UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from____________ to ______________

Commission file number: 001-36421

Aurinia Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Alberta, Canada
(State or other jurisdiction of incorporation or organization)

#1203-4464 Markham Street
Victoria, British Columbia V8Z 7X8
(Address of principal executive offices)

98-1231763
(I.R.S. Employer Identification Number)

Registrant's telephone number, including area code:
(250) 708-4272

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Symbol	Name of Each Exchange on Which Registered
Common shares, no par value	AUPH	The Nasdaq Global Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of common shares held by non-affiliates of the registrant totaled approximately $1.42 billion based on the closing price for the registrant's common shares as reported by the Nasdaq Global Market on June 30, 2022 (the last business day of the registrant's second fiscal quarter). Such value excludes common shares held by executive officers and directors, but does not exclude shares held by organizations whose ownership exceeds 5% of the registrant's outstanding common shares that have represented that they are registered investment advisers or investment companies registered under section 8 of the Investment Company Act of 1940.

As of February 27, 2023, there were 142,576,689 of the registrant's common shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	10-K Part
Portions of the registrant's definitive proxy statement to be filed with the U.S. Securities and Exchange Commission pursuant to Regulation 14A within 120 days after registrant's fiscal year end of December 31, 2022 are incorporated by reference into Part III of this Annual Report on Form 10-K.	III

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PART I

INTRODUCTION

Unless the context otherwise requires, references in this Annual Report on Form 10-K for the year ended December 31, 2022, or this Annual Report, to “we”, “us”, “our” or similar terms, as well as references to “Aurinia”, refer to Aurinia Pharmaceuticals Inc., together with our subsidiaries.

We maintain our books and records in U.S. dollars, and prepare our financial statements in accordance with generally accepted accounting principles in the United States (U.S. GAAP) as issued by the Financial Accounting Standards Board (FASB).

The terms “dollar,” “U.S. dollar” or “$” refer to United States dollars, the lawful currency of the United States, the term “CA$,” refers to Canadian dollars, the lawful currency of the Canada and "CHF", refers to Swiss Francs, the lawful currency of Switzerland. All references to “shares” or "common shares" in this Annual Report refer to common shares of Aurinia Pharmaceuticals Inc., with no par value per share.

We have made rounding adjustments to some of the figures included in this Annual Report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains “forward-looking statements” within the meaning of Section 27A of the *Securities Act of 1933*, as amended (the Securities Act) and Section 21E of the *Securities Exchange Act of 1934*, as amended (the Exchange Act) which are subject to the “safe harbor” created by those sections, as well as “forward-looking information” as defined in applicable Canadian securities laws. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part I, Item 1A. “Risk Factors” in this Annual Report. We strongly encourage all readers to read Part I, Item 1A. "Risk Factors" in full.

A statement is forward-looking when it uses what we know and expect today to make a statement about the future. Forward-looking statements may include words such as “anticipate”, “believe”, “intend”, “expect”, “goal”, “may”, “outlook”, “plan”, “seek”, “project”, “should”, “strive”, “target”, “could”, “continue”, “potential”, “estimated”, "would", and "will" or the negative of such terms or comparable terminology. You should not place undue reliance on the forward-looking statements, particularly those concerning anticipated events relating to the development, clinical trials, regulatory approval, and marketing of LUPKYNIS® (voclosporin) or any other aspect of our business and the timing or magnitude of those events, as they are inherently risky and uncertain.

These forward-looking statements include, but are not limited to, statements concerning the following:

- our belief in the duration of patent exclusivity for voclosporin and that the patents owned by us are valid;
- our belief in receiving extensions to patent life based on certain events or classifications;
- our expectation that patent protection for the composition of matter of voclosporin will be extended in the United States and certain other major markets, including Europe and Japan, until at least October 2027;
- our plans and expectations and the timing of commencement, enrollment, completion and release of results of clinical trials;
- our belief that voclosporin possesses pharmacologic properties with the potential to demonstrate best-in-class differentiation;
- our strategy to optimize the clinical and commercial value of voclosporin and become a commercial biopharmaceutical company with a global product portfolio focused on autoimmune, kidney and other rare diseases with a high unmet medical need;
- our estimates as to the market potential for LUPKYNIS, including estimates as to the number of patients with systemic lupus erythematosus (SLE) that are diagnosed with LN;
- our estimate, based on our patient-specific estimated glomerular filtration rate (eGFR) dosing regimens, the average utilization in our clinical trials, and accounting for factors including mandatory rebates, channel discounts, and anticipated patient adherence, that we expect our average annualized net revenue per patient to be approximately $65,000;
- our belief that our net product revenue will continue to increase as we continue to execute on our post approval commercialization strategy for LUPKYNIS;
- our expectation that we will continue to incur significant expenses in Selling, General and Administrative (SG&A) as we commercialize LUPKYNIS;
- our belief that we have enough inventory on hand and manufacturing capacity to meet forecasted demand;

- our intention on how to use the net proceeds from our financings;
- our belief that we have sufficient cash resources to adequately fund our current business plans for at least the next few years, and our expectations in terms of go forward costs (including short and long term cash requirements) and revenues;
- our belief that additional patents may be granted in other major global pharmaceutical markets based on our filings under the Patent Cooperation Treaty (PCT);
- our intention to list our newly allowed U.S. Patent Application (No. 17/713,140) patent in the Orange Book once issued;
- management's estimates and assumptions made in conformity with U.S. GAAP that affect the reported amounts of assets and liabilities as discussed further in notes to the consolidated financial statements;
- our belief that our results of operations or cash flows would not be affected to any significant degree by a sudden change in market interest rates relative to our investment portfolio;
- the potential impact of widespread health concerns, including COVID-19 on our business operations, nonclinical and clinical trials, regulatory timelines, supply chain, and potential commercialization; and
- our belief that we will file Investigational New Drug Applications (INDs) for AUR200 in 2023 and AUR300 in 2024.

Such statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based on a number of estimates and assumptions that, while considered reasonable by management, as at the date of such statements, are inherently subject to significant business, economic, competitive, political, regulatory, legal, scientific social uncertainties and other contingencies, many of which, with respect to future events, are subject to change. The factors and assumptions used by management to develop such forward-looking statements include, but are not limited to:

- the assumption that we will be able to obtain approval from regulatory agencies on executable development programs with parameters that are satisfactory to us;
- the assumption that recruitment to clinical trials will occur as projected;
- the assumption that we will successfully complete and enroll our clinical programs in compliance with good clinical practices (GCP) on a timely basis and meet regulatory requirements for approval of marketing authorization applications and new drug approvals, as well as favorable product labeling;
- the assumption that our planned studies will achieve positive results;
- the assumptions regarding the costs and expenses associated with our clinical trials and commercialization of LUPKYNIS;
- the assumption that regulatory requirements and commitments will be maintained;
- the assumption that we and our licensees will be able to meet good manufacturing practice (GMP) standards and manufacture and secure a sufficient supply of LUPKYNIS on a timely basis to successfully complete the development and commercialization of LUPKYNIS;
- the assumptions on the market value for the LN program;
- the assumptions related to our estimated pricing for LUPKYNIS are accurate, including that the average utilization of LUPKYNIS in our clinical trials will remain applicable, the amount of mandatory rebates and degree of patient adherence;
- the assumption that our patent portfolio is sufficient and valid;
- the assumption that we will be able to extend our patents to the fullest extent allowed by law, on terms most beneficial to us;
- the assumptions that our third party partners and suppliers will comply with their obligations under their agreements with us;
- the assumptions about future market activity;
- the assumption that there is a potential commercial value for LUPKYNIS and other indications for voclosporin;
- the assumption that market data and reports reviewed by us are accurate;
- the assumptions on the burn rate of our cash for operations;
- the assumption that another company will not violate our intellectual property rights or regulatory exclusivity periods;
- the assumption that our current good relationships with our suppliers, service providers and other third parties will be maintained;
- the assumption that we will be able to attract and retain a sufficient amount of skilled staff;
- the assumption that our third party service providers and partners will comply with their contractual obligations; and/or
- the assumptions relating to the capital required to fund our operations for at least the next few years.

It is important to know that:

- actual results could be materially different from what we expect if known or unknown risks affect our business, or if our estimates or assumptions turn out to be inaccurate. As a result, we cannot guarantee that any forward-looking statement will materialize and, accordingly, you are cautioned not to place undue reliance on these forward-looking statements; and

- forward-looking statements do not take into account the effect that transactions or non-recurring or other special items announced or occurring after the statements are made may have on our business. For example, they do not include the effect of mergers, acquisitions, other business combinations or transactions, dispositions, sales of assets, asset write-downs or other charges announced or occurring after the forward-looking statements are made. The financial impact of such transactions and non-recurring and other special items can be complex and necessarily depend on the facts particular to each of them. Accordingly, the expected impact cannot be meaningfully described in the abstract or presented in the same manner as known risks affecting our business.

Forward-looking statements are provided for the purpose of presenting information about management's current expectations and plans relating to the future and readers are cautioned that such statements may not be appropriate for other purposes. If our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. Any forward-looking statement made by us in this Annual Report speaks only as of the date of this Annual Report or as of the date on which the statement was made. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the U.S. Securities and Exchange Commission as exhibits to this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This Annual Report may contain market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information and there is no assurance as to the accuracy or completeness of this data. While we believe the market position, market opportunity and market size information included in this Annual Report is generally reliable, such information is inherently imprecise.

Below is a summary of material factors which could cause actual results to differ materially from those expressed or implied in the forward-looking statements contained in this Annual Report. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Special Note Regarding Forward-Looking Statements" and Part I, Item 1A. "Risk Factors" in this Annual Report. The below summary is qualified in its entirety by those more complete discussions of such risks and uncertainties. You should consider carefully the risks and uncertainties described under Part I, Item 1A. "Risk Factors" in this Annual Report as part of your evaluation of an investment in our common shares. Important factors that could cause such differences include, among other things, the following:

Business Risks

- difficulties we may experience in completing the marketing and commercialization of LUPKYNIS;
- unknown impact and difficulties imposed by supply chain challenges, high inflation, increasing interest rates, the ongoing COVID-19 pandemic and the impacts of the Russian Ukraine war on our business and operations including sales, marketing, operations, nonclinical and clinical and our supply chain;
- legislative, regulatory and commercial activities, including new laws regulating the pricing of LUPKYNIS;
- difficulties obtaining adequate reimbursements from third party payors;
- difficulties obtaining formulary acceptance;
- we are single sourced within our manufacturing supply chain, including key suppliers;

- we rely on commercial and clinical partners who may not be able to comply with their contractual obligations with us; and
- competitors may arise with similar products, or existing competition may be taken up and become more preferred as treatment for LN.

Business Growth Risks

- difficulties in meeting GMP standards and the manufacturing and securing of a sufficient supply of voclosporin on a timely basis to successfully complete the development and commercialization of LUPKYNIS;
- difficulties, delays or failures in obtaining necessary regulatory approvals;
- not being able to extend or protect our patent portfolio for LUPKYNIS;
- our patent portfolio not covering all of our proposed or contemplated uses of LUPKYNIS;
- the market for the LN business (or any other indication for LUPKYNIS) may not be as we have estimated;
- insufficient acceptance of and demand for LUPKYNIS;
- difficulties in identifying and completing the acquisition of, and successfully developing potential targets for expansion of our product portfolio; and
- difficulty with executing business development, integrating acquisitions and recognizing benefits of acquired assets.

Underlying Business Risks

- product liability, patent infringement and other civil litigation;
- injunctions, court orders, regulatory and other compliance issues or enforcement actions;
- we may have to pay unanticipated expenses, and/or estimated costs for clinical trials or operations may be underestimated, resulting in our having to make additional expenditures to achieve our current goals;
- difficulties, restrictions, delays, or failures in obtaining appropriate reimbursement from payors for LUPKYNIS;
- difficulties in retaining key personnel and attracting other qualified individuals;
- our assets or business activities may be subject to disputes that may result in litigation or other legal claims;
- difficulties, delays, or failures we may experience in the conduct of and reporting of results of our clinical trials for LUPKYNIS and other pipeline assets, including unfavorable results;
- difficulties we may experience in identifying and successfully securing appropriate vendors to support the development and commercialization of LUPKYNIS;
- our significant reliance on information technology and any failure, inadequacy, or security lapse of that technology, including any cybersecurity incidents;
- we are dependent upon key personnel to achieve our business objectives;
- the potential need for additional capital in the future to continue to fund our development programs and commercialization activities, and the effect of capital market conditions and other factors on capital availability; and
- our ability to raise future resources when required.

Item 1. Business

OVERVIEW

Aurinia is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations that are impacted by autoimmune, kidney and rare diseases with a high unmet medical need. In January 2021, we introduced LUPKYNIS (voclosporin), the first FDA-approved oral therapy for the treatment of adult patients with active LN. We continue to conduct pre-clinical, clinical and regulatory activities to support the LUPKYNIS development program as well as our other assets. We engaged with Otsuka Pharmaceutical Co., Ltd. (Otsuka) as a collaboration partner for the development and commercialization of LUPKYNIS in the European Union (EU) and Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine (collectively, the Otsuka Territories).

LUPKYNIS is an orally administered CNI immunosuppressant that has been demonstrated to improve near and long-term outcomes in LN when used in combination with mycophenolate mofetil (MMF) (although MMF is not currently approved as such) and steroids. By inhibiting calcineurin, LUPKYNIS reduces cytokine activation and blocks interleukin IL-2 expression and T-cell mediated immune responses. LUPKYNIS also potentially stabilizes podocytes, which can protect against proteinuria.
Voclosporin, the active ingredient in LUPKYNIS, is made by a modification of a single amino acid of the cyclosporine molecule. The mechanism of action of LUPKYNIS has been validated with certain earlier generation CNIs for the prevention of
rejection in patients undergoing solid organ transplants and in several autoimmune indications, including uveitis, keratoconjunctivitis sicca, psoriasis, rheumatoid arthritis, and for LN in Japan.

Earlier generation CNIs have demonstrated efficacy for a number of conditions, including transplant and other autoimmune diseases; however, side effects exist which can limit their long-term use and tolerability. Some clinical complications of earlier generation CNIs include hypertension, hyperlipidemia, diabetes, and both acute and chronic nephrotoxicity. We believe that LUPKYNIS possesses pharmacologic properties with the potential to demonstrate best-in-class differentiation.

On August 17, 2021, we announced the addition of two newly acquired novel assets AUR200 and AUR300. AUR300 is exclusively licensed from Riptide Biosciences. Both assets are currently undergoing pre-clinical development with projected submission of Investigational New Drug Applications (INDs) to the FDA for AUR200 in 2023 and for AUR300 in 2024.

STRATEGY

Our business strategy is to optimize the clinical and commercial value of LUPKYNIS and evolve as a commercial biopharmaceutical company with a global product portfolio focused on autoimmune, kidney and rare diseases with high unmet medical needs.

We have developed a strategic plan to execute on our commercialization of LUPKYNIS as a treatment of adult patients with active LN. The key tactics to achieve our corporate strategy are:

- focusing on educating physicians, patients and payers to increase their awareness of the risks and impacts of LN as a disease (including that abnormal proteineuria levels can have significant impact on kidneys and the disease needs to be diagnosed and addressed quickly), and the benefits of LUPKYNIS (as demonstrated in our clinical trials) as a treatment option;
- engaging Otsuka as a collaboration partner for the development and commercialization of LUPKYNIS in the Otsuka Territories;
- conducting post-market studies to satisfy regulatory requirements and better understand LUPKYNIS' characteristics in real-world usage;
- ensuring adequate supply of LUPKYNIS by entering into strategic long term supply agreements with our key suppliers;
- conducting R&D activities to further the advancement of our existing pipeline; and
- evaluating external assets with the potential to be synergistic and complementary to our clinical, regulatory and therapeutic areas of expertise.

DEVELOPMENTS

Regulatory/Commercial

- On September 15, 2022, the European Commission (EC) granted marketing authorization of LUPKYNIS in the EU. The centralized marketing authorization is valid in all EU member states as well as in Iceland, Liechtenstein, Norway

and Northern Ireland. The approval triggered a $30.0 million milestone payment to us by Otsuka, which we recognized as collaboration revenue in 2022.
- On November 29, 2022 Aurinia announced that the MHRA has granted marketing authorization of LUPKYNIS in Great Britain. We continue to progress with regulatory approval with Otsuka in the other Otsuka Territories.

Corporate
- On July 14, 2022, we announced the appointment of Volker Knappertz, MD, as Executive Vice President (EVP), Research and Development to lead the consolidated R&D function and to further enhance and advance the Aurinia pipeline. Additionally, Scott Habig was named Chief Commercial Officer, to lead and enhance Aurinia's commercial capabilities.
- On January 3, 2023, we announced that we had entered into a settlement agreement with Sun Pharmaceutical Industries, Inc., Sun Pharmaceuticals Industries, Ltd., and Sun Pharma Global FZE (collectively, Sun Pharmaceuticals) that involved both Aurinia and Sun Pharmaceuticals filing a joint motion to terminate the ongoing Inter Partes Review (IPR) directed at Aurinia’s U.S. Patent No. 10,286,036, as well as settlement of the ongoing patent infringement litigation in the United States (U.S.) related to Sun’s CEQUA® product. Under the settlement agreement, which was contingent upon the U.S. Patent Trial and Appeal Board (PTAB) approving the joint motion to terminate the IPR, both parties agreed to dismiss their claims and counterclaims against each other and cease bringing any future further action against the other. On January 25, 2023, the PTAB terminated the IPR.
- On January 24, 2023, we announced that the United States Patent and Trademark Office (USPTO) has allowed a method of use patent application titled IMPROVED PROTOCOL FOR TREATMENT OF LUPUS NEPHRITIS. Aurinia’s newly allowed U.S. Patent Application (No. 17/713,140) reflects the unique and proprietary dosing regimen of its currently marketed product, LUPKYNIS. Specifically, this patent further refines the method of using LUPKYNIS in combination with mycophenolate mofetil (MMF) and corticosteroids using eGFR as a method of pharmacodynamically dosing the product in patients with LN. The newly allowed application provides patent coverage that supplements Aurinia’s existing U.S. Patent No. 10,286,036, which is listed in the Orange Book and claims an FDA-approved method of using LUPKYNIS. The claims in this additional patent add further specificity on dosing consistent with the FDA approved product label. This patent has the potential to provide an additional layer of patent protection for LUPKYNIS up to 2037. We intend to list this newly allowed patent in the Orange Book once issued.

Study Updates
- In December 2021, we announced the initiation of ENLIGHT-LN®, a U.S. based prospective, observational registry of adult patients with LN treated with LUPKYNIS. The registry is intended to support the interests of patients, clinicians, regulatory bodies, payers and industry by obtaining longitudinal data on LUPKYNIS. During the first quarter of 2022, we began actively enrolling patients.
- For the ENLIGHT-LN registry, we now have 42 activated sites toward our goal of having 75 sites total. We plan to leverage real-world data collected from this study to gain further knowledge about patients taking LUPKYNIS and help clinicians and payers to improve patient care and ensure access to therapy.
- We also remain on track to meet our LUPKYNIS post-approval FDA commitments.

Market Potential and Commercial Considerations

We have conducted market research and analyses of peer reviewed publications to assess market potential and commercial opportunity. Our physician research included more than 1,100 rheumatologists and nephrologists across the United States, Europe and Japan to assess the potential market for adoption of LUPKYNIS and estimate pricing and treatment paradigms as well as learning directly about the market by our ongoing interaction with physicians, payers, patients and other stakeholders. The National Institute of Diabetes and Digestive and Kidney Diseases estimates that up to 50% of adults with SLE are diagnosed with LN at some point in their journey with lupus. Using the research and publication analyses, we estimate the number of SLE patients diagnosed with LN to be about 80,000 to 120,000 in the United States.

Similar to other autoimmune disorders, LN is a flaring and remitting disease. The disease can cycle from being in remission to being in an active flare, to achieving partial response and potentially to achieving a complete response and therefore back in remission. Treatment objectives between LN and other autoimmune diseases are remarkably similar. In other autoimmune conditions such as multiple sclerosis, Crohn’s, rheumatoid arthritis and SLE, physicians’ goals are to induce and maintain a remission of disease, decrease frequency of hospital or ambulatory care visits and limit long term disability. In LN specifically, physicians are trying to avoid further kidney damage, kidney failure, dialysis, kidney transplantation, and death. The ability to get patients into remission quickly correlates with better long-term kidney outcomes as noted above. Achieving a complete response, and most importantly, rapidly reducing the level of protein in urine, is also believed to be an important factor in delaying and/or reducing the rate of progression to kidney failure and need for replacement therapy. Kidney failure is associated with extremely poor health outcomes as a life-long, costly state in which patients are dependent upon dialysis or the availability of a kidney transplant.

The population of people with LN will be in different cycles of their disease at any one time. Prior to the approval of LUPKYNIS, physicians would generally use a combination of MMF and steroids to treat people with LN throughout the disease cycles. The clinical data generated in our Phase 2 AURA-LV and our Phase 3 AURORA studies has demonstrated that LUPKYNIS can achieve a more than two times higher rate of complete response than when given in combination with MMF and steroids. The clinical data generated in our AURORA 2 continuation study demonstrated a continuation of these results over an aggregate of a three year period for the patients that enrolled, with no severe unexpected safety signals.

The price of LUPKYNIS is based on one unit of 60 capsules we refer to as a “wallet”. As of February 28, 2023, the wholesale acquisition cost (WAC) of a LUPKYNIS wallet is $4,561. Based on our patient-specific eGFR dosing regimens, the average utilization in our clinical trials, and accounting for factors including mandatory rebates, channel discounts, and anticipated patient adherence, duration of therapy and compliance, we expect the average annualized net revenue per patient for us to be approximately $65,000. When determining the price of LUPKYNIS, we considered the burden of LN disease in the context of value that LUPKYNIS offers to patients and the U.S. healthcare system.

Voclosporin Mechanism of Action

Voclosporin reversibly inhibits immunocompetent lymphocytes, particularly T-Lymphocytes in the G0 and G1 phase of the cell-cycle, and also reversibly inhibits the production and release of lymphokines. Through a number of processes voclosporin inhibits and prevents the activation of various transcription factors necessary for the induction of cytokine genes during T-cell activation. It is believed that the inhibition of activation of T-cells will have a positive modulatory effect in the treatment of LN. In addition to these immunologic impacts, recent data suggests that CNIs have another subtle but important impact on the structural integrity of the podocytes. This data suggests that inhibition of calcineurin in patients with autoimmune kidney diseases helps stabilize the cellular actin-cytoskeleton of the podocytes thus having a structural impact on the podocyte and the subsequent leakage of protein into the urine, which is a key marker of patients suffering from LN.

Scientific Rationale for Treatment of LN with LUPKYNIS

While SLE is a highly heterogeneous autoimmune disease (often with multiple organ and immune system involvement), LN has straightforward disease outcomes. T-cell mediated immune response is an important feature of the pathogenesis of LN while the podocyte injury that occurs in conjunction with the ongoing immune insult in the kidney is an important factor in the clinical presentation of the disease. An early response in LN correlates with long-term outcomes and is clearly measured by proteinuria.

The use of LUPKYNIS, for the treatment of adult patients with active LN, provides a novel approach to treating this disease. LUPKYNIS has shown to have potent effects on T-cell activation leading to its immunomodulatory effects. Additionally, recent evidence suggests that inhibition of calcineurin has direct physical impacts on the podocytes within the kidney. Inhibition of calcineurin within the podocytes can prevent the dephosphorylation of synaptopodin which in turn inhibits the degradation of the actin cytoskeleton within the podocyte. This process is known to directly impact on the levels of protein in the urine which is a key marker of LN disease activity.

FDA Approval and Commercial Launch of LUPKYNIS

On January 22, 2021, the FDA approved LUPKYNIS in combination with a background immunosuppressive therapy regimen to treat adult patients with active LN. As a condition of approval, we were required to conduct four Post Marketing Studies (PMRs) and one Post Marketing Commitment (PMC). We submitted the final study report for AURORA-2 continuation study (PMR) in March 2022 and a drug-drug interaction study (PMC) was submitted in October 2022. The remaining PMRs are all progressing within the expected timelines. We expect to complete two pediatric studies due in 2025 and 2031, and a milk only lactation study with a report due in 2026.

Completion of AURORA 2 Continuation Study

On December 9, 2021, we announced positive topline results from the AURORA 2 two-year continuation study evaluating the long-term safety and tolerability of LUPKYNIS. AURORA 2 (NCT03597464) was a Phase 3 randomized, double-blind, placebo-controlled clinical trial to assess the long-term safety and tolerability of voclosporin, in addition to MMF and steroids. Patients who completed 12 months of treatment in the Phase 3 AURORA 1 study were eligible to enroll in the AURORA 2 continuation study with the same randomized treatment of voclosporin at 23.7 mg twice daily or placebo, in combination with MMF at 1 g twice daily with low-dose oral steroids, for up to an additional 24 months. A total of 216 LN patients out of 357 who were enrolled in the AURORA 1 study continued into AURORA 2, with 116 patients in the voclosporin group and 100 patients in the control group. 90 and 78 patients, respectively, received 36 months of total treatment at the completion of the study. Compared to the active control group, the voclosporin-treated group showed an increase from baseline eGFR at the end of the studies of +2.7 mL/min. The study demonstrated a favorable risk/benefit profile over a three-year period, with safety comparable to AURORA 1, and sustained efficacy.

Investigator-Initiated Trial to Evaluate Antiviral Activity of LUPKYNIS in Kidney Transplant Recipients with COVID-19 (VOCOVID)

On October 27, 2020, we announced the initiation of an open-label exploratory trial evaluating the antiviral effects of voclosporin in kidney transplant recipients (KTRs) with COVID-19 (SARS-CoV-2) or the VOCOVID study. The single-center, investigator-initiated trial (IIT) is being conducted by Drs. Aiko P.J. de Vries and Y.K. Onno Teng at the Leiden University Medical Center (LUMC) in the Netherlands and will compare voclosporin against tacrolimus.

Organ transplant recipients who contract COVID-19 are at greater risk for complications due to the requirement of daily immunosuppressive medications to prevent organ rejection. CNIs, like voclosporin, have been shown in prior *in vitro* studies to inhibit viral replication. The team at LUMC demonstrated that voclosporin inhibited viral replication of COVID-19 at an 8-fold lower concentration than tacrolimus *in vitro*, while maintaining cell viability of infected cells. In contrast to voclosporin, tacrolimus did not show antiviral activity against COVID-19 *in vitro* at clinically relevant concentrations. Therefore, given its potency and dosing advantages, voclosporin is a potentially attractive CNI for COVID-19 infected transplant patients who are already using legacy CNIs as part of their chronic immunosuppressive therapy.

This 56-day open-label IIT is designed to evaluate the antiviral effects of voclosporin compared to tacrolimus in stable KTRs who contracted COVID-19. At study entry, 20 KTRs testing positive for COVID-19 and currently on dual immunosuppressives of prednisone and tacrolimus were randomized 1:1 to remain on tacrolimus or be switched to voclosporin. The primary endpoint is the reduction in COVID-19 viral load over 56 days, as measured by reverse transcription polymerase chain reaction. The study will also assess predefined endpoints as surrogate markers of improved viral clearance including time to 3-log reduction in viral load concentration, time to clinical recovery – defined as free of symptoms for five days or more, and safety and tolerability. As of December 31, 2022, the data collection was complete. The present study provides evidence that voclosporin has a favorable benefit-risk profile for immunocompromised kidney disease patients who contract a SARS-CoV-2 infection while requiring the continuation of their immunosuppressants.

INTELLECTUAL PROPERTY

Patents and other proprietary rights are essential to our business. Our policy 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.

We have been granted patent portfolio covering voclosporin, including granted United States patents, for composition of matter, methods of use, formulations and synthesis, and the rights to certain corresponding Canadian, South African and Israeli patents are owned by Paladin Labs Inc. We anticipate that patent protection for patents related to the composition of matter of voclosporin will be extended in the United States and certain other major markets, including Europe and Japan, until at least October 2027 under the *Hatch-Waxman Act* in the United States and comparable patent extension laws in other countries (including the Supplementary Protection Certificate program in Europe). We have applied for a patent term extension, and are awaiting confirmation from the USPTO. As the patent term extension was not granted prior to the expiry of the patent term for our composition of matter patent for voclosporin, we applied for, and on July 19, 2022 received, an interim patent term extension until October 17, 2023. If the patent term extension is not granted prior to the expiration of the interim patent term extension that was granted, we intend to file future interim patent term extensions until the USPTO completes its review of the patent term extension application. In addition to patent rights, we have received "new chemical entity" exclusivity for LUPKYNIS in the United States, which provides for exclusivity until January 22, 2026, and “new chemical entity” exclusivity for voclosporin in certain other countries, which provides exclusivity for up to ten years in Europe.

In May 2019, we were granted U.S. Patent No. 10,286,036 (the '036 patent) with a term extending to December 2037, with claims directed at our LUPKYNIS dosing protocol for LN used in our clinical trials. This dosing protocol is reflected on the prescribing information approved by the FDA for LUPKYNIS. Notably, the allowed claims cover a method of modifying the dose of LUPKYNIS in patients with LN based on patient specific pharmacodynamic parameters. We have also filed for protection of this subject matter under the Patent Cooperation Treaty (PCT) and are applying for similar protection in the member countries thereof. This may lead to the granting of similar claims in other major global pharmaceutical markets. In connection with the PCT filing, in December 2022 we received a Notice of Intention to Grant notice from the European Patent Office for a patent application containing similar claims to those in the ‘036 patent.

In January 2023, the USPTO allowed a method of use patent application titled IMPROVED PROTOCOL FOR TREATMENT OF LUPUS NEPHRITIS. This newly allowed patent application reflects the unique and proprietary dosing regimen of LUPKYNIS. Specifically, this patent further refines the method of using LUPKYNIS in combination with MMF and corticosteroids using eGFR as a method of pharmacodynamically dosing LUPKYNIS in patients with LN. The newly allowed application provides patent coverage that supplements our existing ‘036 patent. The claims in this additional patent add further specificity on dosing consistent with the FDA approved product label. This patent has the potential to provide an additional layer of patent protection for LUPKYNIS up to 2037. We intend to list this newly allowed patent in the Orange Book once issued.

COMPETITION

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Many companies, including major pharmaceutical as well as specialized biotechnology companies, are engaged in activities focused on medical conditions that are the same as, or similar to, those targeted by us. For example, another treatment was approved by the FDA for LN approximately one month before we received approval for LUPKYNIS, and physicians have and continue to treat LN in the United States using other drugs with off-label prescribing, such as a combination of MMF and steroids or tacrolimus. Many of the biotechnology, pharmaceutical or biopharmaceutical companies that could or do compete with us or our products have substantially greater financial and other resources, larger research and development staff, and more extensive marketing and manufacturing organization than we do. Many of these companies have significant experience in pre-clinical testing, human clinical trials, product manufacturing, commercialization, marketing and distribution, and other regulatory approval procedures. In addition, colleges, universities, government agencies, and other public and private research organizations conduct research and may market commercial products on their own or through collaborative agreements and these institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. These companies, institutions, and organizations also compete with us in recruiting and retaining highly qualified scientific personnel, as well as other personnel needed for our business. Certain products may also be available at prices that are substantially lower than the cost of LUPKYNIS, whether or not studied in, or receiving approval for use by the FDA for, LN.

We believe key competitive factors that will affect the development and commercial success of LUPKYNIS and future potential product candidates include, but are not limited to, diagnosis, market development, efficacy, safety and tolerability profile, reliability, convenience of dosing, pricing, the level of generic competition and reimbursement. As we and our competitors introduce new products and offerings, and as existing products evolve, we expect that we may become subject to additional competition.

REGULATORY

We worked with Otsuka to prepare an MAA filing with the EMA that was filed during the first half of 2021; an MAA filing with Swissmedic that was filed during the second half of 2021, and an MAA filing submitted to the UK's Medicines and Healthcare products (MHRA) for approval in Great Britain. These ultimately led to the EC and MHRA approvals received in the second half of 2022, while the Swissmedic review is ongoing. In February 2022, Swissmedic also granted orphan drug designation to voclosporin. Otsuka is required under the Otsuka License Agreement to use commercially reasonable efforts to prepare and submit filings for regulatory approvals in the other territories in which we have granted them rights, including Japan and selected other European countries.

Regulatory Requirements

The development, manufacturing and marketing of LUPKYNIS is subject to regulations relating to the demonstration of safety and efficacy of the products as established by the government or regulatory authorities in those jurisdictions where this product is to be marketed. We, or our licensees, are required to seek and obtain regulatory approvals in the United States, Europe and

Japan in order to commercialize LUPKYNIS in these jurisdictions. Depending upon the circumstances surrounding the clinical evaluation of LUPKYNIS, we may undertake clinical trials, contract clinical trial activities to contract research organizations, or rely upon corporate partners for such development. As noted above, we have obtained the requisite approvals for LUPKYNIS to treat active LN in adult patients in the United States and have received marketing approvals from the EC and MHRA. We believe this will allow us to make cost effective developmental decisions in a timely fashion. We cannot predict or give any assurances as to whether regulatory approvals will be received or how long the process of seeking regulatory approvals will take.

Although only the jurisdictions of the United States, Europe and Japan are discussed in this section, we may also seek regulatory approval in other jurisdictions in the future and may initiate other clinical studies if and where appropriate.

Government Regulation

Our worldwide business activities are subject to various laws, rules, and regulations of the United States as well as of foreign governments. Compliance with these laws, rules, and regulations has not had a material effect upon our capital expenditures, results of operations, or competitive position, and we do not currently anticipate material capital expenditures for environmental control facilities. Nevertheless, compliance with existing or future governmental regulations, including, but not limited to, those pertaining to product development and approval, business acquisitions, healthcare, consumer and data protection, employee health and safety, and taxes, could have a material impact on our business in subsequent periods. Refer to Part I, Item 1A. “Risk Factors” for a discussion of these potential impacts.

United States—FDA Process

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of drug products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the *Federal Food, Drug, and Cosmetic Act* (FDCA), and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applications (NDAs), warning letters, fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Drug Approval Process. No drug product candidates may be marketed in the United States until the drug has received FDA approval. The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA’s GLP requirements and other applicable regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (IRB) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the drug substance and finished drug product are produced and tested to assess compliance with current GMPs; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Pre-clinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the conduct of the trial, such as whether human research subjects will be exposed to an unreasonable health risk. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be provided to the FDA as part of a separate submission to the IND. Further, an IRB for each medical center proposing to conduct the clinical trial must review and approve the study protocol and informed consent information for study subjects for any clinical trial before it commences at that center, and the IRB must monitor the study until it is completed. There are also requirements governing reporting of ongoing clinical trials and clinical trial results to public registries. Study subjects must sign an informed consent form before participating in a clinical trial.

Clinical trials necessary for product approval typically are conducted in three sequential phases, but the phases may overlap. Phase 1 usually involves the initial introduction of the investigational drug into a limited population, typically healthy humans, to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population impacted by the disease to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific targeted indications. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. Phase 3 trials, commonly referred to as pivotal studies, are undertaken in an expanded patient population at multiple, geographically dispersed clinical trial centers to further evaluate clinical efficacy and test further for safety by using the drug in its final form. Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Furthermore, the sponsor, the FDA or an IRB may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, such as in the circumstances where the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2 clinical testing, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach consensus on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support submission of an NDA.

Concurrent with clinical trials, companies usually complete additional animal safety studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with GMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and the manufacturer must develop methods for testing the quality, purity and potency of the final drugs. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Assuming successful completion of the required clinical testing, the results of pre-clinical studies and of clinical trials, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. An NDA must be accompanied by a significant user fee.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is GMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the *Prescription Drug User Fee Act* (PDUFA) guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to a filing review before the FDA accepts it for filing and substantive review.

The FDA also may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA may inspect the facility or the facilities at which the drug and/or its drug substance is manufactured and may withhold approval of the product if the manufacturing is not in compliance with GMPs and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A complete response letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data and/or additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA could approve the NDA with a Risk Evaluation and Mitigation Strategy to mitigate risks of the drug, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. Once the FDA approves a drug, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety effects of approved products that have been commercialized. The FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Expedited Review and Approval. The FDA has various programs, including fast track designation, priority review, accelerated approval, and breakthrough therapy designation, which are intended to expedite or simplify the process for reviewing certain drugs and in the case of accelerated approval, provide for approval on the basis of surrogate or intermediate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life-threatening diseases or conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. Fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

For example, fast track designation is designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and which demonstrate the potential to address an unmet medical need for such diseases or conditions. With regard to a fast track-designated product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

Drug products intended for serious or life threatening conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome, or an effect on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval.

The *Food and Drug Administration Safety and Innovation Act* established a category of drugs referred to as “breakthrough therapies” that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies receive all the benefits of a fast track designation, as well as intensive guidance on efficient drug development and organizational commitment involving senior managers in the FDA.

Post-Approval Requirements. After a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. In addition, certain changes to an approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. A company cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

If post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to (i) report certain adverse reactions to the FDA and maintain pharmacovigilance programs to proactively look for these adverse events; (ii) comply with certain requirements concerning advertising and promotional labeling for their products; and (iii) continue to have quality control and manufacturing procedures that conform to GMPs after approval. The FDA periodically inspects the sponsor’s records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of ongoing compliance with GMPs. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain GMP compliance. We use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Patent Term Restoration and Marketing Exclusivity. Depending upon the timing, duration and specifics of FDA approval of the use of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the *Drug Price Competition and Patent Term Restoration Act of 1984*, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the extension must be requested prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. We have filed for a patent term extension for one of our U.S. patents, which is being considered by the USPTO. Only one U.S. patent is permitted to be extended for the currently approved drug product and its uses.

Data and market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance.

During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or an NDA submitted under section 505(b)(2) of the FDCA by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent or from accepting and reviewing an application referencing the approved drug's application. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to all of the pre-clinical studies and clinical trials necessary to demonstrate safety and effectiveness.

Foreign Regulation

In addition to regulations in the United States, we may become subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of LUPKYNIS or other potential future products. In many cases, we must obtain approval of the country's regulatory authorities in order to conduct clinical trials or market products, although in selected countries there are regulations that permit marketing a product on the basis of an approval that has been received in the U.S., EU, or elsewhere. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

As an example, in the European Economic Area (EEA), which is comprised of the member states of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of MAs:

- Community MAs – These are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA, and are valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA; for products that constitute a significant therapeutic, scientific or technical innovation; or for products that are in the interest of public health in the EU.

- National MAs – These are issued by the competent authorities of the member states of the EEA and only cover their respective territory and are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a member state of the EEA, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure, an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state. The competent authority of the reference member state prepares a draft assessment report, a draft summary of the product characteristics (SmPC) and a draft of the labeling and package leaflet, which are sent to the other member states (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling or packaging proposed by the reference member state, the product is subsequently granted a national MA in all the member states, i.e., in the reference member state and the Member States Concerned.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the member states of the EEA assess the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor's generic product. For example, if any of our products receive marketing approval in the EEA, we expect they will benefit from eight years of data exclusivity and 10 years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), we (or our licensee or partner) obtain an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies. The data exclusivity period begins on the date of the product's first marketing authorization in the EEA and prevents generics from relying on the marketing authorization holder's pharmacological, toxicological and clinical data for a period of eight years. After eight years, a generic product application may be submitted, and generic companies may rely on the marketing authorization holder's data. However, a generic cannot launch until two years later (or a total of 10 years after the first marketing authorization in the EU of the innovator product), or three years later (or a total of 11 years after the first marketing authorization in the EU of the innovator product) if the marketing authorization holder obtains marketing authorization for a new indication with significant clinical benefit within the eight-year data exclusivity period.

When conducting clinical trials in the EU, we must adhere to the provisions of the European Union Clinical Trials Directive (Directive 2001/20/EC) and the laws and regulations of the EU member states implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the competent Member State authority is obtained before commencing the clinical trial. In April 2014, the EU passed the Clinical Trials Regulation (Regulation 536/2014), which will replace the current Clinical Trials Directive. To ensure that the rules for clinical trials are identical throughout the European Union, the EU Clinical Trials Regulation was passed as a regulation that is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive until the Clinical Trials Regulation becomes applicable. The Clinical Trials Regulation became applicable January 31, 2023.

Japan Regulatory Process

In Japan, the Pharmaceutical and Medical Devices Agency (PMDA) is the main regulatory agency that oversees the review and approval of the drugs in Japan. There is the potential for PMDA to require additional clinical trials to be conducted to generate data in a Japanese population.

Japan's regulatory system requires the Japanese New Drug Application (J-NDA) documents to be prepared in the common technical document format. Once the applicant files the J-NDA, PMDA reviews the application and may carry out a GMP investigation of manufacturing site. If there are any major issues, PMDA reviewer will prepare a summary of the main issues, discuss with the applicant and may organize an expert discussion, which involves a discussion between the PMDA reviewer and external expert on the proposed major issue(s).

Following this review meeting, PMDA may again hold another expert discussion (if necessary) and prepares a review report for final approval within the Japanese government. The standard time for approval of a J-NDA is approximately 12 months. In Japan, our products may be eligible for eight years of data exclusivity. There can be no assurance that we will qualify for such regulatory exclusivity, or that such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies.

Coverage and Reimbursement

In the United States and internationally, sales of LUPKYNIS and any other products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of adequate coverage and reimbursement from third-party payors, such as state and federal governments, managed care providers and private insurance plans. These organizations routinely implement cost-cutting and reimbursement initiatives that have the ability, or potential, to impact a patient's overall access to our product. Examples of these initiatives include, but are not limited to, establishing formularies that govern the drugs and biologics that are eligible for reimbursement and the out-of-pocket obligations of member patients for such products.

In addition, particularly in the United States and increasingly in other countries, we could be required to provide discounts, rebates and/or other price concessions to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted to potentially impact reimbursement rates or rebates for the products we are developing and may develop in the future and could further impact the levels of discounts and rebates paid to federal and state government entities. Any legislation that impacts these areas could impact, in a significant way, our ability to generate revenues from sales of products in which we have a commercial interest.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our future business. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the ACA established:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts for eligible beneficiaries during their coverage gap period, often referred to as the donut hole; and
- a formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

Additionally, in August 2022, the Inflation Reduction Act of 2022 was passed by the U.S. Congress which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which will take effect in 2023. This legislation contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated “maximum fair price” for certain selected drugs covered by Medicare or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Legislative, administrative, and private payor efforts to control drug costs span a range of proposals, including drug price negotiation, Medicare Part D redesign, drug price inflation rebates, international mechanisms, generic drug promotion and anticompetitive behavior, manufacturer reporting, and reforms that could impact therapies utilizing the accelerated approval pathway.

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. Recently, there has also been heightened governmental (federal and state) 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.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system and international healthcare systems. Future legislation, or regulatory actions implementing recent or future legislation may have a significant effect on our business. Our ability to successfully commercialize products depends in part on the extent to which reimbursement for the costs of our products and related treatments will be available in the United States and worldwide from government health administration authorities, private health insurers and other organizations. The adoption of certain proposals could limit the prices we are able to charge for our products, the amounts of reimbursement available for our products, and limit the acceptance and availability of our products. Therefore, substantial uncertainty exists as to the reimbursement status of newly approved health care products by third-party payors.

MANUFACTURING AND SUPPLY CHAIN

In order to supply commercial inventory for LUPKYNIS and semi-finished products, we have established relationships with contract manufacturing organizations (CMOs) coupled with supply agreements, for the manufacturing of active pharmaceutical ingredient or drug substance, encapsulation of voclosporin 7.9 mg capsules as well as packaging of LUPKYNIS commercial cartons.

Manufacturing of Drug Substance

Voclosporin requires a specialized drug substance manufacturing process and is manufactured by Lonza, our sole supplier for drug substance. Pricing for supply is determined through supply agreements between us and Lonza and is based on the kilograms produced and the cost of the raw materials used in the drug substance manufacturing process. As at the date of this Annual Report, we have not experienced any difficulty in obtaining the raw materials required with respect to the manufacturing of voclosporin. We believe we have enough inventory on hand and manufacturing capacity to meet forecasted demand.

We have entered into a collaborative agreement with Lonza to build a dedicated manufacturing capacity within Lonza's existing small molecule facility in Visp, Switzerland. The dedicated facility (also referred to as monoplant) will be equipped with state-of-the-art manufacturing equipment to provide cost and production efficiencies for the manufacture of voclosporin, while expanding existing capacity and providing supply security to meet future commercial demand. Upon completion of the monoplant expected in 2023, we will maintain sole dedicated use of the monoplant by paying a required quarterly fixed facility fee. We anticipate regulatory approvals of the monoplant for use for commercial products in 2025.

Encapsulation

Catalent Pharma Solutions (Catalent) is currently the sole supplier for the preparation of our voclosporin 7.9 mg capsules. Pricing for these services is determined by a supply agreement between Catalent and us. We expect that Catalent will continue to provide contract manufacturing services with respect to encapsulating voclosporin in order to manufacture voclosporin 7.9 mg capsules that are required for our future commercial and clinical supply needs. We have entered into an agreement for a backup manufacturing encapsulation site in Beinheim, France expected to be completed in 2025.

Packaging

We currently use a sole supplier for the blistering and packaging of LUPKYNIS commercial cartons for sale in the United States and for the blistering of semi finished products. Pricing for these services is determined by a supply agreement between us and our supplier. We expect that our supplier will continue to provide contract manufacturing services with respect to the packaging of LUPKYNIS commercial cartons for the U.S. market.

Marketing, Sales and Distribution

We have built a commercial organization with deep expertise and a focus on rheumatology and nephrology to support the commercialization of LUPKYNIS. The commercial team consists of sales, marketing, commercial operations, commercial supply chain, patient services, market access, and professional and advocacy relations.

Material Licensing Contracts

For terms of material licensing contracts, refer to Part IV, Item 15, Note 10 – License and Collaboration Agreements.

HUMAN CAPITAL MANAGEMENT

As of December 31, 2022, we employed approximately 300 employees in the United States, Canada, and the United Kingdom, all of whom are expected to support our vision, mission and values, and adhere to our Code of Ethics and Conduct.

The Compensation Committee of our Board of Directors has the primary responsibility for overseeing our human capital management activities, including assessing the effectiveness of employee programs and advising management on strategic goals and overall human resource strategies. Other committees may also have responsibilities that impact our human capital management.

Talent Management and Retention

Recruiting and retaining top talent is key to advancing our mission of changing the trajectory of autoimmune diseases. We strive to engage and retain our employees throughout the employment life cycle. Within management, our human resources function has global responsibility for advising and assisting the overall business on human resource matters and executing our overall human capital management strategies.

Effective performance management is key to goal attainment. All our employees are provided with routine performance feedback aligned with our pay for performance philosophy, which ties compensation to performance.

As part of our annual review of compensation, we include the most current industry market compensation data compiled by Radford to assess whether our employee pay is fair and competitive. We take proactive measures to ensure there are no pay gaps related to race, age, gender and ethnicity across the organization, functions, and levels. We offer a competitive benefit plan as part of our total rewards package.

Health and Safety

Our employees' health, safety, and overall well-being is a priority for us. We track this in a variety of ways, including measuring the number of employees participating in our health and wellness webinars, working to ensure all of our employees are covered by an occupational health and safety management system, and minimizing work-related injuries annually.

We are committed to providing safe and healthy working conditions and an atmosphere of open communication for all our employees. In response to the COVID-19 pandemic, we implemented safety and health standards and protocols for our employees while continuing to offer a safe environment as an essential service to our customers. Under the current conditions, employees are empowered to work from the office, home, or both. Our offices are equipped with personal protective equipment (including access to COVID-19 test kits), other equipment, and enhanced cleaning supplies. When recommended or mandated by the Centers for Disease Control and Prevention or local regulations, we required our employees to adhere to appropriate protocols for social distancing, limiting density, reporting and documenting exposures, and wearing masks. We have followed the COVID-19 guidance provided by local medical authorities for each of our offices. We have also established periodic mental health sessions to help our employees during this unprecedented time to manage stress and anxiety.

Under the oversight of the Audit Committee of our Board of Directors, we have established a Whistleblower Policy, which includes that we maintain a whistleblower hotline that is available to all our employees to report any concerns. The hotline is facilitated by an independent third party and all communications are routed to our General Counsel for investigation and resolution. The single exception to this routing is if a complaint implicates the General Counsel, in which case it will automatically go to the Chair of the Audit Committee. We also have defined a Bullying and Harassment Policy, which is available to our employees on our internal website.

Environmental, Social and Governance

Environmental, Social and Governance (ESG) sustainability is an approach that looks beyond the traditional environmental aspect of sustainability. ESG also includes Social and Governance aspects, such as employee well being, talent development and retention, cybersecurity, fair remuneration, employee recognition, and many others.

ESG helps break down how an organization is managing risks and opportunities for its stakeholders. A company's stakeholders have a vested interest in the business, and includes members such as employees, customers, investors, and the Board.

For us, by disclosing key aspects of ESG, Aurinia's stakeholders can better understand our values, and what we are undertaking to address the long-term financial risks and impacts that affect us.

In line with our mission to changing the trajectory of autoimmune, kidney and rare diseases, we believe that we must take a wholistic approach to address/improve our impact on the communities we serve. Therefore, we've established environmental, social, and governance priorities. The Governance & Nomination Committee of our Board of Directors is responsible for ensuring the mentioned goals are pursued and are assessed periodically. Progress on these goals will be disclosed in future sustainability reports.

We are working on preparing our first ESG report, and expect to make that report public in 2023.

CORPORATE INFORMATION

Aurinia is organized under the *Business Corporations Act* (Alberta). We have two wholly-owned subsidiaries: Aurinia Pharma U.S., Inc., (Delaware incorporated) and Aurinia Pharma Limited (United Kingdom incorporated). Our principal executive office is located at #1203-4464 Markham Street, Victoria, British Columbia, V8Z 7X8, Canada and our phone number is +1 (250) 744-2487. Our registered office is located at #201, 17873 -106A Avenue, Edmonton, Alberta, Canada and our U.S. commercial office is located at 77 Upper Rock Circle, Suite 700, Rockville, Maryland 20850.

Our website address is www.auriniapharma.com and our investor relations website is located at https://ir.auriniapharma.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act are filed with the SEC and are available at the SEC's website at www.sec.gov. Such reports and other information are also available free of charge on our investor relations website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information posted on, or that can be accessed through, our website and investor relations website is not incorporated into this Annual Report and the contents of these websites are not intended to be incorporated by reference into any report or document we file with, or furnish to, the SEC. Certain documents are also filed with securities regulators in Canada and are available under our profile at the website www.sedar.com.

Item 1A. Risk Factors

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 use 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 and if we are not able to achieve our financial targets related to commercializing* LUPKYNIS*, then we may need to curtail or cease operations.

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. 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 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 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 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 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 benefits, administration and use of LUPKYNIS;
- train, deploy, and support a qualified sales 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, most of our product revenue comes from a limited number of direct customers. Revenues from the Company's two main customers in the U.S. accounted for approximately 45% and 35%, respectively, of our total revenues for the year ended December 31, 2022. 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 forecast and 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 pandemic;
- 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- or third-line therapy;
- adverse publicity about our product or favorable publicity about competitive products;
- convenience and ease of administration of 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, and future growth prospects could be materially and adversely affected by widespread health concerns, such as the COVID-19 pandemic.

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, 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.

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 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 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.

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, do not infringe the patents or intellectual property of others;
- that our patents or regulatory protections will provide sufficient duration for our products to reach a level of profitability; or
- that we will be able to obtain any extensions of the applicable patent terms.

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), 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 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. 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.

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, we had an accumulated deficit of $864.3 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.

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. higher than anticipated acquisition costs and expenses;
c. the difficulty and expense of integrating operations, systems, and personnel of acquired companies;
d. disruption of our ongoing business;
e. inability to retain key customers, distributors, vendors and other business partners of the acquired company;
f. diversion of management’s time and attention; and
g. 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 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, business planning, business development, raising capital, developing, manufacturing, and, more recently, marketing and commercializing LUPKYNIS. 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, 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.

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 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.

***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.

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, therefore, have the potential to adversely affect our business, financial condition, results of operations and cash flows.

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% of the Company's net revenue for the year ended December 31, 2022.

We also depend 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 and milestone 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 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 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 in Ukraine, 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 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 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.

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.

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.

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, 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 weakened in 2022 driven by high inflation, supply chain challenges and the impacts of 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. 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 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.

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. 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; 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.

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 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 may become 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 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. We intend, for the foreseeable future, to retain our future earnings, if any, to finance our commercial activities and further research and the expansion of our business. 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.

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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease approximately 13,206 square foot facility in Victoria, British Columbia, which is used primarily as our headquarters as well as for research and development and administrative purposes. As of December 31, 2022, the fixed lease term ended for Victoria and we entered a month to month lease. We lease approximately 4,375 square feet of space in Edmonton, Alberta, which is used for general and administrative purposes. We lease approximately 30,531 square feet of space in Rockville, Maryland, which serves as our commercial office and is used for marketing as well as general and administrative purposes. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional or alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

Information pertaining to legal proceedings can be found under in Note 13 Commitments and Contingencies to our consolidated financial statements included in "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common shares are traded on The Nasdaq Global Market under the symbol "AUPH".

Holders of Record

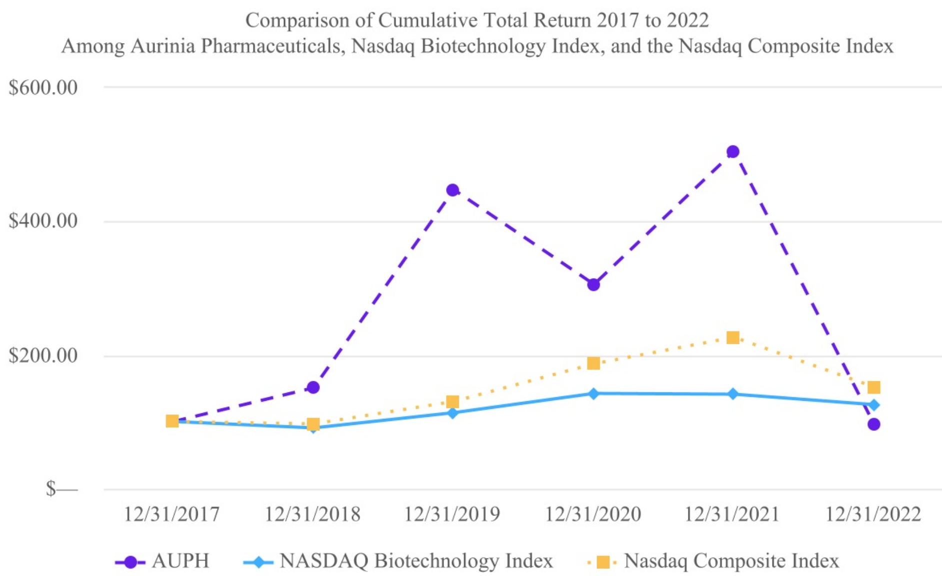
As of February 22, 2023, there were approximately 45 registered holders of record of our common shares. The actual number of shareholders is greater than this number of registered holders of record, and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans are incorporated by reference to Item 12 of Part III of this Annual Report.

Stock Performance Graph

The following graph shows the value of an investment of $100 from December 31, 2017 through December 31, 2022, in our common shares, the Nasdaq Biotechnology Index, and Nasdaq Composite Index. The historical share price performance of our common shares shown in the performance graph is not necessarily indicative of future share price performance.



	Ticker	Cumulative Total Return Date Ended December 31, 2017		December 31, 2018		December 31, 2019		December 31, 2020		December 31, 2021		December 31, 2022	
Aurinia Pharmaceuticals Inc.	AUPH	$	100.00	$	150.55	$	447.24	$	305.30	$	504.86	$	95.36
NASDAQ Biotechnology Index	^NBI	$	100.00	$	90.68	$	112.81	$	141.78	$	140.88	$	125.52
NASDAQ Composite Index	^IXIC	$	100.00	$	96.12	$	129.97	$	186.69	$	226.63	$	151.61

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, except to the extent that we specifically incorporate this information by reference therein, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Recent Sales of Unregistered Securities

During the year ended December 31, 2022, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the three months ended December 31, 2022.

Dividends

We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business and operations, including the commercialization of LUPKYNIS and further advancement of our pipeline, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends (in any currency), if any, will be at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other facts our Board of Directors may deem relevant.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

None.

Item 6. Reserved.

Not required.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following management's discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and the notes thereto included in this Annual Report. In addition to historical consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Annual Report. Our actual results may differ materially from those contained in any forward-looking statements. You should carefully read "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

The following generally discusses 2022 and 2021 items and year-to-year comparisons between 2022 and 2021. Discussion of historical items and year-to-year comparisons between 2021 and 2020 that are not included in this discussion can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 28, 2022 and such comparisons are incorporated herein by reference.

Overview

Aurinia is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations that are impacted by autoimmune, kidney and rare diseases with a high unmet medical need. In January 2021, we introduced LUPKYNIS (voclosporin), the first FDA-approved oral therapy for the treatment of adult patients with active LN. We continue to conduct pre-clinical, clinical and regulatory activities to support the LUPKYNIS development program as well as our other assets. We engaged with Otsuka as a collaboration partner for development and commercialization of LUPKYNIS in the Otsuka Territories.

LUPKYNIS is an orally administered CNI immunosuppressant that has been demonstrated to improve near and long-term outcomes in LN when used in combination with MMF (although MMF is not currently approved as such) and steroids. By inhibiting calcineurin, LUPKYNIS reduces cytokine activation and blocks interleukin IL-2 expression and T-cell mediated immune responses. LUPKYNIS also potentially stabilizes podocytes, which can protect against proteinuria.

Voclosporin, the active ingredient in LUPKYNIS, is made by a modification of a single amino acid of the cyclosporine molecule. The mechanism of action of LUPKYNIS has been validated with certain earlier generation CNIs for the prevention of rejection in patients undergoing solid organ transplants and in several autoimmune indications, including uveitis, keratoconjunctivitis sicca, psoriasis, rheumatoid arthritis, and for LN in Japan. We believe that LUPKYNIS possesses pharmacologic properties with the potential to demonstrate best-in-class differentiation.

On September 15, 2022, the EC granted marketing authorization of LUPKYNIS. The centralized marketing authorization is valid in all EU member states as well as in Iceland, Liechtenstein, Norway and Northern Ireland. The approval triggered a $30.0 million milestone payment to us, which was recognized as collaboration revenue during the third quarter in 2022. We continue to progress with regulatory approval with Otsuka in the other Otsuka Territories.

Our net product revenue in 2022 increased to $103.5 million from $45.5 million in 2021. We did not have any products approved for sale before 2021. We expect our net product revenue to continue to increase as we continue to execute on our post approval commercialization strategy for LUPKYNIS.

Our total cost of sales and operating expenses increased in 2022 to $245.5 million from $226.3 million in 2021, primarily as a result of additional efforts related to the commercialization of LUPKYNIS, along with an increase in cost of sales recognized for product sales. We anticipate continuing to spend in R&D to support our development programs and post approval commitments to the FDA for LUPKYNIS and in respect of our two additional assets, AUR200 and AUR300.

We ended 2022 with $389.4 million in cash, cash equivalents and restricted cash and short-term investments, which we believe to be sufficient to fund our current business plans for at least the next few years.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of revenue and expenses during the reporting periods. In accordance with U.S. GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, are reflected in our financial statements prospectively from the date of the change in estimate.

We define our critical accounting policies as those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Annual Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Product Revenues

In the United States (and territories), we sell LUPKYNIS primarily to specialty pharmacies and specialty distributors. These customers subsequently resell our products to health care providers and patients. Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer.

Reserves for discounts and allowances: Product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer).

Our estimates established for variable consideration are calculated based upon utilizing the expected value method. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Amounts related to such items are estimated at contract inception and updated at the end of each reporting period as additional information becomes available.

Significant judgment is required in estimating variable consideration. In making these estimates, we consider historical data, including patient mix and inventory sold to our customers that has not yet been dispensed. We use a data aggregator and historical claims to estimate variable consideration for inventory sold to our customers, including specialty pharmacies and specialty distributors, that has not yet been dispensed. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment. As of December 31, 2022, we did not have any material adjustments to variable consideration estimates based on actual results.

License, Collaboration and Other Revenues

We enter into out-licensing agreements in which we license certain rights to our product candidates to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees, development, regulatory and commercial milestone payments, payments for collaboration services we provide through our contract manufacturers, and royalties on net sales of licensed products. Each of these payments results in license, collaboration and other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues. We recorded $50.0 million for upfront, non-refundable revenue in 2020 related to the Otsuka agreement. The upfront fee of $50.0 million was fixed consideration for the transfer of the license and distribution rights and was recognized upon transfer in December 2020. In 2022, we recognized $30.6 million in license and collaboration revenue from Otsuka.

Deferred Compensation Arrangements

We have recorded deferred compensation arrangements in liabilities for estimated future employee benefits relating to applicable historical employment arrangements. In 2012, deferred compensation arrangements were approved by a resolution of the board of directors. Pursuant to ASC Topic 710 – *Compensation*, we recognize future benefits provided by employee retention arrangements, as deferred compensation, which is recognized when we determine that it is probable to make future payments. The deferred compensation is based on an income approach for the estimated future net revenues of voclosporin using an internal risk-adjusted net present value of the future payments to be made to the individuals.

Initially, these obligations are measured at the present value of expected future payments to be made in respect of services provided by employees up to the end of the reporting periods. Subsequent re-measurements as a result of performance obligations we meet or changes in assumptions are recognized in the consolidated statement of operations. There have been no material historical adjustments to amounts recorded in the consolidated statement of operations in prior periods.

Impact of Recently Issued Accounting Pronouncements

For information of recent accounting pronouncements and their impact on our consolidated financial statements or disclosures, see Note 2 "Summary of Significant Accounting Policies" to our consolidated financial statements included in "Financial Statements and Supplementary Data" in this Annual Report.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table sets forth our results of operations for the years ended December 31, 2022 and 2021:

	Years Ended December 31,		
(in thousands)	**2022**	**2021**	**Change**
Revenue:			
Product revenue, net	**$ 103,468**	$ 45,488	$ 57,980
License and collaboration revenue	**30,562**	117	30,445
Total revenue, net	**134,030**	45,605	88,425
Operating expenses:			
Cost of sales	**5,664**	1,091	4,573
Selling, general and administrative	**196,371**	173,536	22,835
Research and development	**44,988**	51,139	(6,151)
Other (income) expense, net	**(1,523)**	574	(2,097)
Total cost of sales and operating expenses	**245,500**	226,340	19,160
Loss from operations	**(111,470)**	(180,735)	69,265
Interest income	**5,118**	529	4,589
Net loss before income taxes	**(106,352)**	(180,206)	73,854
Income tax expense	**1,828**	760	1,068
Net loss	**$ (108,180)**	$ (180,966)	$ 72,786

Revenues

Total net revenue were $134.0 million and $45.6 million for the years ended December 31, 2022 and 2021, respectively. Our total net revenue during 2022 increased primarily as a result of net product revenue from our two main customers for LUPKYNIS driven predominantly by further penetration in the LN market, as well as the recognition of a $30.0 million milestone payment from Otsuka following the EC granting marketing authorization of LUPKYNIS in September 2022. Revenues from our two main customers in the U.S. accounted for approximately 45% and 35%, respectively, of our total revenues for the year ended December 31, 2022.

Cost of Sales

Cost of sales were $5.7 million and $1.1 million for the years ended December 31, 2022 and 2021, respectively. The increase was primarily due to an increase in product related revenue, coupled with an increase in our inventory reserves which were mainly related to reserves on process validation batches used for FDA approval.

Gross margin for the years ended December 31, 2022 and 2021 was approximately 96% and 98%, respectively.

Selling, General and Administrative Expenses

SG&A expenses increased to $196.4 million for the year ended December 31, 2022 compared to $173.5 million for the year ended December 31, 2021. SG&A expenses consisted of the following:

	Years Ended December 31,		Change
(in thousands)	2022	2021	
Salaries, incentive pay and employee benefits	$ **82,129**	$ 78,991	$ 3,138
Professional fees and services	**58,759**	45,551	13,208
Share-based compensation expense	**28,438**	26,432	2,006
Other corporate costs	**15,826**	14,733	1,093
Travel, trade shows and sponsorships	**11,219**	7,829	3,390
	$ **196,371**	$ 173,536	$ 22,835

The primary drivers for the increase of $22.8 million in SG&A were an increase of professional fees and services mainly related to corporate legal matters and pharmacovigilance; and travel, trade shows and sponsorships to support the commercialization of LUPKYNIS. Additionally, salaries, incentive pay and employee benefits increased due to inflationary increases and routine year over year merit and promotion increases.

We expense SG&A costs in the periods in which they are incurred. We anticipate continuing to incur significant expenses in SG&A to support the commercialization of LUPKYNIS.

Research and Development Expenses

R&D expenses decreased to $45.0 million for the year ended December 31, 2022 compared to $51.1 million for the year ended December 31, 2021. R&D expenses consisted of the following:

	Years Ended December 31,		Change
(in thousands)	2022	2021	
Contract research organizations (CRO) and developmental expenses	$ **18,451**	$ 31,098	$ (12,647)
Clinical supply and distribution	**8,614**	4,180	4,434
Salaries, incentive pay and employee benefits	**14,034**	11,008	3,026
Share-based compensation expense	**3,271**	4,442	(1,171)
Other costs	**618**	411	207
	$ **44,988**	$ 51,139	$ (6,151)

The primary drivers for the decrease of R&D were due to the $10.0 million upfront license and accrued milestone expense within the CRO and developmental expenses line item for AUR300 in the prior year, offset partially by additional expenses related to AUR200 and AUR300 for the year ended December 31, 2022.

We spent approximately $13.5 million and $16.0 million on early stage pre-clinical research programs in the years ended December 31, 2022 and 2021, respectively. The spend does not include internal resource expenses as we currently do not track these for early stage research programs, prior to IND.

We expect our R&D expenses will increase as we continue to meet our post-approval obligations for LUPKYNIS with the FDA, invest in R&D activities related to developing voclosporin and product candidates, and as programs advance into later stages of development and we begin to conduct larger clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and R&D is highly uncertain. As a result, we are unable to determine the duration and completion costs of our R&D projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Other Expenses (Income), Net

Other income was $1.5 million for the year ended December 31, 2022 compared to other expense of $0.6 million for the year ended December 31, 2021. The primary driver for the change was the revaluation of deferred compensation based on a change in discount rate.

Interest Income

Interest income was $5.1 million for the year ended December 31, 2022 compared to $0.5 million for the year ended December 31, 2021. The increase was mainly due to higher yields on our investments as a result of increasing interest rates.

Liquidity and Capital Resources

As of December 31, 2022, we had cash, cash equivalents and restricted cash of $94.2 million and short-term investments of $295.2 million compared to cash, cash equivalents and restricted cash of $231.9 million and short-term investments of $234.2 million at December 31, 2021. Cash, cash equivalents and restricted cash and investments are primarily held in U.S. dollars. As of December 31, 2022 and 2021, we had working capital of $396.4 million and $472.7 million, respectively.

We are devoting the majority of our operational efforts and financial resources towards the commercialization and post approval commitments of our approved drug, LUPKYNIS. We are also expending efforts towards the development of our AUR200 and AUR300 assets. Taking into consideration the cash, cash equivalents and restricted cash and investments as of December 31, 2022, we believe that our cash position is sufficient to fund our current plans which include funding commercial activities, including our FDA related post-approval commitments, manufacturing and packaging commercial drug supply, funding our supporting commercial infrastructure, advancing our R&D programs and funding our working capital obligations for at least the next few years.

The following table summarizes our cash flows for December 31, 2022, 2021 and 2020:

(in thousands)	2022	2021	2020
Net cash (used in) provided by:			
Operating activities	$ (79,529)	$ (157,692)	$ (69,858)
Investing activities	(60,632)	(103,870)	(158,186)
Financing activities	2,433	221,112	194,375
Net change in cash and cash equivalents	$ (137,728)	$ (40,450)	$ (33,669)

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 was $79.5 million, compared to $157.7 million, for the year ended December 31, 2021. Net cash used in both periods was primarily related to the continued investment in commercialization activities, payments made for our ongoing post approval obligations, advancement of our pipeline, and inventory purchases partially offset by cash receipts from sales of LUPKYNIS. The decrease in net cash used for operating activities is primarily due to an increase in cash receipts from sales of LUPKYNIS and the milestone payment received from Otsuka in 2022 related to the EC marketing authorization.

Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2022 was $60.6 million compared to $103.9 million for the year ended December 31, 2021. Investing activities during 2022 consisted primarily of $524.0 million for purchases of investments of commercial paper and corporate bonds offset by $464.3 million in proceeds as discussed in Note 4 of the audited consolidated financial statements for the year ended December 31, 2022. The decrease in cash used in investing activities is mainly related to the shift to a shorter duration of investments in our portfolio in 2022 in addition to upfront lease and license payments made in 2021 not recurring in 2022.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2022 was $2.4 million compared to cash provided by financing activities of $221.1 million for the year ended December 31, 2021. The decrease in cash provided by financing activities is mainly due to the Company not completing financings and less stock option exercises occurring in 2022.

A discussion of changes in our cash flow from the year ended December 31, 2020 to the year ended December 31, 2021 can be found in Part II, Item 7, "Management's Discussion and Analysis of Financial Conditions and Results of Operations" of the 2021 Form 10-K.

November 2021 ATM facility

In November 2021, we entered into an Open Market Sale Agreement under which we issued 10.2 million common shares, resulting in net proceeds of $196.7 million through December 31, 2022. There were no sales subsequent to December 31, 2021. In February 2022, we terminated the Open Market Sale Agreement and no further sales occurred.

We intend to use the net proceeds to fund our operations, which includes, but is not limited to, commercial activities, including our FDA related post approval commitments, manufacturing and packaging commercial drug supply, funding our supporting commercial infrastructure, advancing our R&D programs and funding our working capital obligations.

Material Cash Requirements

As of December 31, 2022, our material short-term cash requirements are approximately $181.4 million. We anticipate our long-term cash requirements to be approximately $157.5 million, which does not include per annum requirements related to human capital, insurance and government payor rebates, each of which we anticipate to fluctuate based on future requirements (those per annum amounts, calculated on a short-term cash requirement basis, amount to approximately $104.9 million). These short and long-term cash requirement estimates are all based on our current operating plans and strategies, and could fluctuate if our plans were to change.

Our material cash requirements include the following:

- short-term per annum expenses for human capital (which includes estimates for personnel headcount, performance bonuses, salaries, benefits and commissions);
- payor and government rebates and co-payment programs;
- marketing and promotional services;
- corporate insurance premiums;
- cash requirements related to R&D projects, clinical trials, milestone expenses and post-approval related studies and support;
- short-term and long-term lease liabilities included on our consolidated balance sheet or Note 15 Leases for further details;
- deferred compensation arrangements included on our consolidated balance sheet or Note 14, Deferred Compensation and Other Non-Current Liabilities for further details; and
- purchases for inventory and production costs to support our commercial and clinical product supply requirements, as well as capital expenditures. For further details see Note 13, Commitments and Contingencies.

There are several factors that we believe could impact our future cash requirements, including:

- the amount of revenue received from commercial sales of LUPKYNIS, from our licensing partners and potential future drug candidates;
- the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other related regulatory requirements and activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of the R&D assets we seek to acquire, develop or commercialize;
- the expenses needed to attract and retain skilled personnel as well as any other personnel changes that we may implement; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

Our activities can expose us to market risks which include interest rate risk, foreign currency risk, inflation risk and credit risk. Risk management is carried out by management under policies approved by our Board of Directors. Our overall risk management program seeks to minimize adverse effects on our financial performance.

Interest Rate Risk

Financial assets and financial liabilities with variable interest rates expose us to cash flow interest rate risk. We manage our interest rate risk by maximizing the interest income earned on excess funds while maintaining the liquidity necessary to conduct operations on a day-to-day basis. As of December 31, 2022 our investment portfolio includes cash. cash equivalents and restricted cash and investments of $389.4 million that earn interest at market rates. Our investment portfolio is maintained in accordance with our investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. Our investments held during the year were comprised of highly rated instruments such as certificates of deposits, money market instruments, obligations issued by the U.S. government and U.S government agencies as well as corporate debt securities. As of December 31, 2022, these instruments have a maturity of less than a year.

As of December 31, 2022, a hypothetical annual change of 100 basis points on the interest rates of our investments would result in a $3.0 million fluctuation of interest income in our portfolio.

Accounts receivable, accounts payable and accrued liabilities bear no interest. 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.

Foreign Currency Risk

We are exposed to financial risk related to the fluctuation of foreign currency exchange rates. Foreign currency risk for the Company is the risk variations in exchange rates between the U.S. dollar and foreign currencies, primarily with the Canadian dollar, Swiss Franc and Great British Pound, which could affect our operating and financial results.

As of December 31, 2022, we had approximately $2.2 million of foreign denominated third-party payables included in the Company's accounts payable and accrued liabilities balance. An assumed 10% fluctuation in the exchange rates would have an approximate $0.2 million fluctuation in the amounts due. There were no other foreign currency fluctuations that would have had a material impact on our financial condition or results of operations as of December 31, 2022.

Inflation Risk

Inflation has continued to increase during 2022 and is expected to continue to increase for the near future. Inflation generally affects us by increasing our cost of labor, commercial support, manufacturing and clinical trial expenditures. In addition, our investment portfolio may experience the risk of realized losses on our investments if we were to sell before maturity due to the market volatility caused by increasing interest rates.

Credit Risk

Our exposure to credit risk generally consists of cash and cash equivalents, short-term investments and accounts receivable. We place our cash and cash equivalents with highly rated financial institutions and invest the excess cash in highly rated investments. Our investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restriction on maturities and concentrations by asset class and issuer. 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 subject to credit risk in connection with our accounts receivable due from our two customers which accounted for all of our accounts receivable, net balances as of December 31, 2022. We monitor economic conditions and the creditworthiness of our customers. We regularly communicate with our customers regarding the status of receivable balances and have not experienced any issues with collectability. The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Our standard credit terms range from 30 to 45 days. In 2022, we did not recognize any allowance for doubtful accounts receivable related to credit risk for our customers or write any amounts off.

ITEM 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-34 of this report and is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive and financial officers (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Management’s Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2022.

The effectiveness of our internal control over financial reporting has been audited by PricewaterhouseCoopers LLP an independent registered public accounting firm, as stated in their attestation report herein, which appears in the "Index to Consolidated Financial Statements" in Part IV.

Inherent Limitations of Internal Controls

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes.

During the quarter ended December 31, 2022, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this Item and not set forth below will be set forth in the section headed "—Election of Directors" and "Information Regarding the Board of Directors and Corporate Governance" in our definitive Proxy Statement for our 2023 Annual Meeting of Shareholders (or amended Annual Report on Form 10-K) to be filed with the SEC by April 28, 2023 (our Proxy Statement) and is incorporated in this Annual Report by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Corporate Code of Ethics and Conduct. The Corporate Code of Ethics and Conduct is available on our website at *http://www.auriniapharma.com* under the Corporate Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Shareholders may request a free copy of the Corporate Code of Ethics and Conduct from c/o Aurinia Pharmaceuticals Inc., #1203-4464 Markham St., Victoria, BC, V8Z 7X8, Attn: Corporate Secretary.

Item 11. Executive Compensation

The information required by this Item will be set forth in the section headed "Executive Compensation" in our Proxy Statement and is incorporated in this Annual Report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item will be set forth in the section headed "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement and is incorporated in this Annual Report by reference.

Information regarding our equity compensation plans will be set forth in the section headed "Executive Compensation" in our Proxy Statement and is incorporated in this Annual Report by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this Item will be set forth in the section headed "Transactions With Related Persons" in our Proxy Statement and is incorporated in this Annual Report by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item will be set forth in the section headed "Appointment of Selection of Independent Registered Public Accounting Firm" in our Proxy Statement and is incorporated in this Annual Report by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

a. We have filed the following documents as part of this Annual Report:

1. Consolidated Financial Statements.

   The following financial statements are filed as part of this report:

   Our consolidated financial statements are listed under Part II, Item 8. "Index to Consolidated Financial Statements" in this Annual Report.

2. Financial Statement Schedules

   All financial statement schedules have been omitted because they are not applicable, not material or the required information is shown under Part II, Item 8. “Index to Consolidated Financial Statements” in this Annual Report.

3. Exhibits

   The following exhibits, as required by Item 601 of Regulation S-K, which are incorporated herein by reference, are filed or furnished with this Annual Report, in each case as indicated therein.

		Incorporation by Reference			
Exhibit Number	Description	Form	SEC File No.	Exhibit	Filing Date
3.1	Articles of Amalgamation, as amended, as currently in effect	10-K	001-36421	3.1	02/24/21
3.2	Amended and Restated By-Law No. 2 amended as currently in effect	8-K	001-36421	3.2	04/27/21
4.1	Form of Common Shares Certificate of the Company	10-K	001-36421	4.1	02/24/21
4.2	Reference is made to Exhibits 3.1 and 3.2				
4.3	Description of the Registrant's Common Shares	10-K	001-36421	4.3	02/24/21
10.1+	Form of Indemnity Agreement between the Registrant and each of its Directors and Executive Officers	10-K	001-36421	10.1	02/24/21
10.2+	Form of Option Commitment under the Equity Incentive Plan	S-8	333-216447	99.2	03/03/2017
10.3+	Aurinia Pharmaceuticals Inc. Amended and Restated Equity Plan	S-8	333-257424	10.1	06/25/21
10.4+	Aurinia Pharmaceuticals Inc. 2021 Employee Share Purchase Plan	S-8	333-257424	10.2	06/25/21
10.5	Collaboration and Licensing Agreement between the Registrant and Otuska Pharmaceutical Co. Ltd. dated December 17, 2020	6-K	001-36421	99.2	12/30/20
10.6#	Manufacturing Services Agreement between the Registrant and Lonza Ltd. dated November 16, 2020	10-K	001-36421	10.5	02/24/21
10.7#	Collaboration & License Agreement between Aurinia Pharmaceuticals Inc. and Riptide Bioscience Inc. dated August 16, 2021	8-K	001-36421	99.1	08/17/21
10.8#	Lease agreement for space at 77 Upper Rock Circle, Rockville, MD between BOF II MD 77 Upper Rock LLC and Aurinia Pharma U.S. Inc. dated March 12, 2020	10-K	001-36421	10.6	02/24/21

10.9#	Lease agreement for space at Suite No. 1203 and No. 1201 Building No. 100, 4464 Markham Street Victoria, BC between University of Victoria Properties Investments, Inc. and the Registrant dated October 30, 2020	10-K	001-36421	10.8	02/24/21
10.10#	Softgel Commercial Supply Agreement between the Registrant and Catalent Pharma Solutions, LLC dated August 28, 2020	10-K	001-36421	10.9	02/24/21
10.11	Settlement Agreement among ILJIN Life Science Co. Ltd., Isotechnika Pharma Inc., and Aurinia Pharmaceuticals Inc., dated April 3, 2013	10-K	001-36421	10.10	02/24/21
10.12+#	Employment Agreement between Aurinia Pharma U.S., Inc. and Peter Greenleaf dated April 11, 2019	10-K	001-36421	10.11	02/24/21
10.13+#	Employment Agreement between Aurinia Pharma U.S. Inc. and Max Donley dated July 15, 2019	10-K	001-36421	10.13	02/24/21
10.14+#	Employment Agreement between the Registrant and Michael Martin dated October 1, 2017	10-K	001-36421	10.15	02/24/21
10.15+#	Employment Agreement between Aurinia Pharma U.S. Inc. and Joe Miller dated April 8, 2020	10-K	001-36421	10.16	02/24/21
10.16+#	Employment Agreement between the Registrant and Stephen Robertson dated September 29, 2020	10-K	001-36421	10.17	02/24/21
10.17+	Form of Inducement Grant Option Commitment	10-K	001-36421	10.20	02/24/21
10.18+#	Employment Agreement between Aurinia U.S. Pharma Inc., and Volker Knappertz, M.D., dated July 11, 2022	10-Q	001-36421	10.22	11/03/22
10.19+#	Employment Agreement between Aurinia U.S. Pharma Inc., and Scott Habig, dated June 27, 2022	10-Q	001-36421	10.23	11/03/22
10.20+*	Form of Inducement Restricted Stock Unit Award				
10.21+*	Form of Restricted Stock Unit Award under the Equity Incentive Plan				
21.1*	List of Subsidiaries of Registrant				
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm				
24.1*	Power of Attorney (contained in signature page of this report)				
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

*	Filed herewith.
**	Furnished herewith. Exhibit 32.1 and Exhibit 32.2 are being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.
+	Indicates a management contract or compensatory plan.
#	Certain portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because they are not material and are the type that Aurinia treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

		AURINIA PHARMACEUTICALS INC.
February 27, 2023	By:	/s/ Peter Greenleaf
		Peter Greenleaf Chief Executive Officer *(Principal Executive Officer)*

SIGNATURES AND POWER OF ATTORNEY

We, the undersigned directors and officers of Aurinia Pharmaceuticals Inc., hereby severally constitute and appoint Peter Greenleaf and Joseph Miller, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Peter Greenleaf Peter Greenleaf	Chief Executive Officer, Director *(Principal Executive Officer)*	February 27, 2023
/s/ Joseph Miller Joseph Miller	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 27, 2023
/s/ Brinda Balakrishnan Brinda Balakrishnan, M.D., Ph.D.	Director	February 27, 2023
/s/ Daniel Billen Daniel Billen, Ph.D.	Director	February 27, 2023
/s/ Joseph P. Hagan Joseph P. Hagan	Director	February 27, 2023
/s/ David R.W. Jayne David R.W. Jayne, M.D., FRCP, FRCPE, FMedSci	Director	February 27, 2023
/s/ Jill Leversage Jill Leversage	Director	February 27, 2023
/s/ R. Hector MacKay-Dunn R. Hector MacKay-Dunn, J.D., Q.C.	Director	February 27, 2023
/s/ George M. Milne, Jr. George M. Milne, Jr., Ph.D.	Chairman	February 27, 2023

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Aurinia Pharmaceuticals Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting
We have audited the accompanying consolidated balance sheets of Aurinia Pharmaceuticals Inc. and its subsidiaries (together, the Company) as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control – Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control – Integrated Framework* (2013) issued by the COSO.

Basis for Opinions
The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

PricewaterhouseCoopers LLP
PwC Centre, 354 Davis Road, Suite 600, Oakville, Ontario, Canada L6J 0C5
T: +1 905 815 6300, F: +1 905 815 6499

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Measurement of Deferred Compensation Liability

As described in Notes 2 and 14 to the consolidated financial statements, the Company recorded deferred compensation and other non-current liabilities of $12 million as of December 31, 2022 which primarily included the deferred compensation liability. The deferred compensation arrangements are the result of a resolution of the board of directors of the Company dated March 8, 2012 whereby certain executive officers at that time were provided with future potential employee benefit obligations for remaining with the Company, for a certain period of time, and these obligations were also contingent on the occurrence of uncertain future events. The Company recognizes future benefits provided by employee retention arrangements as a deferred compensation liability when the Company determines that it is probable to make future payments. The deferred compensation liability, which is based on the income approach, is the present value of the future payments to be made to the individuals (the model). These future payments are based on royalty rates applied to estimated future net revenues of voclosporin (estimated future net revenues). The royalty rates applied to the estimated future net revenues are dependent on the type of net revenue earned. Significant judgments and estimates are used in determining the deferred compensation liability which include the determination of assumptions related to estimated future net revenues and the discount rate. The estimated future net revenues for the United States includes assumptions related to the number of patients being treated, dosing adjustments, duration of treatment, timing of generics and competitors entering the market, market penetration and potential future use in new indications which management developed with the assistance of an internal scientific team and third party consultants (management's specialists).

The principal considerations for our determination that performing procedures relating to measurement of the deferred compensation liability is a critical audit matter are (i) the significant judgment by management, including the use of management's specialists, when developing the assumptions to determine the deferred compensation liability, which in turn led to; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures related to the assumptions used by management and management's specialists including the estimated future net revenues for the United States and the discount rate; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the measurement of the deferred compensation liability, including controls over management's development of the number of patients being treated, dosing adjustments, duration of treatment, timing of generics and competitors entering the market, market penetration, potential future use in new indications and discount rate assumptions utilized in the measurement of the deferred compensation liability. These procedures also included, among others (i) evaluating and testing management's process for determining the deferred compensation liability; (ii) evaluating the appropriateness of the model used; and (iii) testing the completeness and accuracy of underlying data used in the determination of the deferred compensation liability. The work of management's specialists was used in performing the procedures to evaluate the estimated future net revenues which included evaluating the reasonableness of the assumptions relating to the number of patients being treated, dosing adjustments, duration of treatment, timing of generics and competitors entering the market, market penetration and potential future use in new indications. As a basis for using this work, the qualifications of management's specialists were understood and the Company's relationship with management's specialists was assessed. The procedures performed also included evaluation of the model and assumptions used by management's specialists, tests of the data used by management's specialists and an evaluation of the findings of management's specialists. The evaluation of the number of patients being treated, dosing adjustments, duration of treatment, timing of generics and competitors entering the market, market penetration and potential future use in new indications included considering available industry and third party data, including scientific and market studies, that management's specialists used. Professionals with specialized skill and knowledge were used to assist in the evaluation of the Company's discount rate assumption.

/s/ PricewaterhouseCoopers LLP

Chartered Professional Accountants, Licensed Public Accountants

Oakville, Canada
February 27, 2023

We have served as the Company's auditor since at least 1997. We have not been able to determine the specific year we began serving as auditor of the Company.

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	As of December 31,	
(in thousands)	**2022**	**2021**
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	**$ 94,172**	$ 231,900
Short-term investments	**295,218**	234,178
Accounts receivable, net	**13,483**	15,414
Inventories, net	**24,752**	19,326
Prepaid expenses	**13,580**	11,710
Other current assets	**1,334**	796
Total current assets	**442,539**	513,324
Non-current assets:		
Other non-current assets	**13,339**	11,838
Property and equipment, net	**3,650**	4,418
Acquired intellectual property and other intangible assets, net	**6,425**	8,404
Right-of-use assets, net	**4,907**	5,383
Total assets	**$ 470,860**	$ 543,367
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	**39,990**	34,947
Deferred revenue	**3,148**	190
Other current liabilities	**2,033**	4,450
Operating lease liabilities	**936**	1,059
Total current liabilities	**46,107**	40,646
Non-current liabilities:		
Deferred compensation and other non-current liabilities	**12,166**	15,950
Operating lease liabilities	**7,152**	7,680
Total liabilities	**65,425**	64,276
Commitments and Contingencies (Note 13)		
Shareholders' Equity:		
Common shares - no par value, unlimited shares authorized, 142,268 and 141,600 shares issued and outstanding at December 31, 2022 and 2021, respectively	**1,185,309**	1,177,051
Additional paid-in capital	**85,489**	59,014
Accumulated other comprehensive loss	**(1,061)**	(852)
Accumulated deficit	**(864,302)**	(756,122)
Total shareholders' equity	**405,435**	479,091
Total liabilities and shareholders' equity	**$ 470,860**	$ 543,367

The accompanying notes are an integral part of these consolidated financial statements.

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years ended December 31,		
(in thousands, except per share data)	**2022**	**2021**	**2020**
Revenue:			
Product revenue, net	**$ 103,468**	$ 45,488	$ —
License and collaboration revenue	**30,562**	117	50,118
Total revenue, net	**134,030**	45,605	50,118
Operating expenses:			
Cost of sales	**5,664**	1,091	—
Selling, general and administrative	**196,371**	173,536	97,272
Research and development	**44,988**	51,139	50,327
Other (income) expense, net	**(1,523)**	574	6,809
Total cost of sales and operating expenses	**245,500**	226,340	154,408
Loss from operations	**(111,470)**	(180,735)	(104,290)
Interest income	**5,118**	529	1,516
Net loss before income taxes	**(106,352)**	(180,206)	(102,774)
Income tax expense	**1,828**	760	(94)
Net loss	**(108,180)**	(180,966)	(102,680)
Other comprehensive loss:			
Unrealized loss on available-for-sale securities, net of tax of nil	**(209)**	(47)	—
Comprehensive loss	**$ (108,389)**	$ (181,013)	$ (102,680)
Basic and diluted loss per common share	**$ (0.76)**	$ (1.40)	$ (0.87)
Weighted-average common shares outstanding used in computation of basic and diluted loss per share	**141,915**	129,369	118,473

The accompanying notes are an integral part of these consolidated financial statements.

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(in thousands)	Common Shares Shares	Common Shares Amount	Additional Paid-In Capital	Accumulated other comprehensive loss	Accumulated Deficit	Total Shareholders' Deficit
Balance - January 1, 2020	111,798	$ 746,487	$ 25,394	$ (805)	$ (472,476)	$ 298,600
Issuance of common shares upon public offerings, net of issuance costs	13,333	187,732	—	—	—	187,732
Exercise of warrants	1	2	(1)	—	—	1
Exercise of stock options	1,593	10,107	(3,464)	—	—	6,643
Share-based compensation	—	—	17,454	—	—	17,454
Net loss	—	—	—	—	(102,680)	(102,680)
Balance at December 31, 2020	126,725	$ 944,328	$ 39,383	$ (805)	$ (575,156)	$ 407,750
Issuance of common shares upon public offerings, net of issuance costs	10,166	196,740	—	—	—	196,740
Exercise of warrants	1,434	2,102	(1,737)	—	—	365
Exercise of stock options	3,238	33,073	(9,652)	—	—	23,421
Issuance of common shares in conjunction with ESPP program	37	808	(223)	—	—	585
Share-based compensation	—	—	31,243	—	—	31,243
Unrealized loss on available-for-sale securities, net	—	—	—	(47)	—	(47)
Net loss	—	—	—	—	(180,966)	(180,966)
Balance at December 31, 2021	141,600	$ 1,177,051	$ 59,014	$ (852)	$ (756,122)	$ 479,091
Shares issued on exercise of stock options and vesting of performance awards and restricted stock units	**383**	**5,064**	**(4,543)**	**—**	**—**	**521**
Issuance of common shares in conjunction with ESPP program	**285**	**3,194**	**(1,282)**	**—**	**—**	**1,912**
Share-based compensation	**—**	**—**	**32,300**	**—**	**—**	**32,300**
Unrealized loss on available-for-sale securities, net	**—**	**—**	**—**	**(209)**	**—**	**(209)**
Net loss	**—**	**—**	**—**	**—**	**(108,180)**	**(108,180)**
Balance at December 31, 2022	**142,268**	**$ 1,185,309**	**$ 85,489**	**$ (1,061)**	**$ (864,302)**	**$ 405,435**

The accompanying notes are an integral part of these consolidated financial statements.

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

		Years ended December 31,				
(in thousands)		**2022**		**2021**		**2020**
Cash flows from operating activities:						
Net loss	**$**	**(108,180)**	$	(180,966)	$	(102,680)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:						
Depreciation and amortization		**2,706**		2,761		1,371
Upfront license and milestone expense		**—**		10,000		—
Share-based compensation		**32,300**		31,243		17,454
Write-down of inventory		**3,646**		245		—
Other, net		**(3,184)**		658		9,477
Net changes in operating assets and liabilities:						
Accounts receivable, net		**1,927**		(15,415)		(650)
Inventories, net		**(9,072)**		(5,644)		(13,927)
Prepaid expenses and other current assets		**(2,404)**		(5,335)		2,559
Non-current assets		**(839)**		247		—
Right of use assets		**476**		106		(5,489)
Accounts payable and accrued liabilities		**699**		4,076		13,620
Deferred revenue		**3,048**		—		—
Lease liabilities		**(652)**		332		8,407
Net cash used in operating activities		**(79,529)**		(157,692)		(69,858)
Cash flows from investing activities:						
Proceeds from investments		**464,316**		354,427		52,108
Purchase of investments		**(523,993)**		(438,958)		(202,951)
Upfront lease payment		**(663)**		(11,838)		—
Upfront license payment		**—**		(6,000)		—
Purchase of long-lived assets and intangibles		**(292)**		(303)		(5,668)
Additions to internal use-software implementation costs		**—**		(1,198)		(1,675)
Capitalized patent costs		**—**		—		—
Net cash used in investing activities		**(60,632)**		(103,870)		(158,186)
Cash flows from financing activities:						
Proceeds from issuance of common shares pursuant to Public Offering, net of issuance costs		**—**		196,740		187,732
Proceeds from exercise of stock options and employee share purchase plan		**2,433**		24,007		6,642
Proceeds from exercise of warrants		**—**		365		1
Net cash provided by financing activities		**2,433**		221,112		194,375
Net (decrease) increase in cash and cash equivalents during the year		**(137,728)**		(40,450)		(33,669)
Cash and cash equivalents, beginning of the year		**231,900**		272,350		306,019
Cash, cash equivalents and restricted cash, end of the year	**$**	**94,172**	$	231,900	$	272,350
Supplemental cash flow information:						
Cash received for interest	**$**	**2,344**	$	749	$	1,884
Cash paid for taxes	**$**	**(1,979)**	$	(257)	$	(261)
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets						
Cash, cash equivalents	**$**	**94,088**	$	231,643	$	272,350
Restricted cash		**84**		257		—
Total cash, cash equivalents and restricted cash	**$**	**94,172**	$	231,900	$	272,350

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and Description of Business

Aurinia Pharmaceuticals Inc. (Aurinia or the Company) is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations that are impacted by autoimmune, kidney and rare diseases with a high unmet medical need. In January 2021, the Company introduced LUPKYNIS® (voclosporin), the first U.S. Food and Drug Administration (FDA) approved oral therapy for the treatment of adult patients with active lupus nephritis (LN) and continues to conduct pre-clinical, clinical and regulatory activities to support the LUPKYNIS development program as well as our other assets. We engaged with Otsuka Pharmaceutical Co., Ltd. (Otsuka) as a collaboration partner for development and commercialization of LUPKYNIS in the European Union (EU), Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine (collectively, the Otsuka Territories).

On August 17, 2021, the Company announced the addition of two novel assets AUR200 and AUR300. AUR200 and AUR300 are currently undergoing pre-clinical development with projected submission of Investigational New Drug Applications (INDs) to the FDA for AUR200 in 2023 and for AUR300 in 2024.

On September 15, 2022, the European Commission (EC) granted marketing authorization of LUPKYNIS to Otsuka. The centralized marketing authorization is valid in all EU member states as well as in Iceland, Liechtenstein, Norway and Northern Ireland.

Aurinia's head office is located at #1203-4464 Markham Street, Victoria, British Columbia, Canada and its registered office is located at #201, 17873-106 A Avenue, Edmonton, Alberta. Aurinia also has a U.S. Commercial office located at 77 Upper Rock Circle, Rockville, Maryland, United States.

Aurinia is incorporated pursuant to the Business Corporations Act (Alberta). The Company's common shares are traded on the Nasdaq Global Market (Nasdaq) under the symbol AUPH.

2. Summary of Significant Accounting Policies

Basis of presentation: The Company follows accounting standards established by the Financial Accounting Standards Board (FASB) to ensure consistent reporting of financial condition, results of operations, and cash flows. References to generally accepted accounting principles (GAAP) or U.S. GAAP in these footnotes are to the FASB Accounting Standards Codification (ASC or the Codification). At the end of the second quarter of 2020, the Company determined that it no longer qualified as a Foreign Private Issuer under the SEC rules. As a result, beginning January 1, 2021 the Company is required to report with the SEC on domestic forms and comply with domestic company rules in the United States.

Certain prior year amounts and notes to the consolidated financial statements have been reclassified to conform with the current year presentation. Other current assets and deferred revenue which were previously included in prepaid expenses and other current liabilities respectively, has been separately presented on the consolidated balance sheets as of December 31, 2022. Inventory reserves which was previously included in other, net on the consolidated statements of cash flows, has been separately presented for the years ended December 31, 2022 and December 31, 2021. Additionally, amortization of intangible assets which was presented separately on the statements of operations, has been included in SG&A and is included with depreciation on the consolidated statements of cash flows. Accounts payable and accrued liabilities and cash, cash equivalents and restricted cash and short-term investments balances have been reclassified in the notes to the consolidated financial statements. These reclassifications have no impact on previous reported total assets, total liabilities, net loss, stockholders' equity or operating cash flows.

Principles of consolidation: These financial statements present the consolidated financial position of the Company and its wholly owned subsidiaries, Aurinia Pharma U.S., Inc. (Delaware incorporated) and Aurinia Pharma Limited (UK incorporated) as of December 31, 2022 and 2021, and the results of operations and cash flows for the three years ended December 31, 2022, 2021 and 2020. All intercompany accounts and transactions have been eliminated in consolidation.

Use of estimates: The preparation of the accompanying financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from those estimates.

Segment information: The Company operates in one operating segment engaged in the research, development and commercialization of therapeutic drugs in which revenues are derived from product, license, and contract revenues. Operating segments are defined as components of an enterprise where separate financial information is evaluated regularly by the chief operating decision maker (CODM), the chief executive officer, in deciding how to allocate resources and assessing performance. The Company's CODM allocates resources and assesses performance based upon discrete financial information at the consolidated level.

Functional currency: The functional currency for the Company and all of its foreign subsidiaries is determined to be the U.S. dollar, therefore there is no currency translation adjustment upon consolidation as the remeasurement of gains or losses are recorded in the consolidated statement of operations. All monetary assets and liabilities denominated in a foreign currency are remeasured into U.S. dollars at the exchange rate on the balance sheet date. Non-monetary assets and liabilities (along with their related expenses) are translated at the rate of exchange in effect on the date assets were acquired. Monetary income and expense items are translated at the average foreign currency period. Foreign exchange gains and losses arising on translation or settlement of a foreign currency denominated monetary item are included in the consolidated statements of operations.

COVID-19: U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the annual consolidated financial statements and accompanying notes. The annual consolidated financial statements reflect all adjustments of a normal, recurring nature that are, in the opinion of management, necessary for a fair presentation of results for these interim periods. The full extent to which the novel coronavirus (COVID-19) pandemic will directly or indirectly impact the Company's financial statements related to our estimates and assumptions or results of operations will depend on future developments that are uncertain at this time. As events continue to evolve and additional information becomes available, the Company's estimates may change materially in future periods.

Fair value measurements: The Company's financial instruments consist primarily of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued liabilities. The Company has determined the carrying values of these financial instruments approximate their fair value because of the relatively short period to maturity of the instruments.

Financial assets and liabilities are categorized based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

Concentration of credit risk: Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash, cash equivalents and restricted cash, short term investments and accounts receivable, net. The Company attempts to minimize the risks related to cash and cash equivalents and restricted cash and investments by investing in a range of financial instruments. The Company established guidelines related to credit ratings and maturities intended to safeguard principal balances, earn a return on investments and to maintain liquidity. The Company's investment portfolio is maintained in accordance with its investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. The Company does not enter into any investment transaction for trading or speculative purposes.

The Company's investment policy limits investments to certain types of instruments such as certificates of deposit, money market instruments, obligations issued by the U.S. government and U.S. government agencies as well as high quality corporate debt securities, and places restrictions on maturities and concentration by type and issuer. The Company maintains cash balances in excess of amounts insured by the Federal Deposit Insurance Corporation and Canada Deposit Insurance Corporation and concentrated within a limited number of financial institutions. The accounts are monitored by management to mitigate the risk.

The Company is exposed to financial risk related to the fluctuation of foreign currency exchange rates which could have a material effect on its future operating results or cash flows. Foreign currency risk is the risk that variations in exchange rates between the U.S. dollar and foreign currencies, primarily with the Canadian dollar, Swiss Franc and Great British Pound will affect the Company's operating and financial results. The Company holds the majority of its cash and cash equivalents in U.S. dollars and the majority of its expenses, including commercial and clinical trial costs are also denominated in U.S. dollars, which mitigates the risk of material foreign exchange fluctuations.

Major customers: The Company currently has two main customers for U.S. commercial sales of LUPKYNIS and a collaboration partner for sales of LUPKYNIS in the Otsuka Territories. Revenues from the Company's two main customers in the U.S. accounted for approximately 45% and 35%, respectively, of the Company's total revenues for the year ended December 31, 2022. The two main customers accounted for 100% of the Company's accounts receivable, net balance as of December 31, 2022. Otsuka, the Company's collaboration partner for sales outside the U.S. accounted for approximately 20% of the Company's total revenue for the year ended December 31, 2022.

In late March 2022, the Company provided a nominal additional discount to both of its two main U.S. customers, applicable for the 2022 calendar year, in connection with holding additional amounts of LUPKYNIS on hand due to supply chain concerns. In December 2022, the Company extended the nominal discount to the end of 2023. Such discounts, or any future discounts, may result in reduced sales to these customers in subsequent periods and substantial fluctuations in our revenues from period to period. The Company monitors economic conditions, the creditworthiness of customers and government regulations and funding, both domestically and abroad. The Company regularly communicates with its customers regarding the status of receivable balances. Global economic conditions and customer specific factors may require the Company to periodically re-evaluate the collectability of its receivables and based on this evaluation the Company could potentially incur credit losses. The Company has had no historical write-offs related to our customers or receivables.

Accounts receivable, net: Accounts receivables are stated at their net realizable value. The Company's accounts receivable represents amounts due to the Company from product sales and from its Otsuka collaboration agreement (Note 10). Sales and services that have not been invoiced as of the balance sheet date are recorded as unbilled accounts receivable. As of December 31, 2022 and December 31, 2021, accounts receivable, net are $13.5 million and $15.4 million, respectively. The timing between the recognition of revenue for product sales and the receipt of payment is not significant. The Company's standard credit terms range from 30 to 45 days. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between the transfer of the promised good to the customer and receipt of payment will be one year or less.

The Company's estimates the allowance for doubtful accounts using the current expected credit loss (CECL) model. Under the CECL model, the allowance for doubtful accounts reflects the net amount expected to be collected from the account receivables. The Company evaluates the collectability of these cash flows based on the asset's amortized cost, the risk of loss even when that risk is remote, losses over an asset's contractual life, and other relevant information available to us. Accounts receivable balances are written off against the allowance when it is probable that the receivable will not be collected. Given the nature of the Company's accounts receivable, it determined that an allowance for doubtful accounts was nil at December 31, 2022 and December 31, 2021.

Accounts receivables are recorded net of estimates of variable consideration for which reserves are established and which result from discounts that are offered within contracts between us and two specialty pharmacies and one specialty distributor in the United States. These reserves are recorded as a reduction of accounts receivable.

Cash and cash equivalents: The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents consist primarily of operating accounts, money market funds and bank money market accounts which are recorded at fair value. Cash and cash equivalents totaled $94.2 million as of December 31, 2022. The Company has invested its cash reserves in short term U.S. dollar denominated, fixed rate, highly liquid and highly rated financial instruments such as treasury notes, banker acceptances, bank bonds, and term deposits.

Restricted cash: Restricted cash consists of the 2021 Employee Share Purchase Plan (ESPP) deposits of $0.1 million and $0.3 million as of December 31, 2022 and December 31, 2021, respectively.

Investments: The Company classifies its debt securities as either held to maturity or available-for-sale in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 320, *Investments — Debt Securities*. Investments classified as held to maturity are carried at amortized cost when management has the positive intent and ability to hold them to maturity. Investments classified as available-for-sale are carried at fair value with unrealized losses reported in other comprehensive loss within shareholders' equity. Realized losses on available-for-sale securities are recorded in other income (expense), net. Interest income (expense) is recorded separately on the consolidated statements of operations. The cost of securities sold is based on the specific-identification method.

Intangible assets: Intangible assets are amortized over their useful lives using methods that correlate to the pattern in which the economic benefits are expected to be realized. All intangible assets are amortized on a straight-line basis. The Company evaluates the estimated remaining useful life of its intangible assets and whether events or changes in circumstances warrant a revision to the remaining period of amortization. The carrying amounts of these assets are periodically reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. Refer to the long-lived assets section below for impairment considerations.

Acquired intellectual property and patents

External patent costs specifically associated with preparing, filing, obtaining and protecting patents are capitalized and amortized straight-line over the shorter of the estimated useful life and the patent life, commencing in the year of the grant of the patent. Other intellectual property expenditures are recorded as R&D expenses on the consolidated statements of operations as incurred. Patents do not contain the option to extend or renew. External legal costs incurred to defend a patent are capitalized when it is believed that the future economic benefit of the patent will be increased and a successful defense is probable.

Separately acquired intellectual property is shown at historical cost. The initial recognition of a reacquired right is recognized as an intangible asset measured on the basis of the remaining contractual term of the related contract. If the terms of the contract giving rise to a reacquired right are favorable relative to the terms of current market transactions for the same or similar items, the difference is recognized as a gain or loss in the consolidated statements of operations and comprehensive loss. Purchased intellectual property and reacquired rights are capitalized and amortized on a straight-line basis in the consolidated statements of operations and comprehensive loss over periods ranging from 10 to 20 years.

Property, plant and equipment: Property, plant and equipment are recorded at cost and are depreciated using the straight-line method. Expenditures for additions are capitalized and leasehold improvements are amortized over the lesser of the expected lease term or the estimated useful life of the improvement. Expenditures for maintenance and repairs are charged to expense as incurred; however, maintenance and repairs that improve or extend the life of existing assets are capitalized. The carrying amount of assets disposed of and the related accumulated depreciation are eliminated from the accounts in the year of disposal. Gains or losses from property and equipment disposals are recognized in the year of disposal.

Recoverability and impairment of long-lived assets: ASC Topic 360 requires long-lived assets, including definite-lived intangible assets, to be evaluated for impairment when events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The judgments made related to the expected useful lives of long-lived assets, definitions of lease terms and the Company's ability to realize undiscounted cash flows in excess of the carrying amounts of these assets are affected by factors such as the ongoing maintenance and improvements of the assets, changes in economic conditions, changes in usage or operating performance and other factors. If indicators are present, assets are grouped to the lowest level for which identifiable cash flows are largely independent of other asset groups and cash flows are estimated for each asset group over the remaining estimated life of each asset group. If the undiscounted cash flows estimated to be generated by the asset group are less than the asset's carrying amount, impairment is recognized in the amount of excess of the carrying value over the fair value. The Company recorded no asset impairment charges during the years ended December 31, 2022, 2021 and 2020.

Leases: The Company assesses all contracts at inception to determine whether a lease exists. The Company's leases are all classified either as operating or finance leases per ASC 842. The Company leases office space under operating leases that typically provide for the payment of minimum annual rentals and may include scheduled rent increases. The Company also entered into a manufacturing agreement that contained an embedded lease of a dedicated manufacturing facility that will be accounted for as a finance lease once lease commencement begins (see Note 15).

The Company made an accounting policy election, the practical expedient that allows lessees to treat the lease and non-lease components of leases as a single lease component. Leases with an initial term of 12 months or less are not recorded on the Company's consolidated balance sheets and to recognize those lease payments on a straight-line basis in its consolidated statements of operations. Fixed costs associated with these arrangements are disclosed in Note 15 of the financial statements.

Operating lease ROU assets and lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company used the incremental borrowing rate for all of its leases, as the implicit interest rate was not readily determinable. In determining the Company's incremental borrowing rate of each lease, the Company considered recent rates on secured borrowings, observable risk-free interest rates and credit spreads correlating to the Company's creditworthiness, the impact of collateralization and the term of each of the Company's lease agreements. The lease terms range from 12 to 128 months.

Deferred Compensation Arrangements: The Company has recorded deferred compensation arrangements in liabilities for estimated future employee benefits relating to applicable historical employment arrangements. The deferred compensation arrangements are part of the resolution of the board of directors of the company dated March 8, 2012. Pursuant to ASC Topic 710, the Company recognizes future benefits provided by employee retention arrangements, as deferred compensation, which is recognized when the Company determines that it is probable to make future payments. The deferred compensation is based on an income approach for the estimated future net revenues of voclosporin using an internal risk-adjusted net present value of the future payments to be made to the individuals.

The Company is required to use judgment to determine the most appropriate model to use to measure the deferred compensation liability and is required to use significant judgment and estimates in determining the inputs into the model. The royalty rates applied to the net revenue are dependent on the type of net revenue earned, which includes product sales and royalty revenue. There are multiple unobservable and inherently uncertain inputs. The determination of this deferred compensation is subject to significant judgments and estimates in determining the assumptions related to future net revenues and the determination of the discount rate for the net present value calculation. The net revenue estimate for the United States includes assumptions related to the number of patients being treated (including patients who initially start taking the product but subsequently discontinue), dosing adjustments, duration of treatment, timing of generics and competitors entering the market, market penetration and potential future use in new indications. Additional variables for ex-U.S. geographies include timing of approval in ex-U.S. territories, escalating royalty rates, net pricing, government payor coverage of the product, and market penetration. In determining the estimate for ex-U.S. revenues, the Company relies on forecasts provided by its collaboration partner.

Management developed the model and inputs in conjunction with their internal scientific team and utilized third party scientific studies, information provided by third party consultants engaged by the Company, information from medical and pharmacy claims databases and research papers as sources to develop their inputs; application and usage of these inputs is also informed by product sales and distribution data, ongoing market research fielded by the company and third parties, and our continually evolving understanding of the market as the U.S. launch progresses. Management believes the liability is based on reasonable assumptions; however, these assumptions may be incomplete or inaccurate and unanticipated events and circumstances may occur. There are numerous significant inputs into the model all of which individually or in combination may result in a material change to the obligation.

Initially, these obligations are measured at the present value of expected future payments to be made in respect of services provided by employees up to the end of the reporting periods. Subsequent re-measurements as a result of performance obligations met by the Company or changes in assumptions are recognized in the consolidated statement of operations.

Contingencies: In the normal course of business, the Company may be subject to loss contingencies, such as legal proceedings, amounts arising from contractual arrangements and claims arising out of the Company's business that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability, and tax matters. In accordance with ASC Topic 450, *Accounting for Contingencies*, (ASC 450), the Company records accruals for such loss contingencies when it is probable that a liability will be incurred, and the amount of loss can be reasonably estimated. The Company, in accordance with this guidance, does not recognize gain contingencies until realized or realizable.

Common Shares: The Company's shares have no par value and therefore, upon issuance of shares, all amounts related to the shares are credited to common shares on the balance sheet. The value of common shares includes cash amounts received or paid for the shares and the fair value of equity awards and warrants. Amounts for common shares are offset by share issue costs associated with equity offerings.

Inventories: Inventories are valued under a standard costing methodology on a first-in, first-out basis and are stated at the lower of cost or net realizable value. The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, status of regulatory approval, information regarding safety, efficacy and expectations relating to commercial sales and recoverability of costs. Capitalized costs of inventories mainly include third party manufacturing costs, transportation, storage, insurance and allocated internal labor. The Company assesses recoverability of inventory each reporting period to determine any write down to net realizable value resulting from excess or obsolete inventories.

Revenue Recognition: Pursuant to Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), the Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. Revenue is recognized through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. Revenue is recognized for the applicable performance element when each distinct performance obligation is satisfied.

Product Revenues

In the United States (and territories), the Company sells LUPKYNIS primarily to a limited number of specialty pharmacies and specialty distributors. These customers subsequently resell the Company's products to health care providers and patients. Revenues from product sales are recognized when the customer obtains control of the Company's product, which typically occurs upon delivery to the customer.

Reserves for discounts and allowances: Product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer).

The Company's estimates of reserves established for variable consideration are calculated based upon utilizing the expected value method. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Amounts related to such items are estimated at contract inception and updated at the end of each reporting period as addition information becomes available.

Significant judgment is required in estimating variable consideration. In making these estimates, the Company considers historical data, including patient mix and inventory sold to our customers that has not yet been dispensed. The Company uses a data aggregator and historical claims to estimate variable consideration for inventory sold to our customers, including specialty pharmacies and specialty distributors, that has not yet been dispensed. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment. As of December 31, 2022, the Company did not have any material adjustments to variable consideration estimates based on actual results.

More specifically, these adjustments include the following:

Prompt Pay Discounts: The Company generally provides invoice discounts on product sales to its customers for prompt payment. The Company estimates that its customers will earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

Customer Fees: The Company pays certain customer fees, such as fees for certain data that customers provide to the Company. The Company records fees paid to its customers as a reduction of revenue, unless the payment is for a distinct good or service from the customer and the Company can reasonably estimate the fair value of the goods or services received. If both conditions are met, the Company records the consideration paid to the customer as SG&A expense.

Government Rebates: The Company estimates its government rebates, primarily Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses on the consolidated balance sheet.

Medicaid rebates relate to the Company's estimated obligations to states under established reimbursement arrangements. Rebate accruals are recorded in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability, which is included in other current liabilities. The Company's liability for Medicaid rebates consists of estimates for claims that a state will make for the current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, invoices received for claims from the prior quarters that have not been paid and an estimate of potential claims that will be made for inventory that exists in the distribution channel at period end.

For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company’s liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Co-payment Assistance: Co-payment assistance represents financial assistance to qualified patients, assisting them with prescription drug co-payments required by insurance. The program is administered by the specialty pharmacies. The calculation of the accrual for co-payment assistance is based on the co-payments administered on the Company's behalf by the specialty pharmacies.

Payor Rebates and Administration Fees: Payor rebates and administration fees represent our estimated obligations to third parties, primarily benefit managers. Accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability. These rebates and fees result from formulary position and price increase limit allowances (price protection) and administration fees. The calculation of the accrual for these items are based on the estimated payors buying patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period.

Manufacturing Supply Services: The Company also has agreements with its partners that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee’s discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the licensee exercises these options, any additional payments are recorded as product sales when the licensee obtains control of the goods, which is typically upon delivery. Certain agreements include terms where the Company can partially bill for drug substance used before the manufacturing cycle is complete, resulting in a deferred revenue which is to be recognized once delivery occurs.

License and Collaboration Revenue

The Company enters into out-licensing agreements that are within the scope of ASC 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments, payments for manufacturing supply services the Company provides through its contract manufacturers, and royalties on net sales of licensed products. Each of these payments results in license, collaboration and other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Licenses of Intellectual Property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development or commercial sales milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

Other Services Revenue: The Company's agreements may include R&D, manufacturing or other services to be performed by the Company on behalf of the counterparty. If these services are determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to these services as revenue either over time based on an appropriate measure of progress when the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date or at a point in time as the related performance obligations are satisfied.

Royalty Revenue

For arrangements that include sales-based royalties, revenue is recognized when the underlying product sales have occurred. Revenue is recorded based on estimated quarterly net sales reports provided by our partner. Differences between actual results and estimated amounts are adjusted in the period in which they become known, which typically follows the quarterly period in which the estimate is made. Sales based milestone payments are recognized in the period once the milestone objectives have been achieved.

Costs to obtain a contract

As the majority of our contracts are short-term in nature, sales commissions are generally expensed when incurred as the amortization period would have been less than one year. The costs are recorded within SG&A.

Cost of sales: Cost of sales consist primarily of cost of inventories for LUPKYNIS and semi-finished product, which mainly includes third party manufacturing costs, transportation, storage, insurance and allocated internal labor. Cost of sales also includes costs related to collaboration revenues.

Research and development costs: R&D costs are accounted for in accordance with ASC Topic 730, *Research and Development*, (ASC 730) and are expensed as incurred. R&D costs consist primarily of the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, subcontractors and materials used for R&D activities, including nonclinical studies, clinical trials, manufacturing costs and professional services. The costs of services performed by others in connection with the R&D activities of the Company, including R&D conducted by others on behalf of the Company, shall be included in R&D costs and expensed as the contracted work is performed.

We accrue the costs incurred under our agreements with these third parties based on actual work completed in accordance with agreements established with these third parties. We determine the accruals for R&D costs through monitoring invoices received and discussions with internal personnel and external service providers as to the progress or stage of completion of the clinical studies and the agreed-upon fee to be paid for such services. Where contingent milestone payments are due to third parties under R&D arrangements or license agreements, the milestone payment obligations are expensed when the milestone results are probable to be achieved.

R&D expenses for the years ended December 31, 2022, 2021 and 2020, were $45.0 million, $51.1 million and $50.3 million, respectively, and are included in total cost of sales and operating expenses on the accompanying consolidated statements of operations.

Selling, general and administrative expenses: The Company's SG&A expenses include commercial and allocated administrative personnel, corporate facility and external costs required to support the marketing and sales of LUPKYNIS. These
SG&A costs include corporate facility operating expenses and allocated depreciation; commercial, marketing, advertising, pharmacovigilance, publications, tradeshows, advisory boards, samples and operations in support of LUPKYNIS; patient assistance program costs; human resources; finance, legal, information technology and support personnel expenses; and other corporate costs such as telecommunications, insurance, audit and government affairs. We expense SG&A expenses as they are incurred.

The Company uses a third-party logistics provider to perform a full order to cash service, which includes warehousing and shipping directly to two specialty pharmacies and receiving orders from a specialty distributor for shipping to hospitals, on our behalf. As such, since these costs are not integral to bringing the inventories to a salable condition, we elected not to treat shipping and handling costs as a fulfillment activity. Shipping and handling costs related to order fulfillment are recorded in SG&A expenses.

Advertising and marketing costs are expensed as incurred and included in SG&A. For the years ended December 31, 2022, 2021 and 2020, advertising and marketing costs totaled $16.3 million, $15.4 million and $10.0 million, respectively.

SG&A expenses for the years ended December 31, 2022, 2021 and 2020 were $196.4 million, $173.5 million and $97.3 million, respectively, and are included in total cost of sales and operating expenses on the accompanying consolidated statements of operations.

Shared-based compensation: The Company follows ASC Topic 718, *Compensation - Stock Compensation* (ASC 718), which requires the measurement and recognition of compensation expense, based on estimated fair values, for all share-based awards made to employees and directors. The Company records compensation expense based on the fair value on the grant date using the graded accelerated vesting method for all share-based payments related to stock options, performance awards (PAs), restricted stock units (RSUs) and purchases under the Company's 2021 ESPP. The estimated fair value of performance-based awards is measured on the grant date and is recognized when it is determined that it is probable that the performance condition will be achieved. The Company has elected a policy for all share-based awards to estimate forfeitures based on historical forfeiture experience at the time of grant and revise in subsequent periods if actual forfeitures differ from those estimates.

Income taxes: The Company accounts for income taxes under the asset and liability method in accordance with ASC Topic 740, *Income Taxes* (ASC 740). Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that such tax rate changes are enacted. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance. Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount that is more likely than not to be realized upon ultimate settlement. The Company's policy is to record interest and penalties on uncertain tax positions as a component of income tax expense.

Recently adopted accounting pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. The adoption of the standard as of January 1, 2020 did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirement for Fair Value Measurement*. Topic 820 requires to disclose transfers into and out of Level 3 of the fair value hierarchy and purchases and issues of Level 3 assets and liabilities. For investments in certain entities that calculate net asset value, an entity is required to disclose the timing of liquidation of an investee's assets and the date when the restrictions from redemptions might lapse only if the investee has communicated the timing to the entity or announced the timing publicly. The new standard also amends that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date. The new standard is effective for fiscal years beginning after December 15, 2019. The standard should be applied retrospectively to the date of initial application of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The Company elected to adopt the amendment as of January 1, 2020, which did not have a material impact on the consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40)-Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the accounting for implementation costs incurred in a hosting arrangement that is a service contract with the accounting for implementation costs incurred to develop or obtain internal-use software under ASC 350-40, in order to determine which costs to capitalize and recognize as an asset and which costs to expense. ASU 2018-15 is effective for annual reporting periods, and interim periods within those years, beginning after December 15, 2019, and can be applied either prospectively to implementation costs incurred after the date of adoption or retrospectively to all arrangements. The Company adopted ASU 2018-15 effective January 1, 2020 and applied the standard prospectively to implementation costs incurred in its cloud computing arrangements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangement (Topic 808): Clarifying the Integration between Topic 808 and Topic 606.* The new standard clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. Further, the new standard adds unit-of-account guidance to Topic 808 to align with the guidance in Topic 606 when an entity is assessing whether the collaborative arrangement or part of the arrangement is within the scope of Topic 606. The new standard requires that in transactions with a collaborative arrangement participant that is not directly related to sales to third parties, presenting under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The new standard is effective for fiscal years beginning after December 15, 2019. The standard should be applied retrospectively to the date of initial application of ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The Company elected to adopt the amendment as of January 1, 2020, which did not have a material impact on the consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740)*: Simplifying the Accounting for Income Taxes, which clarifies and simplifies certain aspects of the accounting for income taxes. The standard is effective for years beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2020. The Company adopted the ASU effective January 1, 2021 with no material impact on the consolidated financial statements.

In November 2021, the FASB issued ASU No. 2021-10, *Government Assistance (Topic 832)*: Disclosures by Business Entities about Government Assistance, which requires business entities to make annual disclosures about transactions with a government (including government assistance) by analogizing to a grant or contribution accounting model. The required disclosures include the nature of the transaction, the entity's related accounting policy, the financial statement line items affected and the amounts reflected in the current period financial statements, as well as any significant terms and conditions. The guidance is effective for financial statements issued for annual periods beginning after December 15, 2021. The Company adopted the ASU effective January 1, 2022, with no material impact on the consolidated financial statements.

3. Fair Value Measurement

The Company's financial instruments consist primarily of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued liabilities. The carrying value of accounts receivable, accounts payable and accrued liabilities approximate their fair values because of their short-term nature. Estimated fair values of available-for-sale debt securities are generally based on prices obtained from commercial pricing services.

In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from sources independent from the Company) and to minimize the use of unobservable inputs (the Company’s assumptions about how market participants would price assets and liabilities). As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 - Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 - Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3 - Unobservable inputs that reflect the reporting entity’s own assumptions.

The following table summarizes the financial assets (cash, cash equivalents, restricted cash and short-term investments) measured at fair value on a recurring basis:

	December 31, 2022			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Financial assets:				
Cash, cash equivalents and restricted cash	**$ 94,172**	**$ —**	**$ —**	**$ 94,172**
U.S. agency security	**—**	**4,948**	**—**	**4,948**
Corporate bond	**—**	**104,080**	**—**	**104,080**
Commercial paper	**—**	**125,187**	**—**	**125,187**
Treasury bill	**—**	**12,282**	**—**	**12,282**
Treasury bond	**—**	**42,220**	**—**	**42,220**
Yankee bond	**—**	**6,501**	**—**	**6,501**
Total financial assets	**$ 94,172**	**$ 295,218**	**$ —**	**$ 389,390**

	December 31, 2021			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Financial assets:				
Cash, cash equivalents and restricted cash	$ 231,900	$ —	$ —	$ 231,900
Certificates of deposit	—	3,140	—	3,140
Corporate bond	—	21,820	—	21,820
Commercial paper	—	206,724	—	206,724
Treasury bill	—	2,494	—	2,494
Total financial assets	$ 231,900	$ 234,178	$ —	$ 466,078

The Company's Level 1 instruments include cash, cash equivalents and restricted cash that are valued using quoted market prices. We estimate the fair values of our investments in corporate debt securities, government and government related securities and certificates of deposits by taking into consideration valuations obtained from third-party pricing services. The fair value of our short-term investments classified within Level 2 is based upon observable inputs that may include benchmark yield curves, reported trades, issuer spreads, benchmark securities and reference data including market research publications. At December 31, 2022 and December 31, 2021, we reclassified $125.2 million and $206.7 million of commercial paper from Level 1 to Level 2, respectively. Additionally, at December 31, 2022 and December 31, 2021, the weighted average remaining contractual maturities of our Level 2 investments were approximately for 7 months and 8 months, respectively. It is the Company's intent for these investments to have an overall rating of A-1, or higher, by Moody's, Standard & Poor's and Fitch.

No credit loss allowance was recorded as of December 31, 2022 and December 31, 2021, as we do not believe the unrealized loss is a result of a credit loss due to the nature of our investments. We also considered the current and expected future economic and market conditions and determined that the estimate of credit losses was not significantly impacted.

Refer to Note 4, "Cash, Cash Equivalents and Restricted Cash and Short-Term Investments," for the carrying amount and related unrealized gains (losses) by type of investment.

4. Cash, Cash Equivalents and Restricted Cash and Short-Term Investments

As of December 31, 2022 and December 31, 2021, the Company had $389.4 million and $466.1 million, respectively of cash, cash equivalents, restricted cash and short-term investments, summarized below. As of December 31, 2022, $295.5 million were available-for-sale debt securities which are carried at fair market value and nil were held to maturity. As of December 31, 2021, $215.0 million were classified as available-for-sale and $19.2 million were held to maturity which was carried at amortized cost and was approximately equal to fair market value.

	December 31, 2022			
(in thousands)	**Amortized Cost**	**Unrealized Gains**	**Unrealized Losses**	**Estimated Fair Value**
Cash, cash equivalents and restricted cash	**$ 94,172**	**$ —**	**$ —**	**$ 94,172**
U.S. agency security	**4,951**	**—**	**(3)**	**4,948**
Corporate bond	**104,174**	**—**	**(94)**	**104,080**
Commercial paper	**125,255**	**—**	**(68)**	**125,187**
Treasury bill	**12,290**	**—**	**(8)**	**12,282**
Treasury bond	**42,301**	**—**	**(81)**	**42,220**
Yankee bond	**6,503**	**—**	**(2)**	**6,501**
Total cash, cash equivalents, restricted cash and short-term investments	**$ 389,646**	**$ —**	**$ (256)**	**$ 389,390**

	December 31, 2021			
(in thousands)	**Amortized Cost**	**Unrealized Gains**	**Unrealized Losses**	**Estimated Fair Value**
Cash, cash equivalents and restricted cash	$ 231,900	$ —	$ —	$ 231,900
Certificates of deposit	3,144	—	(4)	3,140
Corporate bond	2,593	—	(1)	2,592
Commercial paper	206,764	—	(40)	206,724
Treasury bill	2,496	—	(2)	2,494
Total	$ 446,897	$ —	$ (47)	$ 446,850
Held-to-maturity securities corporate bond	19,228			19,228
Total cash, cash equivalents, restricted cash and short-term investments				$ 466,078

As of December 31, 2022 and December 31, 2021, accrued interest receivable from the investments were $1.1 million and $0.1 million, respectively and recorded as prepaid expenses and other current assets on the consolidated balance sheets. As of December 31, 2022 and December 31, 2021, the Company had $0.3 million and $47 thousand of unrealized losses on available-for-sale securities, net of tax, respectively, which are included as a component of comprehensive loss on the consolidated statement of operations. Currently the Company does not intend to sell the investments before recovery of their amortized cost basis, which may be maturity. We have determined that the gross unrealized losses on our investments at December 31, 2022 were temporary in nature. Realized gains or losses were immaterial for the years ended December 31, 2022 and December 31, 2021.

The Company's investments as of December 31, 2022 mature at various dates through September 2023.

5. Inventories, net

Inventories are valued under a standard costing methodology on a first-in, first-out basis and are stated at the lower of cost or net realizable value. The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, status of regulatory approval, information regarding safety, efficacy and expectations relating to commercial sales and recoverability of costs. Capitalized costs of inventories mainly include third party manufacturing costs, transportation, storage, insurance, and allocated internal labor.

The Company assesses recoverability of inventory each reporting period to determine any write down to net realizable value resulting from excess or obsolete inventories. As of December 31, 2022, we have recorded reserves of finished good inventories of approximately $3.9 million which were primarily related to process validation batches used for FDA approval. Additionally, as of December 31, 2022 and December 31, 2021 we have inventory deposits of $5.5 million and $3.9 million that are primarily related to the purchase of drug substance that are currently recorded under prepaid expenses and other current assets.

The components of inventories, net are as follows:

(in thousands)	**December 31, 2022**	**December 31, 2021**
Raw materials	**$ 2,217**	$ 2,217
Work in process	**21,059**	12,566
Finished goods	**1,476**	4,543
Total inventories, net	**$ 24,752**	$ 19,326

6. Prepaid Expenses

Prepaid expenses are as follows:

(in thousands)	December 31, 2022	December 31, 2021
Prepaid assets	$ **5,451**	$ 5,316
Prepaid deposits	**6,330**	4,762
Prepaid insurance	**1,799**	1,632
Total prepaid expenses	$ **13,580**	$ 11,710

7. Property and Equipment, net

Property and equipment, net are as follows:

(in thousands)	Estimated Useful Life (in years)	December 31, 2022	December 31, 2021
Construction in progress	—	$ **255**	$ 393
Leasehold improvements	Shorter of term of the lease or estimated useful life	**2,978**	2,978
Office equipment	5	**645**	645
Furniture	7	**976**	976
Computer equipment	3	**251**	262
		5,105	5,254
Less accumulated depreciation		**(1,455)**	(836)
Property and equipment, net		$ **3,650**	$ 4,418

Depreciation expense for the years ended December 31, 2022, 2021 and 2020 was $629 thousand, $663 thousand and $82 thousand, respectively, which is included in SG&A expenses on the consolidated statements of operations.

8. Intangible Assets

The following table summarizes the carrying amount of intangible assets, net of accumulated amortization.

	December 31, 2022			
(in thousands)	**Weighted Average Life (in years)**	**Gross Carrying Value**	**Accumulated Amortization**	**Net Carrying Amount**
Patents	**12**	**$ 1,569**	**$ (1,262)**	**$ 307**
Acquired intellectual property and reacquired rights	**12**	**15,126**	**(9,838)**	**5,288**
Internal-use software implementation costs	**3**	**2,873**	**(2,043)**	**830**
		$ 19,568	**$ (13,143)**	**$ 6,425**

	December 31, 2021			
(in thousands)	**Weighted Average Life (in years)**	**Gross Carrying Value**	**Accumulated Amortization**	**Net Carrying Amount**
Patents	12	$ 1,471	$ (1,176)	$ 295
Acquired intellectual property and reacquired rights	12	15,126	(8,804)	6,322
Internal-use software implementation costs	3	2,873	(1,086)	1,787
		$ 19,470	$ (11,066)	$ 8,404

Amortization expense recognized by the Company related to intangible assets was $2.1 million, $2.1 million and $1.3 million for the years ended December 31, 2022, 2021 and 2020, respectively. Amortization expense as it relates to the amortization of acquired intellectual property and other intangible assets resides within amortization on the consolidated statements of operations. The estimated aggregate amortization expense for intangible assets over the next five fiscal years ending December 31, 2023 through December 31, 2027 is approximately $5.6 million.

9. Accounts payable and accrued liabilities

Accounts payable and accrued liabilities are as follows:

	December 31, 2022	December 31, 2021
Employee accruals	**$ 20,157**	$ 18,500
Commercial accruals	**8,620**	5,055
Accrued R&D projects	**5,350**	4,383
Trade payables	**3,087**	3,879
Other accrued liabilities	**2,151**	2,316
Income taxes payable	**625**	814
Total accounts payable and accrued liabilities	**$ 39,990**	$ 34,947

10. License and Collaboration Agreements

Otsuka Contract

On December 17, 2020, the Company entered into a collaboration and license agreement with Otsuka for the development and commercialization of LUPKYNIS in the Otsuka Territories.

As part of the agreement, the Company received an upfront cash payment of $50.0 million in 2020 for the license agreement and has the potential to receive up to $50.0 million in regulatory and pricing approval related milestones. The Company will provide semi-finished product of LUPKYNIS to Otsuka on a cost-plus basis, and will receive tiered royalties on future sales ranging from 10 to 20 percent (dependent on territory and achievement of sale thresholds) on net product sales by Otsuka, along with additional milestone payments based on the attainment of certain annual sales. In addition, certain collaboration services are to be provided to Otsuka on agreed upon rates.

In furtherance of the collaboration and license agreement with Otsuka mentioned above, on August 1, 2022, the Company entered into a commercial supply agreement with Otsuka, formalizing the terms to supply semi-finished goods of LUPKYNIS to Otsuka in the Otsuka Territories, including capacity sharing of the monoplant.

On September 15, 2022, the European Commission (EC) granted marketing authorization of LUPKYNIS. The centralized marketing authorization is valid in all EU member states as well as in Iceland, Liechtenstein, Norway and Northern Ireland. The
approval triggered a $30.0 million milestone payment to the Company, which was recognized as collaboration revenue for the year ended December 31, 2022.

For the year ended December 31, 2022 and December 31, 2021, the Company recognized $0.5 million and nil, respectively, of additional collaboration revenue from services provided under the agreement.

Riptide License

On August 17, 2021, AUR300 (M2 macrophage modulation via CD206 binding) was secured through a global licensing and research agreement with Riptide Bioscience, Inc. (Riptide), a private company. As part of the agreement, in 2021 the Company paid Riptide an upfront license fee of $6.0 million which was expensed as research and development on the condensed consolidated statements of operations. During the first quarter of 2022, Aurinia paid an additional $4.0 million to Riptide for the achievement of a onetime milestone. Additional payments are due upon certain development, clinical and regulatory milestones, and royalties will be payable upon commercialization.

11. Segment Information and Geographic Data

As the operations comprise a single reporting segment, amounts disclosed in the consolidated financial statements represent those of the single reporting unit. We have elected to disclose geographical revenue from customers based on geographical location of contracting entity (and where the related payment stream of the customer is located). Revenues from our two main customers in the U.S. accounted in total of approximately 45% and 35% of the Company's total revenues for the year ending December 31, 2022. Our collaboration partner for sales outside the U.S. accounted for approximately 20% for the year ending December 31, 2022 of the Company's total revenues.

Revenues from two customers accounted for approximately 56% and 43% for the year ending December 31, 2021. There was one customer that accounted for the vast majority of the revenues for the year ended December 31, 2020.

Revenues by Geographic Location

The following geographic information reflects revenue, net of adjustments, based on customer location:

(in thousands)	**2022**	**2021**	**2020**
Revenue			
United States	**$ 102,460**	$ 45,488	$ —
Japan	**31,481**	—	50,000
Other	**89**	117	118
Total	**$ 134,030**	$ 45,605	$ 50,118

Long-lived Assets by Location

Long-lived assets by location consist of net property and equipment and right-of-use assets:

(in thousands)	December 31, 2022	December 31, 2021
Long-lived assets, net		
Canada	**$ 322**	$ 625
United States	**8,235**	9,176
Total	**$ 8,557**	$ 9,801

12. Income Taxes

Income (losses) before income taxes for the years ended December 31, 2022, 2021 and 2020 was as follows:

(in thousands)	2022	2021	2020
Canada	**$ (112,359)**	$ (180,374)	$ (61,024)
Foreign	**6,007**	168	(41,750)
	$ (106,352)	$ (180,206)	$ (102,774)

The components of income tax expense (benefit) consisted of the following for the years ended December 31, 2022, 2021 and 2020:

(in thousands)	2022	2021	2020
Current:			
Canada	**$ —**	$ —	$ —
Foreign	**1,828**	760	(94)
	1,828	760	(94)
Deferred:			
Canada	**—**	—	—
Foreign	**—**	—	—
Total deferred	**—**	—	—
Income tax expense (benefit)	**$ 1,828**	$ 760	$ (94)

The Company's parent entity is located in Canada and therefore the Canadian statutory rate is utilized. The provision for income taxes varied from the income taxes provided based on the Canadian statutory rate of 26.7%, 26.8%, and 26.8% for the years ending December 31, 2022, 2021 and 2020, respectively. The Company's increase in tax expense is primarily driven by withholding tax payments of $1.2 million paid during 2022.

	2022	2021	2020
Canada statutory income tax benefit	**26.7 %**	26.8 %	26.8 %
Effect of tax rates on foreign jurisdictions	**0.3**	—	(2.4)
Withholding taxes	**(1.1)**	—	—
Impact of future rates and tax rate changes	**(0.1)**	(0.1)	6.1
Foreign tax credit	**1.1**	—	—
Non-deductible share-based compensation	**(8.1)**	(4.5)	(4.5)
Change in valuation allowance	**(21.5)**	(21.8)	(26.0)
Scientific Research and Experimental Development (SRED)	**1.1**	0.3	0.4
Other	**(0.1)**	(1.1)	(0.3)
Effective tax rate	**(1.7)%**	(0.4)%	0.1 %

The net deferred tax assets (liabilities) consisted of the following for the years ending December 31, 2022 and 2021:

(in thousands)	2022	2021
Deferred tax assets:		
Net operating loss carry-forwards	**$ 141,020**	$ 120,274
Share issue costs	**4,209**	6,016
Intangible assets	**1,400**	1,086
SRED (Scientific Research and Experimental Development)	**7,462**	6,059
Capitalized research and development	**1,663**	—
Deferred compensation	**3,391**	3,980
Accruals	**2,887**	2,653
Other	**4,287**	3,473
Gross deferred tax assets	**166,319**	143,541
Valuation allowance	**(164,514)**	(141,348)
Total deferred tax assets	**1,805**	2,193
Deferred tax liabilities:		
Other	**(1,128)**	(1,356)
Property and equipment and intangible assets	**(677)**	(837)
Total deferred tax liabilities	**(1,805)**	(2,193)
Net deferred tax assets (liabilities)	**$ —**	$ —

The Company’s valuation allowance increased by $23.2 million in 2022 as compared to 2021 as a result of the additional pre-tax book losses.

As of December 31, 2022, the Company has $518.1 million of Canada gross net operating loss (NOL) carryforwards with an expiration period of 2029 through 2042. As of December 31, 2022, the Company has approximately $5.8 million of Canada Investment Tax Credits and British Columbia Scientific Research and Experimental Development (SRED) with an expiration period of 2029 through 2042. As of December 31, 2022 the Company has approximately $10.1 million of U.S. federal gross NOL carryforwards that carryforward indefinitely, although limited to eighty percent of taxable income annually.

Additionally, the Company has approximately $0.1 million of various state net operating loss carryforwards with varying expiration periods including carryforwards with indefinite carryforward periods and has approximately $0.4 million of U.K. gross net operating loss carryovers that carryforward indefinitely.

Uncertain Tax Positions

The Company was under examination by the Canadian Revenue Agency for years 2017 and 2018. In March 2022, the Company was notified by the Canadian Revenue Agency that the examination is now complete and there were no findings and as a result, there is no additional tax expense or benefit recognized in regards to the audit. There are no outstanding tax audits ongoing at December 31, 2022. The Company is subject to examination in the U.S., U.K. and Canada. In the U.S. and U.K., tax periods remain open in 2015 through 2022 and 2020 through 2022, respectively. Canada's tax periods remain open from 2009 due to the tax attribute carryforwards.

13. Commitments and Contingencies

The Company may, from time to time, be subject to claims and legal proceedings brought against it in the normal course of business. Such matters are subject to many uncertainties. Management believes the ultimate resolution of such contingencies will not have a material adverse effect on the consolidated financial statements.

On December 18, 2020, the Company commenced an action in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries, Ltd., and Sun Pharma Global FZE (collectively, "Sun"). The action was a claim for patent infringement under the patent laws of the United States arising from Sun's commercial manufacture, use, offer to sell, or sales within the United States, and/or importation into the United States of Sun's CEQUA product. In January 2023, we announced a settlement of this action with Sun.

On February 24, 2022, Sun Pharmaceuticals Inc. petitioned for an IPR by the USPTO in respect of the '036 patent. The IPR was instituted on July 26, 2022. On January 25, 2023, the USPTO announced that the inter partes review had been terminated, based on a Joint Motion for Termination filed by us and Sun Pharmaceuticals Inc.

On April 15, 2022, a purported shareholder class action complaint, Ortmann v. Aurinia Pharmaceuticals, Inc. et al., case no. 1:22-cv-02185, was filed in the United States District Court for the Eastern District of New York (Eastern District of New York), naming us and certain of our officers as defendants. The lawsuit alleges that we made materially false and misleading statements regarding our financial guidance and commercial prospects in violation of certain federal securities laws. The plaintiff seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including reasonable attorneys' fees. On June 2, 2022, the case was transferred from the Eastern District of New York to the United States District Court for the District of Maryland. On February 20, 2023, the Court appointed a lead plaintiff and approved lead plaintiff's selection of lead counsel. We expect that lead plaintiff will file an amended complaint, against which we intend to vigorously defend.

Manufacturing Commitments

The Company has various manufacturing agreements to support our commercial and clinical product supply requirements.

We rely on Lonza, a third party manufacturer, to produce a portion of commercial and clinical quantities of our commercial and clinical drug substance requirements. We have firm orders with Lonza for future purchases of drug substance, with remaining total non-cancellable future commitments of approximately $29.3 million through 2024 of which $5.5 million was paid during 2022. If we terminate certain firm orders with Lonza without cause, we will be required to pay for drug substance scheduled for manufacture under our arrangement.

14. Deferred Compensation and Other Non-current Liabilities

The Company recorded other non-current liabilities of $12.2 million and $16.0 million as of December 31, 2022 and December 31, 2021, respectively. The balance as of December 31, 2022 and December 31, 2021 primarily included deferred compensation arrangements whereby certain executive officers as of March 8, 2012 were provided with future potential employee benefit obligations for remaining with the Company, for a certain period of time. These obligations were also contingent on the occurrence of uncertain future events. At December 31, 2021, the other non-current liabilities also include milestone payments deemed probable to be paid in the future which were reclassed to current liabilities in 2022.

15. Leases

The Company has the following lease obligations:

Victoria, British Columbia

During August 2020, the Company signed a lease for commercial office space in Victoria, British Columbia for a new corporate headquarters that was expected to commence in April 2022.

During the fourth quarter of 2020, the Company entered into 18-month facility and furniture leases for its existing corporate head office located in Victoria, British Columbia. The lease terms commenced on January 1, 2021 with an end date of August 31, 2022.

On August 3, 2022, we provided notice of termination for the lease of the intended new corporate headquarters space in Victoria on the basis that the landlord's work was not completed by the time required under the lease. As a result of the termination, the Company expensed $0.3 million of Construction in Progress (CIP) cost that was related to the new corporate headquarters.

On September 1, 2022, the fixed lease term ended for Aurinia's existing corporate headquarters and the Company exercised its right to enter into a month to month lease, of which expenses are incurred in SG&A.

Rockville, Maryland

During March 2020, the Company entered into a lease for its U.S. commercial office in Rockville, Maryland for a total of 30,531 square feet of office space. The lease has a remaining term of approximately 9 years and has an option to extend for two five-year periods after the 11 years has elapsed and has an option to terminate after seven years. As of December 31, 2022, the Company had a right-of-use asset of $4.9 million and lease liability of $8.0 million included in the consolidated balance sheets. As of December 31, 2021, the Company had a right of use asset of $5.2 million and lease liability of $8.6 million included in the consolidated balance sheets. During 2020, the Company received reimbursements for tenant leasehold improvements by the landlord in the amount of $2.3 million for the Maryland lease. The Company recorded leasehold improvement incentives as additions to the lease liability. The lease term commenced on March 12, 2020. When measuring the lease liability, the Company discounted lease payments using its incremental borrowing rate at March 12, 2020. The incremental borrowing rate applied to the lease liability on March 12, 2020 was 5.2% based on the financial position of the Company, geographical region and terms of lease.

Edmonton, Alberta

During October 2022, the Company entered into a long term lease in Edmonton for a total of 4,375 square feet of office space. The lease is a 6 year lease and has an option to renew of five years at prevailing market rates. The lease commenced on November 1, 2022 and the Company recorded the lease as an operating lease. The lease is not material to the Company's financial position.

The Company incurs variable lease costs under the existing Victoria and Rockville leases. These costs include operation and maintenance costs included in SG&A and are expensed as incurred. The variable lease costs are not material to the Company's financial position.

The operating lease costs for the years ended December 31, 2022 and December 31, 2021 are $1.0 million for both periods respectively.

The weighted-average remaining lease term and discount rate for the years ended December 31, 2022 and December 31, 2021 are as follows:

	2022	2021
Weighted average remaining lease term (in years)	**8.7**	9.5
Weighted average discount rate	**5.3%**	5.2%

Supplemental cash flow information related to operating leases for the years ended December 31, 2022, December 31, 2021 and December 31, 2020 are as follows:

(in thousands)	2022	2021	2020
Cash paid for amounts included in the measurement of lease liabilities	**$ (1,160)**	$ (646)	$ (267)
Initial recognition of operating lease right-of-use asset	**$ 57**	$ 419	$ 5,804

Future maturities of operating lease liabilities as of December 31, 2022 are as follows:

(in thousands)	Operating Lease Payments
2023	$ 982
2024	1,113
2025	1,141
2026	1,169
2027	1,198
Thereafter	4,533
Total lease payments	10,136
Less: imputed interest	(2,048)
Total	**$ 8,088**

On December 15, 2020, the Company entered into a collaborative agreement with Lonza to build a dedicated manufacturing capacity within Lonza's existing small molecule facility in Visp, Switzerland. The dedicated facility (also referred to as "monoplant") will be equipped with state-of-the-art manufacturing equipment to provide cost and production efficiency for the manufacture of voclosporin, while expanding existing capacity and providing supply security to meet future commercial demand.

Following U.S. regulatory approval of voclosporin in January 2021, the Company has commenced a capital expenditure payment program totaling approximately CHF 21.0 million. The first capital expenditure payment was made in February 2021 of $11.8 million (CHF 10.5 million) and was treated as an upfront lease payment and recorded under other non-current assets on the consolidated balance sheets. The second payment is not due until the facility fulfills the required operational qualifications which is estimated to be during the first half of 2023. Upon completion of the monoplant, the Company will maintain sole dedicated use of the monoplant by paying a required quarterly fixed facility fee. The Company expects to account for the arrangement as a finance lease under ASC 842. The present value of the minimum lease payments total approximately $85.0 million, beginning April 2023 and expiring in 2030, and are not included in the above table.

The Company has entered into an equipment and facility finance lease for a backup manufacturing encapsulation site in Beinheim, France that has not yet commenced and is therefore, not included in the above table. As part of the agreement, the Company expects to make payments of approximately $0.9 million prior to lease commencement and the future value of minimum lease payments will total approximately $0.1 million.

16. Shareholders' Equity

Common shares: The Company has authorized an unlimited number of common shares with no par value. As of December 31, 2022, 2021 and 2020, 142.3 million, 141.6 million and 126.7 million Common Shares, respectively, were issued and outstanding. Each common share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Common shareholders are not entitled to receive dividends unless declared by the Company's Board of Directors.

Any future determination regarding the declaration and payment of dividends is expected to be declared and paid in the Company's functional currency, the U.S. dollar.

As discussed below from time to time, we intend to use the net proceeds from the sale of securities to fund our operations, which includes, but is not limited to, commercial activities, including our FDA related post approval commitments, manufacturing and packaging commercial drug supply, funding our supporting commercial infrastructure, advancing our R&D programs and funding our working capital obligations.

November 19, 2021 ATM facility

On November 19, 2021 the Company entered into an Open Market Sale Agreement (Sale Agreement) with Cantor Fitzgerald & Co. pursuant to which the Company may from time to time sell, through ATM offerings, common shares that would have an aggregate offering price of up to $250.0 million. Pursuant to this agreement the Company issued 10.2 million common shares at a weighted average price of $19.90 resulting in gross proceeds of $202.4 million as of December 31, 2021. The Company incurred share issue costs of approximately $5.6 million which included up to a 3% underwriting commission of $5.3 million and professional fees of $0.3 million directly related to the ATM.

On February 25, 2022, the Company gave notice to Cantor Fitzgerald & Co. to terminate the Open Market Sale Agreement. No further sales occurred under the Open Market Sale Agreement.

July 27, 2020 public offering

On July 27, 2020 the Company completed a public offering of 13.3 million common shares at a price of $15.00 per share. Gross proceeds from this offering were $200.0 million and the share issue costs totaled an estimated $12.3 million which included a 6% underwriting commission of $12.0 million and professional fees of $0.3 million.

Warrants:

Warrant related to December 28, 2016 bought deal public offering: On December 28, 2016, the Company completed a $28.8 million Bought Deal public offering (2016 Public Offering). Under the terms of 2016 Public Offering, each Unit consists of one common share and one-half (0.50) of a common share purchase warrant (December 2016 Warrant). The Company issued 12.8 million Units at a subscription price per Unit of $2.25, exercisable for a period of five years from the date of issuance at an exercise price of $3.00. These December 2016 Warrants also meet the scope exceptions provided in ASC 815, *Derivatives and Hedging*, as they are indexed to the Company’s own shares, and therefore are accounted for under ASC 505, *Equity*.

At initial recognition on December 28, 2016, the Company recorded a warrant in the amount of $7.2 million based on the estimated fair value of the December 2016 Warrants with allocated share issuance costs of $655 thousand recognized as a reduction of equity.

During 2019, certain holders of these Warrants exercised at $3.00 per share for gross proceeds of $5.5 million. During 2020, a holder exercised 500 Warrants at $3.00 per share for gross proceeds of $2 thousand. During 2021, 1.7 million warrants had been exercised at $3.00 per share for gross proceeds of $0.3 million. Of these 1.7 million warrants, the Company issued 1.3 million common shares in lieu of 1.6 million warrants. All gross proceeds were recorded as an increase in cash and equity. The remaining 6,000 warrants expired as of December 31, 2021.

There was no warrant activity during 2022. The warrant activity for 2021 is as follows:

	Number of warrants (in thousands)
Balance at December 31, 2020	1,690
Warrants exercised	(1,684)
Warrants expired	(6)
Balance at December 31, 2021	—

17. Shared-Based Compensation

The Company's Amended and Restated Equity Incentive Plan (the Plan), which was adopted and approved by the Company's shareholders in June 2021, allows for an issuance of up to an aggregate of 23.8 million shares (inclusive of then outstanding awards) and provides for grants of stock options, performance awards (PAs) and restricted stock units (RSUs) that may be settled in cash and common shares. Also in June 2021, the Company's shareholders adopted and approved the Company's Employee Stock Purchase Plan (2021 ESPP), which allows for the issuance of up to 2.5 million shares of which 286 thousand and 37 thousand were purchased during 2022 and 2021. The 2021 ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code (the Code) but also permits the Company to include the employees, including non-United States employees, in offerings not intended to qualify under Section 423. The purpose of the 2021 ESPP is to provide eligible employees with opportunities to purchase the Company's common shares at a discounted price.

During 2022, the Company modified the 2021 ESPP for the current and future offerings. The new ESPP terms shortened the plan from four (4) purchases over a 24 month offering period to two (2) purchases over a 12 month offering period. Additionally, the ESPP now contains a rollover mechanism; that is, if the stock price on the purchase date is less than the offering price (as that is determined under the 2021 ESPP), that offering is then canceled and any participants are rolled into the new 12 month offering period at the lower price. As a result of the modification, we recorded incremental expense during 2022 which was immaterial to the consolidated statements of operations.

In addition to stock options, PAs and RSUs granted under the Plan, the Company has granted certain stock options and RSUs as inducements material to new employees entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The inducements were granted outside of the Plan during 2022.

Stock Options

The Plan requires the exercise price of each option not to be less than the closing market price of the Company's common shares on the day immediately prior to the date of grant. The board of directors approves the vesting criteria and periods at its discretion. The options issued under the plan are accounted for as equity-settled share-based payments. The stock options and inducement stock options have a ten-year term and vest over three years with one-third of the shares vesting on the twelve month anniversary from the grant date, and the remaining options vesting in twenty-four equal monthly installments thereafter.

The following table summarizes the number of stock options outstanding under the Plan for the years ended December 31, 2022.

	Number of Shares (in thousands)		Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)		Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	12,074	$	12.84	7.86	$	121,141
Granted	3,913	$	11.14			
Exercised/released	(77)	$	6.55			
Cancelled/forfeited	(2,615)	$	14.32			
Outstanding at December 31, 2022	13,295	$	12.09	7.74	$	21
Options exercisable, December 31, 2022	8,345	$	11.94			
Vested and expected to vest, December 31, 2022	12,884	$	11.98			

The weighted average grant date fair value of stock options granted during the years ended December 31, 2022, 2021 and 2020 was $6.52, $7.34 and $5.58, respectively. The total fair value of options vested during the years ended December 31, 2022, 2021 and 2020 was $49.2 million, $24.9 million and $14.9 million, respectively.

Total intrinsic value of options exercised was $0.9 million, $50.3 million and $13.1 million for years ended December 31, 2022, 2021 and 2020, respectively.

In determining the fair value of the options granted, the Company uses the Black-Scholes option pricing model and reviews the following assumptions each reporting period:

Expected Term - Expected term (in years) is based upon the contractual term, taking into account expected employee exercise and expected post-vesting employment termination behavior. Based on the Company's historical expected lives data and the growth during 2022 and 2021, the expected life extends further into the contractual life increasing the expected life. The increase of the expected life in 2022 is in line with historic data and what management expects in the future.

Volatility - The Company considers historical volatility of its common shares in estimating its future stock price volatility. The expected life is used to determine market volatility of the underlying stock. The change in the volatility from in 2022 and 2021 was due to the Company's stock being more volatile. Given the growth of the Company, the expected life used to determine previous market volatility and comparable peer group reflects an appropriate estimate of future volatility.

Risk-free interest rate - The risk-free interest rate for the expected life of the options was based on the yield available on government benchmark bonds with an approximate equivalent remaining term at the time of the grant.

Dividend yield - The Company has never paid dividends on its common shares and has no plans to pay dividends on our common shares in the near future. Therefore, the Company dividend yield is zero.

The following weighted average assumptions were used to estimate the fair value of the options granted during the years ended December 31, 2022, 2021 and 2020:

	2022	2021	2020
Expected term (in years)	**5 years**	4 years	3 years
Volatility	**70 %**	66 %	52 %
Risk-free interest rate	**2.06 %**	0.46 %	0.55 %
Dividend yield	**0.0 %**	0.0 %	0.0 %

Performance Awards and Restricted Stock Units

On October 23, 2020, the Company issued 439,000 PAs to executive management of the Company whose vesting was contingent upon meeting specific performance metrics based on the results for the year ended December 31, 2021. Each PA which vested entitled the participant to receive common shares on the basis of the performance metrics set. On March 18, 2021 performance metrics were set and formally communicated. Therefore, March 18, 2021 was the grant date and the fair value on the grant date was $13.56. The PAs vested in 2022 and the participant was required to achieve at least one of the performance metrics to obtain the portion of the award associated with the metric.

On August 6, 2021, the Company granted approximately 619,000 PAs and RSUs. The grant date for the PAs and RSUs was August 6, 2021 and the fair value on the grant date was $14.42 as this was the date performance measures were set and communicated to employees. The PAs vested on the employee's first anniversary of the grant date and the employee was required to achieve at least one of the performance metrics to obtain the portion of the award associated with the metric. The RSUs had no performance metrics and vested on the one year anniversary of the grant.

During 2022, the Company has granted RSUs and intends to grant RSUs under the Plan, as well as inducements for certain new hires as discussed above. The RSUs are fair valued based on the market price of our common shares on the date of the grant. The RSUs and inducement RSUs shall vest in three equal annual installments on the first, second and third anniversary of the grant date.

The following table summarizes the PA and RSU activity for the year ended December 31, 2022:

	Number of Shares (in thousands)	Weighted-Average Grant Date Fair Value
Unvested balance, December 31, 2021	347	$ 13.33
Granted	2,374	$ 11.16
Vested	(305)	$ 14.17
Forfeited	(436)	$ 12.21
Unvested balance, December 31, 2022	1,980	$ 10.84

Compensation Expense

Share-based compensation expense for the years ended December 31, 2022, 2021 and 2020 totaled approximately $32.3 million, $31.2 million and $17.5 million, respectively, as shown in the table below.

(in thousands)	**2022**	**2021**	**2020**
Research and development	**$ 3,271**	$ 4,442	$ 3,730
Selling, general and administrative	**28,438**	26,432	13,615
Capitalized under inventories	**591**	369	109
Share-based compensation expense	**$ 32,300**	$ 31,243	$ 17,454

The Company recorded approximately $11.4 million of share-based compensation expense related to PAs and RSUs during the year ended December 31, 2022.

Unrecognized Share-Based Compensation Expense and Weighted Average Remaining Amortization Period

As of December 31, 2022, the unrecognized share-based cost, and the estimated weighted-average amortization period, using the straight-line attribution method, was as follows (in thousands, except amortization period):

		Unrecognized share-based compensation expense	Weighted average remaining amortization period (in years)
Stock Options	$	10,869	1.12
Restricted Stock Units		10,584	1.52
ESPP		1,327	0.52
Total unrecognized share-based compensation expense	$	22,780	1.30

18. Net Loss Per Common Share

Basic and diluted net loss per Common Share is computed by dividing net loss by the weighted average number of common shares outstanding. The numerator and denominator used in the calculation of basic and diluted net loss amounts per Common Share are as follows:

		2022		2021		2020
Net loss for the year	**$**	**(108,180)**	$	(180,966)	$	(102,680)
Weighted average number of common shares outstanding		**141,915**		129,369		118,473
Net loss per common share (expressed in $ per share)	**$**	**(0.76)**	$	(1.40)	$	(0.87)

The Company did not include the securities in the following table in the computation of the net loss per common share because the effect would have been anti-dilutive during each period:

	2022	2021	2020
Outstanding stock options	**13,295**	12,074	14,047
Unvested performance awards	—	64	—
Unvested restricted units	**1,980**	191	—
Warrants	—	—	1,690
	15,275	12,329	15,737

19. Related-Party Transactions

ILJIN SNT Co., Ltd (ILJIN) was considered to be a related party due to their equity ownership of over 5% as per their public filings. During 2021, Aurinia paid $6.0 million upon achievement of specific milestones. The amount payable to ILJIN is nil as of December 31, 2022 and 2021.

20. Selected Quarterly Financial Information (unaudited)

The following condensed quarterly financial information is for the years December 31, 2022 and 2021:

(in thousands, except per share data)	March 31, 2022	June 30, 2022	September 30, 2022	December 31, 2022
Total revenue, net	$ 21,625	$ 28,191	$ 55,779	$ 28,435
Cost of sales and operating expenses	59,507	64,180	65,278	56,535
Loss from operations	(37,882)	(35,989)	(9,499)	(28,100)
Net loss	(37,630)	(35,515)	(8,989)	(26,046)
Basic and diluted loss per common share	$ (0.27)	$ (0.25)	$ (0.06)	$ (0.18)

	March 31, 2021	June 30, 2021	September 30, 2021	December 31, 2021
Total revenue	$ 914	$ 6,620	$ 14,667	$ 23,404
Operating expenses	51,457	53,754	65,020	56,109
Loss from operations	(50,543)	(47,134)	(50,353)	(32,705)
Net loss	(50,379)	(47,010)	(50,255)	(33,322)
Basic and diluted loss per common share	$ (0.40)	$ (0.37)	$ (0.39)	$ (0.25)

21. Subsequent Events

On January 3, 2023, the Company announced that it had entered into a settlement agreement with Sun to file a joint motion to terminate the ongoing IPR and to settle the ongoing patent infringement litigation in the United States related to Sun's CEQUA product. The settlement agreement was contingent on receipt of termination of the IPR by the USPTO in respect of our '036 patent.

On January 24, 2023, the Company announced that the USPTO allowed a method of use patent application titled IMPROVED PROTOCOL FOR TREATMENT OF LUPUS NEPHRITIS. This newly allowed patent application reflects the unique and proprietary dosing regimen of LUPKYNIS. Specifically, this patent further refines the method of using LUPKYNIS in combination with MMF and corticosteroids using eGFR as a method of pharmacodynamically dosing LUPKYNIS in patients with LN. The newly allowed application provides patent coverage that supplements our existing ‘036 patent. The claims in this additional patent add further specificity on dosing consistent with the FDA approved product label. This patent has the potential to provide an additional layer of patent protection for LUPKYNIS up to 2037. The Company intends to list this newly allowed patent in the Orange Book once issued.

On January 25, 2023, the USPTO terminated the IPR it had instituted with respect to Aurinia's '036 patent.

AURINIA PHARMACEUTICALS INC. RESTRICTED STOCK UNIT GRANT NOTICE
(EQUITY INCENTIVE PLAN)

AURINIA PHARMACEUTICALS INC. (the ***"Company"***) has awarded to you (the "***Participant***") the number of restricted stock units specified and on the terms set forth below in consideration of your services (the ***"RSU"***). This Initial Grant is intended to serve as an inducement for you to join the Company and to satisfy the requirements for inducement grants pursuant to Nasdaq Listing Rule 5635(c)(4) which permits the Company to issue you security- based compensation without shareholder approval in order to induce you to enter into an employment arrangement as an employee of the Company. Your RSU is subject to all of the terms and conditions set forth in the Award Agreement (the "***Agreement***"), which are incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Agreement shall have the meanings set forth in the Agreement.

Name of Participant:
Date of Grant:
Vesting Commencement Date:
Number of RSUs:

Vesting Schedule: The RSUs shall vest in the manner set out in Schedule 1 hereto. Notwithstanding the foregoing, vesting shall terminate upon the Participant, if a Director or Officer, ceasing to be a Director or Officer or, if an Employee or other Service Provider, leaving the employ or service of the Company. The RSUs also vest accordance with the terms of the Agreement, including section with respect to a Change in Control (as defined in the Agreement).

Issuance Schedule: Each RSU which vests entitles the Participant to receive Common Shares on the basis of Schedule 1 hereto. Subject to Section 5 of the Award Agreement, the Company may, at its option, elect to compensate the Participant for their RSUs in whole or in part by cash in lieu of Common Shares.

Participant Acknowledgements: By your signature below or by electronic acceptance or authentication in a form authorized by the Company, you understand and agree that:

The RSU is governed by this RSU Grant Notice (the "***Grant Notice***"), and the provisions of the Agreement, all of which are made a part of this document. Unless otherwise provided in this Grant Notice and the Agreement (together, the "***RSU Agreement***") may not be modified, amended or revised except in a writing signed by you and a duly authorized officer of the Company.

You have read and are familiar with the provisions of the RSU Agreement.

The RSU Agreement sets forth the entire understanding between you and the Company regarding the acquisition of RSUs and supersedes all prior oral and written agreements, promises and/or representations on that subject with the exception of: (i) other equity awards previously granted to you, and (ii) any written employment agreement, offer letter, severance agreement, written severance plan or policy, or other written agreement between the Company and you in each case that specifies the terms that should govern this RSU.

This Grant Notice may be executed in any number of counterparts, and delivered by electronic means. Each such counterpart is deemed to be an original and all of them taken together are deemed to constitute one document.

AURINIA PHARMACEUTICALS INC.	**PARTICIPANT:**
	Signature:
Peter Greenleaf Chief Executive Officer Date:	

SCHEDULE 1

VESTING SCHEDULE

The RSUs granted pursuant to this RSU Agreement vest in the following manner:

1. An amount of RSUs that represents 1/3 of the Number of RSUs granted (as listed on page 1), rounded down to the nearest whole number, vest on the first anniversary of the grant date;
2. An amount of RSUs that represents 1/3 of the Number of RSUs granted (as listed on page 1), rounded down to the nearest whole number, vest on the second anniversary of the grant date; and
3. The remaining RSUs (being the total Number of RSUs listed on page 1, less the amounts vested in items 1 and 2 above) vest on the third anniversary of the grant date.

AURINIA PHARMACEUTICALS INC.

Award Agreement (Restricted Stock Unit)

As reflected by your RSU Grant Notice ("***Grant Notice***"), **AURINIA PHARMACEUTICALS INC.** (the "***Company***") has granted you a RSU for the number of RSUs as indicated in your Grant Notice (the "***RSU***"). This Initial Grant is intended to serve as an inducement for you to join the Company and to satisfy the requirements for inducement grants pursuant to Nasdaq Listing Rule 5635(c)(4) which permits the Company to issue you security-based compensation without shareholder approval in order to induce you to enter into an employment arrangement as an employee of the Company. The terms of your RSU as specified in this Award Agreement (including Schedule "A" hereto) for your RSU (the "***Agreement***") and the Grant Notice constitute your "***RSU Agreement***".

The general terms applicable to your RSU are as follows:

1. GRANT OF THE RSU. The Company hereby grants to you the RSUs set forth in the Grant Notice, subject to all of the terms and conditions set forth in the RSU Agreement.

2. DIVIDENDS. You shall receive no benefit or adjustment to your RSU with respect to any cash dividend, stock dividend or other distribution that does not result from an adjustment of the number of Common Shares issueable in connection with the RSUs, as applicable, as provided for in the RSU Agreement; provided, however, that this sentence shall not apply with respect to any Common Shares that are delivered to you in connection with your RSU after such shares have been delivered to you.

3. WITHHOLDING OBLIGATIONS.

(a) Regardless of any action taken by the Company or, if different, the Affiliate to which you have been Continuously Employed by (the "***Service Recipient***") with respect to any income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items associated with the grant or vesting of the RSU or sale of the underlying Common Shares or other tax-related items related to your receipt of these Awards and legally applicable to you (the "***Tax Liability***"), you hereby acknowledge and agree that the Tax Liability is your ultimate responsibility and may exceed the amount, if any, actually withheld by the Company or the Service Recipient. You further acknowledge that the Company and the Service Recipient (i) make no representations or undertakings regarding any Tax Liability in connection with any aspect of this RSU, including, but not limited to, the grant or vesting of the RSU, the issuance of Common Shares pursuant to such vesting, the subsequent sale of shares of Common Shares, and the payment of any dividends on the Common Shares, as applicable; and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the RSU to reduce or eliminate your Tax Liability or achieve a particular tax result. Further, if you are subject to Tax Liability in more than one jurisdiction, you acknowledge that the Company and/or the Service Recipient (or former service recipient, as applicable) may be required to withhold or account for Tax Liability in more than one jurisdiction.

(b) Prior to any relevant taxable or tax withholding event, as applicable, you agree to make adequate arrangements satisfactory to the Company and/or the Service Recipient to satisfy all Tax Liability. As provided in this Award Agreement, you hereby authorize the Company and any applicable Service Recipient to satisfy any applicable withholding obligations with regard to the Tax Liability by any of the following means or by a combination of such means: (i) causing you to pay any portion of the Tax Liability in cash or cash equivalent in a form acceptable to the Company; (ii) withholding from any compensation otherwise payable to you by the Company or the Service Recipient; (iii) except for

Canadian resident Service Providers, withholding Common Shares from the Common Shares issued or otherwise issuable to you in connection with the RSU; *provided*, however, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Board or the Company's Compensation Committee; (iv) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***"), pursuant to this authorization and without further consent, whereby you irrevocably elect to sell a portion of the Common Shares to be delivered in connection with your RSU to satisfy the Tax Liability and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Tax Liability directly to the Company or the Service Recipient; and/or (v) any other method determined by the Company to be in compliance with applicable law. Furthermore, you agree to pay the Company or the Service Recipient any amount the Company or the Service Recipient may be required to withhold, collect, or pay as a result of your receipt of Awards or that cannot be satisfied by the means previously described. In the event it is determined that the amount of the Tax Liability was greater than the amount withheld by the Company and/or the Service Recipient (as applicable), you agree to indemnify and hold the Company and/or the Service Recipient (as applicable) harmless from any failure by the Company or the applicable Service Recipient to withhold the proper amount.

(c) The Company may withhold or account for your Tax Liability by considering statutory withholding amounts or other withholding rates applicable in your jurisdiction(s), including (i) maximum applicable rates in your jurisdiction(s), in which case you may receive a refund of any over-withheld amount in cash (whether from applicable tax authorities or the Company) and you will have no entitlement to the equivalent amount in Common Shares or (ii) minimum or such other applicable rates in your jurisdiction(s), in which case you may be solely responsible for paying any additional Tax Liability to the applicable tax authorities or to the Company and/or the Service Recipient. Except for Canadian resident Service Providers, if the Tax Liability withholding obligation is satisfied by withholding Common Shares, for tax purposes, you are deemed to have been issued the full number of Common Shares subject to the vested portion of the RSU, notwithstanding that a number of Common Shares is held back solely for the purpose of paying such Tax Liability.

(d) You acknowledge that you may not receive Awards or underlying Common Shares and the Company shall have no obligation to deliver Common Shares until you have fully satisfied the Tax Liability, as determined by the Company. Unless any withholding obligation for the Tax Liability is satisfied, the Company shall have no obligation to deliver to you any Common Shares in respect of the RSU.

4. Cash Settlement. For Canadian resident Service Providers, all distributions under this RSU shall be made by the Company in the form of Common Shares. Notwithstanding anything to the contrary in this Agreement, the Company may, in its sole discretion, offer to settle any portion of the RSU otherwise payable in Common Shares in cash and the Service Provider, in its sole discretion, may elect to accept this offer. The cash amount to be paid by the Company upon distribution of any portion of the RSU otherwise payable in Common Shares shall be equal to (i) the number of Common Shares with respect to which the Service Providers is entitled to a distribution multiplied by (ii) the closing trading price for the Common Shares on the stock exchange on which the majority of the Company's Common Shares traded on the applicable distribution date (which may be denominated in either Canadian or US dollars, based on the applicable exchange rate on the day immediately prior to the applicable distribution date) or if the Common Shares are not listed on a stock exchange, then the trading price determined by the Board using good faith discretion.

5. Date of Issuance.

(a) The issuance of shares, if applicable, in respect of the RSU is intended to comply with U.S. Treasury Regulations Section 1.409A-3(a) and will be construed and administered in such a manner. Subject to the satisfaction of the Tax Liability withholding obligation, if any, in the event one or more RSUs payable in Common Shares vests, the Company shall issue to you the number of Common Shares receivable by the Participant pursuant to this Agreement. Each issuance date determined by this paragraph is referred to as an "***Original Issuance Date***."

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Original Issuance Date does not occur (1) during a period when you are able to trade, as determined in accordance with the Company's then-effective policy on insider trading and applicable securities laws, or (2) on a date when you are otherwise permitted to sell Common Shares on an established stock exchange or stock market (including but not limited to under a previously established written trading plan that meets the requirements of Canadian securities laws applicable to automatic securities trading plans and Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "***Automatic Arrangement***)), *and*

(ii) either (1) a Tax Liability withholding obligation does not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Tax Liability withholding obligation by withholding Common Shares from the shares otherwise due, on the Original Issuance Date, to you under this RSU, and (B) not to permit you to enter into a "same day sale" commitment with a broker- dealer (including but not limited to a commitment under an Automatic Arrangement) and (C) not to permit you to pay your Tax Liability in cash, then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling Common Shares in the open public market but, subject to applicable Canadian securities laws, in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with U.S. Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the Common Shares under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of U.S. Treasury Regulations Section 1.409A-1(d).

6. TRANSFERABILITY. Except as otherwise provided in the RSU Agreement, your RSU is not transferable, except by will or by the applicable laws of descent and distribution

7. GOVERNING LAW. This RSU Agreement will be governed, construed and administered in accordance with the laws of the Province of British Columbia and the laws of Canada applicable therein.

8. NO LIABILITY FOR TAXES. As a condition to accepting the RSU, you hereby (a) agree to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from the RSU or other Company compensation and (b) acknowledge that you were advised to consult with your own personal tax, financial and other legal advisors regarding the tax consequences of the RSU and have either done so or knowingly and voluntarily declined to do so.

9. SEVERABILITY. If any part of this Agreement is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this

Agreement not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

10. OTHER DOCUMENTS. By signing the Grant Notice, you acknowledge:

(a) receipt of the Company's Insider Trading Policy; and

(b) that you have read and understand the award terms attached hereto as Schedule "A" and as set out herein and accept the RSU in accordance with the terms of this RSU Agreement.

SCHEDULE “A”

AURINIA PHARMACEUTICALS INC.
(the “Company”)

INDUCEMENT AWARD TERMS

ARTICLE 1
PURPOSE AND INTERPRETATION

Purpose

1.1 The purpose of the award grant is to advance the interests of the Company by encouraging equity participation in the Company through the acquisition of Common Shares of the Company. It is the intention of the Company that the terms of this award agreement (the “**Award Terms**”) will at all times be in compliance with the rules and policies of any applicable stock exchange on which the securities of the Company are listed or quoted for trading and any inconsistencies between these Award Terms and the rules and policies of such exchanges, whether due to inadvertence or changes in such rules or policies, will be resolved in favor of the latter.

Definitions

1.2 In these Award Terms:

“Actively Engaged”, in reference to a certain date, means that the Service Provider is engaged by the Company (including being on vacation or being on a statutory or other leave authorized by the Company) on the applicable date. Except to the minimum extent, if any, required by applicable employment standards legislation, “Actively Engaged” does not include:

(a) any period following the date the Service Provider, if a Director or Officer, ceases to be a Director or Officer upon termination of office or, if an Employee or other Service Provider, ceases to be employed or engaged by the Company upon termination of employment or service, for any reason (whether voluntary or involuntary, and whether with or without just cause, and regardless of whether the termination is lawful or unlawful);

(b) any period in relation to which the Company provides pay in lieu of notice in respect of such termination of office, employment or service; or

any period in relation to which the Company fails to give notice that ought to have been given pursuant to any agreement between the Company and the Service Provider or pursuant to any applicable law, including the common law or civil law, as applicable, in respect of such termination of office, employment or service, and in relation to which damages may be awarded, including for the failure to provide such notice.

“Affiliate” has the meaning assigned by the Securities Act;

“**Award**” means any Option, Restricted Stock, Restricted Stock Unit, or Performance Award covered by these Award Terms, as evidenced by the Award Commitment that these Award Terms are attached;

"Award Commitment" means any written agreement, contract or other instrument or document evidencing any Award granted to a Participant and subject to these Award Terms;

"Award Shares" means Common Shares that may be issued in the future to a Service Provider in connection with the grant, vesting or settlement of or upon the exercise of an Award;

"Black-out Period" means the period during which the relevant Recipient is prohibited from exercising an Award due to trading restrictions imposed by the Company in accordance with its securities trading policies governing trades in the Company's securities;

"Board" means the board of directors of the Company (the "**Company Board**") or any committee thereof duly empowered or authorized to grant Awards, or any Person to whom the board of directors or empowered or authorized committee thereof delegates such authority;

"Business Day" means a day that the NASDAQ Stock Market LLC (or such other exchange on which the highest volume of the Company's securities are traded) is open for trading;

"**Change in Control**" means any of the following transactions, provided, however, that the Board shall determine under parts (iv) and (v) whether multiple transactions are related, and its determination shall be final, binding and conclusive:

(i) consummation of a merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the jurisdiction in which the Company is incorporated;

(ii) the sale, transfer or other disposition of all or substantially all of the assets of the Company;

(iii) the complete liquidation or dissolution of the Company;

(iv) any reverse merger or series of related transactions culminating in a reverse merger (including, but not limited to, a tender offer followed by a reverse merger) in which the Company is the surviving entity but (A) the Common Shares outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (B) in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger or the initial transaction culminating in such merger, but excluding any such transaction or series of related transactions that the Board determines shall not be a Change in Control;

(v) acquisition in a single or series of related transactions by any person or related group of persons (other than the Company or by a Company-sponsored employee benefit plan) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities but excluding any such transaction or series of related transactions that the Board determines shall not be a Change in Control;

(vi) the direct or indirect acquisition by any person or related group of persons (other than an acquisition from or by the Company or by a Company-sponsored employee benefit plan or by a person that directly or indirectly controls, is controlled by, or is under common control with, the Company) of beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's shareholders which a majority of the Continuing Directors who are not Exchange Act Affiliates or Exchange Act Associates of the offeror do not recommend such shareholders accept; or

(vii) a change in the composition of the Company Board over a period of twelve (12) months or less such that a majority of the Company Board members (rounded up to the next whole number) ceases, by reason of one or more contested elections for Company Board membership, to be comprised of individuals who are Continuing Directors.

For the purpose of these Award Terms, "**Continuing Directors**" means members of the Company Board who either (i) have been Company Board members continuously for a period of at least twelve (12) months or (ii) have been Company Board members for less than twelve (12) months and were elected or nominated for election as Board members by at least a majority of the Company Board members described in clause

(i) who were still in office at the time such election or nomination was approved by the Company Board. "**Exchange Act**" means the Securities Exchange Act

of 1934, as amended.

"**Exchange Act Affiliate**" and "**Exchange Act Associate**" shall have the respective meanings ascribed to "Affiliate" and "Associate" in Rule 12b-2 promulgated under the Exchange Act.

"**Code**" means the United States Internal Revenue Code of 1986, as amended.

"Common Shares" means common shares in the capital of the Company;

"Company" means Aurinia Pharmaceuticals Inc. or any successor thereto, and includes an Affiliate;

"Consultant" means an individual or a consultant Company, other than an Employee, Officer or Director who:

(i) provides on an ongoing bona fide basis, consulting, technical, managerial or like services to the Company, other than services provided in relation to a Distribution;

(ii) provides the services under a written contract between the Company and the individual or the Consultant Company;

(iii) in the reasonable opinion of the Company, spends or will spend a significant amount of time and attention on the business and affairs of the Company; and

(iv) has a relationship with the Company that enables the individual or Consultant Company to be knowledgeable about the business and affairs of the Company;

"Consultant Company" means for an individual Consultant, a company or partnership of which the individual is an employee, shareholder or partner;

"Continuously Employed" shall mean the absence of any interruption or termination of service. Continuous Employment with the Company shall not be considered interrupted in the case of the sick leave, military leave or any other leave of absence approved by the Company or protected under applicable law or in the case of transfers between location of the Company; provided that the individual continues to be an Employee of the Company;

"Directors" means the directors of the Company as may be elected or appointed from time to time;

“Disability” shall mean any physical, mental or other health condition which results in it being impossible for the Recipient to perform his or her assigned duties for the reasonably foreseeable future, such that his or her employment or engagement has been frustrated. For purposes of Incentive Stock Options, **“Disability”** shall mean a “permanent and total disability” within the meaning of Section 22(e)(3) of the Code. The Board shall determine whether a Recipient has incurred a Disability on the basis of medical evidence acceptable to the Board. Upon making a determination of Disability, the Board shall, for the purposes of these Award Terms, determine the date of the Recipient’s termination of office, employment or service;

“Employee” means:

(i) an individual who is considered an employee of the Company or its Affiliates under the *Income Tax Act* (Canada) (i.e. for whom income tax, employment insurance and Canada Pension Plan deductions must be made at source) or the tax legislation of another jurisdiction in which the Company or its Affiliates may do business (including the Code);

(ii) an individual who works full-time for the Company (or one of its Affiliates) providing services normally provided by an employee and who is subject to the same control and direction by the Company over the details and methods of work as an employee of the Company, but for whom income tax deductions are not made at source; or

(iii) an individual who works for the Company on a continuing and regular basis for a minimum amount of time per week providing services normally provided by an employee and who is subject to the same control and direction by the Company over the details and methods of work as an employee of the Company, but for whom income tax deductions need not be made at source,

and may include an Officer;

“Exercise Price” means the amount payable per Common Share on the exercise of an Award, if applicable, as determined in accordance with the terms hereof;

“Expiry Date” means the day on which an Award lapses as specified in the Award Commitment therefor or in accordance with the terms of these Award Terms;

“Grant Date” for an Award means the date of grant thereof by the Board;

“Insider” means an insider as defined in the Securities Act;

“Investor Relations Activities” means generally any activities or communications that can reasonably be seen to be intended to or be primarily intended to promote the merits or awareness of or the purchase or sale of securities of the Company;

“Management Company Employee” means an individual employed by another individual or a corporation providing management services to the Company which are required for the ongoing successful operation of the business enterprise of the Company, but excluding a corporation or individual engaged primarily in Investor Relations Activities;

"Market Price" means:

(i) the closing trading price for the Common Shares on the stock exchange on which the majority of the Company's common shares traded on the day immediately prior to the date of determination (which may be denominated in either Canadian or US dollars, based on the applicable exchange rate on the day immediately prior to the date of determination) provided however that the determination date in respect of Options granted to Canadian residents shall be the Grant Date of such Options; or

(ii) if the Common Shares are not listed on a stock exchange, then the trading price determined by the Board using good faith discretion;

"Officer" means a duly appointed senior officer of the Company;

"Option" means an Option granted to a Participant;

"Outstanding Shares" means at the relevant time, the number of outstanding Common Shares of the Company from time to time;

"Recipient" means the recipient of an Award hereunder;

"Participant" means a Service Provider that becomes a Recipient; "**Performance Award**" means a Performance Award granted to

a Participant; **"Person"** means a company or an individual;

"Regulatory Approval" means the approval of any securities regulatory authority (including, if applicable, any stock exchange on which the securities of the Company may be listed or quoted for trading) that may have lawful jurisdiction over these Award Terms;

"**Restricted Stock**" means Restricted Stock granted to a Participant; "**Restricted Stock Unit**" means a Restricted Stock Unit

granted to a Participant;

"Securities Act" means the *Securities Act*, R.S.A. 2000, c. S-4, as amended from time to time;

"Service Provider" means an individual who is a bona fide Director, Officer, Employee, Management Company Employee or Consultant, and also includes a company of which 100% of the share capital is

"Shareholder Approval" means approval by a majority of the votes cast by eligible shareholders at a duly constituted shareholders' meeting; and

"**U.S. Participant**" means a Participant that is resident in or a citizen of the United States of America.

ARTICLE 2 ADMINISTRATION

Administration of Award Terms

2.1 The Board will be responsible for the general administration of the Award Terms and the proper execution of its provisions, the interpretation of the Award Terms and the determination of all questions arising hereunder. The Board has deleted such responsibility to the Compensation Committee of the Board, and may rescind that delegation, or may delegate some or all of such responsibility to any other Committee or member of the Board.

Compliance with Legislation

2.2 The Company will not be required to issue any Common Shares under these Award Terms unless such issuance is in compliance with all applicable laws, regulations, rules, orders of governmental or regulatory authorities and the requirements of any stock exchange upon which Common Shares of the Company are listed. The Company will not in any event be obligated to take any action to comply with any such laws, regulations, rules, orders or requirements.

ARTICLE 3
TERMS AND CONDITIONS OF AWARDS

Recipient Ceasing to be Director, Officer, Employee or Service Provider

3.1 No Award may be exercised after the Recipient, if a Director or Officer, has ceased to be a Director or Officer or, if an Employee or other Service Provider has left the employ or service of the Company, except as follows:

(a) in the case of the death of a Recipient, any vested Award held by him at the date of death will become exercisable by the Recipient's lawful personal representatives, heirs or executors until the earlier of one year after the date of death of such Recipient and the Expiry Date of such Award;

(b) in the case of the Disability of a Recipient, any vested Award held by him at the date of Disability will become exercisable until the earlier of one year from the date of cessation of the Recipient's employment or other office and the Expiry Date of such Award; and

(c) subject to the other provisions of this Section 3.1, vested Awards will expire 90 days after the date the Recipient ceases for any reason whatsoever to be employed by, provide services to, or be a Director or Officer of, the Company and all unvested Awards will immediately terminate without right to exercise same;

but provided that in no event may the term of the Award exceed 10 years, unless determined in the discretion of the Board.

Additional Vesting

3.2 Subject to Sections 3.3 and 3.4, in addition to meeting any other eligibility requirements for receiving an Award, or for an Award to vest (if applicable), the Service Provider must be Actively Engaged by the Company through to, and including on, the established Grant Date or vesting date for such Award, as applicable. For clarity, except to the minimum extent, if any, required by applicable employment standards legislation:

(a) if the Service Provider is not Actively Engaged by the Company on the established Grant Date for an Award for any reason, the Service Provider will not have earned the Award, the Service Provider is deemed to have waived and forfeited any right to earn the Award, and the Service Provider will not be eligible to receive the Award or a pro-rated share of the Award;

(b) if the Service Provider is not Actively Engaged by the Company on the established vesting date for an Award to vest, for any reason, the Award will not vest;

(c) Awards will not be included in the calculation of, or form any part of, contractual or common law pay in lieu of notice, and Awards will not form part of any damages for wrongful dismissal or otherwise; and

(d) this provision is intended to limit or remove the Service Provider's rights to any damages relating to Awards, including during any period in relation to which the Company provides pay in lieu of notice, and including during any period in relation to which the Company fails to give notice that should have been given pursuant to any agreement between the Service Provider and the Company, or pursuant to any applicable law, including the common law or civil law, as applicable.

3.3 Notwithstanding anything else in these Award Terms, if, in the case of a Recipient who is an Employee, that Recipient's employment terminates by reason of death or Disability, subject to the terms of the Award set out in an Award Commitment, any Award held by such Employee who has been Continuously Employed by the Company for a minimum of three (3) years shall become fully vested and exercisable and may thereafter be exercised during the term of the Award set forth in Section 3.1(a) and Section 3.1(b).

3.4 Notwithstanding anything else in these Award Terms, if, in the case of a Recipient who is an Employee, that Recipient's employment is terminated by the Company without cause then, provided that the Recipient has been Continuously Employed by the Company for a minimum of three (3) years, then, subject to the terms of the Award set out in an Award Commitment, all Awards shall become fully vested and exercisable and may thereafter be exercised during the term of the Option set forth in Section 3.1(c).

Change in Control

3.5 The provisions of this Section 3.5 shall apply in the case of a Change in Control, unless otherwise provided in the Award Commitment or any separate agreement with a Participant. In the event of a Change in Control, all Awards will terminate upon the Change in Control unless they are assumed by the surviving entity or otherwise equitably converted, substituted or continued. In that event, Recipients will have a reasonable period prior to the effectiveness of the Change in Control to exercise the vested portion of any Award prior to its termination.

(a) *Awards Not Assumed or Substituted by Surviving Entity. Upon the occurrence of a Change in Control, and except with respect to any Awards assumed by the surviving entity or otherwise equitably converted or substituted in connection with the Change in Control in a manner approved by the Board:*

(i) all outstanding Awards that are subject to time-based vesting requirements shall become vested and fully exercisable immediately prior to, and contingent on, the effectiveness of, the Change in Control;

(ii) all outstanding Awards that are subject to time-based vesting restrictions shall become vested and such restrictions shall lapse immediately prior to, and contingent on, the effectiveness of, the Change in Control; and

(iii) the payout level under all outstanding Awards that are subject to performance-based vesting requirements shall be deemed to have been earned immediately prior to, and contingent on, the effectiveness of, the Change in Control based upon an assumed achievement of all relevant performance goals at the 100% level (or such higher threshold as may have been actually achieved by the effective date of the Change in Control).

(b) *Awards Proposed to be Assumed or Substituted by Surviving Entity. Upon the occurrence of a Change in Control, and except with respect to any Awards that are not proposed to be assumed by the surviving entity or otherwise equitably converted or substituted in connection with the Change in Control in a manner approved by the Board:*

(i) all outstanding Awards that are subject to time-based vesting requirements shall become vested and fully exercisable immediately prior to, and contingent on, the effectiveness of, the Change in Control;

(ii) all outstanding Awards that are subject to time-based vesting restrictions shall become vested and such restrictions shall lapse immediately prior to, and contingent on, the effectiveness of, the Change in Control; and

(iii) the payout level under all outstanding Awards that are subject to performance-based vesting requirements shall be deemed to have been earned immediately prior to, and contingent on, the effectiveness of, the Change in Control based upon an assumed achievement of all relevant performance goals at the 100% level (or such higher threshold as may have been actually achieved by the effective date of the Change in Control).

Non Assignable

3.6 Subject to Section 3.1(a), all Awards will be exercisable only by the Recipient to whom they are granted and will not be assignable or transferable.

Adjustment of the Number of Award Shares

3.7 If there is a change in the outstanding Common Shares by reason of any share consolidation, or split, reclassification or other capital reorganization, or a stock dividend, arrangement, amalgamation, merger or combination, or any other change to, event affecting, exchange of or corporate change or transaction affecting the Common Shares, the Board will make, as it deems advisable and subject to requisite Regulatory Approval, appropriate substitution and/or adjustment in:

(a) the number and kind of shares or other securities or property reserved or to be allotted for issuance pursuant to these Award Terms;

(b) the number and kind of shares or other securities or property reserved or to be allotted for issuance pursuant to any outstanding unexercised Awards, and in the exercise price for such shares or other securities or property; and/or

(c) the vesting of any Awards, including the accelerated vesting thereof on conditions the Board deems advisable,

and if the Company undertakes an arrangement or is amalgamated, merged or combined with another corporation, the Board will make such provision for the protection of the rights of Participants as it deems advisable.

Adjustment of Awards Expiring During Black-out Period

3.8 Should the Expiry date for an Award fall within a Black-out Period, or within the period that is nine Business Days immediately following the expiration of a Black-out Period, such Expiry Date will be automatically adjusted without any further act or formality to that day which is the tenth Business Day after the end of the Black-out Period, such tenth Business Day to be considered the Expiry Date for such Award for all purposes under these Award Terms. Notwithstanding any other provision of these Award Terms, the tenth Business Day period referred to in this Section 3.8 may not be extended by the Board.

Compliance with Section 409A of the Code

3.9 Unless otherwise expressly provided for in an Award Commitment, the terms applicable to Options granted to U.S. Participants will be interpreted to the greatest extent possible in a manner that makes those Options exempt from Section 409A of the Code, and, to the extent not so exempt, that brings the Options into compliance with Section 409A of the Code. Notwithstanding anything to the contrary in these Award Terms (and unless the Award Commitment or other written contract with the U.S. Participant specifically provides otherwise), if the Common Shares are publicly traded, and if a U.S. Participant of an Option that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" under Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six (6) months following the date of such U.S. Participant's "separation from service" or, if earlier, the date of the U.S. Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six (6) month period elapses, with the balance paid thereafter on the original schedule.

ARTICLE 4
COMMITMENT AND EXERCISE PROCEDURES

Manner of Exercise

4.1 A Recipient who wishes to exercise their Award may do so:

4.1.1 by delivering:

(a) a written notice to the Company specifying the number of Award Shares being acquired pursuant to the Award; and

(b) cash, certified cheque or bank draft payable to the Company for the aggregate Exercise Price for the Optioned Shares being acquired and the aggregate of any amounts required by law to be withheld by the Company on the exercise of such Award, or separate certified cheques or bank drafts for such Exercise Price and such amounts to be withheld;

4.1.2 in such other manner as may be specified in the Award Commitment or as may be agreed to by the Company.

Notwithstanding anything else contained in these Award Terms, the Company may, from time to time, implement such other procedures and conditions as it determines appropriate with respect to the payment, funding or withholding of amounts required by law to be withheld on the exercise of Awards under these Award Terms.

Delivery of Certificate and Hold Periods

4.2 As soon as practicable after receipt of the notice of exercise described in Section 4.1 and payment in full for the Awards Shares being acquired (if applicable), the Company will direct its transfer agent to issue to the Recipient the appropriate number of Award Shares. The transfer agent will either issue a certificate representing the Award Shares or a written notice in the case of uncertificated Common Shares. Such issued certificate or written notice, as the case may be, will bear a legend stipulating any resale restrictions required under applicable securities laws.

ARTICLE 5
AMENDMENTS TO AWARD TERMS OR AWARDS

Amendments Generally

5.1 The Board may, at any time and from time to time, amend, suspend or terminate these Award Terms as to any Common Shares as to which Awards have not been made and such action will not constitute a breach of the terms of any agreement between the Service Provider and the Company. The effectiveness of any amendment to these Award Terms shall be contingent on approval of such amendment by the Company's shareholders to the extent provided by the Board or required by applicable laws (including the rules of any stock exchange on which the Common Shares are then listed). No amendment, suspension or termination of the Award Terms shall materially impair rights or obligations under any Award theretofore made without the consent of the Participant.

5.2 With the consent of the affected Participants for any amendment or modification that materially impairs the rights or obligations of a Participant, the Board may amend or modify any outstanding Award in any manner to the extent that the Board would have the authority to initially grant such award as so modified or amended.

Amendment Subject to Approval

5.3 If the amendment of an Award requires Regulatory Approval or Shareholder Approval, such amendment may be made prior to such approvals being given, but no amended Awards may be exercised unless and until such approvals are given.

ARTICLE 6 GENERAL

Employment and Services

6.1 Nothing contained in these Award Terms will confer upon or imply in favor of any Recipient any right with respect to office, employment or provision of services with the Company, or interfere in any way with the right of the Company to terminate the Recipient's office, employment or service at any time.

A change in the status, office, position or duties of a Participant from the status, office, position or duties held by such Participant on the date on which the Award was granted to such Participant will not result in the termination of the Award granted to such Participant provided that such Participant remains a Service Provider.

Taxes

6.2 The Company may make such provisions as it may deem appropriate for the withholding of any taxes which it determines is required in connection with any Awards granted under these Award Terms.

No Representation or Warranty

6.3 The Company makes no representation or warranty as to the future market value of Common Shares issued in accordance with the provisions of these Award Terms or to the effect of the *Income Tax Act* (Canada) or any other taxing statute governing the Awards or the Common Shares issuable thereunder or the tax consequences to a Service Provider. Compliance with applicable securities laws as to the disclosure and resale obligations of each Participant is the responsibility of such participant and not the Company.

Interpretation

6.4 The Award Terms will be governed and construed in accordance with the laws of the Province of British Columbia.

AURINIA PHARMACEUTICALS INC.
RESTRICTED STOCK UNIT GRANT NOTICE
(EQUITY INCENTIVE PLAN)

AURINIA PHARMACEUTICALS INC. (the ***"Company"***) has awarded to you (the "***Participant***") the number of restricted stock units specified and on the terms set forth below in consideration of your services (the ***"RSU"***). Your RSU is subject to all of the terms and conditions as set forth herein and in the Company's Equity Incentive Plan (the ***"Plan"***) and the Award Agreement (the "***Agreement***"), which are incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Agreement shall have the meanings set forth in the Plan or the Agreement.

Name of Participant:
Date of Grant:
Vesting Commencement Date:
Number of RSUs:

Vesting Schedule: The RSUs shall vest in the manner set out in Schedule 1 hereto. Notwithstanding the foregoing, vesting shall terminate upon the Participant, if a Director or Officer, ceasing to be a Director or Officer or, if an Employee or other Service Provider, leaving the employ or service of the Company. The RSUs also vest accordance with the terms of the Plan, including section 3.9 thereof with respect to a Change in Control (as defined in the Plan).

Issuance Schedule: Each RSU which vests entitles the Participant to receive Common Shares on the basis of Schedule 1 hereto. Subject to Section 5 of the Award Agreement, the Company may, at its option, elect to compensate the Participant for their RSUs in whole or in part by cash in lieu of Common Shares.

Participant Acknowledgments: By your signature below or by electronic acceptance or authentication in a form authorized by the Company, you understand and agree that:

- The RSU is governed by this RSU Grant Notice (the "***Grant Notice***"), and the provisions of the Plan and the Agreement, all of which are made a part of this document. Unless otherwise provided in the Plan, this Grant Notice and the Agreement (together, the "***RSU Agreement***") may not be modified, amended or revised except in a writing signed by you and a duly authorized officer of the Company.
- You have read and are familiar with the provisions of the Plan and the RSU Agreement. In the event of any conflict between the provisions in the RSU Agreement and the terms of the Plan, the terms of the Plan shall control.
- The RSU Agreement sets forth the entire understanding between you and the Company regarding the acquisition of RSUs and supersedes all prior oral and written agreements, promises and/or representations on that subject with the exception of: (i) other equity awards previously granted to you, and (ii) any written employment agreement, offer letter, severance agreement, written severance plan or policy, or other written agreement between the Company and you in each case that specifies the terms that should govern this RSU.

This Grant Notice may be executed in any number of counterparts, and delivered by electronic means. Each such counterpart is deemed to be an original and all of them taken together are deemed to constitute one document.

AURINIA PHARMACEUTICALS INC. **Participant:**

Signature:

Peter Greenleaf
Chief Executive Officer
Date:

SCHEDULE 1

VESTING SCHEDULE

The RSUs granted pursuant to this RSU Agreement vest in the following manner:

1. An amount of RSUs that represents 1/3 of the Number of RSUs granted (as listed on page 1), rounded down to the nearest whole number, vest on the first anniversary of the grant date;
2. An amount of RSUs that represents 1/3 of the Number of RSUs granted (as listed on page 1), rounded down to the nearest whole number, vest on the second anniversary of the grant date; and
3. The remaining RSUs (being the total Number of RSUs listed on page 1, less the amounts vested in items 1 and 2 above) vest on the third anniversary of the grant date.

AURINIA PHARMACEUTICALS INC.
(EQUITY INCENTIVE PLAN)
AWARD AGREEMENT (RESTRICTED STOCK UNIT)

As reflected by your RSU Grant Notice ("***Grant Notice***"), **AURINIA PHARMACEUTICALS INC.** (the "***Company***") has granted you a RSU under its Equity Incentive Plan (the "***Plan***") for the number of RSUs as indicated in your Grant Notice (the "***RSU***"). The terms of your RSU as specified in this Award Agreement for your RSU (the "***Agreement***") and the Grant Notice constitute your "***RSU Agreement***". Defined terms not explicitly defined in this Agreement but defined in the Grant Notice or the Plan shall have the same definitions as in the Grant Notice or Plan, as applicable.

The general terms applicable to your RSU are as follows:

1. Governing Plan Document. Your RSU is subject to all the provisions of the Plan. Your RSU is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the RSU Agreement and the provisions of the Plan, the provisions of the Plan shall control.

2. Grant of the RSU. The Company hereby grants to you the RSU set forth in the Grant Notice, subject to all of the terms and conditions set forth in the RSU Agreement. As applicable, any additional RSUs that become subject to the RSU pursuant to an adjustment of the number of Award Shares provisions as set forth in the Plan and the provisions of Section 3 below, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other RSUs covered by your RSU.

3. Dividends. You shall receive no benefit or adjustment to your RSU with respect to any cash dividend, stock dividend or other distribution that does not result from an adjustment of the number of Award Shares, as applicable, as provided in the Plan; provided, however, that this sentence shall not apply with respect to any Common Shares that are delivered to you in connection with your RSU after such shares have been delivered to you.

4. Withholding Obligations.

(a) Regardless of any action taken by the Company or, if different, the Affiliate to which you have been Continuously Employed by (the "***Service Recipient***") with respect to any income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items associated with the grant or vesting of the RSU or sale of the underlying Common Shares or other tax-related items related to your participation in the Plan and legally applicable to you (the "***Tax Liability***"), you hereby acknowledge and agree that the Tax Liability is your ultimate responsibility and may exceed the amount, if any, actually withheld by the Company or the Service Recipient. You further acknowledge that the Company and the Service Recipient (i) make no representations or undertakings regarding any Tax Liability in connection with any aspect of this RSU, including, but not limited to, the grant or vesting of the RSU, the issuance of Common Shares pursuant to such vesting, the subsequent sale of shares of Common Shares, and the payment of any dividends on the Common Shares, as applicable; and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the RSU to reduce or eliminate your Tax Liability or achieve a particular tax result. Further, if you are subject to Tax Liability in more than one jurisdiction, you acknowledge that the Company and/or the Service Recipient (or former service recipient, as applicable) may be required to withhold or account for Tax Liability in more than one jurisdiction.

(b) Prior to any relevant taxable or tax withholding event, as applicable, you agree to make adequate arrangements satisfactory to the Company and/or the Service Recipient to satisfy all Tax Liability. As provided in Article 4 of the Plan, you hereby authorize the Company and any applicable Service Recipient to satisfy any applicable withholding obligations with regard to the Tax Liability by any of the following means or by a combination of such means: (i) causing you to pay any portion of the Tax Liability in cash or cash equivalent in a form acceptable to the Company; (ii) withholding from any compensation otherwise payable to you by the Company or the Service Recipient; (iii) except for Canadian resident Service Providers, withholding Common Shares from the Common Shares issued or otherwise issuable to you in connection with the RSU; *provided*, however, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Board or the Company's Compensation Committee; (iv) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***"), pursuant to this authorization and without further consent, whereby you irrevocably elect to sell a portion of the Common Shares to be delivered in connection with your RSU to satisfy the Tax Liability and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Tax Liability directly to the Company or the Service Recipient; and/or (v) any other method determined by the Company to be in compliance with applicable law. Furthermore, you agree to pay the Company or the Service Recipient any amount the Company or the Service Recipient may be required to withhold, collect, or pay as a result of your participation in the Plan or that cannot be satisfied by the means previously described. In the event it is determined that the amount of the Tax Liability was greater than the amount withheld by the Company and/or the Service Recipient (as applicable), you agree to indemnify and hold the Company and/or the Service Recipient (as applicable) harmless from any failure by the Company or the applicable Service Recipient to withhold the proper amount.

(c) The Company may withhold or account for your Tax Liability by considering statutory withholding amounts or other withholding rates applicable in your jurisdiction(s), including (i) maximum applicable rates in your jurisdiction(s), in which case you may receive a refund of any over-withheld amount in cash (whether from applicable tax authorities or the Company) and you will have no entitlement to the equivalent amount in Common Shares or (ii) minimum or such other applicable rates in your jurisdiction(s), in which case you may be solely responsible for paying any additional Tax Liability to the applicable tax authorities or to the Company and/or the Service Recipient. Except for Canadian resident Service Providers, if the Tax Liability withholding obligation is satisfied by withholding Common Shares, for tax purposes, you are deemed to have been issued the full number of Common Shares subject to the vested portion of the RSU, notwithstanding that a number of Common Shares is held back solely for the purpose of paying such Tax Liability.

(d) You acknowledge that you may not participate in the Plan and the Company shall have no obligation to deliver Common Shares until you have fully satisfied the Tax Liability, as determined by the Company. Unless any withholding obligation for the Tax Liability is satisfied, the Company shall have no obligation to deliver to you any Common Shares in respect of the RSU.

5. Cash Settlement. For Canadian resident Service Providers, all distributions under this RSU shall be made by the Company in the form of Common Shares. Notwithstanding anything to the contrary in this Agreement, the Company may, in its sole discretion, offer to settle any portion of the RSU otherwise payable in Common Shares in cash and the Service Provider, in its sole discretion, may elect to accept this offer. The cash amount to be paid by the Company upon distribution of any portion of the RSU otherwise payable in Common Shares shall be equal to (i) the number of Common Shares with respect to which the Service Providers is entitled to a distribution multiplied by (ii) the closing trading price for the Common Shares on the stock exchange on which the majority of the Company's Common Shares traded on the applicable distribution date (which may be denominated in either Canadian or US dollars, based on the applicable exchange rate on the day immediately prior to the applicable distribution date) or if the Common Shares are not listed on a stock exchange, then the trading price determined by the Board using good faith discretion.

6. Date of Issuance.

(a) The issuance of shares, if applicable, in respect of the RSU is intended to comply with U.S. Treasury Regulations Section 1.409A-3(a) and will be construed and administered in such a manner. Subject to the satisfaction of the Tax Liability withholding obligation, if any, in the event one or more RSUs payable in Common Shares vests, the Company shall issue to you the number of Common

Shares receivable by the Participant pursuant to this Agreement. Each issuance date determined by this paragraph is referred to as an "***Original Issuance Date***."

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Original Issuance Date does not occur (1) during a period when you are able to trade, as determined in accordance with the Company's then-effective policy on insider trading and applicable securities laws, or (2) on a date when you are otherwise permitted to sell Common Shares on an established stock exchange or stock market (including but not limited to under a previously established written trading plan that meets the requirements of Canadian securities laws applicable to automatic securities trading plans and Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "***Automatic Arrangement***")), *and*

(ii) either (1) a Tax Liability withholding obligation does not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Tax Liability withholding obligation by withholding Common Shares from the shares otherwise due, on the Original Issuance Date, to you under this RSU, and (B) not to permit you to enter into a "same day sale" commitment with a broker-dealer (including but not limited to a commitment under an Automatic Arrangement) and (C) not to permit you to pay your Tax Liability in cash, then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling Common Shares in the open public market but, subject to applicable Canadian securities laws, in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with U.S. Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the Common Shares under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of U.S. Treasury Regulations Section 1.409A-1(d).

7. Transferability. Except as otherwise provided in the Plan, your RSU is not transferable, except by will or by the applicable laws of descent and distribution

8. Governing Law. This RSU Agreement will be governed, construed and administered in accordance with the laws of the Province of British Columbia and the laws of Canada applicable therein.

9. No Liability for Taxes. As a condition to accepting the RSU, you hereby (a) agree to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from the RSU or other Company compensation and (b) acknowledge that you were advised to consult with your own personal tax, financial and other legal advisors regarding the tax consequences of the RSU and have either done so or knowingly and voluntarily declined to do so.

10. Severability. If any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

11. Other Documents. By signing the Grant Notice, you acknowledge:

(a) receipt of the Company's Insider Trading Policy;

(b) that you have read and understand the Plan and accept the RSU in accordance with the terms of this RSU Agreement and the Plan; and

(c) that you agree to be bound by the terms and conditions of the Plan, as the same may be amended, modified, terminated or otherwise changed, in whole or in part pursuant to the terms of the Plan.

Exhibit 21.1

LIST OF SUBSIDIARIES

The following is a list of subsidiaries of Aurinia Pharmaceuticals Inc. as of December 31, 2022.

Subsidiary	**State or Other Jurisdiction of Incorporation or Organization**
Aurinia Pharma U.S., Inc.	Delaware
Aurinia Pharma Limited	United Kingdom

pwc

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the registration statements on Forms S-8 (No. 333-257424, No. 333-253454, No. 333-239048, No. 333-233765, No. 333-225538, and No. 333-216447) and Form S-3 (No. 333-261242) of Aurinia Pharmaceuticals Inc. of our report dated February 27, 2023 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/PricewaterhouseCoopers LLP

Chartered Professional Accountants, Licensed Public Accountants
Oakville, Ontario
Canada
February 27, 2023

Exhibit 31.1

**CERTIFICATION PURSUANT TO RULE 13a-14 OR 15d-14 OF
THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Peter Greenleaf, certify that:

1. I have reviewed this annual report of Aurinia Pharmaceuticals Inc. on Form 10-K;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the period presented in this report;

4. The issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the issuer and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and

5. The issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Dated: February 27, 2023 AURINIA PHARMACEUTICALS INC.

/s/ Peter Greenleaf

Name: Peter Greenleaf

Title: Chief Executive Officer

Exhibit 31.2

**CERTIFICATION PURSUANT TO RULE 13a-14 OR 15d-14 OF
THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Joseph Miller, certify that:

1. I have reviewed this annual report of Aurinia Pharmaceuticals Inc. on Form 10-K;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the period presented in this report;

4. The issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the issuer and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and

5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Dated: February 27, 2023		AURINIA PHARMACEUTICALS INC.
	/s/ Joseph Miller	
Name:	Joseph Miller	
Title:	Chief Financial Officer	

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Aurinia Pharmaceuticals Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter Greenleaf, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2023	AURINIA PHARMACEUTICALS INC.
	/s/ Peter Greenleaf
Name:	Peter Greenleaf
Title:	Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Aurinia Pharmaceuticals Inc. (the “Company”) on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Joseph Miller, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2023	AURINIA PHARMACEUTICALS INC.
	/s/ Joseph Miller
Name:	Joseph Miller
Title:	Chief Financial Officer