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, 2020

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	**Not applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
#1203-4464 Markham Street Victoria, British Columbia V8Z 7X8	**46-4129078**
(Address of principal executive offices)	

Registrant's telephone number, including area code:

(250) 708-4272

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

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

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

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

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

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

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

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

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

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

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

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 the common shares held by non-affiliates of the registrant as of December 31, 2020 totaled approximately $1.74 billion based on the closing price for the registrant's common shares on that day as reported by the Nasdaq Global Market. Such value excludes common shares held by executive officers, and directors as of December 31, 2020.

As of February 24, 2021, there were 127,450,815 of the registrant's common shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	**10-K Part**
Portions of the registrant's definitive proxy statement to be filed with the U.S. Securities and Exchange Commission pursuant to Regulation 14A within 120 days after registrant's fiscal year end of December 31, 2020 are incorporated by reference into Part III of this Annual Report on Form 10-K.	III

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PART I

INTRODUCTION

Unless the context otherwise requires, references in this Annual Report on Form 10-K for the year ended December 31, 2020, or this Annual Report, to "we", "us", "our" or similar terms, as well as references to "Aurinia", refer to Aurinia Pharmaceuticals Inc., together with our subsidiaries.

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

The term "CA$," refers to Canadian dollars, the lawful currency of the Canada, and the terms "dollar," "U.S. dollar" or "$" refer to United States dollars, the lawful currency of the United States. 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, or the Securities Act, and Section 21E of the *Securities Exchange Act of 1934*, as amended, or 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.

A statement is forward-looking when it uses what we know and expect today to make a statement about the future. Forward-looking statements may include words such as "anticipate", "believe", "intend", "expect", "goal", "may", "outlook", "plan", "seek", "project", "should", "strive", "target", "could", "continue", "potential" and "estimated", 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) and the timing or magnitude of those events, as they are inherently risky and uncertain.

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

- our belief in the duration of patent exclusivity for voclosporin and that the patents owned by us are valid;
- our belief in receiving extensions to patent life based on certain events or classifications;
- our expectation that patent protection for voclosporin will be extended in the United States and certain other major markets, including Europe and Japan, until at least October 2027;
- our plans and expectations and the timing of commencement, enrollment, completion and release of results of clinical trials;
- our intention to demonstrate our belief that voclosporin possesses pharmacologic properties with the potential to demonstrate best-in-class differentiation with first-in-class status for the treatment of adult patients with active lupus nephritis (LN) outside of Japan;
- our belief of the key potential benefits of LUPKYNIS in the treatment of LN;
- our belief that LUPKYNIS has the potential to improve near and long-term outcomes in LN when added to mycophenolate mofetil (MMF);
- our belief of specified key benefits of LUPKYNIS in the treatment of LN versus marketed calcineurin inhibitors (CNIs) (the cornerstone of therapy for the prevention of organ transplant rejection);
- our strategy to optimize the clinical and commercial value of voclosporin and become a commercial biopharmaceutical company with a global product portfolio focused on less common kidney and autoimmune diseases with a high unmet need;
- our strategy for the potential expansion of the existing label for additional kidney indications, the evaluation of voclosporin in novel formulations for the treatment of other autoimmune related disorders, as well as the addition of new pipeline assets that align with our core expertise;
- our plans to ensure adequate supply of LUPKYNIS by entering into long term supply agreements with our key suppliers;

- our belief that LUPKYNIS has the potential to address critical needs for LN by controlling active disease rapidly, lowering the overall steroid burden, and doing so with a convenient oral twice-daily treatment regimen;
- our expectation to receive "new chemical entity" exclusivity for LUPKYNIS in certain countries, which provides this type of exclusivity for five years in the United States and up to ten years in Europe;
- our belief that the voclosporin modification of a single amino acid of the cyclosporine molecule may result in a more predictable pharmacokinetic and pharmacodynamics relationship, an increase in potency, an altered metabolic profile, and easier dosing without the need for therapeutic drug monitoring;
- our belief in voclosporin being potentially a best-in-class CNI with benefits over existing commercially available CNIs;
- our estimates as to the market potential for LUPKYNIS, including estimates as to the number of patients with systemic lupus erythematosus (SLE) that are diagnosed with LN;
- our estimate, based on our patient-specific estimated glomular filtration rate (eGFR) dosing regimens, the average utilization in our clinical trials, and accounting for factors including mandatory rebates, channel discounts, and anticipated patient adherence, that we expect our average annualized net revenue per patient to be approximately $65,000;
- our belief that we have enough inventory on hand and manufacturing capacity to meet forecasted demand;
- our belief that we have built a world class commercial organization;
- our intention to use the net proceeds from financings for the stated purposes;
- our belief that we have sufficient cash resources to adequately fund our plans for at least the next 12 months;
- our plan to file, together with Otsuka Pharmaceutical Co. Ltd. (Otsuka), a marketing authorization application (MAA) with the European Medicines Agency (EMA) during the first half of 2021;
- statements concerning the potential market for LUPKYNIS;
- our belief that additional patents may be granted worldwide based on our filings under the Patent Cooperation Treaty (PCT);
- our belief that patents corresponding to United States Patent No. 10,286,036 issued to us covering dosing protocol, which reads upon our U.S. Food and Drug Administation (FDA) approved label for LUPKYNIS in LN, could be granted with similar claims in all major global pharmaceutical markets;
- our strategy to become a global commercial biopharmaceutical company;
- our plan to evaluate LUPKYNIS in pediatric patients and additional patient populations diagnosed with LN;
- 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; and
- the potential impact of COVID-19 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 and social uncertainties and contingencies, many of which, with respect to future events, are subject to change. The factors and assumptions used by management to develop such forward-looking statements include, but are not limited to:

