

**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, 2023

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)

#140, 14315 - 118 Avenue  
Edmonton, Alberta T5L 4S6

(Address of principal executive offices)

98-1231763

(I.R.S. Employer  
Identification Number)

**Registrant's telephone number, including area code:**

(250) 744-2487

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

<u>Title of Each Class</u>	<u>Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 \$ 1.38 billion based on the closing price for the registrant's common shares as reported by the Nasdaq Global Market on June 30, 2023 (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 14, 2024, there were 144,617,762 of the registrant's common shares outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

**Document Description**

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, 2023 are incorporated by reference into Part III of this Annual Report on Form 10-K.

**10-K Part**

III

## Table of Contents

	<u>Page</u>
<b><u>PART I.</u></b>	
Item 1.	<a href="#">Business</a> 5
Item 1A.	<a href="#">Risk Factors</a> 22
Item 1B.	<a href="#">Unresolved Staff Comments</a> 48
Item 1C.	<a href="#">Cybersecurity</a> 48
Item 2.	<a href="#">Properties</a> 50
Item 3.	<a href="#">Legal Proceedings</a> 50
Item 4.	<a href="#">Mine Safety Disclosures</a> 50
<b><u>PART II.</u></b>	
Item 5.	<a href="#">Market for Registrant’s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities</a> 51
Item 6.	<a href="#">Reserved</a> 52
Item 7.	<a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a> 52
Item 7A.	<a href="#">Quantitative and Qualitative Disclosures about Market Risk</a> 60
Item 8.	<a href="#">Financial Statements and Supplementary Data</a> 62
Item 9.	<a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a> 63
Item 9A.	<a href="#">Controls and Procedures</a> 63
Item 9B.	<a href="#">Other Information</a> 64
Item 9C.	<a href="#">Disclosure Regarding Foreign Jurisdictions the Prevent Inspections</a> 64
<b><u>PART III.</u></b>	
Item 10.	<a href="#">Directors, Executive Officers and Corporate Governance</a> 65
Item 11.	<a href="#">Executive Compensation</a> 65
Item 12.	<a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters</a> 65
Item 13.	<a href="#">Certain Relationships and Related Transactions and Director Independence</a> 65
Item 14.	<a href="#">Principal Accountant Fees and Services</a> 65
<b><u>PART IV.</u></b>	
Item 15.	<a href="#">Exhibits, Financial Statement Schedules</a> 66
Item 16.	<a href="#">Form 10-K Summary</a> 66

---

## PART I

### INTRODUCTION

Unless the context otherwise requires, references in this Annual Report on Form 10-K for the year ended December 31, 2023, or this Annual Report, to “we”, “us”, “our” or similar terms, as well as references to “Aurinia” and “the Company,” 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 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, 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.

All statements, other than statements of historical fact, are forward-looking statements 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), our strategic plan following the conclusion of our strategic review process, including the anticipated timing, design, costs and benefits of the restructuring program, 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 strategy, future operations, future financial position, future revenues, projected costs, prospects and plans;
- objectives of management;
- 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 potential to receive certain payments and royalties under our agreement with Otsuka Pharmaceuticals Co. Ltd;
- our plans to conduct a share repurchase program and the timing, pricing and terms regarding such program;
- the receipt of exemptive relief from Canadian regulators regarding the share repurchase program in a timely manner or at all;
- our strategic plan following the conclusion of our strategic review process, including the anticipated timing, design, benefits and costs of the restructuring program;
- Aurinia’s estimates as to the amount and type of headcount reductions resulting from the restructuring;
- our belief in the duration of patent protection and exclusivity for voclosporin and that the patents owned by us are valid and enforceable;
- our belief in receiving extensions to patent life based on certain events or classifications;
- our plans and expectations and the timing of commencement, enrollment, completion and release of results of clinical trials;
- our belief that LUPKYNIS 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 estimate on the timing to obtain regulatory approval for the use of the monoplant facility;
- our estimate on the timing to obtain backup encapsulation facilities;
- our estimates as to the key potential benefits of and 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 estimates as to the trajectory and timing of completion of post-marketing studies and commitments to the FDA;
- the potential impact of shareholder activism on our business;
- our belief that our net product revenue will continue to increase as we continue to execute on our commercialization strategy for LUPKYNIS;
- our expectation that we will continue to incur significant expenses in Selling, General and Administrative (SG&A) in our commercialization of LUPKYNIS, and that research and development spend will decrease;
- 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 additional patents may be granted in other major global pharmaceutical markets based on our filings under the Patent Cooperation Treaty (PCT);
- 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; and
- the potential impact of widespread health concerns on our business operations, nonclinical and clinical trials, regulatory timelines, supply chain, and potential commercialization.

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;
- our assumptions related to timing of generics and competitors entering the market;
- 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;
- assumptions related to the costs, benefits and scope of the restructuring program, including the steps and elements involved therein;
- 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 continued commercial value for LUPKYNIS in LN 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 and elevated interest rates, and global hostilities on our business and operations including sales, marketing, operations, nonclinical and clinical and our supply chain;
- legislative, regulatory and commercial activities, including laws regulating the pricing of LUPKYNIS;
- difficulties obtaining adequate reimbursements from third party payors;
- uncertainties related to the restructuring program and our ability to realize the anticipated benefits thereof;
- 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, 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 people living with autoimmune diseases with high unmet medical needs. 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 clinical and regulatory activities to support the LUPKYNIS development program. We contracted with Otsuka Pharmaceutical Co., Ltd. (Otsuka) as a collaboration partner for the 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).

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. 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 for the year ended December 31, 2022. On November 29, 2022 the Medicines and Healthcare products Regulatory Agency (MHRA) had granted marketing authorization of LUPKYNIS in Great Britain. On April 24, 2023, LUPKYNIS received regulatory approval in Switzerland. During the third quarter of 2023, the Company received notification that the pricing and reimbursement milestone was secured. As a result, this triggered a \$10.0 million milestone which was recognized as collaboration revenue for the year ended December 31, 2023. On November 10, 2023, Otsuka filed a new drug application (NDA) for voclosporin for the treatment of LN with the Japanese Ministry of Health, Labour, and Welfare for the manufacture and sale in Japan of voclosporin.

### 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 elevated proteinuria 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-marketing 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; and
- evaluating external assets with the potential to be synergistic and complementary to our clinical, regulatory and therapeutic areas of expertise.

## DEVELOPMENTS

### Conclusion and Overview of Strategic Review Process

Effective February 14, 2024, the Board of Directors (the Board) elected to conclude its strategic review process.

Effective immediately, we are discontinuing our future development of AUR200 and AUR300 research and development programs and prioritizing resource allocation. This will result in a one-time charge in the first quarter of 2024 of approximately \$11 - \$15 million and expected operational cost savings of approximately \$50 - \$55 million annually, with approximately 75% of the savings being recognized in 2024 excluding the one-time restructuring charge in the first quarter of 2024. The Board also approved a share repurchase program of up to \$150 million worth of our common shares, affirming its confidence in the Company's growth prospects. The maximum value of the share repurchase program is subject to receipt of regulatory approval in Canada.

The Board initiated a robust strategic review at the end of June 2023 to review all strategic options for Aurinia. Together with management, JP Morgan, our financial advisor in the strategic review process, engaged with more than 60 parties, receiving only one non-binding expression of interest, which included a due diligence process, but did not result in a formal offer.

Aurinia also explored potentially acquiring or licensing other entities or assets during this time. After assessing a range of alternatives over the last seven months, the Board elected to conclude Aurinia's strategic review process. The Board ultimately determined that none of the explored opportunities that were available to it to pursue were in the best near-term interests of the Company to execute on and that the best path forward is for management to streamline its operations and focus on our commercial execution.

Additionally, in 2018, the Company under previous management and at the Board's discretion, engaged a leading investment bank to conduct a confidential strategic review process. During the 2018 process, we received only one non-binding expression of interest to acquire the Company, which included a due diligence process, but did not result in a formal offer.

Outside of these two expressions of interest, we have never received an offer of any kind to acquire the Company. The Board and management remain open to exploring opportunities that are in the best interests of the Company and are open to considering any bona fide offers that we may receive.

We are reaffirming our commitment to enhancing value by driving LUPKYNIS growth, while maintaining a sharp focus on operating efficiencies and maximizing cash flows. As a result, we are ceasing future development efforts on AUR200 and AUR300. Correspondingly, we expect to take a restructuring charge of approximately \$11 - \$15 million in the first quarter of 2024. The Company anticipates reducing employee headcount by at least 25% by the end of the first quarter of 2024. There is no planned reduction in headcount in commercial or commercial supporting roles.

The charge will primarily be made up of severance costs, contract termination costs and other costs associated with terminating the programs. We expect to recognize annual cost savings of approximately \$50 - \$55 million, with approximately 75% of the savings being recognized in 2024 excluding the one-time restructuring charge in the first quarter of 2024, with no impact on commercial investment.

In addition, the Board has approved a share repurchase program of up to \$150 million of Common Shares, reflecting confidence in Aurinia's growth prospects and a continued commitment to creating long-term value to shareholders and other stakeholders. We have submitted an exemptive relief application to applicable Canadian securities regulators which, if granted, would permit us to purchase up to 15% of the issued and outstanding Common Shares of the Company in any 12 month period for 36 months (the Exemptive Relief). There is no assurance the Exemptive Relief will be granted on the terms applied for or at all. If the Exemptive Relief is not granted, the maximum we may purchase under this share repurchase program in reliance on the normal course issuer bid exemption under applicable Canadian securities regulation is 5% of our current issued and outstanding Common Shares (being 7,230,888 Common Shares).

Purchases under the share repurchase program will commence on or around February 21, 2024. The expiry date of the share repurchase program is not currently known. This program may be implemented through open market or privately negotiated purchases, including under a plan intended to benefit from the affirmative defense under Rule 10b5-1, Rule 10b-18 or an automatic securities purchase plan, an accelerated share repurchase program, or other mechanisms. The timing and amount of repurchase transactions will be determined by management based on its evaluation of market conditions, share price, legal requirements, including applicable blackout period restrictions, and other factors. The purchase price of any Common Shares will be determined in accordance with applicable U.S. securities laws and subject to receiving the Exemptive Relief, the value

of the consideration offered per Common Share will not exceed the market price of the Common Shares calculated pursuant to applicable Canadian securities regulation.

### **Regulatory/Commercial**

On April 11, 2023, we announced that the United States Patent and Trademark Office (USPTO) had issued a new and refined method of use patent titled IMPROVED PROTOCOL FOR TREATMENT OF LUPUS NEPHRITIS. Our newly issued U.S. Patent (No. 11,622,991) 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 MMF and corticosteroids using eGFR as a method of pharmacodynamically dosing the product in patients with LN. The newly issued patent provides 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. U.S. Patent No. 11,622,991 is listed in the Orange Book.

On December 20, 2023, we announced the submission of our Investigational New Drug application (IND) to the FDA for AUR200, a potential next generation therapy for B-cell mediated autoimmune diseases. The IND was made effective on January 18, 2024. On February 15, 2024, we announced that we are ceasing future development of AUR200 and AUR300 research and development programs and prioritizing resource allocation.

### **Refreshment of Board of Directors**

On August 18, 2023, we appointed Dr. Karen Smith and Jeffrey A. Bailey to our Board of Directors. Dr. Smith and Mr. Bailey both have deep experience in biopharma leadership, commercial strategy, mergers and acquisitions and advancing therapeutic pipelines. We also appointed Dr. Daniel G. Billen as Chair of the Board of Directors. He has been a member of the Board since 2019.

On September 21, 2023, pursuant to the Cooperation Agreement dated as of September 21, 2023, by and among Aurinia, MKT Capital Ltd., MKT Tactical Fund, SP and Antoine Khalife, we appointed Dr. Robert T. Foster to our Board of Directors. Dr. Foster founded Isotechnika Pharma Inc. (the former name of Aurinia) in 1993 and was its Chairman and CEO for approximately 21 years. During his tenure at Isotechnika, Dr. Foster invented voclosporin. For further discussion, refer to Note 19, "Related Party".

### **Study Updates**

On April 5, 2023, we announced promising results from the AURORA Renal Biopsy Sub-Study. The addition of LUPKYNIS on top of the then current standard of care MMF and low-dose steroids in our Phase 3 AURORA 1 and AURORA 2 studies led to significantly earlier and greater reductions in proteinuria while maintaining stable renal function, as evidenced by a stable eGFR slope over time. To further characterize the long-term impact of LUPKYNIS on the kidney at the histologic level, repeat biopsies were collected from selected patients in both treatment arms (the active control arm with patients treated with only MMF and steroids, and the study arm of voclosporin in combination with MMF and steroids). The patients in the voclosporin treatment arm demonstrated histologic activity improvement with stable chronicity scores similar to the active control arm of MMF and low dose steroids alone over the 18-months average treatment period at the time of repeat biopsy.

### **Market Potential and Commercial Considerations**

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 an almost three 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 and evidence of better preservation of kidney function in the LUPKYNIS-treated group.

The price of LUPKYNIS is based on one unit of 60 capsules we refer to as a “wallet”. As of January 1, 2024, the wholesale acquisition cost (WAC) of a LUPKYNIS wallet is \$4,898. 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, a drug-drug interaction study (PMC) was submitted in October 2022 and a milk only lactation study was submitted in June 2023. The remaining PMRs are all progressing within the expected timelines. We expect to complete two pediatric studies due in 2025 and 2031.

#### **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.

#### **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. Patent protection for patents related to the composition of matter of voclosporin are expected to 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 have received, an interim patent term extension until October 17, 2024. 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" equivalent exclusivity for voclosporin in certain European 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 April 2023, the USPTO issued a new and refined method of use patent. Our newly issued U.S. Patent (No. 11,622,991) 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 the product in patients with LN. The newly issued patent provides coverage that supplements the '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, and is listed in the Orange Book.

## **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 treated 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 first generation CNIs such as tacrolimus. Many of the biotechnology, pharmaceutical or biopharmaceutical companies that could or do compete with LUPKYNIS 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 include, but are not limited to, diagnosis, market development, efficacy, safety and tolerability profile, reliability, convenience of dosing, pricing, the level and timing of generic competition and reimbursement. As 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 our collaboration partner 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 European Commission (EC) and MHRA approvals received in the second half of 2022 and the Swissmedic approval was received in the first half of 2023. 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, (in which the Japanese New Drug Application (J-NDA) was submitted on November 10, 2023) 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, Swissmedic 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, now that LUPKYNIS has received marketing approval in the EEA, we expect that we and Otsuka will benefit from eight years of data exclusivity and 10 years of marketing exclusivity from approval. 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 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 sites. 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, LUPKYNIS 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 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 LUPKYNIS 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 LUPKYNIS 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 LUPKYNIS.

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 (IRA) 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 took 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 use a dedicated manufacturing capacity within Lonza’s existing small molecule facility in Visp, Switzerland. The dedicated facility (also referred to as monoplant) is 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. We 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 obtain regulatory approval 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 and market access.

#### **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, 2023, 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.

## LIVING OUR VALUES

*We are a dedicated team of experts committed to changing the trajectory of autoimmune diseases with unmet medical needs. We are relentless in our pursuit to provide transformative medical treatments. We are resilient. We care for our patients and for each other.*



### 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. We have also established periodic mental health sessions to help our employees 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 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, our 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 change the trajectory of autoimmune, kidney and rare diseases, we believe that we must take a holistic approach to address/improve our impact on the communities we serve. Therefore, we have established environmental, social, and governance priorities. The Governance & Nomination Committee of our Board of Directors is responsible for ensuring our ESG goals are pursued and assessed periodically. Progress on these goals will be disclosed in future sustainability reports.

### Corporate Values and Ethics

We understand that adhering to established best practices of corporate governance is critical to earning and maintaining the trust of our shareholders, customers, employees, and other stakeholders, and is essential to building long-term value. Our Governance and Nomination Committee is responsible for developing our approach to ESG issues and implementing high

standards of corporate governance practices. Our CEO and CFO are also responsible for leading and managing our approach to corporate social responsibility.

Our Board of Directors adopted and regularly reviews the Code of Conduct, which applies to all of our employees, officers and directors. Adherence to the Code of Conduct helps ensure that all employees can feel a part of an organization that emphasizes adherence to laws and policies covering the industry in which we work. Our Code of Conduct also emphasizes each employee's accountability for making decisions and taking actions in a highly ethical manner with a focus on honesty, fairness and integrity and treating all fellow employees in a respectful and inclusive manner. We have established a reporting hotline that enables employees to file anonymous reports of any suspected violations of the Code of Conduct. We believe that providing an ethical environment in which to work is vital to our efforts to attract, retain and develop our employees.

### ***Diversity and Inclusion***

We seek to build and maintain a diverse team of employees that are passionate about and committed to having a positive impact on the lives of patients and their families. We value and celebrate the unique talents, backgrounds and perspectives each employee contributes to achieving our mission and corporate objectives. Our diverse and inclusive culture is key to attract, develop and retain our talent pool.

As an equal opportunity employer, we strive to attract and connect with diverse talent who best match our core values and who will be successful and thrive at Aurinia. Our recruiting team partners with hiring managers and we select diverse interview panels to help provide insight at every stage of the process to identify the best possible candidate – whether internal or external – to fill open roles in the company.

### ***Professional Development for Employees at All Levels***

We are firmly committed to employee development as an essential driver of our future growth and overall success of Aurinia. Developing employees' skills and capabilities align with our commitment to investing in our people, as well as our commitment to quality and safety. It also ensures we have the right talent in the right places across the organization to be successful.

In 2023 we conducted a needs analysis, based on our competency model. As a result, we offered new training to all employees on topics such as collaboration, communication, and listening. We also offered programs on engagement, performance management, and launched a popular "Talk About" series where employees learn about different groups at Aurinia and how they contribute to our Vision and Mission.

Developing our managers continues to be an important priority for the Company. In 2023 we piloted a program dedicated to that population, *Dynamic Leadership @ Aurinia*. The focus of this interactive, multi-week program is to develop an authentic leadership style grounded in Aurinia's values. Participant feedback about the program was outstanding and the program will continue to be offered in 2024.

We provide our employees with developmental training in accordance with their specific role and career path, paying considerable attention to any new upcoming regulations and procedures. All employees also attend or participate in compliance, harassment prevention, and safety training and we offer education assistance for college and university courses, training seminars and educational conference attendance opportunities to our employees. To monitor progress, we review our succession plan for key senior management positions as part of our annual talent review and identify development opportunities to help ensure potential successor readiness.

