensely competitive and subject to rapid and significant technological change. Our products face intense competition, including from major multinational pharmaceutical and dietary supplement companies, established biotechnology companies, specialty pharmaceutical, and generic drug companies. Many of these companies have greater financial and other resources, such as larger R & D staffs and more experienced marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval more rapidly and may be more effective in selling and marketing their products. They also may invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make the products that we sell or develop obsolete. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. If our licensees are unable to economically promote or maintain our brand, our business, results of operations and financial condition could be severely harmed. In addition, loss of exclusivity may provide opportunity for competing products, particularly generics, to ~~erode~~ siphon off our consumers. In February 2020, we received a Paragraph IV certification notice letter (the " IMVEXXY Notice Letter ") regarding an ANDA submitted to the FDA by Teva Pharmaceuticals USA, Inc. (" Teva "). See " If **our efforts or** the efforts of our licensees to protect the proprietary nature of the intellectual property covering our hormone therapy pharmaceutical products and other products are not adequate, we may not be able to compete effectively in our market " below for more information regarding the IMVEXXY Notice Letter. Additionally, on March 2020, we received a Paragraph IV certification notice letter (the " BIJUVA Notice Letter ") regarding an ANDA submitted to FDA by Amneal Pharmaceuticals. See Item 1. Business – Pharmaceutical Regulation – Regulatory Exclusivity for more information on the BIJUVA Notice Letter. In addition, we cannot predict what additional ANDAs could be filed by Teva or other potential generic competitors requesting approval to market generic forms of our products, which if approved, could result in significant decreases in the revenue derived from royalties sales of our marketed products and thereby harm our business and financial condition. **for** ~~and results of operations in~~ 2021 and 2022 were,and our financial condition and results of operations ~~in the future~~ **for 2023 and beyond** may be,adversely affected by the **ongoing** COVID- 19 pandemic and any future pandemics or epidemics.Our business ~~was~~ **has been,and we anticipate that it will continue to be,** impacted by the COVID- 19 pandemic and ~~it may be impacted by~~ any future pandemics or epidemics.The severity of the impact of ~~any~~ **the COVID- 19** pandemic on our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted. ~~During the COVID- 19 pandemic,stay~~ **Stay** at home,quarantine,and social distancing orders and closures and restrictions on travel negatively affected the ability of our sales force to access healthcare providers to promote our products and the ability of patients to visit their healthcare professionals for non- emergent matters.The sales force of our licensees may continue to use a hybrid model of office visits when necessary and digital engagement tools and tactics and virtual detailing,which may be less effective than their ordinary course sales and marketing programs. **Our** ~~Further.our~~ future results of operations and liquidity could be adversely affected ~~during or following any future pandemics or epidemics~~ by extended billing and collection cycles at our company,our licensees,or otherwise;delays in payments of outstanding receivable amounts beyond normal payment terms,including royalty payments;supply chain disruptions;and uncertain demand. ~~Also,disruptions~~ **Disruptions** have occurred and may occur in the future that affect our licensees' ability to obtain supplies or other components for our products,manufacture additional products,or deliver inventory in a timely manner.This would result in lost sales (and royalties) and damage to our reputation.Our business may also be affected by negative impacts of **the COVID- 19 pandemic and** any future pandemic or epidemic on capital markets and economies worldwide,and it is possible that ~~a~~ **the** pandemic could cause a local and / or global economic recession.While policymakers globally have responded with fiscal policy actions to support the healthcare industry and economy as a whole,the magnitude and overall effectiveness of these actions remains uncertain.We may also experience other unknown impacts from COVID- 19 or any future pandemics or epidemics that cannot be predicted.Accordingly,disruptions to our business as a result of COVID- 19 and other pandemics or epidemics could continue to result in an adverse effect on our business,results of operations,financial condition and prospects in the near **- term and beyond 2023** Failure to obtain regulatory approval outside the U. S. will prevent our licensees from marketing our hormone therapy pharmaceutical products in non- U. S. markets. We have entered into licensing and supply agreements with Knight and Theramex to commercialize IMVEXXY and BIJUVA in non- U. S. markets. To market these products in the European Union and many other non- U. S. jurisdictions, our licensees must obtain separate regulatory approvals. We have had limited interactions with non- U. S. regulatory authorities, the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval or clearance. Approval or clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more non- U. S. regulatory authorities does not ensure approval by other regulatory authorities in other countries or by the FDA. The non- U. S. regulatory approval process may include all risks associated with obtaining FDA approval or clearance. For these non- U. S. regulatory approvals, our licensees may not obtain them on a timely basis, if at all. Our licensees' failure to receive necessary non- U. S. regulatory approvals to commercialize IMVEXXY and BIJUVA in a given market could have an adverse effect on our business, financial condition, results of operations, and prospects. In addition, by seeking to obtain approval to market IMVEXXY and BIJUVA in one or more non- U. S. markets, we or our licensees will be subject to rules and regulations in those markets relating to our products. In some countries, particularly countries of the European Union, each of which has developed its own rules and regulations, pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of regulatory approval for a drug. To obtain reimbursement or pricing approval in some countries, our licensees may be required to conduct a clinical trial that compares the cost- effectiveness of our pharmaceutical product to other available products. If reimbursement of our pharmaceutical product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our licensees may be unable to generate revenues and achieve or sustain profitability with respect to any given market, which could have an adverse effect on our business, financial condition, results of operations, and prospects. If our licensees obtain approval to market IMVEXXY or

BIJUVA in one or more non- U. S. markets, there will be additional pharmacovigilance reporting requirements for our products. To the extent that the non- U. S. markets in which our licensees distribute our products have different pharmacovigilance reporting requirements than the U. S., there is a risk that the marketing of our drugs in those countries may increase the number of adverse events reported for our products. Our success is tied to our licensees' distribution channels. Our revenue is dependent on our licensees' distribution through wholesale distributors and retail pharmacy distributors. Our business would be harmed if our licensees' customers refused to distribute our products and if our licensees were not able to replace such customers through their distribution channels. Our ability to utilize net operating loss carryforwards may be limited. As of December 31, ~~2022~~ **2023** , we had federal net operating loss (" NOL ") carryforwards of $ ~~640~~ **577** . 0 million. Subject to applicable limitations, our NOL may be used to offset future taxable income, to the extent we generate any taxable income, and thereby reduce our future federal income taxes otherwise payable. Section 382 of the Internal Revenue Code of 1986, as amended, imposes limitations on a corporation' s ability to utilize NOL carryforwards if it experiences an ownership change as defined in Section 382. In general terms, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50 percent over a three- year period. If an ownership change has occurred, or were to occur, utilization of our NOL carryforwards would be subject to an annual limitation under Section 382 determined by multiplying the value of our stock at the time of the ownership change by the applicable long- term tax- exempt rate. Any unused annual limitation may be carried over to later years. We may be found to have experienced an ownership change under Section 382 because of events in the past or the issuance of shares of our common stock in the future. If so, the use of our NOL carryforwards, or a portion thereof, against our future taxable income may be subject to an annual limitation under Section 382. In 2017, the U. S. federal government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the " 2017 Tax Act "). The 2017 Tax Act makes broad and complex changes to the U. S. federal tax code, including, but not limited to reducing the U. S. federal corporate tax rate from 34 percent to 21 percent and imposing new restrictions on the use of NOL carryforwards. The 2017 Tax Act reduced the corporate tax rate to 21 percent, effective January 1, 2018. Management assessed the valuation allowance analyses with respect to our NOL carryforwards as affected by various aspects of the 2017 Tax Act and determined that a full valuation allowance continues to be appropriate. Additionally, to address the impact of the COVID- 19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted into law in March 2020. The CARES Act includes several significant business tax provisions that, among other things, includes further statutory amendments to the rules governing NOL carryforwards, as amended by the 2017 Tax Act. The CARES Act limits the NOL deduction in taxable years beginning in 2021 to the lesser of the NOL carryforwards or 80 % of the taxpayer ~~'~~ **'** s taxable income (after considering the deduction for NOL arising in tax years beginning before January 1, 2018), which may restrict our ability to offset future taxable income with NOL carryforwards and increase our future federal income taxes otherwise payable. Any failure of our licensees to adequately maintain a sales force or adequately promote our products will impede our growth. We are substantially dependent on the sales forces of our licensees to attract new business and to manage existing customer relationships. There is significant competition for qualified, productive direct sales personnel with advanced sales skills and technical knowledge. Our ability to achieve growth in revenue in the future will depend, in large part, on our licensees' success in recruiting, training, and retaining direct sales personnel, and their decision to adequately promote our products. If our licensees are unable to hire, engage, and develop enough productive sales personnel or ~~fails~~ **fail** to adequately promote our products, our business prospects could suffer. Risks related to our intellectual property **If our efforts or the efforts of our licensees to protect the proprietary nature of the intellectual property covering our hormone therapy pharmaceutical products and other products are not adequate, we may not be able to compete effectively in our market.** Our commercial success will depend in part on ours and our licensees' ability to obtain additional patents and protect our existing patent positions as well as our ability to maintain adequate protection of other intellectual property for our hormone therapy pharmaceutical products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The patent positions of pharmaceutical companies are highly uncertain. The legal principles applicable to patents are in transition due to changing court precedent and legislative action, and we cannot be certain that the historical legal standards surrounding questions of validity will continue to be applied or that current defenses relating to issued patents in these fields will be sufficient in the future. Changes in patent laws in the U. S., such as the America Invents Act of 2011, may affect the scope, strength, and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U. S., and we may encounter significant problems in protecting 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 are covered by valid and enforceable patents or are effectively maintained as trade secrets. These risks include the possibility of the following: ~~•~~ ● the patent applications that we **or our licenses** have filed ~~to that our licensees~~ may fail to result in issued patents in the U. S. or in foreign jurisdictions; ~~•~~ ● patents issued or licensed to us, or our partners, may be challenged or discovered to have been issued on the basis of insufficient, incomplete, or incorrect information, and thus held to be invalid or unenforceable; ~~•~~ ● the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents; ~~•~~ ● we, the Population Council, or our licensees were not the first to make the inventions covered by each of our issued patents and pending patent applications **, or may have created bars under U. S. or foreign laws that would preclude the issuance of patents** ; ~~•~~ ● we, the Population Council, or our licensees may not have been the first inventors to invent or file patent applications for these technologies in the U. S. or were not the first to file patent applications directed to these technologies abroad; ~~•~~ ● we may fail to comply with procedural, documentary, fee payment, and other similar provisions during the patent application process, which can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights; ~~•~~ ● future pharmaceutical product candidates may not be patentable; ~~•~~ ● others may claim rights or ownership regarding patents and other

proprietary rights that we hold or license; ● delays in development, testing, clinical trials, and regulatory review may reduce the period during which we could market our pharmaceutical products under patent protection; and ● we or our licensees may fail to timely apply for patents on our technologies or products. While we apply for patents covering our technologies and products, as we deem appropriate, many third parties may already have filed patent applications or have received patents in our areas of product development. These entities' applications, patents, and other intellectual property rights may conflict with patent applications to which we have rights and could prevent us from obtaining patents or could call into question the validity of any of our patents, if issued, or could otherwise adversely affect our ability to develop, manufacture, or commercialize our pharmaceutical products. In addition, if third parties file patent applications in the technologies that also claim technology to which we have rights, we may have to participate in interference, derivation, or other proceedings with the USPTO or foreign patent regulatory authorities to determine our rights in the technologies, which may be time- consuming and expensive. Moreover, issued patents may be challenged in the courts or in post- grant proceedings at the USPTO, or in similar proceedings in foreign countries. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims. If we, the Population Council, our licensees, or our strategic partners fail to obtain and maintain patent protection for our products, or our proprietary technologies and their uses, companies may be dissuaded from collaborating with us **or our licensees** . In such event, ~~our~~ **ours or our licensee' s** ability to commercialize our pharmaceutical products may be threatened, we could lose our competitive advantage, and the competition we face could increase, all of which could adversely affect our business, financial condition, results of operations, and prospects. In addition, mechanisms exist in much of the world permitting some form of challenge by generic drug marketers to our patents before, or immediately following, the expiration of any regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as " at risk " launches **or the post-grant approval processes that exists in the U. S. and foreign jurisdictions** to challenge relevant patent rights. In February 2020, we received the IMVEXXY Notice Letter regarding an ANDA submitted to the FDA by Teva. The ANDA submitted by Teva seeks approval from the FDA to commercially manufacture, use, or sell a generic version of the 4 mcg and 10 mcg doses of IMVEXXY. In the IMVEXXY Notice Letter, Teva alleges that IMVEXXY Patents listed in the FDA' s Orange Book that claim compositions and methods of IMVEXXY are invalid, unenforceable, and / or will not be infringed by Teva' s commercial manufacture, use, or sale of its proposed generic drug product. The IMVEXXY Patents identified in the IMVEXXY Notice Letter expire in 2032 or 2033. In April 2020, we filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey arising from Teva' s ANDA filing with the FDA. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva' s ANDA would be a date no earlier than the expiration of the IMVEXXY Patents and equitable relief enjoining Teva from infringing the IMVEXXY Patents. Teva has filed its answer and counterclaim to the complaint, alleging that the IMVEXXY Patents are invalid and not infringed. In September 2021, the District Court made available a public version of the order following the parties' agreement to a consent motion to redact information Teva contended was confidential. The order provides that the statutory stay that prevents FDA from granting final approval of the ANDA for 30 months from the date of the Notice Letter will be extended for the number of days that the stay of the IMVEXXY litigation is in place. The length of the stay of the IMVEXXY litigation is dependent on further action by Teva. We cannot assure you that any patent infringement lawsuit that we or our licensees may file will prevent the introduction of a generic version of IMVEXXY for any particular length of time, or at all. If Teva' s ANDA is approved, and a generic version of IMVEXXY is introduced, the sales of IMVEXXY could be adversely affected and our license revenue could be significantly decreased. In addition, we cannot predict what additional ANDAs could be filed by Teva, or other potential generic competitors requesting approval to market generic forms of our products, which could require us **or our licensees** to incur significant additional expense and result in distraction for our management team, and if approved, result in significant decreases in the revenue derived from sales of our marketed products and thereby harm our business and financial condition. Our business also may rely on unpatented proprietary technology, know- how, and trade secrets. If the confidentiality of this intellectual property is breached, it could adversely impact our business. We must rely on Mayne Pharma to file lawsuits or take other actions to protect or enforce our patents and there can be no assurance they will ~~be~~ take such actions or be successful. Competitors may infringe our patents or the patents of the ANNOVERA licensor. Following the Mayne Transaction, we no longer have the express right to enforce our intellectual property. To counter infringement or unauthorized use, we must rely on Mayne Pharma to file infringement claims, including with respect to Teva' s IMVEXXY Notice Letter. There can be no assurance that Mayne Pharma will have sufficient financial or other resources to file and pursue such infringement claims in the United States, which typically last for years before they are concluded. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, in an infringement proceeding, a court may decide that a patent of ours or of the ANNOVERA licensor is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents, or those of the ANNOVERA licensor, do not cover the technology in question or on other grounds. An adverse result in any litigation or defense proceedings could put one or more of our patents, or those of the ANNOVERA licensor, at risk of being invalidated, held unenforceable, or interpreted narrowly. Moreover, we may not be able to prevent, alone or with our licensees, or the ANNOVERA licensor, misappropriation of our proprietary rights, particularly in countries in which the laws may not protect those rights as fully as in the U. S. or in those countries in which we do not file national phase patent applications. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, if securities analysts or investors perceive public announcements of the results of hearings, motions, or other interim proceedings or developments to be negative, the price of our common stock could be adversely affected. The occurrence of any of the above could adversely affect our business, financial condition, results of

operations, and prospects. Risks related to ownership of our common stock **We may be treated as** ~~In January 2023, we received~~ a ~~deficiency letter (the~~ " ~~Notice~~ **public shell** " ~~) from the Listing Qualifications Department of the~~ **company which could have negative consequences, including potential** Nasdaq ~~Stock Market, LLC (" Nasdaq ") notifying us that we were not in compliance with the rules for continued listing~~ **delisting** ~~as set forth in Nasdaq Listing Rule 5620 (a) (the " Annual Meeting Rule ") due to our failure to hold an annual meeting~~ of ~~stockholders within 12 months after our fiscal year ended December 31, 2021. The Notice had no immediate effect on the listing of our Common Stock. We did not hold an annual meeting of stockholders during 2022 due to our then ongoing strategic processes. The Notice stated that, under Nasdaq Listing Rule 5810 (c) (2) (G), we had 45 calendar days, or until February 20, 2023, to submit a plan to regain compliance with the Annual Meeting Rule. We timely submitted such plan, and Nasdaq granted us an extension until June 29, 2023, to regain compliance. It our intent to hold an annual meeting of stockholders in 2023 prior to such deadline and to fully regain compliance with all applicable Nasdaq listing standards. However, there can be no assurance that we will be able to regain compliance with the Annual Meeting Rule or that we will otherwise remain in compliance with the other listing standards for the Nasdaq listing requirements. If we are unable to comply with the Nasdaq listing requirements,~~ our common stock ~~could~~ **. Our common stock is currently listed on the Nasdaq Global Select Market. We have no current plans to delist our common stock from Nasdaq. However, following the transaction with Mayne Pharma, when we changed our business to become a royalty company, we may** be **treated as a " public shell " company under the Nasdaq rules and the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act. Although Nasdaq evaluates whether a listed company is a public shell company based on a facts and circumstances determination, a Nasdaq- listed company with no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets is generally considered to be a public shell company. Listed companies determined to be public shell companies by Nasdaq may be subject to delisting proceedings or additional and more stringent listing criteria. If our common stock is** delisted from Nasdaq, **or if in the future we determine to delist our common stock, we would expect that such securities would qualify for trading over- the- counter, or OTC, in the United States on a market colloquially referred to as the " Pink Sheets. " Securities quoted OTC are generally subject to lesser requirements than securities listed for trading on a U. S. national stock exchange, such as Nasdaq, including reduced corporate governance and public reporting standards. If Nasdaq should delist our common stock from trading, or if in the future we determine to delist our common stock, a reduction in some or all of the following may occur, each of** which could have **a** material adverse ~~effects~~ **effect** on **holders of** our **common stock: the liquidity of our common stock; the market price of our common stock; the number of institutional and general investors that will consider investing in our common stock; the number of investors in general that will consider investing in our common stock; the number of market makers in our common stock; the availability of information concerning the trading prices and volume of our common stock; and the number of broker- dealers willing to execute trades in our common stock. In addition to the foregoing, there are certain consequences under the Securities Act of being a public shell company, including the unavailability of Rule 144 thereunder for the resale of restricted securities and the** ~~ability~~ **inability** to **utilize Form S- 8 for** ~~finance our operations and our stockholders' ability to monetize~~ the ~~investment in our Company~~ **registration of employee benefit plan securities** . Our principal stockholder owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of December 31, ~~2022~~ **2023** , Rubric Capital Management LP (" Rubric ") and its affiliates beneficially owned approximately ~~18~~ **25** . ~~5~~ **6** % of our common stock. Rubric may be able to largely determine the outcome of all matters requiring stockholder approval. For example, Rubric may be able to largely control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. If we fail to maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired. Pursuant to Section 404 of the Sarbanes- Oxley Act, our management is required annually to deliver a report that assesses the effectiveness of our internal control over financial reporting. Due to our current filing status, we are not required to have our independent registered public accounting firm deliver an attestation report on the effectiveness of our internal control over financial reporting. If we are unable to maintain effective internal control over financial reporting or our independent auditors are unwilling or unable to provide us with an attestation report on the effectiveness of internal control over financial reporting for future periods as required by, or voluntarily followed under, Section 404 of the Sarbanes- Oxley Act, we may not be able to produce accurate financial statements, and investors may therefore lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions. We do not **currently** intend to pay dividends on our common stock so any returns ~~will~~ **may** be limited to the value of our stock. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain any future earnings for the operation of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may also preclude us from paying dividends. Any return to stockholders ~~will~~ **may** be limited to the capital appreciation, if any, of their stock. Some provisions of our charter documents and Nevada law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our articles of incorporation and bylaws, as well as certain provisions of Nevada law, could make it more difficult for a third- party to acquire us or increase the cost of acquiring us, even if an acquisition would benefit our stockholders, and could also make it more difficult to remove our current management. These provisions in our articles of incorporation and bylaws include the following: ~~•~~ ● authorizing the issuance of " blank check " preferred stock that could be issued by our board of directors **(the " Board ")** to increase the number of outstanding shares and thwart a takeover attempt; ~~•~~ ● prohibiting cumulative voting in the election of

directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and • ● advance notice provisions in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors. In addition, we are subject to Nevada' s Combination with Interested Stockholders statute (Nevada Revised Statute Sections 78. 411 – 78. 444), which prohibits an " interested stockholder " from entering into a " combination " with a company, unless certain conditions are met. An " interested stockholder " is a person who, together with affiliates and associates, beneficially owns (or within the prior two years, did beneficially own) 10 % or more of the corporation' s capital stock entitled to vote. General risks related to our business Our business may be affected by unfavorable publicity or lack of consumer acceptance. We are highly dependent upon consumer acceptance of the safety and quality of our products, as well as similar products distributed by other companies. Consumer acceptance of a product can be significantly influenced by scientific research or findings, national media attention, and other publicity about product use, products themselves, or marketing campaigns for our products. A product may be received favorably, resulting in high sales associated with that product that may not be sustainable as consumer preferences change. Future scientific research or publicity could be unfavorable to our industry or any of our products and may not be consistent with earlier favorable research or publicity. A future research report or publicity that is perceived by consumers as less than favorable or that may question earlier favorable research or publicity could have an adverse effect on sales of our products and our ability to generate revenue. Adverse publicity in the form of published scientific research, statements by regulatory authorities or otherwise, whether or not accurate, that associates use of our products or any other similar products with illness or other adverse effects, or that questions the benefits of our products or similar products, or that claims that such products do not have the effect intended, or that question the marketing of our products, could have an adverse effect on our business, reputation, financial condition, or results of operations. Our licensees may initiate product recalls or withdrawals or may be subject to regulatory enforcement actions that could negatively affect our business. Our products may be subject to product recalls, withdrawals, or seizures if any of our products are believed to cause injury or illness or if our licensees are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale, or distribution of any of our products. A recall, withdrawal, or seizure of any of our products could adversely affect consumer confidence in our brands and lead to decreased demand for our products, which could adversely affect our business, financial condition and results of operations. Product liability lawsuits could divert our resources, result in substantial liabilities, and reduce the commercial potential of our products. We face an inherent risk of product liability claims because of the commercial availability of our current products. Additionally, considering the history of product liability claims related to other hormone therapy products and contraceptives, we will face an even greater risk through commercialization of our products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, failures to warn of dangers associated with the use of the product, negligence, strict liability, or breaches of warranties. Claims could also be asserted under state consumer fraud and protection statutes. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or pharmaceutical product candidates. Regardless of the merits or eventual outcome, product liability claims may result in any of the following: • ● the inability to commercialize our products; • ● difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed; • ● labeling, marketing, or promotional changes and / or restrictions; • ● product recalls or withdrawals; • ● decreased demand for our products or products that we may develop in the future; • ● loss of revenue; • ● injury to our reputation; • ● initiation of investigations by regulators or actions by state attorney generals or the U. S. Department of Justice; • ● costs to defend the related litigation; • ● a diversion of management' s time and our resources; • ● substantial monetary awards to trial participants or patients; • ● exhaustion of any available insurance and our capital resources; ● ~~and •~~ the obligation to indemnify our licensees that would be a diversion of ~~managements~~ **management' s** time and resources; and • ● a decline in our stock price. Although we maintain general liability insurance and clinical trial liability insurance for our products and product candidates, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, financial condition, results of operations, and prospects. A failure to maintain optimal inventory levels to meet commercial demand for our products could harm our and ~~out~~ **our** licensees' reputation and subject us to financial losses. Our licensees ~~'~~ **'** ability to maintain optimal inventory levels to meet commercial demand depends on the performance of third-party contract manufacturers. In some instances, our products have unique ingredients used under license arrangements. One of our third- party contract manufacturers has ~~recently~~ **in the past** experienced an increase in difficulties with manufacturing of ANNOVERA, resulting in intermittent supply of ANNOVERA for commercial distribution. See " Our dependence upon third parties for the manufacture and supply of our existing women' s healthcare products may cause delays in ~~,~~ or prevent our licensees from ~~,~~ successfully commercializing ~~,~~ and marketing our products " above. If the manufacturers of our products are unsuccessful in obtaining raw materials, if are licensees are unable to manufacture and release inventory on a timely and consistent basis, if our licensees fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged, or if our licensees' inventory reaches its expiration date, patients might not have access to our products, our reputation and brands could be harmed, and physicians may be less likely to recommend our products in the future, each of which could have an adverse effect on our business, financial condition, results of operations, and cash flows. Our business may be impacted by new or changing tax laws or regulations and actions by federal, state, and / or local agencies, or how judicial authorities apply tax laws. In connection with the products we previously sold and the royalties we receive, we calculate, collect, and remit various federal, state, and local taxes, surcharges and regulatory fees, or taxes, to numerous federal, state and local governmental

authorities. In addition, we incur and pay state and local taxes and fees on purchases of goods and services used in our business. Tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. In many cases, the application of tax laws ~~(including the recently enacted Tax Act)~~ is uncertain and subject to differing interpretations, especially when evaluated against new technologies and services. The impact of ~~this~~ tax reform on holders of our common stock is also uncertain and could be adverse. If we have incorrectly described, disclosed, calculated, assessed, or remitted amounts that were due to governmental authorities, we could be subject to additional taxes, fines, penalties, or other adverse actions, which could impact our business, results of operations, and financial condition. We may not be able to maintain effective and efficient information systems or properly safeguard our information systems. Our operations are dependent on uninterrupted performance of our information systems. Failure to maintain reliable information systems, disruptions in our existing information systems or the implementation of new systems could cause disruptions in our business operations, including violations of patient privacy and confidentiality requirements and other regulatory requirements, increased administrative expenses and other adverse consequences. In addition, information security risks have generally increased in recent years because of new technologies and the increased activities of perpetrators of cyber- attacks resulting in the theft of protected health, business, or financial information. ~~During the COVID- 19 pandemic, in particular, cyber- attacks increased as companies shifted to remote work environments, including several high- profile, sophisticated attacks impacting government agencies and security firms alike, the impacts of which are still being uncovered.~~ Despite our layered security controls, experienced computer programmers and hackers may be able to penetrate our information systems **or the information systems of our licensees** and misappropriate or compromise sensitive patient or personnel information or proprietary or confidential information, create system disruptions or cause shutdowns. They also may be able to develop and deploy viruses, worms and other malicious software programs that disable our systems or otherwise exploit any security vulnerabilities. Outside parties may also attempt to fraudulently induce employees to take actions, including the release of confidential or sensitive information or to make fraudulent payments, through illegal electronic spamming, phishing, or other tactics. A failure in or breach of our information systems **or those of our licensees** because of cyber- attacks or other tactics could disrupt our business, result in the release or misuse of protected health information, or PHI, confidential or proprietary business information or financial loss, damage our reputation, increase our administrative expenses, and expose us to additional risk of liability to federal or state governments or individuals. Although we believe that we have robust information security procedures and other safeguards in place, as cyber threats continue to evolve, we may be required to expend additional resources to continue to enhance our information security measures or to investigate and remediate any information security vulnerabilities. Our remediation efforts may not be successful and could result in interruptions, delays or cessation of service and loss of existing or potential patients and disruption of our operations. In addition, breaches of our security measures and the unauthorized dissemination of patient healthcare and other sensitive information, proprietary or confidential information about us or other third- parties could expose such persons' private information to the risk of financial or medical identity theft or expose us or such persons to a risk of loss or misuse of this information, result in litigation and potential liability for us, damage our brand and reputation or otherwise harm our business. Any of these disruptions or breaches of security could have an adverse effect on our business, financial condition, and results of operations. Our failure to comply with foreign data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation the (" GDPR ") in May 2018. The GDPR, which is wide- ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third- party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the U. S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to € 20 million or 4 % of the annual global revenues of the non- compliant company, whichever is greater. The ~~recent~~ implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process ~~, including in clinical trials~~ , and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management' s attention and increase our cost of doing business. In July 2020, the Court of Justice of the European Union issued its long- awaited decision in the case Data Protection Commission v. Facebook Ireland, Schrems. The decision on this case ~~invalidates~~ **invalidated** the European Commission' s adequacy decision for the EU- U. S. Privacy Shield Framework, calling into question personal data transfers from the EU to the U. S. **On October 7, 2022, President Biden introduced an Executive Order to facilitate a new Trans- Atlantic Data Privacy Framework (the " DPF "), and on July 10, 2023, the European Commission adopted its Final Implementing Decision granting the U. S. adequacy (Adequacy Decision) for EU- U. S. transfers of personal information for companies that self- certify to the DPF.** While we have yet to determine the full impact of the ~~invalidation~~ **DPF on our business, any transfers by us or our vendors or licensees** of **personal information subject to** the ~~EU~~ **GDPR may not comply with data protection law and may increase our exposure to the GDPR' s heightened sanctions for violations of its cross** - **border data** ~~US Privacy Framework on our business, we anticipate increased legal and technological costs as we evaluate any trans- Atlantic transfers~~ - **transfer restrictions** ~~as well as the impact on any business that we may conduct in the EU~~ . In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the U. S., the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business. Our employees and business partners may not

appropriately secure and protect confidential information in their possession. Each of our employees and business partners is responsible for the security of the information in our systems or under our control and to ensure that private and financial information is kept confidential. Should an employee or business partner not follow appropriate security measures, including those related to cyber threats or attacks or other tactics, as well as our privacy and security policies and procedures, the improper release of personal information, including PHI, or confidential business or financial information, or misappropriation of assets could result. The release of such information or misappropriation of assets could have an adverse effect on our business, financial condition, and results of operations. ~~Our employees~~ **Employees** may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately, or to disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations 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. We have adopted a Code of Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with these laws or regulations. If any such actions are instituted against us **or our licensees** , and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. General risks related to our intellectual property If we are sued for infringing intellectual property rights of third parties, litigation will be costly and time consuming and could prevent or delay us from developing or commercializing our pharmaceutical product candidates. Our commercial success depends, in part, on our not infringing the patents and proprietary rights of other parties and not breaching any collaboration or other agreements we entered with regard to our technologies and products. We are aware of numerous third- party U. S. and non- U. S. issued patents and pending applications that exist in the technical areas of our pharmaceutical products, including compounds, formulations, treatment methods, and synthetic processes, which may be applied towards the synthesis of hormones, for example. Patent applications are confidential when filed and remain confidential until publication, approximately 18 months after initial filing, while some patent applications remain unpublished until issuance. As such, there may be other third- party patents and pending applications of which we are currently unaware with claims directed towards composition of matter, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products or product candidates. Therefore, we cannot ever know with certainty the nature or existence of every third- party patent filing. We cannot provide assurances that our licensees or their partners will be free to manufacture or market our products as planned or that we or the ANNOVERA licensors' and partners' patents will not be opposed or litigated by third parties. If any third- party patent was held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, or methods of treatment related to the use or manufacture of any of our products, the holders of any such patent may be able to block our ability to commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. There can be no assurances that we will be able to obtain a license to such patent on favorable terms or at all. Failure to obtain such license may have an adverse effect on our business. There is a substantial amount of litigation involving intellectual property in the pharmaceutical industry generally. If a third- party asserts that we infringe its patents or other proprietary rights, we could face many risks that could adversely affect our business, financial condition, results of operations, and prospects, including the following: • infringement and other intellectual property claims, which would be costly and time- consuming to defend, whether or not we are ultimately successful, which in turn could delay the regulatory approval process, consume our capital, and divert management' s attention from our business; • substantial damages for past infringement, which we may have to pay if a court determines that our products or technologies infringe a competitor' s patent or other proprietary rights; • a court prohibiting us from selling or licensing our technologies or future products unless the third- party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; • if a license is available from a third- party, we may have to pay substantial royalties or lump sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license; or • redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. We are party from time to time to legal proceedings relating to our intellectual property, and third parties in the future may file claims asserting that our technologies, processes, or products infringe on their intellectual property. We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology licensed to us or our licensees, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our pharmaceutical product candidates, an adverse outcome could subject us to significant liabilities to such third parties, and force us or our partners to curtail or cease the development of some or all of our pharmaceutical product candidates, which could adversely affect our business, financial condition, results of operations, and prospects. If we are unable to protect the confidentiality of certain information, the value of our products and technology could be adversely affected. We **rely and** previously relied on trade secrets, know- how, and continuing technological advancement to develop and maintain our competitive position. To protect this competitive position, we regularly enter into confidentiality and proprietary information agreements with third parties, including employees, independent contractors, suppliers, and collaborators. We cannot, however, ensure that these protective arrangements will be honored by third parties, and we may not have adequate remedies if these arrangements are breached. In addition, enforcement of claims that a third- party has illegally

obtained and is using trade secrets, know- how, or technological advancements is expensive, time- consuming, and uncertain. Non- U. S. courts are sometimes less willing than U. S. courts to protect this information. Moreover, our trade secrets, know-how, and technological advancements may otherwise become known or be independently developed by competitors in a manner providing us with no practical recourse against the competing parties. If any such events were to occur, they could adversely affect our business, financial condition, results of operations, and prospects. We may be subject to claims that our former employees wrongfully used or disclosed alleged trade secrets of their former employers or of other third parties with whom we have obligations of confidentiality. As is common in the pharmaceutical industry, ~~prior to the Mayne Transaction~~ we **employ and** previously employed individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these former employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Such claims may lead to material costs for us, or an inability to protect or use valuable intellectual property rights, which could adversely affect our business, financial condition, results of operations, and prospects. General risks related to ownership of our Common Stock The market price of our common stock may be highly volatile, and you could lose all or part of your investment. The trading price of our common stock on Nasdaq is likely to be volatile. This volatility may prevent you from being able to sell your shares at or above the price you paid for your shares. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include the following: • changes in laws or regulations applicable to our products; • unanticipated serious safety concerns related to the use of our products; • the inability for our licensees to obtain adequate supply for our products or the inability to do so at acceptable prices; • adverse regulatory decisions; • the introduction of new products or technologies offered by our competitors; • the effectiveness of our licensees' commercialization efforts; • the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community; • disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; • actual or anticipated variations in quarterly operating results; • the failure to meet or exceed the estimates and projections of the investment community; • the overall performance of the U. S. equity markets and general political and economic conditions; • announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors; • additions or departures of key management personnel; • adverse market reaction to any indebtedness we may incur or securities we may issue in the future; • sales of our common stock by us or our stockholders in the future; • significant lawsuits, including patent or stockholder litigation; • changes in the market valuations of similar companies; • the trading volume of our common stock; • increases in our common stock available for sale upon expiration of lock- up agreements; • effects of natural or man- made catastrophic events or other business interruptions; and • other events or factors, many of which are beyond our control. In addition, the stock market in general, and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which might cause our stock price and trading volume to decline. Future sales and issuances of equity securities, convertible securities or other securities could result in additional dilution of the percentage ownership of holders of our common stock. Our stockholders may experience dilution upon future equity issuances, including convertible debt or equity securities we may issue in the future, the exercise of stock options to purchase common stock granted to our employees, consultants and directors, including options to purchase common stock granted under our stock option and equity incentive plans or the issuance of common stock in settlement of previously issued awards under our stock option and equity incentive plans that may vest in the future. We expect that additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell equity securities, convertible securities or other securities in one or more transactions at prices and in a manner we determine from time to time. If we sell equity securities, convertible securities or other securities current investors may be materially diluted by subsequent sales. We may also need our stockholders to authorize the issuance of additional shares of common stock under our articles of incorporation if we do not have sufficient authorized shares to raise such additional capital or issue future awards under our stock option and equity incentive plans. New investors could also gain rights, preferences, and privileges senior to those of holders of our existing equity securities.