- the assumption that we will be able to obtain approval from regulatory agencies on executable development programs with parameters that are satisfactory to us;
- the assumption that recruitment to clinical trials will occur as projected;
- the assumption that we will successfully complete and enroll our clinical programs in compliance with good clinical practices (GCP) on a timely basis and meet regulatory requirements for approval of marketing authorization applications and new drug approvals, as well as favorable product labeling;
- the assumption that the planned studies will achieve positive results;
- the assumptions regarding the costs and expenses associated with our clinical trials and commercialization of LUPKYNIS, including that the COVID-19 pandemic will not have a significant impact on the costs and expenses planned for our clinical trials and commercialization of LUPKYNIS;
- the assumption that regulatory requirements and commitments will be maintained;
- the assumption that we 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 (including Otsuka) and suppliers will comply with their obligations under their agreements with us;
- the assumptions about future market activity;
- the assumption that there is a potential commercial value for LUPKYNIS and other indications for voclosporin;
- the assumption that market data and reports reviewed by us are accurate;
- the assumptions on the burn rate of our cash for operations;
- the assumption that another company will not violate our intellectual property rights or regulatory exclusivity periods;
- the assumption that our current good relationships with our suppliers, service providers and other third parties will be maintained;
- the assumption that we will be able to attract and retain a sufficient amount of skilled staff;
- the assumption that our third party service providers and partners will comply with their contractual obligations; and/or
- the assumptions relating to the capital required to fund operations for at least the next 12 months.

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.

The factors discussed below and other considerations discussed in the Item 1A Risk Factors section of this Annual Report could cause our actual results to differ significantly from those contained in any forward-looking statements. We strongly encourage all investors to read Item 1A Risk Factors of this Annual Report in full.

Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to differ materially from any assumptions, further results, performance or achievements expressed or implied by such forward-looking statements.

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 it is 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.

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. 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.

RISK FACTOR SUMMARY

Below is a summary of material factors that make an investment in our Common Shares speculative or risky. 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 development, marketing and commercialization of LUPKYNIS;
- unknown impact and difficulties imposed by the COVID-19 pandemic on our business operations including sales, marketing, nonclinical and clinical and our supply chain;
- legislative, regulatory and commercial activities, including new laws regulating the pricing of LUPKYNIS;
- difficulties obtaining adequate reimbursements from third party payors;
- difficulties obtaining formulary acceptance;
- our partners, including suppliers, may not be able to comply with their contractual obligations with us;
- competitors may arise with similar products, or existing competition may be taken up and become the first line of treatment for LN; and
- difficulties in gaining alignment among the regulatory authorities (including the FDA, EMA and Pharmaceutical and Medical Devices Agency), which may require further clinical activities.

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 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; and
- difficulties in identifying and completing the acquisition of, and successfully developing potential targets for expansion of our product portfolio.

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;
- 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;
- 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; and
- our ability to raise future resources when required.

Item 1. Business

Overview

Aurinia is a biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. We have commercially launched LUPKYNIS in the United States for the treatment of adult patients with active LN, and continue to conduct pre-clinical, clinical, and regulatory activities to support the voclosporin development program.

On July 21, 2020, we announced that the FDA had accepted the filing of the new drug application (NDA) for LUPKYNIS, as a potential treatment of adult patients with active LN. LUPKYNIS is a novel and potentially best-in-class CNI with clinical data in over 2,600 subjects across various indications including LN, transplantation, psoriasis, various forms of uveitis and dry eye syndrome. The last module of this rolling NDA was submitted on May 26, 2020, after our December 4, 2019 release of positive AURORA Phase 3 trial results. The FDA granted Priority Review for the NDA, which provided an expedited six-month review, and assigned a PDUFA target action date of January 22, 2021. Priority review is granted to therapies that the FDA determines have the potential to provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition.

On January 22, 2021, the FDA approved LUPKYNIS in combination with a background immunosuppressive therapy regimen to treat adult patients with active LN.

In addition, we plan to prepare an MAA to be filed with the EMA by our partner Otsuka during the first half of 2021 seeking approval for the use of LUPKYNIS for the treatment of adult patients with active LN in the European Union, which includes Norway, Iceland and Liechenstein.

LUPKYNIS is a CNI immunosuppressant, that has the potential to improve near and long-term outcomes in LN when used in combination with MMF, the current standard of care for LN (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.

Earlier generation CNIs have demonstrated efficacy for a number of conditions, including transplant and other autoimmune diseases; however, side effects exist which can limit their long-term use and tolerability. Some clinical complications of earlier generation CNIs include hypertension, hyperlipidemia, diabetes, and both acute and chronic nephrotoxicity.

Based on published data, we believe the key potential benefits of LUPKYNIS in the treatment of adult patients with active LN versus marketed CNIs include:

- increased potency compared to cyclosporine A, allowing for lower dosing requirements and potentially fewer off-target effects;
- limited inter- and intra-patient variability, allowing for easier dosing without the need for monitoring blood levels for therapeutic levels of drug;
- less cholesterolemia and triglyceridemia than cyclosporine A; and
- limited incidence of glucose intolerance and new onset diabetes at therapeutic doses compared to tacrolimus.

Strategy

Our business strategy is to optimize the clinical and commercial value of LUPKYNIS and become a commercial biopharmaceutical company with a global product portfolio focused on less common kidney and autoimmune diseases with high unmet medical needs. This includes the potential expansion of the existing label for additional kidney indications, the evaluation of LUPKYNIS in novel formulations for the treatment of other autoimmune related disorders, as well as the addition of new pipeline assets that align with our core expertise.

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

- obtaining FDA approval for use of LUPKYNIS for the treatment of active LN, which was achieved on January 22, 2021;
- conducting pre- and post-commercial activities including build out of the organization to efficiently and effectively market LUPKYNIS as a treatment of adult patients with active LN;
- engaging Otsuka as a collaboration partner for development and commercialization of LUPKYNIS in Europe; as part of this, we expect to file an MAA with the European Medicines Agency in the first half of 2021, and seek regulatory approval in other territories including the United Kingdom, Switzerland, Russia, and Japan;
- 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.

Market Potential and Commercial Considerations

We have conducted extensive market research and analyses of peer reviewed publications to assess market potential and commercial opportunity. Our physician research included more than 1,100 rheumatologists and nephrologists across the United States, Europe and Japan to assess the potential market for adoption of LUPKYNIS and estimate pricing and treatment paradigms. The National Institute of Diabetes and Digestive and Kidney Diseases estimates that up to 50% of adults with SLE are diagnosed with lupus nephritis 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/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 is also believed to be 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. Physicians currently use existing LN standard of care including immunosuppressant drugs and high dose steroids to treat people with LN throughout the disease cycles. The clinical data generated in our Phase 2 AURA-LV and our Phase 3 AURORA studies has demonstrated that LUPKYNIS can achieve a more than two times higher rate of complete response than the current standard of care when given in combination with a MMF and steroids. We believe that LUPKYNIS efficacy results compared to the standard of care in addition to the product being administered orally versus via infusion or injection can support a rapid market adoption.

The price of LUPKYNIS is based on one unit of 60 capsules we refer to as a "wallet". The wholesale acquisition cost (WAC) of a LUPKYNIS wallet is $3,950. 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 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 this innovative product offers to patients and the US 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 in combination with the current standard of care for the treatment of adult patients with active LN provides a novel approach to treating this disease (similar to the standard approach in preventing kidney transplant rejection). 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 expected to have a direct impact on the levels of protein in the urine which is a key marker of LN disease activity.

Voclosporin Development History

More than 2,600 subjects have been dosed with voclosporin in clinical trials including studies where voclosporin was compared to placebo or active control. The safety and tolerability profile of the drug has been well characterized. Phase 2 or later clinical studies that have been completed include studies in the following indications:

Psoriasis: Two Phase 3 clinical studies in patients with moderate to severe psoriasis have been completed. The primary efficacy endpoint in both studies was a reduction in Psoriasis Area and Severity Index, which is a common measure of psoriasis disease severity. The first study treatment with voclosporin resulted in statistically significantly greater success rates than treatment with placebo by the twelfth week. In a second study comparing voclosporin against cyclosporine, the drug was not shown to be statistically non-inferior to cyclosporine in terms of efficacy; however, voclosporin proved superior in terms of limiting elevations in hyperlipidemia. Due to the evolving psoriasis market dynamics and the changing standard of care for the treatment of this disease, we have decided not to pursue further Phase 3 development.

Kidney Transplantation: A Phase 2b clinical trial in de novo kidney transplant recipients was completed. Study ISA05-01, the PROMISE Study was a six-month study with a six-month extension comparing voclosporin directly against tacrolimus on a background of MMF and corticosteroids. Voclosporin was shown to be equivalent in efficacy (prevention of acute rejection of the transplanted kidney), but superior to tacrolimus with respect to the incidence of new onset diabetes after transplantation. Due to the ongoing evolution of the commercial market in kidney transplantation, including tacrolimus losing patent exclusivity in most world markets, combined with the cost and timeline that would have been associated with additional clinical trials, we have chosen not to pursue further internal clinical development in kidney transplantation.

Uveitis: Multiple studies in various forms of non-infectious uveitis were completed by Lux, one of our former licensees, indicating mixed efficacy. In all but one of the studies, completed by the licensee, an impact on disease activity was shown in the voclosporin group. However, achievement of the primary end-points in multiple studies could not be shown. Uveitis is a notoriously difficult disease to study due to the heterogeneity of the patient population and the lack of validated clinical end-points. However, in all of the uveitis studies completed, the safety results were consistent, and the drug was well tolerated. We retained a portfolio of additional patents that Lux had been prosecuting that are focused on delivering effective concentrations of voclosporin to various ocular tissues following the termination of our licensing agreement in 2014.

Dry eye syndrome (DES): We completed a Phase 2 head to head study for the treatment of DES versus Restasis®, with results reported in January 2019. Both drugs were shown to be well tolerated and there was no statistical difference for the primary endpoint. However, on key pre-specified secondary endpoints of Schirmer Tear Test (STT) and fluorescein corneal staining, voclosporin showed rapid and statistically significant improvements over Restasis®. As a result, we followed up with a Phase 2/3 study which reported results in November 2020. That study did not achieve statistical significance on its primary endpoint compared to vehicle. As a result, we suspended the development of voclosporin for DES.

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 will be required to conduct two pediatric studies (with

reports due in 2025 and 2031), a milk only lactation study (with a report due in 2026), a drug-drug interaction study (with a report due in 2023) and submit a final study report on our AURORA-2 continuation study (by March 2022).

Collaboration and Licensing Agreement with Otsuka Pharmaceutical Co., Ltd.

On December 17, 2020, we entered into a collaboration and licensing agreement with Otsuka for the development and commercialization of oral LUPKYNIS for the treatment of adult patients with active LN in the EU, Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine.

As part of the agreement, we received an upfront cash payment of $50 million and we have the potential to receive up to $50 million in regulatory and reimbursement milestone payments. We will receive tiered royalties ranging from 10 to 20 percent (dependent on achievement of sale milestones) on net sales upon commercialization, along with additional milestone payments based on the attainment of certain annual sales by Otsuka.

Agreement for Dedicated Voclosporin Manufacturing Capacity

On December 15, 2020, we entered into a collaborative agreement with Lonza Ltd. (Lonza) to build a dedicated manufacturing capacity within Lonza's existing small molecule facility in Visp, Switzerland. The dedicated facility (also referred to as "monoplant") will be equipped with state-of-the-art manufacturing equipment to provide cost and production efficiencies for the manufacture of voclosporin, while expanding existing capacity and providing supply security to meet future commercial demand. Either we or Lonza may terminate this agreement if the other party breaches its terms, or if the other party is liquidated or is petitioned for bankruptcy. We also have the right to terminate if we withdraw LUPKYNIS from being marketed in either the United States or the European Economic Area (EEA).

Upon completion of the monoplant, we will have the right to maintain unobstructed use of the monoplant by paying a quarterly fixed facility fee. The first capital expenditure payment was made in February 2021 with the second payment due upon operational qualification of the facility which is expected in 2023.

Completion of Phase 2/3 AUDREY™ clinical trial of VOS

On November 2, 2020 we announced topline data from the Phase 2/3 AUDREY™ clinical study evaluating voclosporin ophthalmic solution (VOS) for the potential treatment of DES. The trial did not achieve statistical significance on its primary endpoint of a 10mm or greater improvement in STT scores at four weeks between active dose groups of VOS compared to vehicle. We suspended the development program for VOS based upon these results.

The AUDREY trial was a randomized, double-masked, vehicle-controlled, dose-ranging study evaluating the efficacy and safety of VOS in subjects with DES. A total of 508 subjects were enrolled. The study consisted of four arms with a 1:1:1:1 randomization schedule, in which patients received either 0.2% VOS, 0.1% VOS, 0.05% VOS or vehicle, dosed twice daily for 12 weeks. The primary outcome measure for the trial was the proportion of subjects with a 10mm or greater improvement in STT at four weeks.

Secondary outcome measures evaluated in the trial included STT at other time points, Fluorescein Corneal Staining at multiple time points, change in eye dryness, burning/stinging, itching, photophobia, eye pain and foreign body sensation at multiple time points, and additional safety endpoints. Initial analysis of these secondary outcomes suggests dose-dependent activity and safety were observed across dose groups compared to vehicle.

Focal Segmentation Glomerulosclerosis (FSGS), a Proteinuric Kidney Disease

FSGS is a rare disease that attacks the kidney's filtering units (glomeruli) causing serious scarring which leads to permanent kidney damage and even kidney failure. FSGS is one of the leading causes of Nephrotic Syndrome (NS) and is identified by biopsy and proteinuria. NS is a collection of signs and symptoms that indicate kidney damage, including large amounts of protein in urine; low levels of albumin and higher than normal fat and cholesterol levels in the blood, this is often accompanied by edema. In June of 2018 we initiated an open-label Phase 2 Study in FSGS with the goal of enrolling approximately 20 treatment-naïve patients in the United States. This protocol was subsequently amended during the summer of 2019 to permit enrollment of subjects who had received limited corticosteroid exposure in the past as well as the addition of clinical trial sites outside of the United States.

As a consequence of the continued difficulty identifying and enrolling primary FSGS patients, in the first quarter of 2020 we decided to invest our capital resources in other ways and close the enrollment of the trial. As a result, we suspended the FSGS exploratory study but continue to support patients who have participated in the study.

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

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

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

This 56-day open-label IIT is designed to evaluate the antiviral effects of voclosporin compared to tacrolimus in stable KTRs who contracted COVID-19. At study entry, 20 KTRs testing positive for COVID-19 and currently on dual immunosuppressives of prednisone and tacrolimus were randomized 1:1 to remain on tacrolimus or be switched to voclosporin. The primary endpoint is the reduction in COVID-19 viral load over 56 days, as measured by reverse transcription polymerase chain reaction. The study will also assess predefined endpoints as surrogate markers of improved viral clearance including time to 3-log reduction in viral load concentration, time to clinical recovery – defined as free of symptoms for five days or more, and safety and tolerability. Following the 56-day treatment period, there will be an extended safety follow-up of voclosporin treated patients for up to one year.

Submission of NDA to the FDA

On July 21, 2020, we announced that FDA had accepted the filing of the NDA for LUPKYNIS, as a potential treatment for LN. The FDA granted Priority Review for the NDA, which provided an expedited six-month review, and assigned a *Prescription Drug User Fee Act* (PDUFA) target action date of January 22, 2021.

Priority review is granted to therapies that the FDA determines have the potential to provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition. Under PDUFA, a Priority Review targets a review time of six months compared to a standard review time of 10 months. LUPKYNIS was also granted Fast Track designation by the FDA in 2016.

Rolling Submission of our NDA

On March 16, 2020 we announced that we had initiated a "rolling submission of our NDA" to the FDA for LUPKYNIS for the treatment of LN. The rolling NDA allowed completed portions of an NDA to be submitted and reviewed by the FDA on an ongoing basis. We submitted the nonclinical module in March of 2020 and the chemistry, manufacturing and controls module in April of 2020.

Change in International Financial Reporting Standards (IFRS) / Foreign Private Issuer Status

Prior to June 30, 2020, we qualified as a foreign private issuer or FPI as such term is defined in Rule 3b-4 under the Exchange Act, and we utilized the multijurisdictional disclosure system (MJDS) as permitted for Canadian corporations for filing reports with the SEC. We are required under SEC rules to test our FPI status annually at the end of our second fiscal quarter. If an issuer fails to qualify as an FPI at the end of its second fiscal quarter, it remains eligible to use the forms and rules applicable to FPIs until the end of that financial year. Historically, we met the definition of an FPI, and as such, prepared our consolidated financial statements in accordance with IFRS and complied with SEC rules applicable to Canadian corporations filing reports using MJDS.

As of June 30, 2020, since more than 50% of our Common Shares were held by U.S. residents and a majority of our executive officers were U.S. citizens or residents, we no longer qualified as an FPI. As a result, we transitioned to U.S. domestic reporting

status and became subject to U.S. domestic reporting requirements beginning January 1, 2021. These reporting requirements require, among other things, that our financial statements be presented in accordance with U.S. GAAP for all periods, which will include fiscal 2020 comparative financial information. Therefore, the last period under which we reported under IFRS was the third quarter ended September 30, 2020. In addition, we are now required to file annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K with the SEC, our executive officers and directors are required to comply with Section 16 of the Exchange Act with respect to reporting transactions in our Common Shares and short-swing trading rules, and we are subject to the proxy rules under Section 14 of the Exchange Act, among other requirements.

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 an extensive granted patent portfolio covering voclosporin, including granted United States patents, for composition of matter, methods of use, formulations and synthesis. Certain corresponding Canadian, South African and Israeli patents are owned by Paladin Labs Inc. We anticipate that patent protection for voclosporin will be extended in the United States (Patent Term Extension) 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 the Patent Term Extension, and are awaiting confirmation from the U.S. Patent and Trademark Office. Opportunities may also be available to add an additional six months of exclusivity related to pediatric studies which are currently in the planning process. In addition to patent rights, we also expect to receive "new chemical entity" exclusivity for voclosporin in certain countries, which provides exclusivity for five years in the United States and up to ten years in Europe.

In May 2019, we were granted U.S. Patent No. 10,286,036 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 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.

We had licensed the development and distribution rights to voclosporin for China, Hong Kong and Taiwan to 3SBio Inc. This license was royalty bearing. We do not expect to receive any royalty revenue pursuant to this license.

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. In particular, another treatment was approved by the FDA for LN approximately one month before we received approval for LUPKYNIS. Many of these companies 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, 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.

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

REGULATORY

We are currently working with Otsuka to prepare an MAA filing with the EMA, and we anticipate that the MAA will be filed during the first half of 2021. Otsuka has also taken on customary obligations to use commercially reasonable efforts to prepare

and submit filings for regulatory approvals in the other territories in which we have granted them rights, including Japan and selected other European countries.

Regulatory Requirements

The development, manufacturing and marketing of LUPKYNIS is subject to regulations relating to the demonstration of safety and efficacy of the products as established by the government or regulatory authorities in those jurisdictions where this product is to be marketed. We, or our licensees, are required to seek and obtain regulatory approvals in US, 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 in the United States. We believe this approach 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 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 Investigational New Drug application (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 active pharmaceutical ingredient, or API, 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 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 II 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 II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support submission of an NDA.

A sponsor may request a special protocol assessment or SPA to reach an agreement with the FDA that the protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. If such an agreement is reached, it will be documented and made part of the administrative record, and it will be binding on the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, if the relevant data, assumptions, or information provided by the sponsor in a request for SPA change are found to be false statements or misstatements or omit relevant facts, or if the sponsor fails to follow the protocol that was agreed upon with the FDA. A documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. There is no guarantee that a study will ultimately be adequate to support an approval, even if the study is subject to an SPA.

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, which is waived for the first NDA submitted by a qualifying small business.

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 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 active pharmaceutical ingredient (API) 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 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 U.S. Patent and Trademark Office, or 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, or 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 noninfringement. 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 US, 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 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, or 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, or SmPC, and a draft of the labeling and package leaflet, which are sent to the other member states (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling or packaging proposed by the reference member state, the product is subsequently granted a national MA in all the member states, i.e., in the reference member state and the member states concerned.

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

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

When conducting clinical trials in the EU, we must adhere to the provisions of the European Union Clinical Trials Directive (Directive 2001/20/EC) and the laws and regulations of the EU Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the competent Member State authority is obtained before commencing the clinical trial. In April 2014, the EU passed the Clinical Trials Regulation (Regulation 536/2014), which will replace the current Clinical Trials Directive. To ensure that the rules for clinical trials are identical throughout the European Union, the EU Clinical Trials Regulation was passed as a regulation that is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive until the Clinical Trials Regulation becomes applicable. According to the current plans of the EMA, the Clinical Trials Regulation is expected to become applicable in December 2021.

Japan

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

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

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

Coverage and Reimbursement

In the United States and internationally, sales of LUPKYNIS and any other products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of adequate coverage and reimbursement from third-party payors, such as state and federal governments, managed care providers and private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and the out-of-pocket obligations of member patients for such products. We may need to conduct pharmacoeconomic studies to demonstrate the cost-effectiveness of our products for formulary coverage and reimbursement. Even with such studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

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

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 changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, ACA establishes:

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

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the *Budget Control Act of 2011*, among other things, included 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 to the statute, will remain in effect through 2029 unless additional Congressional action is taken. The *American Taxpayer Relief Act of 2012*, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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. For example, the *21st Century Cures Act* changes the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain drugs.

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, we have established relationships with contract manufacturing organizations or CMOs, coupled with supply agreements, for the manufacturing of active pharmaceutical ingredient or API, and encapsulation of LUPKYNIS 7.9 mg capsules.

Manufacturing of API

LUPKYNIS requires a specialized API manufacturing process and is manufactured by Lonza. 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 API 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 voclopsorin. We believe we have enough inventory on hand and manufacturing capacity to meet forecasted demand.

Encapsulation

Catalent Pharma Solutions (Catalent) is currently the sole supplier for the encapsulation and the packaging of our voclosporin drug supply. 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 LUPKYNIS 7.9 mg and capsules required for our future commercial and clinical supply needs.

Marketing, Sales and Distribution

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

HUMAN CAPITAL MANAGEMENT

As of December 31, 2020, we employed 294 employees across the United States, Canada and the United Kingdom, all of whom are expected to be guided by our vision and values and by an underlying set of ethical principles. We are committed to treating each of our employees fairly, and to maintaining employment practices based on equal opportunity for all employees. We respect each other's privacy and treat each other with dignity and respect irrespective of age, race, color, sex, sexual preference, nationality, or physical condition. We are committed to providing safe and healthy working conditions and an atmosphere of open communication for all of our employees.

While the Compensation Committee of our board of directors has the primary responsibility of overseeing our human capital management activities (including assessing the effectiveness of employee programs and advising management with regard to establishing our strategic goals and overall human resource strategies), other committees also have responsibilities that impact our human capital management as outlined in their respective charters. Within management, our human resources function has global management responsibility for advising and assisting the business on human resource matters and executing our overall human capital management strategies.

We strive to engage and retain our employees throughout the employment life-cycle with effective recruiting and onboarding; competitive pay, benefits and other total rewards; programs for professional development and career advancement; compliance training; succession planning; and a safe, healthy and respectful workplace.

In response to the COVID-19 pandemic, we quickly implemented safety and health standards and protocols for our employees while continuing to offer a safe environment as an essential service to our customers. Our employees have been working from home since March 2020, but have also been empowered with the option of working from the office if they so choose (in particular in our Victoria office, where the number of COVID-19 cases has been relatively small). Our offices are provided with personal protective equipment, other equipment and enhanced cleaning supplies, and are required to adhere to appropriate protocols for social distancing, limiting density, reporting and documenting exposures and wearing masks at all times, all as recommended by the Centers for Disease Control or mandated by local regulations.

We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages.

We maintain a whistleblower hotline that is available to all of our employees to report (anonymously if desired) any matter of concern. Communications to the hotline (which is facilitated by an independent third party) are routed to our General Counsel for investigation and resolution.

CORPORATE INFORMATION

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

Our website address is www.auriniapharma.com and our investor relations website is located at https://ir.auriniapharma.com. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov. Beginning January 1, 2020, 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 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. Our documents are also filed with securities regulators in Canada and are available under our profile at the website www.sedar.com.

Item 1A. Risk Factors

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

Risks Related to the COVID-19 Pandemic

Our business, results of operations, and future growth prospects could be materially and adversely affected by the COVID-19 pandemic.

Due to the evolving and uncertain impacts of the COVID-19 pandemic, we cannot precisely determine or quantify the impact this pandemic will have on our business operations going forward. In response to the spread of COVID-19, we have closed our offices with our administrative employees continuing their work outside of our offices and restricted on-site staff to only those required to execute their job responsibilities. We have also adapted from a standard marketing routine, as LUPKYNIS was launched in the middle of a pandemic, where our sales force would have the option of meeting with physicians virtually or in-person. As a result of the COVID-19 pandemic, we have and may continue to experience disruptions that severely impact our business, commercialization, pre-clinical studies, and clinical trials, including:

a. delays or difficulties in enrolling patients in our clinical trials;
b. delays or difficulties in building out and maintaining commercial infrastructure;
c. delays in recruiting for key positions;

d. delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
e. interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal, provincial or state governments, employers, and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
f. interruption or delays in the operations of applicable regulatory authorities, which could impact the ability to obtain applicable regulatory approvals, and could impact on ability to commercialize internationally or receive milestone payments from licensees;
g. interruption or delays in receiving supplies of LUPKYNIS 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 pre-clinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
i. limited ability to access accounts and healthcare professionals, in person or at all, to provide medical information to promote; and
j. patient visits to physicians and new patient start might have limited access to prescribers.

The pandemic has significantly impacted economies worldwide, which could result in harm to our business and operations. The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic may impact our business, commercialization, pre-clinical studies, and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease and its new strains, the duration of the outbreak, travel restrictions, and social distancing in Canada, the United States and other countries, business closures or business disruptions and the effectiveness of vaccinations and actions taken in the Canada, the United States and other countries to contain and treat the disease.

To the extent the COVID-19 pandemic harms our business and financial results, it may also have the effect of heightening many of the other risks described in this Annual Report. Because of the highly uncertain and dynamic nature of events relating to the COVID-19 pandemic, it is not currently possible to estimate the impact of COVID-19 on our business. However, these effects could harm our operations, and we will continue to monitor the COVID-19 situation.

Risks Related to Commercialization

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

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

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

Part of our strategy to commercialize LUPKYNIS in the United States is to maintain a direct sales force. These efforts have been and will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully develop and maintain this capability. LUPKYNIS is a newly marketed product and, therefore, none of the members of our sales force had ever promoted LUPKYNIS prior to its commercial launch. In addition, prior to December 2020, there were no FDA approved treatments for LN. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers our efforts to commercialize successfully could be harmed, which would negatively impact our ability to generate product revenue.

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

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

- achieve and maintain compliance with regulatory requirements;
- create and sustain market demand for and achieve market acceptance of LUPKYNIS through our marketing and sales activities and other arrangements established for the promotion of LUPKYNIS;
- educate physicians and patients about the benefits, administration and use of LUPKYNIS;
- train, deploy, and support a qualified sale 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, 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 total 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.

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

Most of our revenue will come from a limited number of direct customers. 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.

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 Securities to decline.***

The commercial success of LUPKYNIS is dependent upon achieving and maintaining market acceptance among physicians, patients, and the medical community. New products that appear promising in development may fail to reach the market or may have only limited or no commercial success. 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;
- lack of 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 and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- 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;
- the degree of market acceptance, and the number of, competitive products;

- adverse publicity about our product or favorable publicity about competitive products;
- convenience and ease of administration of our products; and
- potential product liability claims.

If LUPKYNIS does not achieve an adequate level of acceptance by physicians, patients, and the medical community, we may not generate sufficient revenue, and we may not become or remain profitable. Efforts to educate the medical community and third-party payors on the benefits of LUPKYNIS may require significant resources and may never be successful.

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

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

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

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 newly 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 or AMP, and best price or 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.

Risks Related to Patents and Proprietary Technology

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

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

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

- patent applications will result in the issuance of patents;
- additional proprietary products developed will be patentable;
- patents issued will provide adequate protection or any competitive advantages;
- patents issued will not be successfully challenged and invalidated by third parties;
- LUPKYNIS does not infringe the patents or intellectual property of others; or
- that we will be able to obtain any extensions of the applicable patent terms.

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

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

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

We may need to enter into license agreements in the future. As part of discovery and development activities, we routinely evaluate in-licenses from academic and research organizations. Future license agreements might impose various diligence, milestone payment, royalty, and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners (such as Otsuka) regarding our rights or obligations under the licensing agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partner's ability to utilize the affected intellectual property in our drug discovery and development efforts, and our ability to ensure into collaboration or marketing agreements for an affected product, may be adversely affected.

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

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

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

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

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

Our intellectual property rights in some countries outside of the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners (such as Otsuka) 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 United States Patent and Trademark Office 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 U.S. Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

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

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

Risks Related to Financial Position and Need for Additional Capital

We expect to continue to have negative cash flow and we may never achieve or maintain profitability.

We had negative operating cash flow for multiple years including the financial year ended December 31, 2020. To the extent that we have negative operating cash flow in future periods, we will likely need to allocate a portion of our cash reserves to fund such negative cash flow. We may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that we will be able to generate a positive cash flow from our operations, that additional capital or other types of financing will be available when needed or that these financings will be on terms favorable or acceptable to us.

We have incurred losses and anticipate that our losses will increase as we continue to expand and develop our business and commercialize LUPKYNIS. As of December 31, 2020, we had an accumulated deficit of $575.2 million. Although we received FDA approval and commenced commercialization of LUPKYNIS in the United States in January 2021, we 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. Due to the recent FDA approval of LUPKYNIS and the absence of historical sales data, our revenue from product sales will be difficult to predict. We also expect to have quarter-to-quarter fluctuations in expenses, some of which could be significant, due to research, development, clinical trial activities, regulatory activities, and commercialization activities.

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 credit risks and market risks 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 treasury notes, banker acceptances, bank bonds, and term deposits. 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, will affect our operating and financial results. We hold the majority of our cash reserves in U.S. dollars and the majority of our expenses, including clinical trial costs are also denominated in U.S. dollars, which mitigates the risk of material foreign exchange fluctuations.

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

As part of our business strategy, we may acquire additional companies, products or technologies principally related to, or complementary to, our current operations. At any given time, we may be evaluating new acquisitions of companies, products or technologies or may be exploring new licensing opportunities, and may have entered into confidentiality agreements, non-binding letters of intent or may be in the process of conducting due diligence with respect to such opportunities. Any such acquisitions will be accompanied by certain risks including, but not limited to:

a. exposure to unknown liabilities of acquired companies and the unknown issues with any associated technologies or research;
b. higher than anticipated acquisition costs and expenses;
c. the difficulty and expense of integrating operations, systems, and personnel of acquired companies;
d. disruption of our ongoing business;
e. inability to retain key customers, distributors, vendors and other business partners of the acquired company;
f. diversion of management's time and attention; and
g. possible dilution to shareholders.

We may 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.

We are exposed to risks relating to the write-down of intangible assets, which comprises a significant portion of our total assets.

A significant amount of our total assets relates to our intellectual property. As of December 31, 2020, the carrying value of our intangible assets was approximately $9.3 million. In accordance with U.S. GAAP, we are required to review the carrying value of our intangible assets for impairment periodically or when certain triggers occur. Such impairment will result in a write-down

of the intangible asset and the write-down is charged to income during the period in which the impairment occurs. The write-down of any intangible assets could harm 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, raising capital, developing LUPKYNIS, undertaking nonclinical studies, and conducting clinical trials. We have not yet demonstrated 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.

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 new 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; or
c. we are required to perform additional pre-clinical studies and clinical trials.

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.

Anticipated revenues may not be derived from licensing activities.

Our future performance may be impacted by our ability to generate royalty or other revenues from licenses (such as the license granted to Otsuka) and the successful commercialization of LUPKYNIS. We anticipate that 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; and
d. other factors affecting research and development spending.

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 marketable securities is subject to market, interest and credit risk that may reduce its value.

We maintain a portfolio of marketable securities for investment of our cash. Changes in the value of our portfolio of marketable securities 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.

Risks Related to Drug Development and Regulatory Approval

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside of our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our clinical trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the studied product, the number and nature of competing treatments and ongoing clinical trials of competing products for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Furthermore, any negative results we may report in clinical trials of our product may make it difficult or impossible to recruit and retain patients in other clinical trials of the same product. Delays or failures in planned patient enrollment and/or retention may result in increased costs, program delays or both, which could make us subject to regulatory penalties or fines due to non-fulfillment of our post-marketing requirements and post-marketing commitments with the FDA.

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

We may not be able to continue to identify or develop 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. If we do not successfully identify, develop, and commercialize new products based upon our approach, we will not be able to diversify our portfolio which could result in harm to our financial position and impact the trading price of our Common Shares.

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

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

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

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

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

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

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

LUPKYNIS has undergone safety testing, however, not all adverse effects can be predicted or anticipated. Unforeseen side effects from LUPKYNIS could arise after the approved product has been marketed. