

Risk Factors Comparison 2024-02-15 to 2023-02-28 Form: 10-K

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Our business is subject to numerous risks. You should carefully consider the following risks and all other information contained in or incorporated by reference in this Annual Report, as well as general economic and business risks, together with any other documents we file with the SEC. The risks set out below are not the only risks we face; risks and uncertainties not currently known to us or that we currently deem to be immaterial may also harm our business, operating results and financial condition. If any of the following events occur or risks materialize, it could harm our business, operating results and financial condition and cause the trading price of our common shares to decline.

Risks Related to Commercialization Our success depends on our ability to commercialize LUPKYNIS. We are currently a single approved product company with ~~limited~~ commercial sales experience **since January 2021** and if we are not able to achieve our financial targets related to commercializing LUPKYNIS, then we may need to curtail or cease operations. **Our business strategy is to optimize the clinical and commercial value of LUPKYNIS.** We have invested a significant portion of our efforts and financial resources in the development and commercialization of LUPKYNIS, and we expect LUPKYNIS to constitute our only product revenue for the foreseeable future. Our success depends on our ability to commercialize LUPKYNIS successfully. Successful commercialization of LUPKYNIS is subject to many risks. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than we have. We have limited experience commercializing pharmaceutical products as an organization, **having received marketing approval for LUPKYNIS, our sole commercial product, in January 2021.** In order to market LUPKYNIS successfully, we must continue to build our sales, marketing, managerial, compliance, and related capabilities or make arrangements with third parties to perform these services. If we are unable to establish and maintain adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to commercialize LUPKYNIS appropriately and may not become profitable. Part of our strategy to commercialize LUPKYNIS in the United States is to maintain a direct ~~sales field~~ **work** force. These efforts have been and will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully develop and maintain this capability. LUPKYNIS has only been a marketed product since January 2021. In addition, prior to December 2020, there were no FDA approved treatments for LN. If we are unable to effectively train our ~~sales field work~~ **force** and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers, **our efforts to commercialize successfully could be harmed, which would negatively impact our ability to generate product revenue.** Our ability to successfully commercialize LUPKYNIS will depend on effectively deploying the ~~sales field work~~ **force** we have established and maintaining marketing, manufacturing, and distribution capabilities or relationships. Our ability to generate revenues and meet expectations is contingent on the successful commercialization of LUPKYNIS. A successful commercialization depends on our ability to, amongst other things:

- achieve and maintain compliance with regulatory requirements;
- create and sustain market demand for and achieve market acceptance of LUPKYNIS, **grow the market** through our marketing and sales activities and other arrangements established for the promotion of LUPKYNIS, on a timeline that aligns with our regulatory or intellectual property protection periods;
- educate physicians and patients about the **importance of screening, routine monitoring along with treating to guidelines,** benefits, administration and use of LUPKYNIS;
- train, deploy, and support a qualified ~~sales field work~~ **force**;
- ensure that our third-party manufacturers manufacture LUPKYNIS in sufficient quantities, in compliance with requirements of the FDA, and at acceptable quality and pricing levels in order to meet commercial demand;
- ensure that our third-party manufacturers develop, validate and maintain commercially viable manufacturing processes that are compliant with GMP regulations;
- implement and maintain agreements with wholesalers, special pharmacy partners, distributors, and group purchasing organizations on commercially reasonable terms;
- ensure that our entire supply chain efficiently and consistently delivers LUPKYNIS to our customers;
- receive adequate levels of coverage and reimbursement for LUPKYNIS from commercial health plans and governmental health programs;
- provide co-pay assistance to help qualified patients with out-of-pocket costs associated with their LUPKYNIS prescription and / or other programs to ensure patient access to our product;
- obtain acceptance of LUPKYNIS as safe and effective by patients and the medical community;
- influence the nature of publicity related to LUPKYNIS relative to the publicity related to our competitors' products; and
- maintain and defend our patent protection and regulatory exclusivity for LUPKYNIS.

Many of these factors are beyond our control and if we are not successful in commercializing LUPKYNIS, or are significantly delayed in doing so, our business will be harmed, and we may need to curtail or cease operations. We depend on a limited number of customers and an estimated number of patients for a significant amount of our product revenue, and if we lose any of our significant customers, or if our estimates as to the number of potential patients is wrong, our business could be harmed. ~~As we generally sell to only two specialty pharmacies,~~ **The bulk of our product revenue is generated in the United States from a limited number of direct customers and** most of our product revenue comes from ~~two specialty pharmacies a limited number of direct customers.~~ **our the Company's two main customers in the U. S. accounted for approximately 45-51 % and 35-40 %, respectively, of our total revenues for the year ended December 31, 2022-2023 . Our third main customer is our collaboration partner, Otsuka. When combined, revenues from our two specialty pharmacy customers and Otsuka account for approximately 99 % of our total revenues for the year ended December 31, 2023 .** The loss by us of any of these customers, or a material reduction in their purchases, could harm our business and prospects. In addition, if any of these customers were to fail to pay us in a timely manner, it could negatively impact our cash flow from operations. Sales of our product can be greatly affected by the customer inventory levels

that our customers carry. We monitor customer inventory of our product using a combination of methods, including reports from our customers, and our own internal estimates. Our estimates of customer inventory may differ significantly from actual customer inventory levels. Significant differences between actual and estimated customer inventory levels may result in excessive or insufficient stocking, which could result in ~~our holding~~ substantial quantities of unsold customer inventory, or inadequate supplies of products in the distribution channels. Our customers make the ultimate determination of the amount of inventory to hold. Changes in customer inventory may cause our revenues to fluctuate significantly from quarter to quarter and may cause our operating results for a particular quarter to be below or above our expectations, the expectations of securities analysts, or the expectations of investors. Our estimates of the number of patients who have received or might have been candidates to use LUPKYNIS may not accurately reflect the true market for LUPKYNIS or the extent to which it will actually be used by patients. Our failure to **develop the market for,** forecast **and or** successfully market LUPKYNIS could harm our business, as it could reduce our market potential. LUPKYNIS may not achieve or maintain expected levels of market acceptance among physicians, patients, the medical community, and third- party payors, which could harm our business, financial condition and results of operations and could cause the market value of our common shares to decline. The commercial success of LUPKYNIS is dependent upon achieving and maintaining market acceptance among physicians, patients, and the medical community. Levels of market acceptance for LUPKYNIS could be impacted by several factors, many of which are not within our control, including but not limited to: • limitations or warnings contained in the approved labeling; • changes in the standard of care for the targeted indication; • limitations in the approved clinical indication; • demonstrated clinical safety and efficacy compared to other products; • potential for significant adverse side effects; • sales, marketing, and distribution support; • availability and extent of reimbursement from managed care plans and other third- party payors; • timing of market introduction; • the degree of cost- effectiveness; • ~~the COVID-19~~ **widespread health concerns, such as pandemic pandemics**; • availability of alternative therapies at similar or lower cost, including generic and over- the- counter products; • whether the product is designated under physician treatment guidelines as a first- line therapy or as a second- line or third- line therapy; • adverse publicity about our product or favorable publicity about competitive products; • convenience and ease of administration of **LUPKYNIS our products**; and • potential product liability claims. If LUPKYNIS does not achieve an adequate level of acceptance by physicians, patients, and the medical community, we may not generate sufficient revenue, and we may not become or remain profitable. Efforts to educate the medical community and third- party payors on the benefits of LUPKYNIS may require significant resources and may never be successful. **Our business, results of operations..... other risks described in this Annual Report**. LUPKYNIS may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, which would harm our business. Price controls and price pressure may be imposed in foreign and U. S. markets, which may adversely affect our future profitability. LUPKYNIS may become subject to unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives, which could harm our business. In addition, reimbursement may be limited or unavailable in certain market segments which could make it difficult for us **or our partners** to sell LUPKYNIS profitably. Adverse pricing limitations might hinder our ability to recoup our investment in LUPKYNIS. Our ability to commercialize LUPKYNIS successfully will also depend in part on the extent to which coverage and reimbursement for LUPKYNIS will be available from government authorities, private health insurers and other organizations. In the United States and markets in other countries, patients generally rely on third- party reimbursement for all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to market acceptance of **LUPKYNIS our products**. Our ability to successfully commercialize LUPKYNIS will depend in part on the extent to which coverage and adequate reimbursement of LUPKYNIS will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third- party payors such as private health insurers and health maintenance organizations, decide which medication they will pay for and establish reimbursement levels, which for the product, is beyond our control. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be certain that coverage will be available for LUPKYNIS and, if available, the level of reimbursement. Reimbursement will impact the demand for, or the price of, our approved product. If reimbursement is limited or not available, we might not be able to successfully commercialize LUPKYNIS. There may be delays in obtaining reimbursement for recently approved products and eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, patient services, sale, and distribution. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors. Private third- party payors often rely on Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for our approved product could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize LUPKYNIS and on our overall financial condition. If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, results of operations and financial condition. We participate in the Medicaid Drug Rebate Program, as administered by Centers for Medicare and Medicaid Services, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with products, including LUPKYNIS, that are dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the

government agencies that administer the programs. Pricing and rebate calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The terms, scope and complexity of these government pricing programs change frequently. Responding to current and future changes may increase our costs and the complexity of compliance will be time consuming. In addition, there is increased focus by the Office of Inspector General on the methodologies used by manufacturers to calculate Average Manufacturer Price (AMP), and best price (BP), to assess our compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly / quarterly AMP and BP data on a timely basis could result in a civil monetary penalty per day for each day the submission is late beyond the due date. Failure to make necessary disclosures and / or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U. S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. If Centers for Medicare and Medicaid Services were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient products, which would harm our business.

We report on various metrics relating to LUPKYNIS activity, and no single metric is indicative of, or directly correlated to, our current or future financial performance. We report on various metrics relating to LUPKYNIS activity, including the number of prescriptions / PSFs, conversion rates (being the proportion of PSFs that convert into patients on therapy), persistency rates (being how long patients on therapy remain on therapy), adherence (being the degree to which patients take their prescribed dose of LUPKYNIS in the manner and at the times prescribed by their doctor), numbers of patients on therapy and as of the fourth quarter of 2023, we also include patient restarts and patients resulting from hospital fills (which are estimated based on shipping patterns). None of these metrics, in and of themselves, is indicative of current or future financial performance. There is no guarantee that a patient for whom we receive a PSF will become a patient on therapy, or that the number of patients estimated from hospital fills are accurate. Converting a patient from a PSF into a patient on therapy includes multiple steps, many of which are outside of our control, such as patients and doctors needing to coordinate applications relating to insurance coverage for LUPKYNIS, and potentially one or more appeals if coverage is denied initially. We refer to patients for whom we receive a PSF but that never convert into a patient on therapy as a cancellation. Cancellations result in zero revenue. Even when a patient becomes a patient on therapy, there is no guarantee that they will be a patient for which we receive revenue (as certain patients are eligible for our free drug program), or that they will remain on drug for any period of time (whether due to a reduction in LN activity, an actual (or perceived) drug-related adverse event, or from a lack of taking medication, or otherwise). Patients on therapy may also not take their prescribed dose of LUPKYNIS in the manner and at the times prescribed by their doctor, which could result in reduced orders of LUPKYNIS in respect of that patient on therapy versus a patient that is prescribed a higher dose of LUPKYNIS and follows their prescription exactly as prescribed. We refer to patients who have converted from a PSF into a patient on therapy, but who subsequently cease treatment (for any reason), as discontinuations. A patient on therapy who discontinues treatment generally results in zero future revenue, and discontinuations can occur at any time once a patient commences therapy. Accordingly, our PSF activity, and related metrics, are not in and of themselves directly indicative of our current or future financial performance. Our net product revenue to date is primarily the result of our two main customers in the United States (our two specialty pharmacies) who order LUPKYNIS for dispensing to patients, and from our collaboration partner, Otsuka (see further under "Summary of Significant Accounting Policies-Revenue Recognition" later in this Report for further discussion). The orders for product from our two main customers do not necessarily correlate to our PSF numbers. Our revenue received from Otsuka has no relevance to any of the above noted metrics. Our revenue could therefore fluctuate in a manner contrary to our PSF trends, both where revenue could be greater than a PSF trend would indicate, or where revenue could be lesser than a PSF trend would indicate.

Therefore, while we report on PSFs and related figures to provide an indication of potential prescription activity for LUPKYNIS, there is no single metric that is directly correlated to, or indicative of, our future financial performance.

Risks Related to Patents and Proprietary Technology Our proprietary rights may not adequately protect our intellectual property and product, and if we cannot obtain adequate protection of our intellectual property and product, we may not be able to successfully market our product. Patents and other proprietary rights are essential to our business. Our practice has been to file patent applications to protect technology, inventions, and improvements to our inventions that are considered important to the development of our business. Our success will depend in part on our ability to obtain patents, defend patents, maintain trade secret protection, and operate without infringing on the proprietary rights of others. Interpretation and evaluation of pharmaceutical patent claims present complex and often novel legal and factual questions. Accordingly, there is some question as to the extent to which pharmaceutical discoveries and related products and processes can be effectively protected by patents.

As a result, there can be no assurance that: • patent applications will result in the issuance of patents; • ~~additional proprietary products developed will be patentable;~~ • patents issued will provide adequate protection or any competitive advantages; • patents issued will not be successfully challenged and invalidated by third parties; • ~~our products, including LUPKYNIS~~ **does**, do not infringe the patents or intellectual property of others; • that our patents or regulatory protections will provide sufficient duration for **LUPKYNIS** ~~our products~~ to reach a level of profitability; or • that we will be able to obtain any extensions of the applicable patent terms.

. Even if issued, patents provide finite terms of protection and, in general, those time periods are not able to be extended. Under law, we have been granted new chemical entity exclusivity for the marketing of LUPKYNIS to January 2026 in the United States. Our original composition of matter patent for voclosporin expired in the United States in October 2022. We have sought a patent term extension to extend the term of that United States patent to October 2027, which remains in process. To date, we have been able to obtain interim patent term extensions for that

patent that currently extend its term to October 2024. Our other existing Orange Book listed patents for LUPKYNIS have a term to 2037. Those are the maximum terms for those patents, which are our main protection against generic entrants into the LN market. It is possible that one or more of our patents could be subject to a challenge (such as an inter partes review) which, if successful, could limit the protection offered by that patent even further or eliminate it entirely, which would have a negative impact on our ability to continue our business in its current form.

Several pharmaceutical, biotechnology, and medical device companies and research and academic institutions have developed technologies, filed patent applications, or received patents on various technologies that may be related to our business. Some of these technologies, applications or patents may conflict with or adversely affect our technologies or intellectual property rights. Any conflicts with the intellectual property of others could limit the scope of the patents, if any, that we may be able to obtain or result in the denial of patent applications altogether. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. We may need to license certain intellectual property from third parties, and such licenses may not be available on commercially reasonable terms. An unfavorable outcome in an interference or opposition proceeding or a conflict with the intellectual property of others could preclude us or our collaborators or licensees from making, using or selling product using the technology, or require us to obtain license rights from third parties. It is not known whether any prevailing party would offer a license on commercially acceptable terms, if at all. Further, any such license could require the expenditure of substantial time and resources and could harm our business. If such licenses are not available, we could encounter delays or prohibition of the development or introduction of LUPKYNIS. We may need to enter into license agreements in the future. As part of discovery and development activities, we routinely evaluate in-licenses from academic and research organizations. Future license agreements might impose various diligence, milestone payment, royalty, and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners (such as Otsuka) regarding our rights or obligations under the licensing agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partner's ability to utilize the affected intellectual property in our drug discovery and development efforts, and our ability to ensure into collaboration or marketing agreements for an affected product, may be adversely affected. We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming, and unsuccessful. Competitors or commercial supply companies or others may infringe our patents and other intellectual property rights. To counter such infringement, we may advise such companies of our intellectual property rights, including, in some cases, intellectual property rights that provide protection for our product, and demand that they stop infringing those rights. Such demand may provide such companies the opportunity to challenge the validity of certain of our intellectual property rights, or the opportunity to seek a finding that their activities do not infringe our intellectual property rights. We may also be required to file infringement actions, which can be expensive and time-consuming. In an infringement proceeding, a defendant may assert, and a court may agree with a defendant, that a patent of ours is invalid or unenforceable or may refuse to stop the other party from using the intellectual property at issue. An adverse result in any litigation could put one or more of our patents at risk of being invalidated or interpreted narrowly. 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. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could impact the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, and defending our intellectual property rights in all countries throughout the world would be prohibitively expensive, time consuming, distract our personnel from their normal responsibilities and might be unsuccessful. Our intellectual property rights in some countries outside of the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing product made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with ~~our products (including LUPKYNIS~~ **our products (including LUPKYNIS**), and our intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our intellectual property rights or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our proprietary rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our proprietary rights at risk of

being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products (including LUPKYNIS). As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Patent reform legislation in the United States and other countries could increase those uncertainties and costs. The first-to-file provisions of the current United States patent system only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact those provisions will have on the operation of our business. The implementation and interpretation of new patent laws could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition, there have been recent proposals for additional changes to the patent laws of the U. S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U. S. Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Not all of our trademarks are registered. Failure to secure those registrations could adversely affect our business. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could adversely affect our business. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We will be given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets or other proprietary information. There may be an unauthorized disclosure of the significant amount of confidential information under our control. We maintain and manage confidential information relating to our technology, research and development, production, marketing, and business operations and those of our collaborators, in various forms. Although we have implemented controls to protect the confidentiality of such information, there can be no assurance that such controls will be effective. Unauthorized disclosures of such information could subject us to complaints or lawsuits for damages, in Canada, the United States or other jurisdictions, or could otherwise have a negative impact on our business, financial condition, results of operations, reputation and credibility. Risks Related to Financial Position and Need for Additional Capital We may expect to continue to have negative cash flow and we may never achieve or maintain profitability. We had negative operating cash flow for multiple years, including the year ended December 31, 2022-2023. To the extent that we have negative operating cash flow in future periods, we will likely need to allocate a portion of our cash reserves to fund such negative cash flow. We may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that we will be able to generate a positive cash flow from our operations, that additional capital or other types of financing will be available when needed or that these financings will be on terms favorable or acceptable to us if available at all. We have incurred losses and anticipate that our losses may increase as we continue to expand and develop our business (including developing our pipeline of potential products) and commercialize LUPKYNIS. As of December 31, 2022-2023, we had an accumulated deficit of \$ 864-942.3 million. Although we received FDA approval and commenced commercialization of LUPKYNIS in the United States in January 2021, we have and may continue to incur losses and there can be no assurance that we will be able to generate sufficient product revenue to become profitable at all or on a sustained basis. Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or cause any guidance we may provide to be inaccurate. Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. As we only received FDA approval for LUPKYNIS in 2021, there is an absence of historical sales data. This has resulted in our revenue from product sales being, and we expect will continue to be, difficult to predict. We also expect to have quarter-to-quarter fluctuations in expenses, some of which could be significant, due to research, development, clinical trial activities, regulatory activities, commercialization activities and business development. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. Therefore, comparing our operating results on a period to period basis may not be meaningful. Our past results will not be a reliable indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors, or below any forecast we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts and investors, the price of our common shares could decline significantly. Such decline could occur even when we meet any previously publicly stated revenue or earnings guidance we may provide. Legislative actions, potential new accounting pronouncements, and higher insurance costs are likely to impact our future financial position or results of operations. Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying

interpretations of pronouncements have occurred with greater frequency and are expected to occur in the future. Compliance with changing regulations of corporate governance and public disclosure may result in additional expenses. All these uncertainties are leading generally toward increasing insurance costs, which may harm our business, results of operations, and our ability to purchase any such insurance, at acceptable rates or at all, in the future. We are exposed to inflation risk, credit risk and market risk related to changes in interest rates and foreign currency exchange, each of which could affect the value of our current assets and liabilities. We invest our cash reserves in U. S. dollar denominated, fixed rate, highly liquid and highly rated financial instruments such as corporate bonds, commercial paper, treasury bills and bonds. We do not believe that the results of operations or cash flows would be affected to any significant degree by a sudden change in market interest rates relative to our investment portfolio, due to the short- term nature of the investments and our current ability to hold these investments to maturity. We are exposed to financial risk related to the fluctuation of foreign currency exchange rates which could harm our future operating results or cash flows. Foreign currency risk is the risk that variations in exchange rates between the United States dollar and foreign currencies, primarily with the Canadian dollar, Swiss Franc and Great British Pound which could affect our operating and financial results. We hold the majority of our cash reserves in U. S. dollars and the majority of our revenues and expenses, including clinical trial costs are also denominated in U. S. dollars, which mitigates the risk of material foreign exchange fluctuations. ~~discover that, despite the implementation of our restructuring program, we may require additional capital to continue expanding our business, and we may not be able to obtain such capital on acceptable terms, if at all. Our failure to successfully accomplish any of the above activities and goals may have a material adverse impact on our business, financial condition and results of operations.~~ Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. Our activities to date have been limited to, among other things, organizing and staffing our **Company company**, business planning, business development, raising capital, developing, manufacturing, and, **more recently**, marketing and commercializing LUPKYNIS ~~in~~. **In** addition to undertaking nonclinical studies, and conducting clinical trials and business development. We have limited history demonstrating our ability to manufacture a product at commercial scale or conduct sales, marketing, and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as reliable as they could be if we had a longer and more established operating history. In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We may need to expand our capabilities to support future activities related to the commercialization of LUPKYNIS. We may be unsuccessful in adding such capabilities. Anticipated revenues may not be derived from licensing activities. Our future performance may be impacted by our ability to generate royalty or other revenues (such as commercial and regulatory milestones **and**, product revenue **or upfront collaboration payments**) from licenses (such as the license granted to Otsuka) and the successful commercialization of LUPKYNIS **or other products we may develop or acquire**. We anticipate that some of our revenues in the future may be derived from products licensed to pharmaceutical and biotechnology companies. Accordingly, these revenues will depend, in large part, upon the success of these companies, and our operating results may fluctuate substantially due to reductions and delays in their research, development, and marketing expenditures. These reductions and delays may result from factors that are not within our control, including: a. changes in economic conditions; b. changes in the regulatory environment, including governmental pricing controls affecting health care and health care providers; c. pricing pressures; d. other factors affecting research and development spending; and e. change in strategy of our business partners. The failure of Otsuka or future licensing partners could harm our business or results of operations and the global reputation of LUPKYNIS. Our portfolio of **short- term** investments is subject to market, interest and credit risk that may reduce its value. We maintain a portfolio of **short- term** investments. Changes in the value of our portfolio of **short- term** investments could adversely affect our earnings. In particular, the value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, declines in the value of collateral underlying the securities included in our portfolio and other factors. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our **short- term** investments and continuous monitoring of our portfolio's overall risk profile, the value of our **short- term** investments may nevertheless decline. We may require additional financing to achieve our goals, and failure to obtain such when required could force us to delay, reduce or terminate our commercialization efforts. We may require additional capital resources to expand and develop our business. Advancing LUPKYNIS inside and outside the United States, marketing for LUPKYNIS, or acquisition and development of any other products will require considerable resources and additional access to capital markets. In addition, our future cash requirements may vary materially from those now expected. Our future capital requirements may increase if for example: a. we experience unexpected or increased costs relating to preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, or other lawsuits, brought by either us or our competition; b. we elect to develop, acquire or license new technologies, products or businesses; c. we are required to perform additional pre- clinical studies and clinical trials; or d. we have a change in commercial strategy which could result in increase in headcount, direct to consumer marketing campaigns, and advertising. We could potentially seek additional funding through corporate collaborations and licensing arrangements or through public or private equity or debt financing. However, if capital market conditions in general, or with respect to life sciences companies such as ours, are unfavorable, our ability to obtain significant additional funding on acceptable terms, if at all, will be negatively affected. Additional financing that we may pursue may involve the sale of common shares which could result in significant dilution to our shareholders. If sufficient capital is not available, we may be required **to delay our research and development projects, halt commercialization, relinquish rights to our technologies or products on terms unfavorable to us, which could harm our business, financial condition, prospects or results of operations.** We may not realize the anticipated benefits of acquisitions or product licenses and integration of these acquisitions and any products acquired or licensed may disrupt our business and management. As part of our business strategy,

we may acquire additional companies, products or technologies principally related to, or complementary to, our current operations (as we did with our acquisitions of AUR200 and rights to AUR300). At any given time, we may be evaluating acquisitions of companies, products or technologies or may be exploring licensing opportunities, and may have entered into confidentiality agreements, non-binding letters of intent or may be in the process of conducting due diligence with respect to such opportunities. Any such acquisitions will be accompanied by certain risks including, but not limited to: **a-** exposure to unknown liabilities of acquired companies and the unknown issues with any associated technologies or research; **b-** **inability to recognize expected benefit of synergies and fully recognize return on investment;** **c-** higher than anticipated acquisition costs and expenses; **d-** the difficulty and expense of integrating operations, systems, and personnel of acquired companies; **e-** disruption of our ongoing business; **f-** inability to retain key customers, distributors, vendors and other business partners of the acquired company; **g-** diversion of management's time and attention; and **h-** possible dilution to shareholders. We may never be able to efficiently execute on business development activities, properly integrate acquired assets (including any human capital associated with the acquired assets), or bring management's expectation of benefit from the acquired assets to fruition. We may not be able to successfully overcome these risks and other problems associated with acquisitions and this may harm our business, financial condition, or results of operations. **Our limited operating history may make it..... prospects or results of operations.** Risks Related to Drug Development and Regulatory Approval Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside of our control. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our clinical trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the studied product, the number and nature of competing treatments and ongoing clinical trials of competing products for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Furthermore, any negative results we may report in clinical trials of our product may make it difficult or impossible to recruit and retain patients in other clinical trials of the same product. Delays or failures in planned patient enrollment and / or retention may result in increased costs, program delays or both, which could make us subject to regulatory penalties or fines due to non- fulfillment of our post- marketing requirements and post- marketing commitments with the FDA . **We may not be successful in..... the trading price of our common shares** . Even though the FDA has approved LUPKYNIS, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, LUPKYNIS could be subject to restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with LUPKYNIS. The FDA and other agencies, including the U. S. Department of Justice (DOJ) closely regulate and monitor the post- approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off- label use. If we market LUPKYNIS in a manner inconsistent with our approved labeling and indication, we may be subject to enforcement action for off- label marketing. Violations of the federal FDCA and other statutes, including the False Claims Act (FCA), relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which violations may result in the imposition of significant administrative, civil and criminal penalties. The manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and recordkeeping for LUPKYNIS will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with GMP and GCP for clinical trials that we conduct post- approval. Discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • restrictions on the marketing or manufacturing of our product, withdrawal of the product from the market, or voluntary or mandatory product recalls; • fines, warning letters or holds on clinical trials; • product seizure or detention, or refusal to permit the import or export of products; and • injunctions or the imposition of civil or criminal penalties. There can be no assurance that we will be able to adapt to changes in existing requirements, adopt new requirements or policies, or maintain regulatory compliance. If we fail to maintain compliance, we may lose marketing approval, which would harm our business, prospects, and ability to achieve or sustain profitability. LUPKYNIS may have undesirable side effects which may require it to be taken off the market, include additional safety warnings or otherwise limit sales. LUPKYNIS has undergone safety testing, however, not all adverse effects can be predicted or anticipated. Unforeseen side effects from LUPKYNIS could arise after the approved product has been marketed. Ongoing or future trials of our product may not support the conclusion that LUPKYNIS has an acceptable safety profile or the FDA may disagree with our clinical trial investigators' interpretation of data from clinical trials or post marketing surveillance in determining if adverse or unacceptable side effects are related to LUPKYNIS. There can be no assurance that discovery of previously unknown adverse events or other problems with LUPKYNIS, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, will not occur at any time during commercial and future use of LUPKYNIS. Furthermore, there can be no assurance that disease resistance or other unforeseen factors will not limit the effectiveness of LUPKYNIS. The most common adverse reactions to LUPKYNIS demonstrated in our Phase 3 AURORA study were glomerular filtration rate decrease, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite. These common adverse reactions were also repeated in our AURORA 2 continuation study and our real world experience with LUPKYNIS since our product launch in 2021. Any adverse discoveries may yield various results, including: a. regulatory authorities may require us to take LUPKYNIS off the market; b. regulatory

authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies; c. we may be required to change the way LUPKYNIS is administered, impose other risk- management measures, conduct additional clinical trials or change the labeling of LUPKYNIS; d. we may be subject to limitations on how we may promote LUPKYNIS; e. sales of LUPKYNIS may decrease significantly; f. refusal to approve pending applications or supplements to approve application that we submit; g. recall of products; h. refusal to permit the import or export of LUPKYNIS; and i. we may be subject to litigation or product liability claims. Any of these events could prevent us, our collaborators (including Otsuka) or our potential future partners from achieving or maintaining market acceptance of LUPKYNIS or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of LUPKYNIS. It would harm our business, reputation, prospects and ability to achieve or sustain profitability. We or our partners (including Otsuka) may never obtain full approval or commercialize LUPKYNIS outside of the United States, which would limit our ability to realize their full market potential. To market any products outside of the United States, we and Otsuka or other potential future partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and may require additional pre- clinical studies, clinical trials, or additional administrative review periods, which could result in significant delays, difficulties, and costs for us. While we have obtained approval by the EC and MHRA, specific jurisdictions covered by those approvals (and approvals in other jurisdictions) also require additional regulatory approvals, such as pricing and reimbursement approval, before sales can commence in those jurisdictions . **Not all of those jurisdictions have provided all such approvals to date** . In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. If regulatory approval is obtained it may not be as broad as what was obtained in other jurisdictions. We have limited experience in obtaining regulatory approval in international markets. If we or our current or future partners fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of LUPKYNIS could be harmed. If product liability lawsuits are brought against us, we may incur substantial liabilities and we may be required to limit commercialization of or recall LUPKYNIS. We face an inherent risk of product liability exposure related to the testing of product candidates in human clinical trials, and an even greater risk in connection with our commercialization of LUPKYNIS. If we cannot successfully defend ourselves against claims that LUPKYNIS causes injuries, then we could incur substantial liabilities. Regardless of merit of eventual outcome, liability claims may result in: a. decreased demand for LUPKYNIS; b. injury to our reputation and significant negative media attention; c. withdrawal of clinical trial participants; d. significant costs to defend the related litigation; e. substantial monetary awards to trial participants or patients; f. loss of revenue; and g. the inability to, or restrictions on our ability to, commercialize any approved product. Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. The obligation to pay any product liability claim in excess of whatever insurance we can acquire, or the recall of or limitation on our ability to commercialize LUPKYNIS as a result of product liability concerns, could harm our business, financial condition, and future prospects. Compliance with ongoing post- marketing obligations for LUPKYNIS may uncover new safety information that could give rise to a product recall, updated warnings, or other regulatory actions that could have an adverse impact on our business. After a regulatory body, such as the FDA, approves a drug or biologic for marketing, the product' s sponsor must comply with several post- marketing obligations that continue until the product is discontinued. These post- marketing obligations include the reporting of adverse events to the agency within specified timeframes, the submission of product- specific annual reports that include changes in the distribution, manufacturing, and labeling information, and notification when a drug product is found to have significant deviations from its approved manufacturing specifications (among others). Our ongoing compliance with these types of mandatory reporting requirements could result in additional requests for information from regulatory bodies that govern our products and, depending on the scope of a potential product issue that a regulatory body may decide to pursue, could potentially also result in a request from the agency to conduct a product recall or to strengthen warnings and / or revise other label information about the product. Regulatory bodies may also require or request the withdrawal of the product from the market. Any of these post- marketing regulatory actions could materially affect our sales and **increase our costs and** , therefore, have the potential to adversely affect our business, financial condition, results of operations and cash flows .We may not be successful in our efforts to build out a pipeline of product candidates. We may not be able to continue to identify or develop, at all or in a timely manner, new products ~~(including AUR200 and AUR300)~~. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development or commercialization. If we do not successfully identify, develop, and commercialize new products based upon our approach, we will not be able to diversify our portfolio which could result in harm to our financial position and impact the **trading price of our common shares** .

Risks Related to Our Reliance on Third Parties and Partners We are dependent on Otsuka for the development and commercialization of LUPKYNIS in several countries outside the United States. The failure to meet contractual, regulatory, or other obligations could adversely affect our business. We have entered into an exclusive license agreement with Otsuka that provides the licensee exclusive rights to the development and commercialization of LUPKYNIS in various specified regions outside of the United States. As a result, we are dependent on Otsuka to achieve full regulatory approval of LUPKYNIS for marketing in these regions and for the commercialization of LUPKYNIS, if approved. The timing and amount of any milestone and royalty payments we may receive under this agreement, as well as the commercial success of LUPKYNIS in those regions outside of the United States, will depend on, among other things, the efforts, allocation of resources, and successful commercialization of LUPKYNIS by Otsuka. Otsuka, accounted for approximately **20.8%** of the Company' s **total** net revenue for the year ended December 31, **2022-2023** . We also depend **on** Otsuka to comply with all applicable laws relative to the development and commercialization of LUPKYNIS

in those countries. We do not control the individual efforts of Otsuka and have limited ability to terminate this agreement if Otsuka does not perform as anticipated. The failure of Otsuka to devote sufficient time and effort to the development and commercialization of LUPKYNIS, or the failure of Otsuka to meet their obligations to us, including for future ~~royalty royalties~~ **and, milestone payments, manufacturing services payments and other collaboration** payments; to adequately deploy business continuity plans in the event of a crisis; and / or satisfactorily resolve significant disagreements with us or address other factors, could harm our financial results and operations. If any licensee or authorized sub- licensee of **LUPKYNIS** ~~our products~~ violates, or is alleged to have violated, any laws or regulations during the performance of their obligations for us, it is possible that we could suffer financial and reputational harm, or other negative outcomes, including possible legal consequences. Any termination, breach, or expiration of any of this license agreement could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive milestone payments and royalties. In such an event, we may be required to devote additional efforts and to incur additional costs associated with pursuing regulatory approval and commercialization of LUPKYNIS. Alternatively, we may attempt to identify and transact with a new licensee, but there can be no assurance that we would be able to identify a suitable licensee or transact at all, or on terms that are favorable to us. In addition, license, research, and development agreements with third parties include indemnification and obligation provisions that are customary in the industry. These guarantees generally require us to compensate the other party for certain damages and costs incurred because of third- party claims or damages arising from these transactions. These provisions may survive termination of the underlying agreement. The nature of the potential obligations prevents us from making a reasonable estimate of the maximum potential amount we could be required to pay. We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties in compliance with regulations or meet expected deadlines, we might be subject to regulatory penalties or fines due to non- compliance with our post- marketing approval requirements. We depend upon independent investigators and collaborators, such as contract research organizations or CROs, universities and medical institutions, to conduct clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with regulatory requirements, including GCP requirements, and the applicable protocol. If we, or any of our CROs or third party contractors, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials or make us subject to fines or regulatory penalties, which would materially adversely affect our business. We have limited experience in drug formulation or manufacturing and rely exclusively on third parties, in many cases as sole provider, to formulate and manufacture LUPKYNIS, and any disruption or loss of these relationships could delay our development and commercialization efforts. We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. For example, we are using the following third parties for manufacturing and encapsulation: • Lonza is currently the sole source manufacturer of our drug substance; and • Catalent is solely providing services with respect to encapsulating LUPKYNIS for our commercial and clinical supply, clinical labeling and global distribution for clinical trial purposes. If we are unable to continue our relationships with one or more of our third- party contractors, in particular where those third- party contracts are one of our sole providers, we could experience delays in commercialization and development efforts as we locate and qualify new contractors. Our reliance on a limited number of third- party manufacturers exposes us to the following risks: • We may be unable to identify third- party manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and the FDA must approve any replacement manufacturer. This approval could require new testing and compliance inspections. In addition, a new third- party manufacturer would have to be educated in, or develop substantially equivalent processes for, production of LUPKYNIS after receipt of FDA approval. • Our third- party manufacturers might be unable to formulate and manufacture LUPKYNIS in the volume and of the quality required to meet our clinical and / or commercial needs. • Our third- party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute LUPKYNIS for commercialization, as applicable. • The facilities used by our third- party manufacturers to manufacture LUPKYNIS must be approved by the FDA. • If any third- party manufacturer makes improvements in the manufacturing process for LUPKYNIS, we may not own, or may have to share, the intellectual property rights to the innovation. Each of these risks could delay the commercialization of LUPKYNIS, or result in higher costs or deprive us of potential product revenue. Any disruption or loss of these relationships could delay our development and commercialization efforts and our business could be harmed. We rely on third parties for the supply and manufacture of LUPKYNIS, which can be unpredictable in terms of quality, cost, timing, and availability. If we encounter any such difficulties, our ability to supply LUPKYNIS for commercial sale could be delayed or halted entirely. Manufacturers of pharmaceutical products often encounter difficulties in production ~~, especially in scaling up initial production.~~ These problems include difficulties with production costs and yields, stability, quality control and assurance, and shortages of qualified personnel, as well as compliance with strictly enforced federal, provincial, state, and foreign regulations. We rely on a limited number of third parties to manufacture and supply raw materials for LUPKYNIS. The third parties we choose to manufacture and supply raw materials for LUPKYNIS are not under our control and may not perform as agreed or may terminate their agreements with us, and we may not be able to find other third parties to manufacture and supply raw materials on commercially reasonable terms, or at all. If any of these events were to occur, our operating results and financial condition would be adversely affected. In addition, drug and chemical manufacturers are subject to GMP regulations and various regulatory inspections, including those conducted by the FDA, to ensure strict compliance with GMP and other government regulations. While we are obligated to

audit the performance of our third- party contractors, we do not have complete control over their compliance. We could be adversely impacted if our third- party manufacturers or distributors do not comply with these standards and regulations. For non-compliance, the regulatory authority may levy penalties and sanctions, including fines, injunctions, civil penalties, failure of the government to grant review of submissions or market approval of products, or cause delays, suspension or withdrawal of approvals, product seizures or recalls, operating restrictions, facility closures and criminal prosecutions. Any of this will have an impact on our business, financial condition, and results of operations. The process of manufacturing LUPKYNIS is susceptible to product loss due to a variety of factors, including but not limited to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product or in the manufacturing facilities in which our product are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any adverse developments affecting manufacturing operations for our product may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of **LUPKYNIS** ~~our products~~. We may also have to take inventory write- offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. While we attempt to mitigate against this risk by ordering additional quantities and maintaining a safety stock of our product, we may not estimate the required amounts sufficiently and even this may not provide sufficient mitigation. We may also incorrectly forecast our demand and over- order quantities of our product, or the materials needed to manufacture our product, which could result in write offs, potentially in material amounts. If our third- party manufacturers are unable to produce the required commercial quantities of LUPKYNIS to meet demand on a timely basis or at all, or if they fail to comply with applicable laws for the manufacturing, we will suffer damage to our reputation and commercial prospects and we will lose potential revenue. In response to the ongoing armed ~~conflict~~ **conflicts** in Ukraine **and in the Middle East**, the U. S. government, numerous state governments, the EU and other countries in which we conduct business have imposed a wide range of economic sanctions that restrict commerce and business dealings with Russia, certain regions of Ukraine **, certain regions in the Middle East** and certain entities. Our suppliers rely on some materials that were originally sourced from the areas impacted by the armed conflict which may increase supply disruptions. This could, in turn, adversely impact our ability to manufacture **and distribute** LUPKYNIS. If we are unable to establish and maintain our agreements with third parties to sell and distribute LUPKYNIS to patients, our results of operations and business could be adversely affected. We rely on third parties to commercially sell and distribute LUPKYNIS to patients. For example, we have contracted with a limited number of specialty pharmacies and specialty distributors to sell and distribute LUPKYNIS. The use of specialty pharmacies and specialty distributors involves certain risks, including, but not limited to, risks that these organizations will: • not provide us accurate or timely information regarding their inventories, the number of patients who are using LUPKYNIS or serious adverse reactions, events and / or product complaints regarding LUPKYNIS; • not effectively sell or support LUPKYNIS or communicate publicly concerning LUPKYNIS in a manner that is contrary to FDA rules and regulations; • reduce their efforts or discontinue to sell or support or otherwise not effectively sell or support LUPKYNIS; • not devote the resources necessary to sell LUPKYNIS in the volumes and within the time frames that we expect; • be unable to satisfy financial obligations to us or others; or • cease operations. Any such events may result in decreased product sales and lower product revenue, which would harm our results of operations and business. We are also required to comply with good distribution practices such as maintenance of storage and shipping conditions, as well as security of products, in order to ensure product quality determined by GMP is maintained throughout the distribution network. While we are obligated to audit the performance of our third- party contractors, we do not have complete control over their compliance. We could be harmed if our third- party distributors do not comply with these standards and regulations. Risks Related to Government Regulation Our relationships with customers, healthcare providers, and third- party payors are subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits on future earnings. We are subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third- party payors play a primary role in the recommendation and prescription of LUPKYNIS. Our future arrangements with third- party payors and customers will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute LUPKYNIS. Restrictions under applicable federal and state healthcare laws and regulations include, but are not limited to, the following: • the U. S. federal Anti- Kickback Statute which prohibits, among other things, persons 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 either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the FCA imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. We can be held liable under the FCA even when we do not submit claims directly to government payors if we are deemed to “ cause ” the submission of false or fraudulent claims; • the U. S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for executing a scheme to

defraud any healthcare benefit program regardless of the payor (e. g., public or private), or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the U. S. federal physician payment transparency requirements, sometimes referred to as the “ Sunshine Act ” under the ACA require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’ s Health Insurance Program to report to the Department of Health and Human Services information related to covered health care provider payments and other transfers of value and the ownership and investment interests of such healthcare providers (as defined by the statute) and their immediate family members; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions; • the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services (similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation); • consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • the U. S. federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’ s decision to order or receive items or services reimbursable by the government from a particular provider or supplier; and • analogous state laws and regulations, such as state anti- kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third- party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry’ s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre- empted by HIPAA, thus complicating compliance efforts. In the United States, to help patients who have no or inadequate insurance access to LUPKYNIS, we have a patient support program that we administer in conjunction with our patient support program vendor. If we or our vendors are deemed to fail to comply with relevant laws, regulations, or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of assistance to our patients. Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be 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, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us to modify our patient support programs and could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses. To help patients afford LUPKYNIS, we have implemented a patient support program. These types of programs, designed to assist patients in affording pharmaceuticals, have become the subject of scrutiny. In recent years, some pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their patient support programs and their support of independent charitable patient support foundations in connection with such programs under a variety of federal and state laws. Our patient support program could become the target of similar litigation. In addition, certain state and federal enforcement authorities and members of Congress have initiated inquiries about co- pay assistance programs. Some state legislatures have also been considering proposals that would restrict or ban co- pay coupons. In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical manufacturers to patient assistance programs operated by charitable foundations. For example, the Office of Inspector General of the U. S. Department of Health & Human Services (OIG) has established specific guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations which provide co- pay assistance to Medicare patients, provided that such organizations are bona fide charities, are entirely independent of and not in any way controlled or influenced by the manufacturer, provide aid to applicants on a first- come basis according to consistent financial criteria, and do not link aid to use

of a donor's product. If we establish a program to donate to independent charitable patient support foundations and our vendors or donation recipients are deemed to fail to comply with laws or regulations in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, numerous organizations, including pharmaceutical manufacturers, have received subpoenas from the U. S. Department of Justice (DOJ) and other enforcement authorities seeking information related to their patient assistance programs and support, and certain of these organizations have entered into, or have otherwise agreed to, significant civil settlements with applicable enforcement authorities. In connection with these civil settlements, the U. S. government has and may in the future require the affected companies to enter into complex corporate integrity agreements that impose significant reporting and other requirements on those companies. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may potentially violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses. The failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws, including the Foreign Corrupt Practices Act (FCPA) and similar laws associated with our activities outside of the United States, could subject us to penalties and other adverse consequences. We are subject to the FCPA regulations of the U. S. Office of Foreign Assets Control, and other anti-corruption, anti-bribery and anti-money laundering laws around the world where we conduct activities, including, if approved in such countries, the sale of LUPKYNIS. We face significant risks and liability if we fail to comply with the FCPA and other anti-corruption and anti-bribery laws that prohibit companies and their employees and third-party business partners, such as distributors or resellers, from authorizing, offering or providing, directly or indirectly, improper payments or benefits to foreign government officials, political parties or candidates, employees of public international organizations including healthcare professionals, or private-sector recipients for the corrupt purpose of obtaining or retaining business, directing business to any person, or securing any advantage. We rely on various third parties for certain services outside the United States, including continued development of LUPKYNIS and the commercialization of LUPKYNIS. We may be held liable for the corrupt or other illegal activities of these third parties and intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U. S. government contracts, which could harm our reputation, business, operating results and prospects. In addition, responding to any enforcement action or related investigation may result in a diversion of management's attention and resources and significant defense costs and other professional fees. Compliance with governmental regulation and other legal obligations related to privacy, data protection and information security could result in additional costs and liabilities to us or inhibit our ability to collect and process data, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations. Privacy and data security have become significant issues in the United States, Europe, and in many other jurisdictions where we or our licensing partners may in the future conduct our operations. As we receive, collect, process, use and store personal and confidential data, we are subject to diverse laws and regulations relating to data privacy and security. Compliance with these privacy laws, data breach notification laws, and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations. In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. Risks Related to Human Capital, Information Technology and Managing Growth Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading. We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws 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 commissions, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. In addition, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations. We are

dependent upon key personnel to achieve our business objectives. Our ability to retain key personnel and attract other qualified individuals is critical to our success. As a technology-driven company, intellectual input from key management and personnel is critical to achieve our business objectives. The loss of the services of key individuals might significantly delay or prevent achievement of our business objectives. In addition, because of a relative scarcity of individuals with experience and the high degree of education and scientific achievement required for our business, competition among life sciences companies for qualified employees is intense and the recent move by companies to offer a remote or hybrid work environment may increase the competition for such employees from employers outside of our traditional office locations, as a result, we may not be able to attract and retain such individuals on acceptable terms, or at all. In addition, because we do not maintain “key person” life insurance on any of our officers, employees, or consultants, any delay in replacing such persons, or an inability to replace them with persons of similar expertise, could harm our business, financial condition, and results of operations. We also have relationships with scientific collaborators at academic and other institutions, some of whom conduct research at our request or assist us in formulating our research and development strategies. These scientific collaborators are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, even though our collaborators are required to sign confidentiality agreements prior to working with us, they may have arrangements with other companies to assist such other companies in developing technologies that may prove competitive to us.

Additionally, the workforce reduction we will implement as part of the restructuring program may negatively impact our ability to attract, integrate, retain and motivate highly qualified employees, and may harm our reputation with current or prospective employees. Incentive provisions for our key executives include the granting of equity awards that vest over time, designed to encourage such individuals to stay with us. However, a low share price, whether as a result of lower than expected revenues from LUPKYNIS, disappointing progress in our development programs or as a result of market conditions generally, or other factors, could render such agreements of little value to our key executives. In such event, our key executives could be susceptible to being hired away by our competitors who could offer a better compensation package. If we are unable to attract and retain key personnel, our business, financial conditions and results of operations may be harmed. We may not successfully manage our growth. Our success will depend upon the timely expansion of our operations and our ability to successfully manage our growth. Our future growth, if any, may place a significant strain on our management and on our administrative, operational, and financial resources. Our ability to manage our growth effectively and in a timely fashion will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research, commercialization, and product development without a corresponding increase in our operational, financial and management systems could harm our business, financial condition and results of operations. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize LUPKYNIS and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development and commercialization efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our ~~company~~ **Company**. We rely significantly on information technology and any failure, inadequacy, or security lapse of that technology, including any cybersecurity incidents, could harm us. We believe that companies have been increasingly subject to a wide variety of security incidents, cyberattacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past few years, cyber-attacks have become more prevalent and much harder to detect and defend against. Several key areas of our business depend on the use of information technologies, including production, manufacturing, marketing, and logistics, as well as clinical and regulatory matters. Despite our efforts to prevent such behavior, third parties may nonetheless attempt to hack into our systems and obtain data relating to our pre-clinical studies, clinical trials, patients using LUPKYNIS or our proprietary information on LUPKYNIS or other information relating to us or our business. If we fail to maintain or protect our information systems and data integrity effectively, we could have problems in determining product cost estimates and establishing appropriate pricing, have difficulty preventing, detecting, and controlling fraud, have disputes with physicians, and other health care professionals, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach, or suffer other adverse consequences and reputational damages. While we have invested in the protection of data and information technology, there can be no assurance that our efforts or those of our third-party collaborators, if any, or manufacturers, to implement adequate security and quality measures for data processing would be sufficient to protect against data deterioration or loss in the event of a system malfunction, or to prevent data from being stolen or corrupted in the event of a security breach. Any such loss or breach could harm our business, operating results, and financial condition. **We maintain cyber insurance coverage; however, there is no guarantee that our current coverage will be sufficient or that we can secure insurance coverage in the future at commercially viable rates or with the appropriate limits.** Interruptions in the availability of server systems or communications with Internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility, or integrity of data stored on such systems, could harm our business. We rely upon a variety of Internet service providers, third-party hosting facilities and cloud computing platform providers to support our business. Many of our employees ~~are~~ currently work remotely and therefore we are highly reliant on these services for our operations. Failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems could damage our reputation in the market, cause us to lose revenue or market share, increase our service costs, cause us to incur substantial costs, subject us to liability for damages

and / or fines and divert our resources from other tasks, any one of which could materially adversely affect our business, financial condition, results of operations and prospects. Any damage to, or failure of, such systems, or communications to and between such systems, could result in interruptions in our operations. If our security measures or those of our third- party data center hosting facilities, cloud computing platform providers, or third- party service partners, are breached, and unauthorized access is obtained to our data or our information technology systems, we may incur significant legal and financial exposure and liabilities. We do not have control over the operations of the facilities of our cloud service providers and our third party providers may be vulnerable to damage or interruption from natural disasters, the effect of climate change (such as drought, flooding, wildfires, increased storm severity, and sea level rise), cybersecurity attacks, terrorist attacks, power outages and similar events or acts of misconduct. In addition, any changes in our cloud service providers service levels may harm our ability to meet our requirements and operate our business. Our business is exposed to the risks associated with litigation, investigations and regulatory proceedings. Litigation and regulatory proceedings are inherently uncertain, and adverse rulings could occur, including monetary damages, or an injunction stopping us from manufacturing or selling certain products, engaging in certain business practices, or requiring other remedies. We may be subject to allegations through press, social media, the courts or other mediums that may or may not be founded. We may be required to respond to or defend against these claims and / or allegations, which will divert resources away from our principal business. There can be no assurance that our defense of such claims and / or allegations would be successful, and we may be required to make material settlements. An unfavorable outcome or settlement may harm our business, **LUPKYNIS products and product candidates**, results of operations, financial condition, and corporate reputation. In addition, regardless of outcome, investigations, allegations of wrongdoing, and litigation can be costly, time-consuming, and disruptive to our business and operations. Risks Related to Our Industry Unstable markets and economic conditions may have harmful consequences to business, financial condition, and trading price of our common shares. Global economic conditions **have been impacted weakened in 2022 driven** by high inflation, supply chain challenges and the impacts of **global hostilities, such as** the Russia- Ukraine war. Changes in interest rates, inflation, economic growth, levels of taxation, legal and regulatory matters, foreign exchange and commodity prices may influence product purchases decisions. Our results of operations could be harmed by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our approved product and our ability to raise additional capital when needed on acceptable terms, if at all. Weak global economic conditions could decrease the number of clinical trials sites available to us and hinder our ability to conduct trials required by the FDA. A weak or declining economy could also strain our supplies, partners or third- parties, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business. Actual or anticipated changes to the laws and regulations governing the health care system may have a negative impact on cost and access to health insurance coverage and reimbursement of healthcare items and services. The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell LUPKYNIS profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access to healthcare. In the U. S, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the ACA **and IRA**. While it is difficult to assess the impact of the ACA in isolation, either in general or on our business specifically, it is widely thought that the ACA increases downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, LUPKYNIS. Further, the U. S. and foreign governments regularly consider reform measures that affect healthcare coverage and costs. Such reforms may include changes to the coverage and reimbursement of healthcare services and products. In particular, there have been recent judicial and Congressional challenges to the ACA, which could have an impact on coverage and reimbursement for healthcare services covered by plans authorized by the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. Most recently, the U. S. Tax Cuts and Jobs Act was enacted, which, among other things, removes the penalties for not complying with the ACA' s individual mandate to carry health insurance. On January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. The ACA has also been the subject of numerous court challenges on the basis of, among other things, constitutionality. While the Supreme Court of the United States ruled in summer 2021 that the ACA was constitutional in respect to one such challenge, this does not mean that there will not be future challenges launched, which may or may not be successful. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the ACA will impact the ACA and our business. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the U. S. Budget Control Act of 2011 resulted in aggregate reductions to Medicare payments to providers of 2 % per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the

government to recover overpayments to providers from three to five years. Recently, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the Biden administration has indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take, whether or to what degree they may impact us or **LUPKYNIS** our products, or whether such steps will be successful. We cannot predict all of the ways in which future federal or state legislative or administrative changes relating to healthcare reform will affect our business. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We anticipate that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for LUPKYNIS, and could harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize LUPKYNIS. We may face substantial competition, which may result in others discovering, developing, or commercializing products before, or more successfully than we do. The industry in which we operate is highly competitive and we have numerous potential domestic and foreign competitors, including major pharmaceutical and chemical companies, universities, academic institutions, government agencies, public and private research organizations and large, fully-integrated pharmaceutical companies which have extensive resources and experience in research and development, process development, clinical evaluation, manufacturing, regulatory affairs, commercialization, distribution and marketing. In particular, over the course of the past few years we are aware that a number of companies have announced that they are commencing clinical trials for different treatment options for LN. Many of our potential competitors possess substantially greater research and development skills, financial, technical and marketing expertise and human resources than we do, and may be better equipped to develop, manufacture and market products. There is a risk that new products and technologies may be developed which may be more effective or commercially viable than the product being developed or marketed by us, thus making LUPKYNIS non-competitive or obsolete. There may also be market resistance to the acceptance of our new product in any indication and a risk that LUPKYNIS, even though clinically effective, is not economically viable.

While we have new chemical entity exclusivity to January 2026, and potential patent protection out to 2037, generic entrants could file abbreviated new drug applications as early as January 2025. These applications may or may not be approved by the FDA. If an ANDA is filed, it may have a negative impact on our perceived value. If even one ANDA is approved in a manner that does not violate any then-existing patents we hold, we may be subject to competition at significantly lower prices than we currently sell LUPKYNIS, which could have a materially negative impact on our business.

Use of hazardous materials might expose us to risk in the form of damages. Drug manufacturing processes involve the controlled use of hazardous materials. We and our third-party manufacturing contractors are subject to regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our third-party manufacturers have the required safety procedures for handling and disposing of such materials and comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and such liability could exceed our resources. Health and safety risks associated with producing a product for human ingestion cannot be eliminated and might expose us to substantial risk. While we take substantial precautions such as laboratory and clinical testing, toxicology studies, quality control and assurance testing and controlled production methods, the health and safety risks associated with producing a product for human ingestion cannot be eliminated. **LUPKYNIS** Products produced by us may be found to be, or to contain substances that are harmful to the health of our patients and customers and which, in extreme cases, may cause serious health conditions or death. This sort of finding may expose us to substantial risk of litigation and liability. Further, we would be forced to discontinue production of LUPKYNIS, which would harm our profitability. We maintain product liability insurance coverage; however, there is no guarantee that our current coverage will be sufficient or that we can secure insurance coverage in the future at commercially viable rates or with the appropriate limits. Risks Related to Our Common Shares There is no assurance of a sufficient liquid trading market for our common shares in the future. Our shareholders may be unable to sell significant quantities of common shares into the public trading markets without a significant reduction in the price of their common shares, or at all. There can be no assurance that there will be sufficient liquidity of our common shares on the trading market, and that we will continue to be listed on Nasdaq or achieve listing on any other public listing exchange. The price of our common shares could be subject to volatility related or unrelated to our operations. The market prices for the securities of biotechnology companies, including ours, have historically been volatile. The market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of any particular company. The trading price of the common shares could continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including the results and adequacy of our pre-clinical studies and clinical trials, as well as those of our collaborators, or our competitors; the results of our operations, such as quarterly or annual sales figures; other evidence of the safety or effectiveness of LUPKYNIS or those of our competitors; announcements of technological innovations or new products by our competitors; governmental regulatory actions; developments with

collaborators; developments (including litigation) concerning our patents or other proprietary rights of competitors; period-to-period fluctuations in operating results; guidance we may provide as to the commercial performance of LUPKYNIS; changes in estimates of our performance by securities analysts; market conditions for biotechnology stocks in general; **our ability to repurchase our common shares under any share repurchase program on favorable terms or at all;** global or local political, economic, social and health crises; market rumors; and other factors not within our control could impact the market price of the common shares, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources. **In recent years, shareholder activists have become involved in numerous public companies. Responding to actions by shareholders activists, such as requests for special meetings, potential nominations of candidates for election to our board of directors, requests to pursue a strategic combination or other transaction, or other special requests may disrupt our business and divert the attention of management and employees. In addition, any perceived uncertainties as to our future direction resulting from such a situation could result in the loss of potential business opportunities, be exploited by our competitors, cause concern to our current or potential customers and make it more difficult to attract and retain qualified personnel and business partners, any of which could negatively impact our business. Shareholder activism could result in substantial costs and may cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals of our business. Our common shares may be traded by short sellers which may put pressure on the supply and demand of our common shares. There can be no assurance that we will continue to repurchase Common Shares or that we will repurchase Common Shares at favorable prices. Our Board has the authority to authorized share repurchase programs. On February 15, 2024, we announced that we would commence our first share repurchase program. The amount and timing of common share repurchases are subject to capital availability and our determination that share repurchases are in the best interests of the Company and are in compliance with all respective laws and any applicable contractual obligations. Our ability to repurchase common shares will depend on, among other factors, our cash balances and potential future capital requirements for strategic transactions our results of operations, our financial condition and other factors beyond our control that we may deem relevant. Additionally, the recently enacted IRA includes an excise tax on share repurchases, which will increase the cost of share repurchases. A reduction in repurchases under, or the completion of, our share repurchase programs could have a negative effect on the market price of our common shares. We can provide no assurance that we will repurchase common shares at favorable prices, if at all. Aurinia has submitted an exemptive relief application to applicable Canadian securities regulators related to the repurchase, which, if not granted may limit the number of shares that the Company is able to repurchase significantly from what it is able to repurchase in reliance on applicable U. S. law. If the exemption is not granted, Aurinia would not be able to repurchase in excess of 5 % of its issued and outstanding common shares (being 7, 230, 888 Common Shares) without complying with an alternative process in Canada that may be more costly, time consuming or not available.** You may be unable to enforce actions against us, or certain of our directors and officers under U. S. federal securities laws. As a corporation organized under the provincial laws of Alberta, Canada, it may be difficult to bring actions under U. S. federal securities law against us. Some of our directors and officers reside principally in Canada or outside of the United States. Because all or a substantial portion of our assets and the assets of these persons are located outside of the United States, it may not be possible for investors to effect service of process within the United States upon us or those persons. Furthermore, it may not be possible for investors to enforce against us, or those persons not in the United States, judgments obtained in U. S. courts based upon the civil liability provisions of the U. S. federal securities laws or other laws of the United States. There is doubt as to the enforceability, in original actions in Canadian courts, of liabilities based upon U. S. federal securities laws and as to the enforceability in Canadian courts of judgments of U. S. courts obtained in actions based upon the civil liability provisions of the U. S. federal securities laws. Therefore, it may not be possible to enforce those actions against us or certain of our directors and officers. If securities or industry analysts do not publish, or cease publishing, research reports about us, our business, or our market, or if they change their recommendations regarding our common shares adversely, the trading price and trading volume of our common shares could decline. The trading market for our common shares is and will be influenced by whether industry or securities analysts publish research and reports about us, our business, our market or our competitors and, if any analysts do publish such reports, what they publish in those reports. We may not obtain analyst coverage in the future. Any analysts who do cover us may make adverse recommendations regarding our common shares, adversely change their recommendations from time to time, and / or provide more favorable relative recommendations about our competitors. If any analyst who may cover us in the future were to cease coverage of our ~~company~~ **Company** or fail to regularly publish reports on us, or if analysts fail to cover us or publish reports about us at all, we could lose visibility in the financial markets, which in turn could cause the trading price of our common shares or trading volume to decline. Securities litigation or other litigation could result in substantial damages and may divert management's time and attention from our business. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. We **are and** may become **in the future** the target of securities litigation ~~in the future~~. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of such suits, and we may not prevail. Monitoring and defending against legal actions is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with any such litigation. We have not established any reserves for any potential liability relating to any such potential lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. We currently maintain insurance coverage for

some of these potential liabilities. Other potential liabilities may not be covered by insurance, insurers may dispute coverage or the amount of insurance may not be enough to cover damages awarded. In addition, certain types of damages may not be covered by insurance, and insurance coverage for all or certain forms of liability may become unavailable or prohibitively expensive in the future. A decision adverse to our interests on one or more legal matters or litigation could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our reputation, financial condition and results of operations. Our ability to use our net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be subject to certain limitations. We may also be subject to other potential tax consequences. Under the provisions of the applicable tax legislation, our net operating loss and tax credit carryforwards are subject to review and possible adjustment by applicable tax regulatory authorities. In addition, proposed or actual changes to applicable tax legislation may significantly impact our ability to utilize our net operating losses and tax credit carryforwards to offset taxable income in the future. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of a company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. We may not be able to use some or all of our net operating loss and tax credit carryforwards, even if we attain profitability. Additionally, should an event occur that causes or is deemed to cause a change in the residency of Aurinia Pharmaceuticals Inc. from Canada to the United States, for example, we may be subject to certain tax rules that could cause a deemed disposition of our assets for tax purposes. Should that occur, we may be subject to a material amount of tax owing, without corresponding revenue from any actual disposition of our assets. Our common shares could fall or may not increase.

General Business Risks If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements are incorrect, our actual results may vary from those reflected in our projections and accruals. Our consolidated financial statements have been prepared in accordance with U. S. GAAP. The preparation of these consolidated financial statement requires us to make estimates and judgements that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot promise that our estimates or their underlying assumptions will be correct. Actual results may differ materially from those estimated amounts used in the preparation of our consolidated financial statements if these results differ from our historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us. We are subject to the rules and regulations of the SEC, including those rules and regulations mandated by the Sarbanes- Oxley Act, as well as the rules and regulations imposed by Canadian securities regulatory authorities. Securities legislation requires public companies to include in their annual report a statement of management' s responsibilities for establishing and maintaining adequate internal control over financial reporting, together with an assessment of the effectiveness of those internal controls. Section 404 of the Sarbanes- Oxley Act also requires the independent auditors of certain public companies to attest to, and report on, this management assessment. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of applicable securities legislation could have harm on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common shares. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. An investment in our common shares may result in the loss of an investor' s entire investment. An investment in our common shares is speculative and may result in the loss of an investor' s entire investment. Only potential investors who are experienced in high risk investments and who can afford to lose their entire investment should consider an investment in our common shares. Future issuances of **debt and** equity securities by us may cause the price of the common shares to fall. The market price of the common shares could decline because of issuances by us of additional common shares (whether for financing or acquisition purposes or otherwise), or the perception that these sales could occur. Investors will suffer dilution of their voting power and may experience dilution in earnings per share if we issue additional common shares. We do not intend to pay dividends in the foreseeable future. We have never declared or paid any dividends on the common shares. **While we historically have not paid cash dividends (in We intend, for the foreseeable future, to retain our future earnings, if any currency) , to finance our commercial activities and further research and do not have a current intention to pay cash dividends, we continually review our capital allocation strategies, including, among the other expansion things, payment of our business cash dividends, share repurchases and acquisitions** . As a result, the return on an investment in common shares will likely depend upon any future appreciation in value, if any, and on a shareholder' s ability to sell common shares. The payment of future dividends, if any, will be reviewed periodically by our board of directors and will depend upon, among other things, conditions then existing including earnings, financial conditions, cash on hand, financial requirements to fund our commercial activities, development and growth, and other factors that our board of directors may consider appropriate in the circumstances. We have broad discretion in the use of our cash and cash equivalents and may not use them effectively. Our management has broad discretion to use our cash and cash equivalents to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common shares. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the trading price of our common shares to decline and adversely impact the commercialization of our product. Pending their use to fund our operations, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value. We have incurred and will continue to incur increased

costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices. As a public company, we incur significant legal, accounting, and other expenses. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC, Canadian securities regulators, and the Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. Applicable securities legislation requires us, on an annual basis, to review and evaluate our internal controls. To maintain compliance with Section 404 of the Sarbanes-Oxley Act of 2002, for example, we are required to document and evaluate our internal control over financial reporting, which has been both costly and challenging. We will need to continue to dedicate internal resources, continue to engage outside consultants and follow a detailed work plan to continue to assess and document the adequacy of internal control over financial reporting, continue to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that in the future neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. **Our business, results of operations, and future growth prospects could be materially and adversely affected by widespread health concerns, such as pandemics.** Widespread health concerns, in particular in the United States but also globally, can have evolving and uncertain impacts on our business. **In particular, we are not able to precisely determine or quantify the impact the COVID-19 pandemic has or will have on our business operations going forward. We have implemented policies and procedures in alignment with local (provincial and state) COVID guidelines. While more recently we are seeing a return to forms of in-person marketing similar to those prior to the COVID-19 pandemic, historically and with some continuation we continue to utilize an adaptive marketing approach where our sales force would have the option of meeting with physicians virtually or in-person.** As a result of any widespread health concern, **such as a including the COVID-19 pandemic,** we have and may continue to experience disruptions that severely impact our business, commercialization, ~~pre-clinical studies,~~ and clinical trials, including: a. delays or difficulties in enrolling patients in our clinical trials; b. delays or difficulties in building out and maintaining commercial infrastructure; c. delays in recruiting for key positions; d. delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; e. interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal, provincial or state governments, employers, and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints; f. interruption or delays in the operations of applicable regulatory authorities, which could impact the ability to obtain applicable regulatory approvals, and could impact on ability to commercialize internationally or receive milestone payments from licensees; g. interruption or delays in receiving supplies of our drugs or manufacturing products from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages, and disruptions in delivery systems; h. limitations on employee resources that would otherwise be focused on the conduct of our commercial and promotional activities, ~~pre-clinical studies~~ and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; i. limited ability to access accounts and healthcare professionals, in person or at all, to provide medical information to promote our drug; j. staffing shortages at healthcare professionals' offices that may limit the ability to administratively process prescriptions; and k. reductions in patient visits to physicians and new patients might have limited access to prescribers. Government and health authority intervention in the face of a widespread health concern may vary greatly in the various geographic regions in which we operate. The extent to which a widespread health concern may impact our business, commercialization, ~~pre-clinical studies,~~ and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread, business closures or business disruptions and the effectiveness of vaccinations and actions taken in Canada, the United States and other countries to contain and treat the disease. To the extent there is an impact from a widespread health concern, ~~such as the COVID-19 pandemic,~~ on our business, it has not had, and we anticipate that it would continue to not have, a steady impact but instead an uneven impact on various aspects of our business and operations as the variants of the virus infect different parts of the geographic regions in which we operate at different times and to different degrees. While we are **not able to compare our operational results to prior years to verify, as our sole commercial product was only approved during the COVID-19 pandemic, we believe that the COVID-19 pandemic has harmed our business and operations, in particular in relation to our ability to connect with, and promote LUPKYNIS to, health care professionals, which as a result has limited prescribing opportunities for LUPKYNIS. To the extent a widespread health concern harms our business and financial results, it may also have the effect of heightening many of the other risks described in this Annual Report.** Sales of our common shares by our employees, including our executive officers, could cause the trading price of our common shares to fall or prevent it from increasing for numerous reasons, and sales by such persons could be viewed negatively by other investors. In accordance with the guidelines specified under Rule 10b5-1 under the Exchange Act, as amended, equivalent legislation in applicable jurisdictions, and our policies regarding equity transactions, a number of our employees, including executive officers, may adopt share trading plans pursuant to which they have arranged to sell common shares from time to time in the future. Generally, sales of common shares, including sales under such plans, by our executive officers and directors require public filings. Sales of our common shares by such persons could cause the price of our common shares to fall or prevent it from increasing. If sales by employees, executive officers, or directors cause a substantial number of our common shares to become available for purchase in the public market, the price of our common shares could fall or may not increase. Also, sales by such personnel could be

viewed negatively by holders and potential purchasers of our common shares.