### ***Employee Engagement***

Building trust and a high performing culture is a top priority for Aurinia. We achieve this by providing a platform for employees to give feedback, collaborate on solutions, and discuss how to make changes to help improve our experience at work.

During 2023, Aurinia partnered with Gallup to conduct its first employee Engagement & Inclusion survey designed to assess overall employee engagement and illuminate where engagement can be enhanced. The anonymous survey evaluated four key factors – Basic Needs, Individual Contribution, Teamwork, Growth, and Inclusion. The survey data is being used to start an ongoing internal dialogue, action planning and measurement that will enable leadership to understand and improve company-wide engagement levels, seek employee ideas to sustain areas of strength and improve gaps, turn ideas into actionable strategies

that align with Aurinia's values, prioritize purpose, ownership, and accountability and continue building a culture of engagement, inclusion, and performance excellence.

We hold frequent all-employee meetings that serve as an open forum to share progress on strategy and corporate goals as well as potential at-risk areas, celebrate achievements, and share best practices and learnings.

### ***Compensation & Benefits***

Our compensation and benefits programs, with oversight from the Compensation Committee of our Board of Directors, are designed to attract, retain and reward employees through competitive salaries, annual bonus eligibility, long-term incentive awards, an Employee Stock Purchase Plan, a 401(k) Plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and employee assistance programs. Each year we conduct surveys to benchmark our salaries and benefits and confirm we are satisfied with the competitiveness of our total compensation offering. We also provide a variety of peer-to-peer and corporate recognition programs to celebrate and recognize our employees for their hard work and contributions.

### ***Our Commitment to Safety***

Our employees' health, safety, and overall well-being is a top priority for us. We track this in a variety of ways, including providing all of our employees access to healthcare benefits, measuring the number of employees participating in our health and wellness events, ensuring 100% of our employees are covered by an occupational health and safety management system, and minimizing work-related injuries.

We are committed to maintaining compliance with all legal and regulatory requirements in the countries in which we operate.

We are also deeply committed to the safety and well-being of the communities we serve. With support from patients, family members, caregivers and healthcare providers, we provide up-to-date safety information on our medicines, and ensure the highest quality.

### ***Empowering the Lupus Nephritis Community***

Through our various educational and disease management programs, we encourage people living with LN to take charge of their health through early diagnosis, routine management, and treatment, with a focus on Access, Education, Advocacy, Science and Safety.

### ***Doing Our Part to Help the Environment***

We seek to improve the health and sustainability of our planet, as the well-being of our planet directly impacts the health of humanity. We recognize that energy, water, materials use, greenhouse gas emissions, material and hazardous waste, and transportation are among the largest contributors to our environmental footprint. Many of our impacts on the planet are indirect – for instance, we do not manufacture the drug product, the capsules, or the packaging for LUPKYNIS ourselves, but instead do so through our manufacturing partners located across the globe. Similarly, we use a third-party logistics firm to transport LUPKYNIS to specialty pharmacies and specialty distributors directly, who then in turn dispenses LUPKYNIS to patients and hospitals. These contribute to our Scope 3 emissions as a result.

However, although our direct impact on the environment may be small, we take our direct and indirect role in environmental protection matters very seriously. As a first step to assess our impact, our facilities, manufacturing, supply chain and procurement teams began a process of collecting data across these areas. Our next steps will be to establish better tracking and measurement tools, refine strategies, and determine targets to drive our, and our partners' environmental performance. This process will enable us to increase our internal and external transparency and report progress against specific goals.

### ***Corporate Citizenship***

We believe in supporting the community in which we work and providing our employees multiple opportunities to contribute to the community, including providing company-wide community service days/volunteerism supporting:

- Patient advocacy/healthcare;
- Health disparities;

- Charitable giving;
- Community services (e.g., food, clothing and school supply drives); and
- Participate in company -wide walks for various diseases.

## CORPORATE INFORMATION

Aurinia is organized under the *Business Corporations Act* (Alberta). We have two wholly-owned subsidiaries: Aurinia Pharma US, Inc., (Delaware incorporated) and Aurinia Pharma Limited (United Kingdom incorporated). Our head and registered office is #140, 14315 - 118 Avenue, Edmonton, Alberta, Canada T5L 4S6 and our phone number is +1 (250) 744-2487. Our U.S. commercial office is located at 77 Upper Rock Circle, Suite 700, Rockville, Maryland 20850.

Our website address is [www.auriniapharma.com](http://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](http://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.sedarplus.ca](http://www.sedarplus.ca).

### 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 us or that we currently deem to be immaterial may also harm our business, operating results and financial condition. If any of the following events occur or risks materialize, it could harm our business, operating results and financial condition and cause the trading price of our common shares to decline.

#### Risks Related to Commercialization

*Our success depends on our ability to commercialize LUPKYNIS. We are currently a single approved product company with commercial sales experience since January 2021 and if we are not able to achieve our financial targets related to commercializing LUPKYNIS, then we may need to curtail or cease operations.*

Our business strategy is to optimize the clinical and commercial value of LUPKYNIS. We have invested a significant portion of our efforts and financial resources in the development and commercialization of LUPKYNIS, and we expect LUPKYNIS to constitute our only product revenue for the foreseeable future. Our success depends on our ability to commercialize LUPKYNIS successfully. Successful commercialization of LUPKYNIS is subject to many risks. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than we have.

We have limited experience commercializing pharmaceutical products as an organization, having received marketing approval for LUPKYNIS, our sole commercial product, in January 2021. In order to market LUPKYNIS successfully, we must continue to build our sales, marketing, managerial, compliance, and related capabilities or make arrangements with third parties to perform these services. If we are unable to establish and maintain adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to commercialize LUPKYNIS appropriately and may not become profitable.

Part of our strategy to commercialize LUPKYNIS in the United States is to maintain a direct field work force. These efforts have been and will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully develop and maintain this capability. LUPKYNIS has only been a marketed product since January 2021. In addition, prior to December 2020, there were no FDA approved treatments for LN. If we are unable to effectively train our field work force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers, our efforts to commercialize successfully could be harmed, which would negatively impact our ability to generate product revenue.

***Our ability to successfully commercialize LUPKYNIS will depend on effectively deploying the field work force we have established and maintaining marketing, manufacturing, and distribution capabilities or relationships.***

Our ability to generate revenues and meet expectations is contingent on the successful commercialization of LUPKYNIS. A successful commercialization depends on our ability to, amongst other things:

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

Many of these factors are beyond our control and if we are not successful in commercializing LUPKYNIS, or are significantly delayed in doing so, our business will be harmed, and we may need to curtail or cease operations.

***We depend on a limited number of customers and an estimated number of patients for a significant amount of our product revenue, and if we lose any of our significant customers, or if our estimates as to the number of potential patients is wrong, our business could be harmed.***

The bulk of our product revenue is generated in the United States from a limited number of direct customers and most of our product revenue comes from two specialty pharmacies. Revenues from our two main customers in the U.S. accounted for approximately 51% and 40%, respectively, of our total revenues for the year ended December 31, 2023. Our third main customer is our collaboration partner, Otsuka. When combined, revenues from our two specialty pharmacy customers and Otsuka account for approximately 99% of our total revenues for the year ended December 31, 2023. The loss by us of any of these customers, or a material reduction in their purchases, could harm our business and prospects. In addition, if any of these customers were to fail to pay us in a timely manner, it could negatively impact our cash flow from operations.

Sales of our product can be greatly affected by the customer inventory levels that our customers carry. We monitor customer inventory of our product using a combination of methods, including reports from our customers, and our own internal estimates. Our estimates of customer inventory may differ significantly from actual customer inventory levels. Significant differences between actual and estimated customer inventory levels may result in excessive or insufficient stocking, which could result in substantial quantities of unsold customer inventory, or inadequate supplies of products in the distribution channels. Our customers make the ultimate determination of the amount of inventory to hold. Changes in customer inventory may cause our revenues to fluctuate significantly from quarter to quarter and may cause our operating results for a particular quarter to be below or above our expectations, the expectations of securities analysts, or the expectations of investors.

Our estimates of the number of patients who have received or might have been candidates to use LUPKYNIS may not accurately reflect the true market for LUPKYNIS or the extent to which it will actually be used by patients. Our failure to develop the market for, forecast or successfully market LUPKYNIS could harm our business, as it could reduce our market potential.

**LUPKYNIS may not achieve or maintain expected levels of market acceptance among physicians, patients, the medical community, and third-party payors, which could harm our business, financial condition and results of operations and could cause the market value of our common shares to decline.**

The commercial success of LUPKYNIS is dependent upon achieving and maintaining market acceptance among physicians, patients, and the medical community. Levels of market acceptance for LUPKYNIS could be impacted by several factors, many of which are not within our control, including but not limited to:

- limitations or warnings contained in the approved labeling;
- changes in the standard of care for the targeted indication;
- limitations in the approved clinical indication;
- demonstrated clinical safety and efficacy compared to other products;
- potential for significant adverse side effects;
- sales, marketing, and distribution support;
- availability and extent of reimbursement from managed care plans and other third-party payors;
- timing of market introduction;
- the degree of cost-effectiveness;
- widespread health concerns, such as pandemics;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;
- adverse publicity about our product or favorable publicity about competitive products;
- convenience and ease of administration of LUPKYNIS; 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.

**LUPKYNIS may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.**

Price controls and price pressure may be imposed in foreign and U.S. markets, which may adversely affect our future profitability. LUPKYNIS may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business. In addition, reimbursement may be limited or unavailable in certain market segments which could make it difficult for us or our partners to sell LUPKYNIS profitably. Adverse pricing limitations might hinder our ability to recoup our investment in LUPKYNIS.

Our ability to commercialize LUPKYNIS successfully will also depend in part on the extent to which coverage and reimbursement for LUPKYNIS will be available from government authorities, private health insurers and other organizations. In the United States and markets in other countries, patients generally rely on third-party reimbursement for all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to market acceptance of LUPKYNIS. Our ability to successfully commercialize LUPKYNIS will depend in part on the extent to which coverage and adequate reimbursement of LUPKYNIS will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors such as private health insurers and health maintenance organizations, decide which medication they will pay for and establish reimbursement levels, which for the product, is beyond our control.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be certain that coverage will be available for LUPKYNIS and, if available, the level of reimbursement. Reimbursement will impact the demand for, or the price of, our approved product. If reimbursement is limited or not available, we might not be able to successfully commercialize LUPKYNIS.

There may be delays in obtaining reimbursement for recently approved products and eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, patient services, sale, and distribution. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors. Private third-party payors often rely on Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and

profitable payment rates from both government funded and private payors for our approved product could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize LUPKYNIS and on our overall financial condition.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, results of operations and financial condition.***

We participate in the Medicaid Drug Rebate Program, as administered by Centers for Medicare and Medicaid Services, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with products, including LUPKYNIS, that are dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs.

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

***We report on various metrics relating to LUPKYNIS activity, and no single metric is indicative of, or directly correlated to, our current or future financial performance.***

We report on various metrics relating to LUPKYNIS activity, including the number of prescriptions/PSFs, conversion rates (being the proportion of PSFs that convert into patients on therapy), persistency rates (being how long patients on therapy remain on therapy), adherence (being the degree to which patients take their prescribed dose of LUPKYNIS in the manner and at the times prescribed by their doctor), numbers of patients on therapy and as of the fourth quarter of 2023, we also include patient restarts and patients resulting from hospital fills (which are estimated based on shipping patterns). None of these metrics, in and of themselves, is indicative of current or future financial performance. There is no guarantee that a patient for whom we receive a PSF will become a patient on therapy, or that the number of patients estimated from hospital fills are accurate. Converting a patient from a PSF into a patient on therapy includes multiple steps, many of which are outside of our control, such as patients and doctors needing to coordinate applications relating to insurance coverage for LUPKYNIS, and potentially one or more appeals if coverage is denied initially. We refer to patients for whom we receive a PSF but that never convert into a patient on therapy as a cancellation. Cancellations result in zero revenue. Even when a patient becomes a patient on therapy, there is no guarantee that they will be a patient for which we receive revenue (as certain patients are eligible for our free drug program), or that they will remain on drug for any period of time (whether due to a reduction in LN activity, an actual (or perceived) drug-related adverse event, or from a lack of taking medication, or otherwise). Patients on therapy may also not take their prescribed dose of LUPKYNIS in the manner and at the times prescribed by their doctor, which could result in reduced orders of LUPKYNIS in respect of that patient on therapy versus a patient that is prescribed a higher dose of LUPKYNIS and follows their prescription exactly as prescribed. We refer to patients who have converted from a PSF into a patient on therapy, but who subsequently cease treatment (for any reason), as discontinuations. A patient on therapy who discontinues treatment generally results in zero future revenue, and discontinuations can occur at any time once a patient commences therapy. Accordingly, our PSF activity, and related metrics, are not in and of themselves directly indicative of our current or future financial performance.

Our net product revenue to date is primarily the result of our two main customers in the United States (our two specialty pharmacies) who order LUPKYNIS for dispensing to patients, and from our collaboration partner, Otsuka (see further under "Summary of Significant Accounting Policies - Revenue Recognition" later in this Report for further discussion). The orders for

product from our two main customers do not necessarily correlate to our PSF numbers. Our revenue received from Otsuka has no relevance to any of the above noted metrics. Our revenue could therefore fluctuate in a manner contrary to our PSF trends, both where revenue could be greater than a PSF trend would indicate, or where revenue could be lesser than a PSF trend would indicate. Therefore, while we report on PSFs and related figures to provide an indication of potential prescription activity for LUPKYNIS, there is no single metric that is directly correlated to, or indicative of, our future financial performance.

### **Risks Related to Patents and Proprietary Technology**

***Our proprietary rights may not adequately protect our intellectual property and product, and if we cannot obtain adequate protection of our intellectual property and product, we may not be able to successfully market our product.***

Patents and other proprietary rights are essential to our business. Our practice has been to file patent applications to protect technology, inventions, and improvements to our inventions that are considered important to the development of our business.

Our success will depend in part on our ability to obtain patents, defend patents, maintain trade secret protection, and operate without infringing on the proprietary rights of others. Interpretation and evaluation of pharmaceutical patent claims present complex and often novel legal and factual questions. Accordingly, there is some question as to the extent to which pharmaceutical discoveries and related products and processes can be effectively protected by patents. As a result, there can be no assurance that:

- patent applications will result in the issuance of patents;
- patents issued will provide adequate protection or any competitive advantages;
- patents issued will not be successfully challenged and invalidated by third parties;
- LUPKYNIS does not infringe the patents or intellectual property of others;
- that our patents or regulatory protections will provide sufficient duration for LUPKYNIS to reach a level of profitability; or
- that we will be able to obtain any extensions of the applicable patent terms.

Even if issued, patents provide finite terms of protection and, in general, those time periods are not able to be extended. Under law, we have been granted new chemical entity exclusivity for the marketing of LUPKYNIS to January 2026 in the United States. Our original composition of matter patent for voclosporin expired in the United States in October 2022. We have sought a patent term extension to extend the term of that United States patent to October 2027, which remains in process. To date, we have been able to obtain interim patent term extensions for that patent that currently extend its term to October 2024. Our other existing Orange Book listed patents for LUPKYNIS have a term to 2037. Those are the maximum terms for those patents, which are our main protection against generic entrants into the LN market. It is possible that one or more of our patents could be subject to a challenge (such as an *inter partes* review) which, if successful, could limit the protection offered by that patent even further or eliminate it entirely, which would have a negative impact on our ability to continue our business in its current form.

Several pharmaceutical, biotechnology, and medical device companies and research and academic institutions have developed technologies, filed patent applications, or received patents on various technologies that may be related to our business. Some of these technologies, applications or patents may conflict with or adversely affect our technologies or intellectual property rights. Any conflicts with the intellectual property of others could limit the scope of the patents, if any, that we may be able to obtain or result in the denial of patent applications altogether. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

***We may need to license certain intellectual property from third parties, and such licenses may not be available on commercially reasonable terms.***

An unfavorable outcome in an interference or opposition proceeding or a conflict with the intellectual property of others could preclude us or our collaborators or licensees from making, using or selling product using the technology, or require us to obtain license rights from third parties. It is not known whether any prevailing party would offer a license on commercially acceptable terms, if at all. Further, any such license could require the expenditure of substantial time and resources and could harm our business. If such licenses are not available, we could encounter delays or prohibition of the development or introduction of LUPKYNIS.

We may need to enter into license agreements in the future. As part of discovery and development activities, we routinely evaluate in-licenses from academic and research organizations. Future license agreements might impose various diligence, milestone payment, royalty, and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-

performance between us and our licensing partners (such as Otsuka) regarding our rights or obligations under the licensing agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partner's ability to utilize the affected intellectual property in our drug discovery and development efforts, and our ability to ensure into collaboration or marketing agreements for an affected product, may be adversely affected.

***We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.***

Competitors or commercial supply companies or others may infringe our patents and other intellectual property rights. To counter such infringement, we may advise such companies of our intellectual property rights, including, in some cases, intellectual property rights that provide protection for our product, and demand that they stop infringing those rights. Such demand may provide such companies the opportunity to challenge the validity of certain of our intellectual property rights, or the opportunity to seek a finding that their activities do not infringe our intellectual property rights. We may also be required to file infringement actions, which can be expensive and time-consuming. In an infringement proceeding, a defendant may assert, and a court may agree with a defendant, that a patent of ours is invalid or unenforceable or may refuse to stop the other party from using the intellectual property at issue. An adverse result in any litigation could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could impact the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, and defending our intellectual property rights in all countries throughout the world would be prohibitively expensive, time consuming, distract our personnel from their normal responsibilities and might be unsuccessful.

Our intellectual property rights in some countries outside of the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing product made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with 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 LUPKYNIS.***

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Patent reform legislation in the United States and other countries could increase those uncertainties and costs.

The first-to-file provisions of the current United States patent system only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact those provisions will have on the operation of our business. The implementation and interpretation of new patent laws could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***Not all of our trademarks are registered. Failure to secure those registrations could adversely affect our business.***

If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could adversely affect our business. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We will be given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets or other proprietary information.***

There may be an unauthorized disclosure of the significant amount of confidential information under our control. We maintain and manage confidential information relating to our technology, research and development, production, marketing, and business operations and those of our collaborators, in various forms. Although we have implemented controls to protect the confidentiality of such information, there can be no assurance that such controls will be effective. Unauthorized disclosures of such information could subject us to complaints or lawsuits for damages, in Canada, the United States or other jurisdictions, or could otherwise have a negative impact on our business, financial condition, results of operations, reputation and credibility.

**Risks Related to Financial Position and Need for Additional Capital**

***We may 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, 2023. To the extent that we have negative operating cash flow in future periods, we will likely need to allocate a portion of our cash reserves to fund such negative cash flow. We may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that we will be able to generate a positive cash flow from our operations, that additional capital or other types of financing will be available when needed or that these financings will be on terms favorable or acceptable to us if available at all.

We have incurred losses and anticipate that our losses may increase as we continue to expand and develop our business and commercialize LUPKYNIS. As of December 31, 2023, we had an accumulated deficit of \$942.3 million. Although we received FDA approval and commenced commercialization of LUPKYNIS in the United States in January 2021, we have and may continue to incur losses and there can be no assurance that we will be able to generate sufficient product revenue to become profitable at all or on a sustained basis.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or cause any guidance we may provide to be inaccurate.***

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. As we only received FDA approval for LUPKYNIS in 2021, there is an absence of historical sales data. This has resulted in our revenue from product sales being, and we expect will continue to be, difficult to predict. We also expect to have quarter-to-quarter fluctuations in expenses, some of which could be significant, due to 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.

***Our restructuring program and associated organizational changes may not adequately reduce our operating costs or improve operating margins, may lead to additional workforce attrition, and may cause operational disruptions, and there can be no assurance that we will realize the anticipated benefits of the restructuring program.***

On February 15, 2024, we announced that we were implementing a restructuring program. The restructuring program includes ceasing future development activities on AUR200 and AUR300. This will result in a one-time charge in the first quarter of 2024 of approximately \$11 - \$15 million. The charge will primarily be made up of severance costs, contract termination costs and other costs associated with terminating the programs. We expect to recognize annual cost savings of approximately \$50 - \$55 million, with approximately 75% of the savings being recognized in 2024 excluding the one-time restructuring charge in the first quarter of 2024, with no impact on commercial investment. The Company anticipates reducing employee headcount by at least 25% by the end of the first quarter of 2024. There is no planned reduction in headcount in commercial or commercial supporting roles.

The estimates of charges and expenditures, and the associated annual cost savings, we expect to incur in connection with the restructuring program, and timing thereof, are subject to a number of assumptions, including local law requirements in various

jurisdictions, and we may incur costs that are greater, or recognize lower annual cost savings, than we currently anticipate in connection with the restructuring program.

The restructuring program may yield unintended consequences, such as the loss of institutional knowledge and expertise, employee attrition beyond our intended reduction in force, a reduction in morale among our remaining employees, greater than anticipated costs incurred in connection with implementing the restructuring program, and the risks that we may not achieve the anticipated benefits from the restructuring program to the extent or as quickly as we anticipate, if at all, all of which may materially adversely affect our results of operations or financial condition. These restructuring initiatives could place substantial demands on our management and employees, which could lead to the diversion of our management's and employees' attention from other business priorities. In addition, while certain positions are being eliminated in connection with the restructuring program, many functions necessary to our reduced operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees or to external service providers, which could result in disruptions to our operations. We may also discover that the workforce reduction and other restructuring efforts will make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. We may further discover that, despite the implementation of our restructuring program, we may require additional capital to continue expanding our business, and we may not be able to obtain such capital on acceptable terms, if at all. Our failure to successfully accomplish any of the above activities and goals may have a material adverse impact on our business, financial condition and results of operations.

***Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

Our activities to date have been limited to, among other things, organizing and staffing our Company, business planning, business development, raising capital, developing, manufacturing, and 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 and product revenue) from licenses (such as the license granted to Otsuka) and the successful commercialization of LUPKYNIS. 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 investments is subject to market, interest and credit risk that may reduce its value.***

We maintain a portfolio of investments. Changes in the value of our portfolio of 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 investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

***We may require additional financing to achieve our goals, and failure to obtain such when required could force us to delay, reduce or terminate our commercialization efforts.***

We may require additional capital resources to expand and develop our business. Advancing LUPKYNIS inside and outside the United States, marketing for LUPKYNIS, or acquisition and development of any other products will require considerable resources and additional access to capital markets. In addition, our future cash requirements may vary materially from those now expected. Our future capital requirements may increase if for example:

- a. we experience unexpected or increased costs relating to preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, or other lawsuits, brought by either us or our competition;
- b. we elect to develop, acquire or license new technologies, products or businesses;
- c. we are required to perform additional pre-clinical studies and clinical trials; or
- d. we have a change in commercial strategy which could result in increase in headcount, direct to consumer marketing campaigns, and advertising.

We could potentially seek additional funding through corporate collaborations and licensing arrangements or through public or private equity or debt financing. However, if capital market conditions in general, or with respect to life sciences companies such as ours, are unfavorable, our ability to obtain significant additional funding on acceptable terms, if at all, will be negatively affected. Additional financing that we may pursue may involve the sale of common shares which could result in significant dilution to our shareholders. If sufficient capital is not available, we may be required to delay our research and development projects, halt commercialization, relinquish rights to our technologies or products on terms unfavorable to us, which could harm our business, financial condition, prospects or results of operations.

***We may not realize the anticipated benefits of acquisitions or product licenses and integration of these acquisitions and any products acquired or licensed may disrupt our business and management.***

As part of our business strategy, we may acquire additional companies, products or technologies principally related to, or complementary to, our current operations. 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:

- exposure to unknown liabilities of acquired companies and the unknown issues with any associated technologies or research;
- inability to recognize expected benefit of synergies and fully recognize return on investment;
- higher than anticipated acquisition costs and expenses;
- the difficulty and expense of integrating operations, systems, and personnel of acquired companies;
- disruption of our ongoing business;
- inability to retain key customers, distributors, vendors and other business partners of the acquired company;
- diversion of management's time and attention; and
- 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.

#### **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.

***Even though the FDA has approved LUPKYNIS, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, LUPKYNIS could be subject to restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with LUPKYNIS.***

The FDA and other agencies, including the U.S. Department of Justice (DOJ) closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use. If we market LUPKYNIS in a manner inconsistent with our approved labeling and indication, we may be subject to enforcement action for off-label marketing. Violations of the federal FDCA and other statutes, including the *False Claims Act* (FCA), relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which violations may result in the imposition of significant administrative, civil and criminal penalties.

The manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and recordkeeping for LUPKYNIS will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with GMP and GCP for clinical trials that we conduct post-approval.

Discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

There can be no assurance that we will be able to adapt to changes in existing requirements, adopt new requirements or policies, or maintain regulatory compliance. If we fail to maintain compliance, we may lose marketing approval, which would harm our business, prospects, and ability to achieve or sustain profitability.

***LUPKYNIS may have undesirable side effects which may require it to be taken off the market, include additional safety warnings or otherwise limit sales.***

LUPKYNIS has undergone safety testing, however, not all adverse effects can be predicted or anticipated. Unforeseen side effects from LUPKYNIS could arise after the approved product has been marketed. Ongoing or future trials of our product may not support the conclusion that LUPKYNIS has an acceptable safety profile or the FDA may disagree with our clinical trial investigators' interpretation of data from clinical trials or post marketing surveillance in determining if adverse or unacceptable side effects are related to LUPKYNIS. There can be no assurance that discovery of previously unknown adverse events or other problems with LUPKYNIS, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, will not occur at any time during commercial and future use of LUPKYNIS. Furthermore, there can be no assurance that disease resistance or other unforeseen factors will not limit the effectiveness of LUPKYNIS. The most common adverse reactions to LUPKYNIS demonstrated in our Phase 3 AURORA study were glomerular filtration rate decrease, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite. These common adverse reactions were also repeated in our AURORA 2 continuation study and our real world experience with LUPKYNIS since our product launch in 2021. Any adverse discoveries may yield various results, including:

- a. regulatory authorities may require us to take LUPKYNIS off the market;
- b. regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;

- c. we may be required to change the way LUPKYNIS is administered, impose other risk-management measures, conduct additional clinical trials or change the labeling of LUPKYNIS;
- d. we may be subject to limitations on how we may promote LUPKYNIS;
- e. sales of LUPKYNIS may decrease significantly;
- f. refusal to approve pending applications or supplements to approve application that we submit;
- g. recall of products;
- h. refusal to permit the import or export of LUPKYNIS; and
- i. we may be subject to litigation or product liability claims.

Any of these events could prevent us, our collaborators (including Otsuka) or our potential future partners from achieving or maintaining market acceptance of LUPKYNIS or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of LUPKYNIS. It would harm our business, reputation, prospects and ability to achieve or sustain profitability.

***We or our partners (including Otsuka) may never obtain full approval or commercialize LUPKYNIS outside of the United States, which would limit our ability to realize their full market potential.***

To market any products outside of the United States, we and Otsuka or other potential future partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and may require additional pre-clinical studies, clinical trials, or additional administrative review periods, which could result in significant delays, difficulties, and costs for us. While we have obtained approval by the EC and MHRA, specific jurisdictions covered by those approvals (and approvals in other jurisdictions) also require additional regulatory approvals, such as pricing and reimbursement approval, before sales can commence in those jurisdictions. Not all of those jurisdictions have provided all such approvals to date.

In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. If regulatory approval is obtained it may not be as broad as what was obtained in other jurisdictions. We have limited experience in obtaining regulatory approval in international markets. If we or our current or future partners fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of LUPKYNIS could be harmed.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and we may be required to limit commercialization of or recall LUPKYNIS.***

We face an inherent risk of product liability exposure related to the testing of product candidates in human clinical trials, and an even greater risk in connection with our commercialization of LUPKYNIS. If we cannot successfully defend ourselves against claims that LUPKYNIS causes injuries, then we could incur substantial liabilities. Regardless of merit of eventual outcome, liability claims may result in:

- a. decreased demand for LUPKYNIS;
- b. injury to our reputation and significant negative media attention;
- c. withdrawal of clinical trial participants;
- d. significant costs to defend the related litigation;
- e. substantial monetary awards to trial participants or patients;
- f. loss of revenue; and
- g. the inability to, or restrictions on our ability to, commercialize any approved product.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. The obligation to pay any product liability claim in excess of whatever insurance we can acquire, or the recall of or limitation on our ability to commercialize LUPKYNIS as a result of product liability concerns, could harm our business, financial condition, and future prospects.

***Compliance with ongoing post-marketing obligations for LUPKYNIS may uncover new safety information that could give rise to a product recall, updated warnings, or other regulatory actions that could have an adverse impact on our business.***

After a regulatory body, such as the FDA, approves a drug or biologic for marketing, the product's sponsor must comply with several post-marketing obligations that continue until the product is discontinued. These post-marketing obligations include the reporting of adverse events to the agency within specified timeframes, the submission of product-specific annual reports that include changes in the distribution, manufacturing, and labeling information, and notification when a drug product is found to have significant deviations from its approved manufacturing specifications (among others). Our ongoing compliance with these types of mandatory reporting requirements could result in additional requests for information from regulatory bodies that govern our products and, depending on the scope of a potential product issue that a regulatory body may decide to pursue, could potentially also result in a request from the agency to conduct a product recall or to strengthen warnings and/or revise other label information about the product. Regulatory bodies may also require or request the withdrawal of the product from the market. Any of these post-marketing regulatory actions could materially affect our sales and increase our costs and, therefore, have the potential to adversely affect our business, financial condition, results of operations and cash flows.

***We may not be successful in our efforts to build out a pipeline of product candidates.***

We may not be able to continue to identify or develop, at all or in a timely manner, new products. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development or commercialization. If we do not successfully identify, develop, and commercialize new products based upon our approach, we will not be able to diversify our portfolio which could result in harm to our financial position and impact the trading price of our common shares.

#### **Risks Related to Our Reliance on Third Parties and Partners**

***We are dependent on Otsuka for the development and commercialization of LUPKYNIS in several countries outside the United States. The failure to meet contractual, regulatory, or other obligations could adversely affect our business.***

We have entered into an exclusive license agreement with Otsuka that provides the licensee exclusive rights to the development and commercialization of LUPKYNIS in various specified regions outside of the United States. As a result, we are dependent on Otsuka to achieve full regulatory approval of LUPKYNIS for marketing in these regions and for the commercialization of LUPKYNIS, if approved. The timing and amount of any milestone and royalty payments we may receive under this agreement, as well as the commercial success of LUPKYNIS in those regions outside of the United States, will depend on, among other things, the efforts, allocation of resources, and successful commercialization of LUPKYNIS by Otsuka. Otsuka, accounted for approximately 8% of the Company's total net revenue for the year ended December 31, 2023.

We also depend on Otsuka to comply with all applicable laws relative to the development and commercialization of LUPKYNIS in those countries. We do not control the individual efforts of Otsuka and have limited ability to terminate this agreement if Otsuka does not perform as anticipated. The failure of Otsuka to devote sufficient time and effort to the development and commercialization of LUPKYNIS, or the failure of Otsuka to meet their obligations to us, including for future royalties, milestone payments, manufacturing services payments and other collaboration payments; to adequately deploy business continuity plans in the event of a crisis; and/or satisfactorily resolve significant disagreements with us or address other factors, could harm our financial results and operations.

If any licensee or authorized sub-licensee of LUPKYNIS 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. These problems include difficulties with production costs and yields, stability, quality control and assurance, and shortages of qualified personnel, as well as compliance with strictly enforced federal, provincial, state, and foreign regulations. We rely on a limited number of third parties to manufacture and supply raw materials for LUPKYNIS. The third parties we choose to manufacture and supply raw materials for LUPKYNIS are not under our control and may not perform as agreed or may terminate their agreements with us, and we may not be able to find other third parties to manufacture and supply raw materials on commercially reasonable terms, or at all. If any of these events were to occur, our operating results and financial condition would be adversely affected.

In addition, drug and chemical manufacturers are subject to GMP regulations and various regulatory inspections, including those conducted by the FDA, to ensure strict compliance with GMP and other government regulations. While we are obligated to audit the performance of our third-party contractors, we do not have complete control over their compliance. We could be adversely impacted if our third-party manufacturers or distributors do not comply with these standards and regulations. For non-compliance, the regulatory authority may levy penalties and sanctions, including fines, injunctions, civil penalties, failure of the government to grant review of submissions or market approval of products, or cause delays, suspension or withdrawal of approvals, product seizures or recalls, operating restrictions, facility closures and criminal prosecutions. Any of this will have an impact on our business, financial condition, and results of operations.

The process of manufacturing LUPKYNIS is susceptible to product loss due to a variety of factors, including but not limited to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product or in the manufacturing facilities in which our product are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any adverse developments affecting manufacturing operations for our product may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of LUPKYNIS. 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 conflicts in Ukraine and in the Middle East, the U.S. government, numerous state governments, the EU and other countries in which we conduct business have imposed a wide range of economic sanctions that restrict commerce and business dealings with Russia, certain regions of Ukraine, certain regions in the Middle East and certain entities. Our suppliers rely on some materials that were originally sourced from the areas impacted by the armed conflict which may increase supply disruptions. This could, in turn, adversely impact our ability to manufacture and distribute LUPKYNIS.

***If we are unable to establish and maintain our agreements with third parties to sell and distribute LUPKYNIS to patients, our results of operations and business could be adversely affected.***

We rely on third parties to commercially sell and distribute LUPKYNIS to patients. For example, we have contracted with a limited number of specialty pharmacies and specialty distributors to sell and distribute LUPKYNIS. The use of specialty pharmacies and specialty distributors involves certain risks, including, but not limited to, risks that these organizations will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using LUPKYNIS or serious adverse reactions, events and/or product complaints regarding LUPKYNIS;
- not effectively sell or support LUPKYNIS or communicate publicly concerning LUPKYNIS in a manner that is contrary to FDA rules and regulations;
- reduce their efforts or discontinue to sell or support or otherwise not effectively sell or support LUPKYNIS;
- not devote the resources necessary to sell LUPKYNIS in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

Any such events may result in decreased product sales and lower product revenue, which would harm our results of operations and business.

We are also required to comply with good distribution practices such as maintenance of storage and shipping conditions, as well as security of products, in order to ensure product quality determined by GMP is maintained throughout the distribution network. While we are obligated to audit the performance of our third-party contractors, we do not have complete control over their compliance. We could be harmed if our third-party distributors do not comply with these standards and regulations.

## Risks Related to Government Regulation

*Our relationships with customers, healthcare providers, and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits on future earnings.*

We are subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of LUPKYNIS. Our future arrangements with third-party payors and customers will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute LUPKYNIS. Restrictions under applicable federal and state healthcare laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the FCA imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. We can be held liable under the FCA even when we do not submit claims directly to government payors if we are deemed to “cause” the submission of false or fraudulent claims;
- the U.S. federal *Health Insurance Portability and Accountability Act of 1996* (HIPAA) imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program regardless of the payor (e.g., public or private), or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the ACA require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Department of Health and Human Services information related to covered health care provider payments and other transfers of value and the ownership and investment interests of such healthcare providers (as defined by the statute) and their immediate family members;
- HIPAA, as amended by the *Health Information Technology for Economic and Clinical Health Act of 2009* (HITECH) and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services (similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation);
- consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the

federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

In the United States, to help patients who have no or inadequate insurance access to LUPKYNIS, we have a patient support program that we administer in conjunction with our patient support program vendor. If we or our vendors are deemed to fail to comply with relevant laws, regulations, or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate.

Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of assistance to our patients. Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us to modify our patient support programs and could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.***

To help patients afford LUPKYNIS, we have implemented a patient support program. These types of programs, designed to assist patients in affording pharmaceuticals, have become the subject of scrutiny. In recent years, some pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their patient support programs and their support of independent charitable patient support foundations in connection with such programs under a variety of federal and state laws. Our patient support program could become the target of similar litigation. In addition, certain state and federal enforcement authorities and members of Congress have initiated inquiries about co-pay assistance programs. Some state legislatures have also been considering proposals that would restrict or ban co-pay coupons. In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical manufacturers to patient assistance programs operated by charitable foundations. For example, the Office of Inspector General of the U.S. Department of Health & Human Services (OIG) has established specific guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations which provide co-pay assistance to Medicare patients, provided that such organizations are bona fide charities, are entirely independent of and not in any way controlled or influenced by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. If we establish a program to donate to independent charitable patient support foundations and our vendors or donation recipients are deemed to fail to comply with laws or regulations in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, numerous organizations, including pharmaceutical manufacturers, have received subpoenas from the U.S. Department of Justice (DOJ) and other enforcement authorities seeking information related to their patient assistance programs and support, and certain of these organizations have entered into, or have otherwise agreed to, significant civil settlements with applicable enforcement authorities. In connection with these civil settlements, the U.S. government has and may in the future require the affected companies to enter into complex corporate integrity agreements that impose significant reporting and other requirements on those companies. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may potentially violate the laws or regulations of the jurisdictions in which we operate. Regardless of

whether we have complied with the law, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

***The failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws, including the Foreign Corrupt Practices Act (FCPA) and similar laws associated with our activities outside of the United States, could subject us to penalties and other adverse consequences.***

We are subject to the FCPA regulations of the U.S. Office of Foreign Assets Control, and other anti-corruption, anti-bribery and anti-money laundering laws around the world where we conduct activities, including, if approved in such countries, the sale of LUPKYNIS. We face significant risks and liability if we fail to comply with the FCPA and other anti-corruption and anti-bribery laws that prohibit companies and their employees and third-party business partners, such as distributors or resellers, from authorizing, offering or providing, directly or indirectly, improper payments or benefits to foreign government officials, political parties or candidates, employees of public international organizations including healthcare professionals, or private-sector recipients for the corrupt purpose of obtaining or retaining business, directing business to any person, or securing any advantage.

We rely on various third parties for certain services outside the United States, including continued development of LUPKYNIS and the commercialization of LUPKYNIS. We may be held liable for the corrupt or other illegal activities of these third parties and intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could harm our reputation, business, operating results and prospects. In addition, responding to any enforcement action or related investigation may result in a diversion of management's attention and resources and significant defense costs and other professional fees.

***Compliance with governmental regulation and other legal obligations related to privacy, data protection and information security could result in additional costs and liabilities to us or inhibit our ability to collect and process data, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.***

Privacy and data security have become significant issues in the United States, Europe, and in many other jurisdictions where we or our licensing partners may in the future conduct our operations. As we receive, collect, process, use and store personal and confidential data, we are subject to diverse laws and regulations relating to data privacy and security. Compliance with these privacy laws, data breach notification laws, and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened.

#### **Risks Related to Human Capital, Information Technology and Managing Growth**

***Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately.

In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause harm to our reputation. We have adopted a code of conduct applicable to all of

our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

In addition, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations.

***We are dependent upon key personnel to achieve our business objectives.***

Our ability to retain key personnel and attract other qualified individuals is critical to our success. As a technology-driven company, intellectual input from key management and personnel is critical to achieve our business objectives. The loss of the services of key individuals might significantly delay or prevent achievement of our business objectives. In addition, because of a relative scarcity of individuals with experience and the high degree of education and scientific achievement required for our business, competition among life sciences companies for qualified employees is intense and the recent move by companies to offer a remote or hybrid work environment may increase the competition for such employees from employers outside of our traditional office locations, as a result, we may not be able to attract and retain such individuals on acceptable terms, or at all. In addition, because we do not maintain “key person” life insurance on any of our officers, employees, or consultants, any delay in replacing such persons, or an inability to replace them with persons of similar expertise, could harm our business, financial condition, and results of operations.

We also have relationships with scientific collaborators at academic and other institutions, some of whom conduct research at our request or assist us in formulating our research and development strategies. These scientific collaborators are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, even though our collaborators are required to sign confidentiality agreements prior to working with us, they may have arrangements with other companies to assist such other companies in developing technologies that may prove competitive to us.

Additionally, the workforce reduction we will implement as part of the restructuring program may negatively impact our ability to attract, integrate, retain and motivate highly qualified employees, and may harm our reputation with current or prospective employees.

Incentive provisions for our key executives include the granting of equity awards that vest over time, designed to encourage such individuals to stay with us. However, a low share price, whether as a result of lower than expected revenues from LUPKYNIS, disappointing progress in our development programs or as a result of market conditions generally, or other factors, could render such agreements of little value to our key executives. In such event, our key executives could be susceptible to being hired away by our competitors who could offer a better compensation package. If we are unable to attract and retain key personnel, our business, financial conditions and results of operations may be harmed.

***We may not successfully manage our growth. Our success will depend upon the timely expansion of our operations and our ability to successfully manage our growth.***

Our future growth, if any, may place a significant strain on our management and on our administrative, operational, and financial resources. Our ability to manage our growth effectively and in a timely fashion will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research, commercialization, and product development without a corresponding increase in our operational, financial and management systems could harm our business, financial condition and results of operations.

As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize LUPKYNIS and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development and commercialization efforts and clinical trials effectively and hire, train and integrate additional management, administrative and,

if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our Company.

***We rely significantly on information technology and any failure, inadequacy, or security lapse of that technology, including any cybersecurity incidents, could harm us.***

We believe that companies have been increasingly subject to a wide variety of security incidents, cyberattacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past few years, cyber-attacks have become more prevalent and much harder to detect and defend against.

Several key areas of our business depend on the use of information technologies, including production, manufacturing, marketing, and logistics, as well as clinical and regulatory matters. Despite our efforts to prevent such behavior, third parties may nonetheless attempt to hack into our systems and obtain data relating to our pre-clinical studies, clinical trials, patients using LUPKYNIS or our proprietary information on LUPKYNIS or other information relating to us or our business. If we fail to maintain or protect our information systems and data integrity effectively, we could have problems in determining product cost estimates and establishing appropriate pricing, have difficulty preventing, detecting, and controlling fraud, have disputes with physicians, and other health care professionals, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach, or suffer other adverse consequences and reputational damages. While we have invested in the protection of data and information technology, there can be no assurance that our efforts or those of our third-party collaborators, if any, or manufacturers, to implement adequate security and quality measures for data processing would be sufficient to protect against data deterioration or loss in the event of a system malfunction, or to prevent data from being stolen or corrupted in the event of a security breach. Any such loss or breach could harm our business, operating results, and financial condition. We maintain cyber insurance coverage; however, there is no guarantee that our current coverage will be sufficient or that we can secure insurance coverage in the future at commercially viable rates or with the appropriate limits.

***Interruptions in the availability of server systems or communications with Internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility, or integrity of data stored on such systems, could harm our business.***

We rely upon a variety of Internet service providers, third-party hosting facilities and cloud computing platform providers to support our business. Many of our employees currently work remotely and therefore we are highly reliant on these services for our operations. Failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems could damage our reputation in the market, cause us to lose revenue or market share, increase our service costs, cause us to incur substantial costs, subject us to liability for damages and/or fines and divert our resources from other tasks, any one of which could materially adversely affect our business, financial condition, results of operations and prospects. Any damage to, or failure of, such systems, or communications to and between such systems, could result in interruptions in our operations. If our security measures or those of our third-party data center hosting facilities, cloud computing platform providers, or third-party service partners, are breached, and unauthorized access is obtained to our data or our information technology systems, we may incur significant legal and financial exposure and liabilities. We do not have control over the operations of the facilities of our cloud service providers and our third party providers may be vulnerable to damage or interruption from natural disasters, the effect of climate change (such as drought, flooding, wildfires, increased storm severity, and sea level rise), cybersecurity attacks, terrorist attacks, power outages and similar events or acts of misconduct. In addition, any changes in our cloud service providers service levels may harm our ability to meet our requirements and operate our business.

***Our business is exposed to the risks associated with litigation, investigations and regulatory proceedings.***

Litigation and regulatory proceedings are inherently uncertain, and adverse rulings could occur, including monetary damages, or an injunction stopping us from manufacturing or selling certain products, engaging in certain business practices, or requiring other remedies. We may be subject to allegations through press, social media, the courts or other mediums that may or may not be founded. We may be required to respond to or defend against these claims and/or allegations, which will divert resources away from our principal business. There can be no assurance that our defense of such claims and/or allegations would be successful, and we may be required to make material settlements. An unfavorable outcome or settlement may harm our business, LUPKYNIS, results of operations, financial condition, and corporate reputation. In addition, regardless of outcome,

investigations, allegations of wrongdoing, and litigation can be costly, time-consuming, and disruptive to our business and operations.

## **Risks Related to Our Industry**

### ***Unstable markets and economic conditions may have harmful consequences to business, financial condition, and trading price of our common shares.***

Global economic conditions have been impacted by high inflation, supply chain challenges and the impacts of global hostilities, such as the Russia-Ukraine war. Changes in interest rates, inflation, economic growth, levels of taxation, legal and regulatory matters, foreign exchange and commodity prices may influence product purchases decisions. Our results of operations could be harmed by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our approved product and our ability to raise additional capital when needed on acceptable terms, if at all. Weak global economic conditions could decrease the number of clinical trials sites available to us and hinder our ability to conduct trials required by the FDA. A weak or declining economy could also strain our supplies, partners or third-parties, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

### ***Actual or anticipated changes to the laws and regulations governing the health care system may have a negative impact on cost and access to health insurance coverage and reimbursement of healthcare items and services.***

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell LUPKYNIS profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the U.S, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the ACA and IRA.

While it is difficult to assess the impact of the ACA in isolation, either in general or on our business specifically, it is widely thought that the ACA increases downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, LUPKYNIS. Further, the U.S. and foreign governments regularly consider reform measures that affect healthcare coverage and costs. Such reforms may include changes to the coverage and reimbursement of healthcare services and products. In particular, there have been recent judicial and Congressional challenges to the ACA, which could have an impact on coverage and reimbursement for healthcare services covered by plans authorized by the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. Most recently, the *U.S. Tax Cuts and Jobs Act* was enacted, which, among other things, removes the penalties for not complying with the ACA's individual mandate to carry health insurance. On January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. The ACA has also been the subject of numerous court challenges on the basis of, among other things, constitutionality. While the Supreme Court of the United States ruled in summer 2021 that the ACA was constitutional in respect to one such challenge, this does not mean that there will not be future challenges launched, which may or may not be successful. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the ACA will impact the ACA and our business. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the *U.S. Budget Control Act of 2011* resulted in aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the *American Taxpayer Relief Act of 2012*, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to

product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the Biden administration has indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take, whether or to what degree they may impact us or LUPKYNIS, 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 more successfully than we do.***

The industry in which we operate is highly competitive and we have numerous potential domestic and foreign competitors, including major pharmaceutical and chemical companies, universities, academic institutions, government agencies, public and private research organizations and large, fully-integrated pharmaceutical companies which have extensive resources and experience in research and development, process development, clinical evaluation, manufacturing, regulatory affairs, commercialization, distribution and marketing. In particular, over the course of the past few years we are aware that a number of companies have announced that they are commencing clinical trials for different treatment options for LN. Many of our potential competitors possess substantially greater research and development skills, financial, technical and marketing expertise and human resources than we do, and may be better equipped to develop, manufacture and market products. There is a risk that new products and technologies may be developed which may be more effective or commercially viable than the product being developed or marketed by us, thus making LUPKYNIS non-competitive or obsolete. There may also be market resistance to the acceptance of our new product in any indication and a risk that LUPKYNIS, even though clinically effective, is not economically viable.

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

***Use of hazardous materials might expose us to risk in the form of damages.***

Drug manufacturing processes involve the controlled use of hazardous materials. We and our third-party manufacturing contractors are subject to regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our third-party manufacturers have the required safety procedures for handling and disposing of such materials and comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and such liability could exceed our resources.

***Health and safety risks associated with producing a product for human ingestion cannot be eliminated and might expose us to substantial risk.***

While we take substantial precautions such as laboratory and clinical testing, toxicology studies, quality control and assurance testing and controlled production methods, the health and safety risks associated with producing a product for human ingestion cannot be eliminated. LUPKYNIS may be found to be, or to contain substances that are harmful to the health of our patients and customers and which, in extreme cases, may cause serious health conditions or death. This sort of finding may expose us to substantial risk of litigation and liability. Further, we would be forced to discontinue production of LUPKYNIS, which would

harm our profitability. We maintain product liability insurance coverage; however, there is no guarantee that our current coverage will be sufficient or that we can secure insurance coverage in the future at commercially viable rates or with the appropriate limits.

#### **Risks Related to Our Common Shares**

*There is no assurance of a sufficient liquid trading market for our common shares in the future.*

Our shareholders may be unable to sell significant quantities of common shares into the public trading markets without a significant reduction in the price of their common shares, or at all. There can be no assurance that there will be sufficient liquidity of our common shares on the trading market, and that we will continue to be listed on Nasdaq or achieve listing on any other public listing exchange.

*The price of our common shares could be subject to volatility related or unrelated to our operations.*

The market prices for the securities of biotechnology companies, including ours, have historically been volatile. The market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of any particular company.

The trading price of the common shares could continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including the results and adequacy of our pre-clinical studies and clinical trials, as well as those of our collaborators, or our competitors; the results of our operations, such as quarterly or annual sales figures; other evidence of the safety or effectiveness of LUPKYNIS or those of our competitors; announcements of technological innovations or new products by our competitors; governmental regulatory actions; developments with collaborators; developments (including litigation) concerning our patents or other proprietary rights of competitors; period-to-period fluctuations in operating results; guidance we may provide as to the commercial performance of LUPKYNIS; changes in estimates of our performance by securities analysts; market conditions for biotechnology stocks in general; our ability to repurchase our common shares under any share repurchase program on favorable terms or at all; global or local political, economic, social and health crises; market rumors; and other factors not within our control could impact the market price of the common shares, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources.

In recent years, shareholder activists have become involved in numerous public companies. Responding to actions by shareholder activists, such as requests for special meetings, potential nominations of candidates for election to our board of directors, requests to pursue a strategic combination or other transaction, or other special requests may disrupt our business and divert the attention of management and employees. In addition, any perceived uncertainties as to our future direction resulting from such a situation could result in the loss of potential business opportunities, be exploited by our competitors, cause concern to our current or potential customers and make it more difficult to attract and retain qualified personnel and business partners, any of which could negatively impact our business. Shareholder activism could result in substantial costs and may cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals of our business. Our common shares may be traded by short sellers which may put pressure on the supply and demand of our common shares.

*There can be no assurance that we will continue to repurchase Common Shares or that we will repurchase Common Shares at favorable prices.*

Our Board has the authority to authorized share repurchase programs. On February 15, 2024, we announced that we would commence our first share repurchase program. The amount and timing of common share repurchases are subject to capital availability and our determination that share repurchases are in the best interests of the Company and are in compliance with all respective laws and any applicable contractual obligations. Our ability to repurchase common shares will depend on, among other factors, our cash balances and potential future capital requirements for strategic transactions our results of operations, our financial condition and other factors beyond our control that we may deem relevant. Additionally, the recently enacted IRA includes an excise tax on share repurchases, which will increase the cost of share repurchases. A reduction in repurchases under, or the completion of, our share repurchase programs could have a negative effect on the market price of our common shares. We can provide no assurance that we will repurchase common shares at favorable prices, if at all. Aurinia has submitted an exemptive relief application to applicable Canadian securities regulators related to the repurchase, which, if not granted may limit the number of shares that the Company is able to repurchase significantly from what it is able to repurchase in reliance on applicable U.S. law. If the exemption is not granted, Aurinia would not be able to repurchase in excess of 5% of its issued and

outstanding common shares (being 7,230,888 Common Shares) without complying with an alternative process in Canada that may be more costly, time consuming or not available.

***You may be unable to enforce actions against us, or certain of our directors and officers under U.S. federal securities laws.***

As a corporation organized under the provincial laws of Alberta, Canada, it may be difficult to bring actions under U.S. federal securities law against us. Some of our directors and officers reside principally in Canada or outside of the United States. Because all or a substantial portion of our assets and the assets of these persons are located outside of the United States, it may not be possible for investors to effect service of process within the United States upon us or those persons. Furthermore, it may not be possible for investors to enforce against us, or those persons not in the United States, judgments obtained in U.S. courts based upon the civil liability provisions of the U.S. federal securities laws or other laws of the United States. There is doubt as to the enforceability, in original actions in Canadian courts, of liabilities based upon U.S. federal securities laws and as to the enforceability in Canadian courts of judgments of U.S. courts obtained in actions based upon the civil liability provisions of the U.S. federal securities laws. Therefore, it may not be possible to enforce those actions against us or certain of our directors and officers.

***If securities or industry analysts do not publish, or cease publishing, research reports about us, our business, or our market, or if they change their recommendations regarding our common shares adversely, the trading price and trading volume of our common shares could decline.***

The trading market for our common shares is and will be influenced by whether industry or securities analysts publish research and reports about us, our business, our market or our competitors and, if any analysts do publish such reports, what they publish in those reports. We may not obtain analyst coverage in the future. Any analysts who do cover us may make adverse recommendations regarding our common shares, adversely change their recommendations from time to time, and/or provide more favorable relative recommendations about our competitors. If any analyst who may cover us in the future were to cease coverage of our Company or fail to regularly publish reports on us, or if analysts fail to cover us or publish reports about us at all, we could lose visibility in the financial markets, which in turn could cause the trading price of our common shares or trading volume to decline.

***Securities litigation or other litigation could result in substantial damages and may divert management's time and attention from our business.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. We are and may become in the future the target of securities litigation. 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 from Canada to the United States, for example, we

may be subject to certain tax rules that could cause a deemed disposition of our assets for tax purposes. Should that occur, we may be subject to a material amount of tax owing, without corresponding revenue from any actual disposition of our assets. Our common shares could fall or may not increase.

## **General Business Risks**

*If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements are incorrect, our actual results may vary from those reflected in our projections and accruals.*

Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statement requires us to make estimates and judgements that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot promise that our estimates or their underlying assumptions will be correct. Actual results may differ materially from those estimated amounts used in the preparation of our consolidated financial statements if these results differ from our historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made.

*If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.*

We are subject to the rules and regulations of the SEC, including those rules and regulations mandated by the Sarbanes-Oxley Act, as well as the rules and regulations imposed by Canadian securities regulatory authorities. Securities legislation requires public companies to include in their annual report a statement of management's responsibilities for establishing and maintaining adequate internal control over financial reporting, together with an assessment of the effectiveness of those internal controls. Section 404 of the Sarbanes-Oxley Act also requires the independent auditors of certain public companies to attest to, and report on, this management assessment. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of applicable securities legislation could have harm on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common shares. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

*An investment in our common shares may result in the loss of an investor's entire investment.*

An investment in our common shares is speculative and may result in the loss of an investor's entire investment. Only potential investors who are experienced in high risk investments and who can afford to lose their entire investment should consider an investment in our common shares.

*Future issuances of debt and equity securities by us may cause the price of the common shares to fall.*

The market price of the common shares could decline because of issuances by us of additional common shares (whether for financing or acquisition purposes or otherwise), or the perception that these sales could occur. Investors will suffer dilution of their voting power and may experience dilution in earnings per share if we issue additional common shares.

*We do not intend to pay dividends in the foreseeable future.*

We have never declared or paid any dividends on the common shares. While we historically have not paid cash dividends (in any currency) and do not have a current intention to pay cash dividends, we continually review our capital allocation strategies, including, among other things, payment of cash dividends, share repurchases and acquisitions. As a result, the return on an investment in common shares will likely depend upon any future appreciation in value, if any, and on a shareholder's ability to sell common shares. The payment of future dividends, if any, will be reviewed periodically by our board of directors and will depend upon, among other things, conditions then existing including earnings, financial conditions, cash on hand, financial requirements to fund our commercial activities, development and growth, and other factors that our board of directors may consider appropriate in the circumstances.

*We have broad discretion in the use of our cash and cash equivalents and may not use them effectively.*

Our management has broad discretion to use our cash and cash equivalents to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common shares. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the trading price of our common shares to decline and adversely impact the commercialization of our product. Pending their use to fund our operations, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

***We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices.***

As a public company, we incur significant legal, accounting, and other expenses. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC, Canadian securities regulators, and the Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly.

Applicable securities legislation requires us, on an annual basis, to review and evaluate our internal controls. To maintain compliance with Section 404 of the Sarbanes-Oxley Act of 2002, for example, we are required to document and evaluate our internal control over financial reporting, which has been both costly and challenging. We will need to continue to dedicate internal resources, continue to engage outside consultants and follow a detailed work plan to continue to assess and document the adequacy of internal control over financial reporting, continue to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that in the future neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***Our business, results of operations, and future growth prospects could be materially and adversely affected by widespread health concerns, such as pandemics.***

Widespread health concerns, in particular in the United States but also globally, can have evolving and uncertain impacts on our business. As a result of any widespread health concern, such as a pandemic, we have and may continue to experience disruptions that severely impact our business, commercialization 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 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, 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 on our business, it has not had, and we anticipate that it would continue to not have, a steady impact but instead an uneven impact on various aspects of our business and operations as the variants of the virus infect different parts of the geographic regions in which we operate at different times and to different degrees. While we are not able to compare our operational results to prior years to verify, as our sole commercial product was only approved during the COVID-19 pandemic, we believe that the COVID-19 pandemic has harmed our business and operations, in particular in relation to our ability to connect with, and promote LUPKYNIS to, health care professionals, which as a result has limited prescribing opportunities for LUPKYNIS.

To the extent a widespread health concern harms our business and financial results, it may also have the effect of heightening many of the other risks described in this Annual Report.

***Sales of our common shares by our employees, including our executive officers, could cause the trading price of our common shares to fall or prevent it from increasing for numerous reasons, and sales by such persons could be viewed negatively by other investors.***

In accordance with the guidelines specified under Rule 10b5-1 under the Exchange Act, as amended, equivalent legislation in applicable jurisdictions, and our policies regarding equity transactions, a number of our employees, including executive officers, may adopt share trading plans pursuant to which they have arranged to sell common shares from time to time in the future. Generally, sales of common shares, including sales under such plans, by our executive officers and directors require public filings. Sales of our common shares by such persons could cause the price of our common shares to fall or prevent it from increasing. If sales by employees, executive officers, or directors cause a substantial number of our common shares to become available for purchase in the public market, the price of our common shares could fall or may not increase. Also, sales by such personnel could be viewed negatively by holders and potential purchasers of our common shares.

#### **Item 1B. Unresolved Staff Comments**

None.

#### **Item 1C. Cybersecurity**

##### ***Risk Management and Strategy***

We maintain a cybersecurity risk management program and related policies and processes to identify, assess and manage material risks from cybersecurity threats.

Our Information Security Policy is designed to align with certain best practices, including the EU General Data Protection Regulation (GDPR). This policy promotes the management and execution of our information security framework for preserving the confidentiality, integrity, availability and privacy of our information assets, including by helping enable us to better oversee, monitor and identify certain risks related to the processing of information by authorized third-party service providers. We also have an Information Technology (IT) Steering Committee to help ensure security and compliance across our IT services. We have in the past, and may in the future, engage third parties to assess the effectiveness of our cybersecurity prevention and response systems and processes.

During 2023, we refreshed our business continuity program to assess the resilience of our processes and systems against potential threats, including cyber-attacks. Our refreshed crisis management and business continuity program establishes crisis management instructions with a detailed plan for each business department outlining critical processes, internal and external dependencies and recovery strategies. In addition, routine information security training and updates are regularly rolled out to our employees, and we track certain metrics that we believe help ensure we have a strong security posture.

To date, cybersecurity threats, including those resulting from any previous cybersecurity incidents, have not materially affected our Company, including our business strategy, results of operations or financial condition. We do not believe that cybersecurity threats resulting from any previous cybersecurity incidents of which we are aware are reasonably likely to materially affect our Company.

## *Governance*

One of the key functions of our Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. The Board as a whole regularly (and no less than annually) reviews management's annual enterprise risk assessment, business continuity process and cybersecurity posture. Our Audit Committee is responsible for overseeing the management of risks associated with our financial reporting, accounting and auditing matters, as well as business related risks (such as leadership, continuity, cybersecurity and matters relating to our commercial activities), reviewing as required our processes around the management and monitoring of such risks, as well as conducting a risk assessment review. Our Audit Committee charter sets forth the responsibilities of the Audit Committee consistent with the rules and regulations of the applicable SEC and the Nasdaq rules, including reviewing the Company's approach to risk mitigation with respect to IT and cybersecurity. An information security update is provided quarterly, or as needed, to the Audit Committee, with a detailed review provided at least annually, or as needed.

In addition, our Chief Information Officer (CIO) is responsible for leading the assessment and management of cybersecurity risks. Our CIO has over 20 years of experience in information security and holds an MBA from The George B. Delaplaine School of Business and Economics. Our CIO regularly receives reports from our Head of IT Operations on cybersecurity threats and incidents, as applicable.

**Item 2. Properties update**

We lease approximately 4,375 square feet of space in Edmonton, Alberta, which is primarily our headquarters and 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

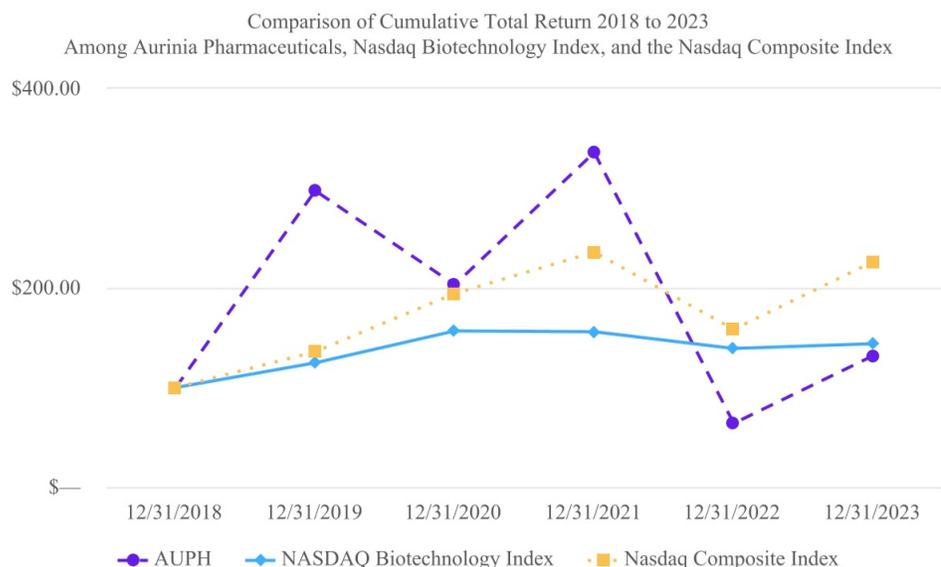
Our common shares are traded on The Nasdaq Global Market under the symbol "AUPH".

#### Holders of Record

As of February 12, 2024, there were approximately 110 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.

#### Stock Performance Graph

The following graph shows the value of an investment of \$100 from December 31, 2018 through December 31, 2023, 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, 2018	December 31, 2019	December 31, 2020	December 31, 2021	December 31, 2022	December 31, 2023
Aurinia Pharmaceuticals Inc.	AUPH	\$ 100.00	\$ 297.07	\$ 202.79	\$ 335.34	\$ 63.34	\$ 131.82
NASDAQ Biotechnology Index	^NBI	\$ 100.00	\$ 124.41	\$ 156.36	\$ 155.37	\$ 138.42	\$ 143.60
NASDAQ Composite Index	^IXIC	\$ 100.00	\$ 135.23	\$ 194.24	\$ 235.78	\$ 157.74	\$ 226.24

*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, 2023, 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.

#### **Dividends**

While we historically have not paid cash dividends (in any currency) and do not have a current intention to pay cash dividends, we continually review our capital allocation strategies, including, among other things, payment of cash dividends, share repurchases and acquisitions. Any future determination regarding the declaration and payment of dividends or share repurchases, 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**

We did not repurchase any securities during the year ended December 31, 2023.

#### **Item 6. Reserved.**

Not applicable.

#### **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 2023 and 2022 items and year-to-year comparisons between 2023 and 2022. Discussion of historical items and year-to-year comparisons between 2022 and 2021 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, 2022, filed with the SEC on February 28, 2023 and such comparisons are incorporated herein by reference.*

#### **Overview**

Aurinia is a fully integrated biopharmaceutical company focused on delivering therapies to people living with autoimmune diseases with high unmet medical needs. 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 clinical and regulatory activities to support the LUPKYNIS development program. We contracted with Otsuka as a collaboration partner for development and commercialization of LUPKYNIS in the Otsuka Territories.

Effective February 14, 2024, the Company's Board of Directors elected to conclude its strategic review process and determined that it was in the best interest of the Company and its shareholders to undergo a restructuring. In principal, the corporate restructuring will involve the Company reaffirming its commitment to enhancing value and driving LUPKYNIS growth, while maintaining a sharp focus on operating efficiencies and maximizing cash flows. As a result, the Company is ceasing future development efforts on AUR200 and its pre-clinical asset AUR300.

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 for the year ended December 31, 2022. On November 29, 2022 the Medicines and Healthcare products Regulatory Agency (MHRA) had granted marketing authorization of LUPKYNIS in Great Britain. On April 24, 2023, LUPKYNIS received regulatory approval in Switzerland. During the third quarter of 2023, the Company received notification that the pricing and reimbursement milestone was secured. As a result, this triggered a \$10.0 million milestone which was recognized as collaboration revenue for the year ended December 31, 2023. On November 13, 2023, Otsuka filed a new drug application (NDA) for voclosporin for the treatment of lupus nephritis (LN) with the Japanese Ministry of Health, Labour, and Welfare for the manufacture and sale in Japan of voclosporin.

### **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 dispense LUPKYNIS 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, 2023, we did not have any material adjustments to variable consideration estimates based on actual results.

### ***License, Collaboration and Royalty Revenues***

We enter into out-licensing agreements in which we license certain rights to LUPKYNIS 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, payments for manufacturing services and royalties on net sales of licensed products. Each of these payments results in license, collaboration and royalty revenues. Our main collaboration partnership is with Otsuka. In 2023 and 2022, we recognized \$16.0 million and \$30.6 million, respectively, in license, collaboration and royalty revenue from Otsuka.

***Manufacturing Services Revenue:*** Our agreements may include manufacturing services to be performed by us on behalf of the counterparty. If these services are determined to be distinct from the other promises or performance obligations identified in the arrangement, we recognize the transaction price allocated to these services as revenue either over time based on an appropriate measure of progress when the performance by us does not create an asset with an alternative use and we have an enforceable right to payment for the performance completed to date or at a point in time as the related performance obligations are satisfied. Certain agreements may include terms where we can partially bill for manufacturing services before the services are provided, resulting in a deferred revenue which is to be recognized once the performance obligation is satisfied.

### ***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, 2023 and 2022

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022:

(in thousands)	Years Ended December 31,		Change
	2023	2022	
Revenue:			
Product revenue, net	\$ 158,533	\$ 103,468	\$ 55,065
License, collaboration and royalty revenue	16,980	30,562	(13,582)
Total revenue, net	175,513	134,030	41,483
Operating expenses			
Cost of sales	14,148	5,664	8,484
Selling, general and administrative	195,036	196,371	(1,335)
Research and development	49,641	44,988	4,653
Other expense (income), net	8,379	(1,523)	9,902
Total cost of sales and operating expenses	267,204	245,500	21,704
Loss from operations	(91,691)	(111,470)	19,779
Interest expense	(2,775)	—	(2,775)
Interest income	16,997	5,118	11,879
Net loss before income taxes	(77,469)	(106,352)	28,883
Income tax expense	551	1,828	(1,277)
Net loss	\$ (78,020)	\$ (108,180)	\$ 30,160

#### Total Revenue, net

Total net revenue was \$175.5 million and \$134.0 million for the years ended December 31, 2023 and 2022, respectively.

The Company currently has two main customers for U.S. commercial sales of LUPKYNIS and a collaboration partnership with Otsuka for sales of semi-finished product and license, collaboration and royalty revenue in Otsuka Territories. The percentage of total revenues, net from our main customers were as follows:

	2023	2022	2021
U.S. main commercial customers	91%	80%	100%
Collaboration partnership	8%	20%	—%

#### Product Revenue, net

Product Revenue, net was \$158.5 million and \$103.5 million for the years ended December 31, 2023 and 2022, respectively. The increase is primarily due to an increase of LUPKYNIS sales to our two main customers, driven predominantly by further penetration of the LN market.

The market penetration can be demonstrated, in part, by 1,791 additional prescriptions (which we generally refer to as patient start forms (PSFs)) received during the year ended December 31, 2023 compared to 1,650 PSFs received during the year ended December 31, 2022. Additionally, during the fourth quarter of 2023, the Company added approximately 101 new patients, which includes, restarts (patients coming back onto therapy who do not require PSF) and an estimate of new patients beginning therapy in the hospital channel. Patient restarts and estimated patients coming through the hospital channel are newly reported in the fourth quarter since they have achieved numerical significance for the first time. Lastly, our 12-month persistency rate has increased from approximately 50% at December 31, 2022 to approximately 55% at December 31, 2023. These factors have

contributed to an increase in our patients on therapy with approximately 2,066 patients on LUPKYNIS therapy at December 31, 2023, compared with 1,525 at December 31, 2022.

*License, Collaboration and Royalty Revenue*

License, collaboration and royalty revenue was \$17.0 million and \$30.6 million for the years ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023, license, collaboration and royalty revenue included a \$10.0 million pricing and reimbursement milestone in September 2023 and additional collaboration and manufacturing services revenue from Otsuka. For the year ended December 31, 2022, license, collaboration and royalty revenue was primarily due to the recognition of a \$30.0 million regulatory milestone from Otsuka following the EC marketing authorization of LUPKYNIS in September 2022.

*Cost of Sales*

Cost of sales were \$14.1 million and \$5.7 million for the years ended December 31, 2023 and 2022, respectively. The increase is primarily due to an increase in sales of LUPKYNIS, coupled with the amortization of the monoplant finance right-of-use asset, which was placed into service in late June 2023.

Gross margin for the years ended December 31, 2023 and 2022 was approximately 92% and 96%, respectively.

*Selling, General and Administrative Expenses*

SG&A expenses decreased to \$195.0 million for the year ended December 31, 2023 compared to \$196.4 million for the year ended December 31, 2022. SG&A expenses consisted of the following:

(in thousands)	Years Ended December 31,		Change
	2023	2022	
Salaries, incentive pay and employee benefits	\$ 82,768	\$ 82,129	\$ 639
Professional fees and services	51,161	58,759	(7,598)
Share-based compensation expense	36,511	28,438	8,073
Other public company costs, facility costs, insurance, information technology, amortization of property and equipment	13,315	15,826	(2,511)
Travel, trade shows and sponsorships	11,281	11,219	62
	<u>\$ 195,036</u>	<u>\$ 196,371</u>	<u>\$ (1,335)</u>

The primary drivers for the decrease in SG&A were a decrease of professional fees and services due to a reduction in expenses associated with corporate legal matters and insurance partially offset by an increase in share-based compensation expense.

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 increased to \$49.6 million for the year ended December 31, 2023 compared to \$45.0 million for the year ended December 31, 2022. R&D expenses consisted of the following:

(in thousands)	Years Ended December 31,		
	2023	2022	Change
Contract research organizations (CRO) and developmental expenses	\$ 17,858	\$ 18,451	\$ (593)
Clinical supply and distribution	9,104	8,614	490
Salaries, incentive pay and employee benefits	14,546	14,034	512
Share-based compensation expense	7,533	3,271	4,262
Travel, insurance, patent annuity fees, legal fees and other	600	618	(18)
	<u>\$ 49,641</u>	<u>\$ 44,988</u>	<u>\$ 4,653</u>

The primary driver for the increase in R&D expenses was due to the increase in share-based compensation expense.

We spent approximately \$17.4 million and \$13.5 million on early stage pre-clinical research programs in the years ended December 31, 2023 and 2022, respectively. The spend does not include internal resource expenses as we currently do not track these for early stage research programs, prior to IND. The increase in spend on our pre-clinical research programs was offset by a decrease in spend associated with clinical voclosporin associated studies.

We expect our R&D expenses will decrease going forward as we cease future development on AUR200 and AUR300 and focus our efforts on the development of voclosporin and our FDA post-approval obligations for LUPKYNIS. We are unable to determine the duration and completion costs of our R&D projects.

#### *Other Expense (Income), Net*

Other expense (income), net was \$8.4 million for the year ended December 31, 2023 compared to other income of \$(1.5) million for the year ended December 31, 2022. The primary drivers for other expense for the year ended 2023 were expenses related to shareholder matters and the foreign exchange loss related to the revaluation of the monoplant finance lease liability, which commenced in June 2023 and is denominated in CHF.

#### *Interest Income*

Interest income was \$17.0 million for the year ended December 31, 2023 compared to \$5.1 million for the year ended December 31, 2022. The increase was mainly due to higher yields on our investments as a result of higher interest rates.

#### **Liquidity and Capital Resources**

As of December 31, 2023, we had cash, cash equivalents and restricted cash of \$48.9 million and investments of \$301.8 million compared to cash, cash equivalents and restricted cash of \$94.2 million and short-term investments of \$295.2 million at December 31, 2022. Cash, cash equivalents and restricted cash and investments are primarily held in U.S. dollars. As of December 31, 2023 and 2022, we had working capital of \$347.6 million and \$396.4 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. Taking into consideration the cash, cash equivalents and restricted cash and investments as of December 31, 2023, we believe that our cash position is sufficient to fund our current plans which include funding commercial activities, such as our FDA related post-approval commitments, manufacturing and packaging commercial drug supply, funding our supporting commercial infrastructure, advancing our LUPKYNIS (voclosporin) related 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, 2023, 2022 and 2021:

(in thousands)	2023	2022	2021
Net cash (used in) provided by:			
Operating activities	\$ (33,461)	\$ (79,529)	\$ (157,692)
Investing activities	(6,706)	(60,632)	(103,870)
Financing activities	(5,130)	2,433	221,112
Net change in cash and cash equivalents	\$ (45,297)	\$ (137,728)	\$ (40,450)

#### *Cash Flows from Operating Activities*

Net cash used in operating activities for the year ended December 31, 2023 was \$33.5 million, compared to \$79.5 million, for the year ended December 31, 2022. The decrease is primarily due to an increase in cash receipts from sales of LUPKYNIS. See "Total Revenue, net" above for further discussion regarding our increased sales of LUPKYNIS.

#### *Cash Flows from Investing Activities*

Net cash used in investing activities for the year ended December 31, 2023 was \$6.7 million compared to \$60.6 million for the year ended December 31, 2022. The decrease was primarily due to the timing of purchases of investments and capital payment for the monoplant, offset by proceeds of maturities of investments.

#### *Cash Flows from Financing Activities*

Cash used in financing activities for the year ended December 31, 2023 was \$5.1 million compared to cash provided by financing activities of \$2.4 million for the year ended December 31, 2022. The change is primarily due to the quarterly lease payments for our monoplant finance lease, which commenced during the second quarter of 2023.

A discussion of changes in our cash flow from the year ended December 31, 2021 to the year ended December 31, 2022 can be found in Part II, Item 7, "Management's Discussion and Analysis of Financial Conditions and Results of Operations" of the 2022 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, 2021. 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 include, but are 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, 2023, our material short-term cash requirements are approximately \$170.0 million. We anticipate our long-term cash requirements to be approximately \$134.0 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 \$116.0 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 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;
- severance costs and potential contract termination costs related to our restructuring program; 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;
- the scope, rate of progress, results and costs of our clinical trials 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 expenses needed to attract and retain skilled personnel as well as any other personnel changes that we may implement;
- the timing of our restructuring program and our ability to execute successfully on the restructuring; 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, 2023 our investment portfolio includes cash, cash equivalents and restricted cash and investments of \$350.7 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, 2023, these instruments have a weighted average remaining maturity of 7 months.

As of December 31, 2023, a hypothetical annual change of 100 basis points on the interest rates of our \$301.8 million investments would result in approximately 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 Swiss Franc, Canadian dollar and Great British Pound, which could affect our operating and financial results.

As of December 31, 2023, we had a \$90.1 million finance lease liability on our balance sheet related to the monoplant. An assumed 10% fluctuation in the Swiss Franc compared to the U.S. dollar would have an approximate \$9.0 million fluctuation in the valuation of the lease liability.

As of December 31, 2023, we had approximately \$1.9 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, 2023.

### ***Inflation Risk***

Inflation has continued to increase during 2023 and is expected to continue to be a risk. 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, 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. It is the Company's intent for these investments to have an overall rating of A-1, or higher, by Standard & Poor's, or an equivalent rating by Moody's or Fitch. 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 main U.S. commercial customers and collaboration partnership with Otsuka which accounted for the majority of our accounts receivable, net balances as of December 31, 2023. 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 and the receipt of payment is not significant. Our standard credit terms range from 30 to 45 days. In 2023, 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.

	<u>Page</u>
<a href="#">Report of Independent Registered Public Accounting Firm (PCAOB ID 271)</a>	F- <u>1</u>
<a href="#">Consolidated Balance Sheets</a>	F- <u>5</u>
<a href="#">Consolidated Statements of Consolidated Statements of Operations and Comprehensive Loss</a>	F- <u>6</u>
<a href="#">Consolidated Statements of Shareholders' Equity</a>	F- <u>7</u>
<a href="#">Consolidated Statements of Cash Flows</a>	F- <u>8</u>
<a href="#">Notes to Financial Statements</a>	F- <u>9</u>

**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, 2023, 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, 2023.

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, 2023, 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**

During the quarter ended December 31, 2023, no directors or Section 16 officers adopted or terminated any “Rule 10b5-1 trading arrangement” or any “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

**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 2024 Annual Meeting of Shareholders (or amended Annual Report on Form 10-K) to be filed with the SEC by April 29, 2024 (our Future Filing) 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., #140, 14315 - 118 Avenue Edmonton, Alberta T5L 4S6, Attn: Corporate Secretary.

The information on our website that we may refer to herein is not incorporated by reference into, and does not form any part of, this Annual Report.

### Item 11. Executive Compensation

The information required by this Item will be set forth in the section headed “Executive Compensation” in our Future Filing 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 Future Filing 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 Future Filing 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 Future Filing 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 Future Filing 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.

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

10.9#	<a href="#">Cooperation Agreement, dated as of September 21, 2023, by and among MKT Capital Ltd., MKT Tactical Fund, SP, Antoine Khalife and Aurinia Pharmaceuticals Inc.</a>	8-K	001-36421	10.1	09/21/23
10.10#	<a href="#">Softgel Commercial Supply Agreement between the Registrant and Catalent Pharma Solutions, LLC dated August 28, 2020</a>	10-K	001-36421	10.9	02/24/21
10.11	<a href="#">Settlement Agreement among ILJIN Life Science Co. Ltd., Isotechnika Pharma Inc., and Aurinia Pharmaceuticals Inc., dated April 3, 2013</a>	10-K	001-36421	10.10	02/24/21
10.12+#	<a href="#">Employment Agreement between Aurinia Pharma U.S., Inc. and Peter Greenleaf dated April 11, 2019</a>	10-K	001-36421	10.11	02/24/21
10.13+#	<a href="#">Employment Agreement between Aurinia Pharma U.S. Inc. and Max Donley dated July 15, 2019</a>	10-K	001-36421	10.13	02/24/21
10.14+#	<a href="#">Employment Agreement between the Registrant and Michael Martin dated October 1, 2017</a>	10-K	001-36421	10.15	02/24/21
10.15+#	<a href="#">Employment Agreement between Aurinia Pharma U.S. Inc. and Joe Miller dated April 8, 2020</a>	10-K	001-36421	10.16	02/24/21
10.16+#	<a href="#">Employment Agreement between the Registrant and Stephen Robertson dated September 29, 2020</a>	10-K	001-36421	10.17	02/24/21
10.17+	<a href="#">Form of Inducement Grant Option Commitment</a>	10-K	001-36421	10.20	02/24/21
10.18+#	<a href="#">Employment Agreement between Aurinia U.S. Pharma Inc., and Volker Knappertz, M.D., dated July 11, 2022</a>	10-Q	001-36421	10.22	11/03/22
10.19+#	<a href="#">Employment Agreement between Aurinia U.S. Pharma Inc., and Scott Habig, dated June 27, 2022</a>	10-Q	001-36421	10.23	11/03/22
10.20+#	<a href="#">Form of Inducement Restricted Stock Unit Award</a>	10-K	001-36421	10.20	02/28/23
10.21+#	<a href="#">Form of Restricted Stock Unit Award under the Equity Incentive Plan</a>	10-K	001-36421	10.21	02/28/23
21.1*	<a href="#">List of Subsidiaries of Registrant</a>				
23.1*	<a href="#">Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm</a>				
24.1*	Power of Attorney (contained in signature page of this report)				
31.1*	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>				
31.2*	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>				
32.1**	<a href="#">Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>				
32.2**	<a href="#">Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>				
97.1+*	<a href="#">Incentive Compensation Recoupment Policy</a>				
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 14, 2024

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.

<b>Name</b>	<b>Title</b>	<b>Date</b>
/s/ Peter Greenleaf Peter Greenleaf	President, Chief Executive Officer, Director <i>(Principal Executive Officer)</i>	February 14, 2024
/s/ Joseph Miller Joseph Miller	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	February 14, 2024
/s/ Brinda Balakrishnan Brinda Balakrishnan, M.D., Ph.D.	Director	February 14, 2024
/s/ Jeffrey A. Bailey Jeffrey A. Bailey	Director	February 14, 2024
/s/ Dr. Karen Smith Dr. Karen Smith	Director	February 14, 2024
/s/ Dr. Robert T. Foster Dr. Robert T. Foster	Director	February 14, 2024
/s/ David R.W. Jayne David R.W. Jayne, M.D., FRCP, FRCPE, FMedSci	Director	February 14, 2024
/s/ Jill Leversage Jill Leversage	Director	February 14, 2024
/s/ R. Hector MacKay-Dunn R. Hector MacKay-Dunn, J.D., Q.C.	Director	February 14, 2024
/s/ Daniel Billen Daniel Billen, Ph.D.	Chairman	February 14, 2024



## 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, 2023 and 2022, 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, 2023, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 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, 2023, 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.

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

PricewaterhouseCoopers LLP  
PwC Tower, 18 York Street, Suite 2500, Toronto, Ontario, Canada M5J 0B2  
T: +1 416 863 1133, F: +1 416 365 8215, ca\_toronto\_18\_york\_fax@pwc.com

\*PwC\* refers to PricewaterhouseCoopers LLP, an Ontario limited liability partnership.



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 \$10.9 million as of December 31, 2023 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 include 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

Toronto, Canada  
February 14, 2024

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**

(in thousands)	As of December 31,	
	2023	2022
<b>ASSETS</b>		
Current assets:		
Cash, cash equivalents and restricted cash	\$ 48,875	\$ 94,172
Short-term investments	301,614	295,218
Accounts receivable, net	24,089	13,483
Inventories, net	39,705	24,752
Prepaid expenses	9,486	13,580
Other current assets	1,031	1,334
<b>Total current assets</b>	<b>424,800</b>	<b>442,539</b>
Non-current assets:		
Long-term investments	201	—
Other non-current assets	1,517	13,339
Property and equipment, net	3,354	3,650
Acquired intellectual property and other intangible assets, net	4,977	6,425
Finance right-of-use asset, net	108,715	—
Operating right-of-use assets, net	4,498	4,907
<b>Total assets</b>	<b>\$ 548,062</b>	<b>\$ 470,860</b>
<b>LIABILITIES</b>		
Current liabilities:		
Accounts payable and accrued liabilities	54,389	39,990
Deferred revenue	4,813	3,148
Other current liabilities (of which \$0.8 million in 2023 is due to a related party)	2,388	2,033
Finance lease liability	14,609	—
Operating lease liabilities	989	936
<b>Total current liabilities</b>	<b>77,188</b>	<b>46,107</b>
Non-current liabilities:		
Finance lease liability	75,479	—
Operating lease liabilities	6,530	7,152
Deferred compensation and other non-current liabilities (of which \$7.6 million in 2023 is due to a related party)	10,911	12,166
<b>Total liabilities</b>	<b>170,108</b>	<b>65,425</b>
Commitments and Contingencies (Note 13)		
<b>SHAREHOLDERS' EQUITY</b>		
Common shares - no par value, unlimited shares authorized, 143,833 and 142,268 shares issued and outstanding at December 31, 2023 and 2022, respectively	1,200,218	1,185,309
Additional paid-in capital	120,788	85,489
Accumulated other comprehensive loss	(730)	(1,061)
Accumulated deficit	(942,322)	(864,302)
<b>Total shareholders' equity</b>	<b>377,954</b>	<b>405,435</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 548,062</b>	<b>\$ 470,860</b>

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

**AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

<b>(in thousands, except per share data)</b>	<b>Years ended December 31,</b>		
	<b>2023</b>	<b>2022</b>	<b>2021</b>
Revenue:			
Product revenue, net	\$ 158,533	\$ 103,468	\$ 45,488
License, collaboration and royalty revenue	16,980	30,562	117
Total revenue, net	<u>175,513</u>	<u>134,030</u>	<u>45,605</u>
Operating expenses			
Cost of sales	14,148	5,664	1,091
Selling, general and administrative	195,036	196,371	173,536
Research and development	49,641	44,988	51,139
Other expense (income), net	8,379	(1,523)	574
Total cost of sales and operating expenses	<u>267,204</u>	<u>245,500</u>	<u>226,340</u>
Loss from operations	<u>(91,691)</u>	<u>(111,470)</u>	<u>(180,735)</u>
Interest expense	(2,775)	—	—
Interest income	16,997	5,118	529
Net loss before income taxes	<u>(77,469)</u>	<u>(106,352)</u>	<u>(180,206)</u>
Income tax expense	551	1,828	760
Net loss	<u>(78,020)</u>	<u>(108,180)</u>	<u>(180,966)</u>
Other comprehensive loss:			
Unrealized gain (loss) on available-for-sale securities, net of tax ofnil	331	(209)	(47)
Comprehensive loss	<u>\$ (77,689)</u>	<u>\$ (108,389)</u>	<u>\$ (181,013)</u>
Basic and diluted loss per share	<u>\$ (0.54)</u>	<u>\$ (0.76)</u>	<u>\$ (1.40)</u>
Weighted-average common shares outstanding used in computation of basic and diluted loss per share	<u>143,236</u>	<u>141,915</u>	<u>129,369</u>

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		Additional Paid- In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance - January 1, 2021	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
Shares issued on 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)
<b>Balance at December 31, 2021</b>	<b>141,600</b>	<b>\$ 1,177,051</b>	<b>\$ 59,014</b>	<b>\$ (852)</b>	<b>\$ (756,122)</b>	<b>\$ 479,091</b>
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)
<b>Balance at December 31, 2022</b>	<b>142,268</b>	<b>\$ 1,185,309</b>	<b>\$ 85,489</b>	<b>\$ (1,061)</b>	<b>\$ (864,302)</b>	<b>\$ 405,435</b>
Shares issued on exercise of stock options and vesting of restricted stock units	1,146	11,256	(8,209)	—	—	3,047
Issuance of common shares in conjunction with ESPP program	419	3,653	(1,803)	—	—	1,850
Share-based compensation	—	—	45,311	—	—	45,311
Unrealized loss on available-for-sale securities, net	—	—	—	331	—	331
Net loss	—	—	—	—	(78,020)	(78,020)
<b>Balance at December 31, 2023</b>	<b>143,833</b>	<b>\$ 1,200,218</b>	<b>\$ 120,788</b>	<b>\$ (730)</b>	<b>\$ (942,322)</b>	<b>\$ 377,954</b>

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

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Years ended December 31,		
	2023	2022	2021
Cash flows from operating activities:			
Net loss	\$ (78,020)	\$ (108,180)	\$ (180,966)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:			
Depreciation and amortization	11,647	2,706	2,761
Net amortization of premiums and discounts on investments	(12,141)	(1,572)	660
Upfront license and milestone expense	—	—	10,000
Share-based compensation	45,311	32,300	31,243
Write-down of inventory	916	3,646	245
Foreign exchange on finance lease liability	5,949	—	—
Other, net	(1,515)	(1,612)	(2)
Net changes in operating assets and liabilities:			
Accounts receivable, net	(10,606)	1,927	(15,415)
Inventories, net	(15,869)	(9,072)	(5,644)
Prepaid expenses and other current assets	4,399	(2,404)	(5,335)
Non-current operating assets	(16)	(363)	353
Accounts payable, accrued and other liabilities	13,394	699	4,076
Deferred revenue	3,763	3,048	—
Operating lease liabilities	(673)	(652)	332
Net cash used in operating activities	(33,461)	(79,529)	(157,692)
Cash flows from investing activities:			
Proceeds from investments	529,376	464,316	354,427
Purchase of investments	(523,500)	(523,993)	(438,958)
Upfront lease payment	(11,864)	(663)	(11,838)
Upfront license payment	—	—	(6,000)
Purchase of long-lived assets and intangibles	(718)	(292)	(303)
Additions to internal use-software implementation costs	—	—	(1,198)
Net cash used in investing activities	(6,706)	(60,632)	(103,870)
Cash flows from financing activities:			
Proceeds from issuance of common shares pursuant to Public Offering, net of issuance costs	—	—	196,740
Proceeds from exercise of stock options, employee share purchase plan and warrants	4,895	2,433	24,372
Finance lease payments	(10,025)	—	—
Net cash (used in) provided by financing activities	(5,130)	2,433	221,112
Net decrease in cash and cash equivalents during the year	(45,297)	(137,728)	(40,450)
Cash and cash equivalents, beginning of the year	94,172	231,900	272,350
Cash, cash equivalents and restricted cash, end of the year	\$ 48,875	\$ 94,172	\$ 231,900
Supplemental cash flow information:			
Cash paid for taxes	\$ (496)	\$ (1,979)	\$ (257)
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets			
Cash, cash equivalents	\$ 48,755	\$ 94,088	\$ 231,643
Restricted cash	120	84	257
Total cash, cash equivalents and restricted cash	\$ 48,875	\$ 94,172	\$ 231,900

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

## AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES

### NOTES TO 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 people living with autoimmune diseases with high unmet medical needs. 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 clinical and regulatory activities to support the LUPKYNIS development program. Aurinia contracted 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 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.

Effective February 14, 2024, the Company's Board of Directors elected to conclude its strategic review process and that it was in the best interest of the Company and its shareholders to undergo a restructuring. In principal, the corporate restructuring will involve the Company reaffirming its commitment to LUPKYNIS growth, while maintaining a sharp focus on operating efficiencies and maximizing cash flows. As a result, the Company is ceasing future development efforts on AUR200 and its pre-clinical asset AUR300.

As of April 1, 2023, Aurinia's head office and registered office is located at #140, 14315-118 Avenue, Edmonton, Alberta, Canada T5L 4S6. Aurinia also has a U.S. commercial office located at 77 Upper Rock Circle Suite 700, Rockville, Maryland, 20850 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. These consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP).

**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, 2023 and 2022, and the results of operations and cash flows for the three years ended December 31, 2023, 2022 and 2021. 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 exchange rate for the 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 and comprehensive loss in other expense (income), net.

**Fair value measurements:** The Company's financial instruments consist primarily of cash and cash equivalents, 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, 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 Swiss Franc, Canadian Dollar 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. The Company's monoplant finance lease is denominated in Swiss Francs. These foreign currency balances can result in fluctuations in foreign exchange gain or loss.

**Major customers:** The Company currently has two main customers for U.S. commercial sales of LUPKYNIS and a collaboration partnership with Otsuka for sales of semi-finished product and royalty, collaboration and manufacturing services revenue in Otsuka Territories. The percentages of total revenues, net from our main customers were as follows:

	2023	2022	2021
U.S. main commercial customers	91%	80%	100%
Collaboration partnership	8%	20%	—%

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 2024. 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 primarily 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, 2023 and December 31, 2022, accounts receivable, net were \$24.1 million and \$13.5 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 allowances using the current expected credit loss (CECL) model. Under the CECL model, the allowances reflect 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 the Company. 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 current expected credit losses was nil at December 31, 2023 and December 31, 2022.

Accounts receivables for the Company's U.S commercial customers 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 U.S. 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 \$48.9 million and \$94.2 million as of December 31, 2023 and December 31, 2022, respectively. The Company has invested its cash reserves mainly 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 \$120 thousand and \$84 thousand as of December 31, 2023 and December 31, 2022, respectively. Refer to note 17 "Share-Based Compensation" for further details on the ESPP.

**Investments:** The Company classifies its debt securities as available-for-sale in accordance with the FASB Accounting Standards Codification (ASC) Topic 320, *Investments — Debt Securities*. Investments classified as available-for-sale are carried at fair value with unrealized gains or losses reported in other comprehensive loss within shareholders' equity. Realized gains and losses on available-for-sale securities are recorded in other income (expense), net. The cost of securities sold is based on the specific-identification method. Interest income is accrued when earned and the amortization of premiums and accretion of discounts to maturity arising from acquisition is included in interest income on the consolidated statements of operations and comprehensive loss.

**Intangible assets:** Intangible assets are amortized on a straight-line basis over their useful lives using methods that correlate to the pattern in which the economic benefits are expected to be realized. 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 reviewed at least annually 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. 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 purchased intellectual property or 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 12 years.

**Property and equipment:** Property 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 at least annually or 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, 2023, 2022 and 2021.

**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 was accounted for as a finance lease when the lease commencement began (see Note 15).

The Company made an accounting policy election to use 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 and comprehensive loss. Fixed costs associated with these arrangements are disclosed in Note 15 of the financial statements.

Operating and finance 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 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 and comprehensive loss.

**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 LUPKYNIS 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 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 additional 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, 2023, 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.

*Supply of Drug Substance and Semi-finished Goods:* The Company also has agreements with its partners that include options related to the promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion. 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, Collaboration and Royalty Revenue*

The Company enters into out-licensing agreements that are within the scope of ASC 606, under which it licenses certain rights to LUPKYNIS 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.

*Manufacturing Services Revenue:* The Company's agreements may include manufacturing 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. The revenue is recognized 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. Certain agreements may include terms where the Company can partially bill for manufacturing services before the services are provided, resulting in a deferred revenue which is to be recognized once the performance obligation is 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.

*Other Services Revenue:* The Company's agreements may include R&D 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.

#### ***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. These costs are recorded within SG&A.

**Cost of sales:** Cost of sales consists 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, 2023, 2022 and 2021, were \$49.6 million, \$45.0 million and \$51.1 million, respectively, and are included in total cost of sales and operating expenses on the accompanying consolidated statements of operations and comprehensive loss.

**Selling, general and administrative (SG&A) expenses:** The Company's SG&A expenses include commercial and allocated administrative cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, corporate facility charges 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, 2023, 2022 and 2021, advertising and marketing costs totaled \$15.4 million, \$16.3 million and \$15.4 million, respectively.

SG&A expenses for the years ended December 31, 2023, 2022 and 2021 were \$195.0 million, \$196.4 million and \$173.5 million, respectively, and are included in total cost of sales and operating expenses on the accompanying consolidated statements of operations and comprehensive loss.

**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.

### ***Recent accounting pronouncements***

In December 2023, the FASB issued final guidance in ASU No. 2023-09, *Income Taxes (ASC 740)*: Improvements to Income Tax Disclosures requiring entities to provide additional information in the rate reconciliation and disclosures about income taxes paid. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The Company is not early adopting, and therefore, this ASU is not adopted in the current period. The Company does not expect this ASU to have a material impact on the consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280)*: Improvements to Reportable Segment Disclosures which requires public entities to disclose significant segment expenses regularly provided to the chief operating decision-maker. Public entities with a single reporting segment have to provide all disclosures required by ASC 280, including the significant segment expense disclosures. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The Company is not early adopting, and therefore is not adopted in the current period. The Company does not expect this ASU to have a 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 in 2022 and 2023.

In December 2019, the FASB issued ASU No. 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.

### **3. Fair Value Measurement**

The Company's financial instruments consist primarily of cash and cash equivalents, 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 investments) measured at fair value on a recurring basis:

(in thousands)	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash, cash equivalents and restricted cash	\$ 48,875	\$ —	\$ —	\$ 48,875
U.S. agency security	—	—	—	—
Corporate bond	—	33,781	—	33,781
Commercial paper	—	39,304	—	39,304
Treasury bill	—	122,806	—	122,806
Treasury bond	—	105,924	—	105,924
Total financial assets	\$ 48,875	\$ 301,815	\$ —	\$ 350,690

(in thousands)	December 31, 2022			
	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

The Company's Level 1 instruments include cash, cash equivalents and restricted cash that are valued using quoted market prices. Aurinia estimates 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 the Company's 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. Additionally, at December 31, 2023 and December 31, 2022, the weighted average remaining contractual maturities of Aurinia's Level 2 investments were approximately 7 months for both periods. It is the Company's intent for these investments to have an overall rating of A-1, or higher, by Standard & Poor's, or an equivalent rating by Moody's or Fitch.

No credit loss allowance was recorded as of December 31, 2023 and December 31, 2022, 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 Investments," for the carrying amount and related unrealized gains (losses) by type of investment.

#### 4. Cash, Cash Equivalents, Restricted Cash and Investments

As of December 31, 2023 and December 31, 2022, the Company had \$350.7 million and \$389.4 million, respectively, of cash, cash equivalents, restricted cash and investments, which are summarized below. As of December 31, 2023 and December 31, 2022, \$301.8 million and \$295.2 million the Company's investments, which are available-for-sale debt securities, are carried at fair market value.

**December 31, 2023**

<b>(in thousands)</b>	<b>Amortized Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Estimated Fair Value</b>
Cash, cash equivalents and restricted cash	\$ 48,875	\$ —	\$ —	\$ 48,875
Corporate bond	33,576	4	—	33,580
Commercial paper	39,305	—	(1)	39,304
Treasury bill	122,757	49	—	122,806
Treasury bond	105,903	21	—	105,924
Total cash, cash equivalents, restricted cash and short-term investments	\$ 350,416	\$ 74	\$ (1)	\$ 350,489
Total long-term investment corporate bond	200	1	—	201
Total cash, cash equivalents, restricted cash and investments	\$ 350,616	\$ 75	\$ (1)	\$ 350,690

**December 31, 2022**

<b>(in thousands)</b>	<b>Amortized Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Estimated Fair Value</b>
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

As of December 31, 2023 and December 31, 2022, accrued interest receivable from the investments were \$0.7 million and \$1.1 million, respectively and recorded as other current assets on the consolidated balance sheets. As of December 31, 2023, December 31, 2022 and December 31, 2021 the Company had \$331 thousand, \$209 thousand and \$47 thousand of net unrealized gains and losses on available-for-sale securities, respectively, which are included as a component of comprehensive loss on the consolidated statement of operations and comprehensive loss. Currently, the Company does not intend to sell the investments before recovery of their amortized cost basis, which may be maturity. Realized gains or losses were immaterial for the years ended December 31, 2023 and December 31, 2022.

The Company's short-term investments as of December 31, 2023 mature at various dates through November 2024 and the long-term investment matures in August 2025.

#### **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 for LUPKYNIS mainly include third party manufacturing costs, transportation, storage, insurance and allocated internal labor. Due to the nature of the Company's supply chain process, inventory that is owned by the Company, is physically stored at third-party warehouses, logistics providers, and contract manufacturers.

The Company assesses recoverability of inventory at each reporting period to determine any write down to net realizable value resulting from excess or obsolete inventories. As of December 31, 2023 and December 31, 2022, Aurinia had recorded reserves

of finished goods inventories of approximately \$0.8 million and \$3.9 million, respectively, which were primarily related to potential inventory obsolescence.

The components of inventories, net are as follows:

<b>(in thousands)</b>	<b>December 31, 2023</b>	<b>December 31, 2022</b>
Raw materials	\$ 1,746	\$ 2,217
Work in process	37,376	21,059
Finished goods	583	1,476
Total inventories, net	<u>\$ 39,705</u>	<u>\$ 24,752</u>

#### 6. Prepaid Expenses

Prepaid expenses are as follows:

<b>(in thousands)</b>	<b>December 31, 2023</b>	<b>December 31, 2022</b>
Prepaid assets	\$ 6,892	\$ 5,451
Prepaid deposits	1,345	6,330
Prepaid insurance	1,249	1,799
Total prepaid expenses	<u>\$ 9,486</u>	<u>\$ 13,580</u>

#### 7. Property and Equipment, net

Property and equipment, net are as follows:

<b>(in thousands)</b>	<b>Estimated Useful Life (in years)</b>	<b>December 31, 2023</b>	<b>December 31, 2022</b>
Construction in progress	—	\$ —	\$ 255
Leasehold improvements	Shorter of term of the lease or estimated useful life	3,243	2,978
Office equipment	5	631	645
Furniture	7	1,155	976
Computer equipment	3	235	251
		<u>5,264</u>	<u>5,105</u>
Less accumulated depreciation		<u>(1,910)</u>	<u>(1,455)</u>
Property and equipment, net		<u>\$ 3,354</u>	<u>\$ 3,650</u>

Depreciation expense for the years ended December 31, 2023, 2022 and 2021 was \$606 thousand, \$629 thousand and \$663 thousand, respectively, which is recorded in operating expenses on the consolidated statements of operations and comprehensive loss.

## 8. Intangible Assets

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

(in thousands)	December 31, 2023			
	Weighted Average Life (in years)	Gross Carrying Value	Accumulated Amortization	Net Carrying Amount
Patents	12	\$ 1,847	\$ (1,297)	\$ 550
Acquired intellectual property and reacquired rights	12	15,126	(10,737)	4,389
Internal-use software implementation costs	3	2,873	(2,835)	38
		<u>\$ 19,846</u>	<u>\$ (14,869)</u>	<u>\$ 4,977</u>

(in thousands)	December 31, 2022			
	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
		<u>\$ 19,568</u>	<u>\$ (13,143)</u>	<u>\$ 6,425</u>

Amortization expense recognized by the Company related to intangible assets was \$1.7 million, \$2.1 million and \$2.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. Amortization expense as it relates to the amortization of acquired intellectual property and other intangible assets is recorded in operating expenses on the consolidated statements of operations and comprehensive loss. The estimated aggregate amortization expense for intangible assets over the next five fiscal years ending December 31, 2024 through December 31, 2028 is approximately \$4.6 million.

## 9. Accounts payable and accrued liabilities

Accounts payable and accrued liabilities are as follows:

	December 31, 2023	December 31, 2022
Employee accruals	\$ 22,486	\$ 20,157
Commercial accruals	16,216	8,620
Accrued R&D projects	5,503	5,350
Trade payables	4,327	3,087
Other accrued liabilities	5,190	2,151
Income taxes payable	667	625
Total accounts payable and accrued liabilities	<u>\$ 54,389</u>	<u>\$ 39,990</u>

## 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 thereafter has received \$40.0 million in regulatory and pricing approval milestones as detailed below. The Company has the potential to receive an additional \$10.0 million milestone related to Japan regulatory approval. The Company provides 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 to provide manufacturing services.

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. On November 29, 2022 Aurinia announced that the Medicines and Healthcare Products Regulatory Agency (MHRA) had granted marketing authorization of LUPKYNIS in Great Britain. On April 24, 2023, LUPKYNIS received regulatory approval in Switzerland. The Company continues to progress with regulatory approval with Otsuka in the other Otsuka Territories.

During the third quarter of 2023, the Company received notification that the pricing and reimbursement milestone was secured. As a result, this triggered a \$10.0 million milestone which was recognized as collaboration revenue in the quarter. On November 13, 2023, Otsuka filed a new drug application (NDA) for voclosporin for the treatment of lupus nephritis (LN) with the Japanese Ministry of Health, Labour, and Welfare for the manufacture and sale in Japan of voclosporin.

For the years ended December 31, 2023, December 31, 2022 and December 31, 2021 the Company recognized \$6.0 million, \$0.5 million and nil respectively, of additional collaboration revenue from services provided under the agreement.

#### *Riptide License*

On August 17, 2021, a license for 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 consolidated statements of operations and comprehensive loss. During the first quarter of 2022, Aurinia paid an additional \$4.0 million to Riptide for the achievement of a onetime milestone, which was expensed as research and development on the consolidated statements of operations and comprehensive loss.

Effective February 14, 2024 the Company is ceasing future development of AUR300.

### **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. Aurinia 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). The Company currently has two main customers for U.S. commercial sales of LUPKYNIS which accounted in total of approximately 51% and 40% and 45% and 35% of the Company's total revenues for the year ending December 31, 2023 and December 31, 2022, respectively. The company has a collaboration partnership with Otsuka for sales of semi-finished product and license, royalty and collaboration revenue in Otsuka Territories. The percentage of total revenues, net from our main customers were as follows:

	<b>2023</b>	<b>2022</b>	<b>2021</b>
U.S. main commercial customers	<b>91%</b>	80%	100%
Collaboration partnership	<b>8%</b>	20%	—%

### Revenues by Geographic Location

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

(in thousands)	2023	2022	2021
<b>Revenue</b>			
United States	\$ 157,958	\$ 102,460	\$ 45,488
Japan	17,555	31,481	—
Other	—	89	117
<b>Total</b>	<b>\$ 175,513</b>	<b>\$ 134,030</b>	<b>\$ 45,605</b>

### 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, 2023	December 31, 2022
<b>Long-lived assets, net</b>		
Switzerland	\$ 108,715	\$ —
United States	7,324	8,235
Canada	528	322
<b>Total</b>	<b>\$ 116,567</b>	<b>\$ 8,557</b>

The increase in Switzerland as of December 31, 2023 was due to the monoplant finance lease. For further discussion, refer to Note 15, "Leases".

## 12. Income Taxes

Income (losses) before income taxes for the years ended December 31, 2023, 2022 and 2021 was as follows:

(in thousands)	2023	2022	2021
Canada	\$ (90,226)	\$ (112,359)	\$ (180,374)
Foreign	12,757	6,007	168
	<b>\$ (77,469)</b>	<b>\$ (106,352)</b>	<b>\$ (180,206)</b>

The components of income tax expense consisted of the following for the years ended December 31, 2023, 2022 and 2021:

(in thousands)	2023	2022	2021
<b>Current:</b>			
Canada	\$ —	\$ —	\$ —
Foreign	551	1,828	760
	<b>551</b>	<b>1,828</b>	<b>760</b>
<b>Deferred:</b>			
Canada	—	—	—
Foreign	—	—	—
Total deferred	—	—	—
<b>Income tax expense (benefit)</b>	<b>\$ 551</b>	<b>\$ 1,828</b>	<b>\$ 760</b>

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 24.6%, 26.7%, and 26.8% for the years ending December 31, 2023, 2022 and 2021, respectively. The decrease in the statutory rate is a result of the Company's Canadian operations moving to primarily Alberta, which has a lower provincial rate. The Company's December 31, 2022 increase in tax expense is primarily driven by withholding tax payments paid, and such decrease for December 31, 2023 is due to such withholding tax payments not recurring during the year.

	2023	2022	2021
Canada statutory income tax benefit	24.6 %	26.7 %	26.8 %
Effect of tax rates on foreign jurisdictions	0.6	0.3	—
Withholding taxes	(0.2)	(1.1)	—
Impact of future rates and tax rate changes	(15.6)	(0.1)	(0.1)
Foreign tax credit	0.2	1.1	—
Non-deductible share-based compensation	(13.8)	(8.1)	(4.5)
State income taxes	(0.9)	(0.1)	—
Change in valuation allowance	3.1	(21.5)	(21.8)
Scientific Research and Experimental Development (SRED) and Research Credits	1.3	1.1	0.3
Other	—	—	(1.1)
Effective tax rate	<u>(0.7)%</u>	<u>(1.7)%</u>	<u>(0.4)%</u>

The net deferred tax assets (liabilities) consisted of the following for the years ended December 31, 2023 and 2022:

(in thousands)	2023	2022
Deferred tax assets:		
Net operating loss carry-forwards	\$ 137,907	\$ 141,020
Share issue costs	2,325	4,209
Lease liability	23,837	1,860
Intangible assets	1,479	1,400
Research credit carry-forwards	8,263	7,462
Capitalized research and development	—	1,663
Deferred compensation	2,384	3,391
Accruals	3,646	2,887
Other	2,688	2,427
Gross deferred tax assets	<u>182,529</u>	<u>166,319</u>
Valuation allowance	(161,898)	(164,514)
Total deferred tax assets	<u>20,631</u>	<u>1,805</u>
Deferred tax liabilities:		
Right-of-use asset	(20,060)	(1,128)
Property and equipment and intangible assets	(571)	(677)
Total deferred tax liabilities	<u>(20,631)</u>	<u>(1,805)</u>
Net deferred tax assets (liabilities)	<u>\$ —</u>	<u>\$ —</u>

The Company's valuation allowance decreased by net \$2.6 million in 2023 as compared to 2022 as a result of the decrease in the deferred blended tax rate applied to Canada deferred tax balances offset by additional pre-tax losses which are not more likely than not to be realized.

The Company's net deferred tax asset, including net operating loss carryforwards, are not more likely than not realizable as a result of the Company's significant cumulative pre-tax losses.

As of December 31, 2023, the Company has \$557.1 million of Canada gross net operating loss (NOL) carryforwards and approximately \$6.5 million of Canada Investment Tax Credits and British Columbia Scientific Research and Experimental Development (SRED) with an expiration period of 2029 through 2043. The Company also has approximately \$4.1 million of U.S. federal gross NOL carryforwards that carryforward indefinitely, although limited to eighty percent of taxable income annually, and research and development tax credits of \$0.1 million with an expiration of 2043. The Company's ability to utilize the U.S. federal and state tax attribute carryforwards to offset any taxable income or tax liability in certain taxable periods may be limited under Section 382/383 of the Internal Revenue Code.

#### ***Uncertain Income Tax Positions***

The Company was under audit by the Comptroller of Maryland for years 2019 through 2021 and during the year was notified that the audit is now complete with no significant changes. The Company is currently under examination by the Canadian Revenue Agency for the years 2019, 2020 and 2021. The Company is subject to examination in the U.S., UK and Canada. In the UK, tax periods remain open from 2021 through 2023. In the U.S. and Canada, tax periods remain open from 2020 through 2023 and 2009 through 2023, respectively, 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. On May 22, 2023, the lead plaintiff filed its amended complaint. On October 20, 2023, we filed a motion to dismiss the amended complaint (the "Motion to Dismiss"). On December 8, 2023, the lead plaintiff filed its opposition to the Motion to Dismiss. On January 12, 2024, we filed our reply in support of the Motion to Dismiss. We intend to vigorously defend ourselves against this action.

#### ***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 \$11.0 million through 2024 of which \$0.9 million was paid during 2023. 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 \$10.9 million and \$12.2 million as of December 31, 2023 and December 31, 2022, respectively. The balance as of December 31, 2023 and December 31, 2022 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. One of the former officers, Dr. Robert T. Foster, is considered a related party following his appointment to the Board of Directors on September 21, 2023. For further discussion, refer to Note 19, "Related Party".

#### 15. Leases

The Company has the following lease obligations:

##### *Victoria, British Columbia*

In December 2020, Aurinia entered into a lease for office space in Victoria, British Columbia. During September 2022, the fixed lease term ended on the Victoria lease and the Company exercised its right to enter into a short-term month to month lease, of which expenses were incurred in SG&A. On March 31, 2023, the Company terminated the Victoria lease.

##### *Rockville, Maryland*

During March 2020, the Company entered into a lease for its U.S. commercial office in Rockville, Maryland for a total of 60,531 square feet of office space. The lease has a remaining term of approximately 8 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. During 2020, the Company received lease incentives for tenant leasehold improvements by the landlord in the amount of \$2.3 million for the Maryland lease. The Company recorded the lease 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 term of lease. As of December 31, 2023, the Company had a right-of-use asset of \$4.5 million and lease liability of \$7.4 million included in the consolidated balance sheets. 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.

##### *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 for a six year term and has an option to renew after 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.

For all operating leases, the Company incurs variable lease costs. 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, 2023, December 31, 2022 and December 31, 2021 were approximately \$0.8 million, \$1.0 million and \$1.0 million, respectively.

##### *Monoplant*

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

Following U.S. regulatory approval of LUPKYNIS in January 2021, the construction of the monoplant began. The Company has completed a capital expenditure payment program for the monoplant totaling approximately CHF 21.0 million. The first capital expenditure payment was made in February 2021 of \$1.8 million (CHF 10.5 million) and was treated as an upfront lease payment and recorded under other non-current assets on consolidated balance sheets. The second payment of \$11.9 million (CHF 10.5 million) became due when the facility fulfilled the required operational qualifications, which occurred during the second quarter of 2023. The Company now has the exclusive right to use the monoplant by paying a quarterly fixed facility fee.

The Company has determined that the monoplant arrangement will be accounted for as a finance lease under ASC 842. Under ASC 842, the lease term begins at the commencement date and is based on the noncancellable period for which a lessee has the right to use an underlying asset. Aurinia determined that the lease commencement occurred at the point when the FDA manufacturing validation process began, which occurred during the three months ended June 30, 2023.

The Company, at lease inception, recorded an ROU asset of approximately \$17.6 million and a corresponding lease liability of \$94.1 million, which is the present value of the minimum lease payments beginning July 2023 and ending in 2030. The incremental borrowing rate applied to value the lease liability at inception is 6.19%, which was based on the financial position of the Company, geographical region and term of lease.

As of December 31, 2023 the ROU asset, net and corresponding lease liability balance were \$08.7 million and \$90.1 million, respectively. For the year ending December 31, 2023, ROU amortization related to the finance lease and interest expense was \$8.9 million and \$2.8 million, respectively. For the year ending December 31, 2023, approximately \$5.9 million foreign exchange loss related to the revaluation of the monoplant finance lease liability was recorded in other expense (income) on the consolidated statements of operations and comprehensive loss. The monoplant finance lease commenced in June 2023 and is denominated in CHF.

The following table represents the weighted-average remaining lease term and discount rates for the Company's leases for the years ended December 31, 2023 and December 31, 2022:

	As of December 31, 2023		As of December 31, 2022	
	Weighted Average Remaining Lease Term (years)	Weighted Average Discount Rate	Weighted Average Remaining Lease Term (years)	Weighted Average Discount Rate
Operating leases	7.6	5.28%	8.7	5.3%
Finance lease	6.3	6.19%	—	—

Supplemental cash flow information related to leases for the years ended December 31, 2023, December 31, 2022 and December 31, 2021 are as follows:

(in thousands)	2023	2022	2021
<b>Cash paid for amounts included in the measurement of lease liabilities</b>			
Financing cash flows from finance lease	\$ (10,025)	\$ —	\$ —
Operating cash flows from finance leases	\$ (2,311)	\$ —	\$ —
Operating cash flows from operating lease	\$ (1,080)	\$ (1,160)	\$ (646)
Initial recognition of operating lease right-of-use asset	\$ —	\$ 57	\$ 419
<b>Supplemental disclosure of noncash transactions</b>			
Finance right-of-use asset obtained in exchange for lease obligations (monoplant)	\$ 117,622	\$ —	\$ —
Finance lease liability arising from obtaining right-of-use assets (monoplant)	\$ 94,140	\$ —	\$ —

Future maturities of lease liabilities as of December 31, 2023 are as follows:

(in thousands)	Finance Lease Payments	Operating Lease Payments
2024	\$ 17,240	\$ 1,114
2025	17,240	1,142
2026	17,240	1,170
2027	17,240	1,199
2028	17,240	1,228
Thereafter	21,551	3,302
Total lease payments	107,751	9,155
Less: imputed interest	(17,663)	(1,636)
Total	\$ 90,088	\$ 7,519

#### Beinheim

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 \$1.0 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, 2023, 2022 and 2021, 143.8 million, 142.3 million and 141.6 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, inventory costs, R&D programs, FDA related post approval commitments and funding our working capital obligations.

#### November 19, 2021 At-the-market (ATM) facility

On November 19, 2021 the Company entered into an Open Market 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.

#### 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 the 2016 Public Offering, each Unit consisted 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 met the scope exceptions provided in ASC 815, *Derivatives and Hedging*, as they were indexed to the Company's own shares, and therefore were accounted for under ASC 505, *Equity*.

At initial recognition on December 28, 2016, the Company recorded warrants 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 2023 and 2022. The warrant activity for 2021 is as follows:

	<b>Number of warrants (in thousands)</b>
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 419 thousand and 286 thousand were purchased during 2023 and 2022, respectively. 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 and comprehensive loss.

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 2023 and 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, 2023.

	Number of Shares (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
<b>Outstanding at December 31, 2022</b>	13,295	\$ 12.09	7.74	\$ 21
Granted	760	\$ 9.53		
Exercised/released	(563)	\$ 5.50		
Cancelled/forfeited	(1,936)	\$ 16.08		
Outstanding at December 31, 2023	11,556	\$ 10.63	7.03	\$ 7,967
<b>Options exercisable, December 31, 2023</b>	9,422	\$ 11.73		
<b>Vested and expected to vest, December 31, 2023</b>	11,379	\$ 11.55		

The weighted average grant date fair value of stock options granted during the years ended December 31, 2023, 2022 and 2021 was \$.86, \$6.52 and \$7.34, respectively. The total fair value of options vested during the years ended December 31, 2023, 2022 and 2021 was \$40.9 million, \$49.2 million and \$24.9 million, respectively.

Total intrinsic value of options exercised was \$2.0 million, \$0.9 million and \$50.3 million for years ended December 31, 2023, 2022 and 2021, 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 during 2023 and 2022, the expected life remained constant. The length of the expected life in 2023 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 in 2023 and 2022 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, 2023, 2022 and 2021:

	2023	2022	2021
Expected term (in years)	5 years	5 years	4 years
Volatility	71 %	70 %	66 %
Risk-free interest rate	3.99 %	2.06 %	0.46 %
Dividend yield	0.0 %	0.0 %	0.0 %

### Performance Awards and Restricted Stock Units

The Company has granted PAs and RSUs and intends to grant RSUs and PAs under the Plan, as well as inducements for certain new hires as discussed above. The RSUs and PAs are fair valued based on the market price of our common shares on the date of the grant. The RSUs and PAs and inducement RSUs and PAs 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, 2023:

	Number of Shares (in thousands)	Weighted-Average Grant Date Fair Value
Unvested balance, December 31, 2022	1,980	\$ 10.84
Granted	6,827	\$ 9.03
Vested	(583)	\$ 11.57
Forfeited	(417)	\$ 9.33
Unvested balance, December 31, 2023	<u>7,807</u>	<u>\$ 9.29</u>

The weighted-average grant date fair value of RSUs and PAs granted during the years December 31, 2023, 2022 and 2021 was \$9.03, \$11.16 and \$14.42, respectively. Total intrinsic value of RSUs and PAs vested and released was \$5.4 million, \$2.9 million and nil for years ended December 31, 2023, 2022 and 2021, respectively.

### Compensation Expense

Share-based compensation expense for the years ended December 31, 2023, 2022 and 2021 totaled approximately \$45.3 million, \$32.3 million and \$31.2 million, respectively, as shown in the table below. Share-based compensation capitalized under inventories is recognized in cost of sales when the related product is expensed.

(in thousands)	2023	2022	2021
Research and development	\$ 7,533	\$ 3,271	\$ 4,442
Selling, general and administrative	36,512	28,438	26,432
Capitalized under inventories	1,266	591	369
Share-based compensation expense	<u>\$ 45,311</u>	<u>\$ 32,300</u>	<u>\$ 31,243</u>

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

As of December 31, 2023, 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	\$ 3,795	
Restricted Stock Units and Performance Awards	25,956	
ESPP	708	
Total unrecognized share-based compensation expense	<u>\$ 30,459</u>	1.3

## 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:

	<u>2023</u>	<u>2022</u>	<u>2021</u>
Net loss for the year	\$ (78,020)	\$ (108,180)	\$ (180,966)
Weighted average number of common shares outstanding	143,236	141,915	129,369
Net loss per common share (expressed in \$ per share)	<u>\$ (0.54)</u>	<u>\$ (0.76)</u>	<u>\$ (1.40)</u>

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:

	<u>2023</u>	<u>2022</u>	<u>2021</u>
Outstanding stock options	11,556	13,295	12,074
Unvested performance awards	921	—	64
Unvested restricted units	6,886	1,980	191
	<u>19,363</u>	<u>15,275</u>	<u>12,329</u>

## 19. Related Party

ILJIN SNT Co., Ltd (ILJIN) is considered to be a related party due to their equity ownership of over 5% as per their public filings. During 2023, 2022 and 2021, Aurinia paid \$0.5 million, nil and \$6.0 million, respectively, upon achievement of specific milestones. The amount payable to ILJIN is nil as of December 31, 2023 and 2022.

On September 21, 2023, the Company appointed Dr. Robert T. Foster to the Board of Directors. Dr. Foster is considered a related party since he is one of the former executive officers of the Company who, as of March 8, 2012 was provided with future potential employee benefit obligations for remaining with the Company for a certain period of time. These obligations are contingent on the occurrence of uncertain future events. Dr. Foster was not a related party of the Company between his resignation from the Company in 2014, and his appointment to the Board of Directors on September 21, 2023. As of December 31, 2023, the Company had \$0.8 million and \$7.6 million of current and noncurrent liabilities related to Dr. Foster, respectively. From the time that Dr. Foster became a related party, the Company made a payment of \$ 0.1 million to him for the deferred compensation.

## 20. Selected Quarterly Financial Information (unaudited)

The following condensed quarterly financial information is for the years December 31, 2023 and 2022:

<b>(in thousands, except per share data)</b>	<b>March 31, 2023</b>	<b>June 30, 2023</b>	<b>September 30, 2023</b>	<b>December 31, 2023</b>
Total revenue, net	\$ 34,409	\$ 41,494	\$ 54,515	\$ 45,095
Cost of sales and operating expenses	63,993	57,664	70,778	74,769
Loss from operations	(29,584)	(16,170)	(16,263)	(29,674)
Net loss	(26,206)	(11,492)	(13,447)	(26,875)
Basic and diluted loss per common share	\$ (0.18)	\$ (0.08)	\$ (0.09)	\$ (0.19)

	<b>March 31, 2022</b>	<b>June 30, 2022</b>	<b>September 30, 2022</b>	<b>December 31, 2022</b>
Total revenue	\$ 21,625	\$ 28,191	\$ 55,779	\$ 28,435
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)

## 21. Subsequent Events

Effective February 14, 2024, the Board of Directors of Aurinia elected to conclude its strategic review process and to discontinue future development of AUR200 and AUR300 research and development programs and prioritize resource allocation. This will result in a one-time charge in the first quarter of 2024 of approximately \$11 - \$15 million. The charge will primarily be made up of severance costs, contract termination costs and other costs associated with terminating the programs. The Board also approved a share repurchase program of up to \$150 million worth of the Company's common shares (each, a "common share") (the maximum value of which is subject to receipt of regulatory approval in Canada).

**LIST OF SUBSIDIARIES**

The following is a list of subsidiaries of Aurinia Pharmaceuticals Inc. as of December 31, 2023.

<b>Subsidiary</b>	<b>State or Other Jurisdiction of Incorporation or Organization</b>
Aurinia Pharma U.S., Inc.	Delaware
Aurinia Pharma Limited	United Kingdom



**Consent of Independent Registered Public Accounting Firm**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-272244, 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 14, 2024 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**

Toronto, Canada  
February 14, 2024

**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 14, 2024

AURINIA PHARMACEUTICALS INC.

*/s/ Peter Greenleaf*

Name: Peter Greenleaf  
Title: Chief Executive Officer

**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 14, 2024

AURINIA PHARMACEUTICALS INC.

*/s/ Joseph Miller*

Name: Joseph Miller  
Title: Chief Financial Officer

**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, 2023, 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 14, 2024

AURINIA PHARMACEUTICALS INC.

/s/ Peter Greenleaf

Name:

Peter Greenleaf

Title:

Chief Executive Officer

**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, 2023, 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 14, 2024

AURINIA PHARMACEUTICALS INC.

/s/ Joseph Miller

Name: Joseph Miller

Title: Chief Financial Officer

## Aurinia Pharmaceuticals Inc.

## Incentive Compensation Recoupment Policy

(Approved November 22, 2023)

**1. Introduction**

The Board of Directors (the “**Board**”) of Aurinia Pharmaceuticals Inc., an Alberta corporation (the “**Company**”), has determined that it is in the best interests of the Company and its shareholders to adopt this Incentive Compensation Recoupment Policy (this “**Policy**”) providing for the Company’s recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder (“**Rule 10D-1**”) and Nasdaq Listing Rule 5608 (the “**Listing Standards**”).

**2. Effective Date**

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the “**Effective Date**”). Incentive Compensation is deemed “**received**” in the Company’s fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

**3. Definitions**

“**Accounting Restatement**” means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

“**Accounting Restatement Date**” means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

“**Administrator**” means the Compensation Committee or, in the absence of such committee, the Board.

“**Code**” means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

“**Compensation Committee**” means the Compensation Committee of the Board. “**Covered Officer**” means each current and former Executive Officer. “**Exchange**” means the Nasdaq Stock Market.

“**Exchange Act**” means the U.S. Securities Exchange Act of 1934, as amended.

“**Executive Officer**” means the Company’s president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company’s parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions

---

for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

**“Financial Reporting Measures”** means measures that are determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total shareholder return (“**TSR**”). A measure need not be presented in the Company’s financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

**“Incentive Compensation”** means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

**“Lookback Period”** means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company’s fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

**“Recoverable Incentive Compensation”** means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

**“SEC”** means the U.S. Securities and Exchange Commission.

#### **4. RECOUPMENT**

**(a) Applicability of Policy.** This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

---

**(b) Recoupment Generally.** To the extent permitted by applicable law, pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. To the extent permitted by applicable law, recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

**(c) Impracticability of Recovery.** Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards;

(ii) recoupment of the applicable Recoverable Incentive Compensation would violate home country law where that law was adopted prior to November 28, 2022; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to the Exchange, that recoupment would result in such a violation, and shall provide such opinion to the Exchange in accordance with the Listing Standards; or

(iii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

**(d) Sources of Recoupment.** To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. Subject to compliance with any applicable law, the Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

**(e) No Indemnification of Covered Officers.** Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate

---

of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

**(f) Indemnification of Administrator.** Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

**(g) No “Good Reason” for Covered Officers.** Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) “good reason” for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

## **5. Administration**

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee’s responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

## **6. Severability**

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

## **7. No Impairment of Other Remedies**

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer’s obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 (“**SOX 304**”) that are applicable to the Company’s Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation

---

recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

**8. Amendment; Termination**

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

**9. Successors**

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

**10. Required Filings**

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

---

**Aurinia Pharmaceuticals Inc.**

**Incentive Compensation Recoupment Policy**

**Form of Executive Acknowledgment**

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Aurinia Pharmaceuticals Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "**Policy**"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Aurinia Pharmaceuticals Inc. (the "**Company**") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

**Agreed and Acknowledged:**

Name: \_\_\_ Title: \_\_\_ Date: \_\_\_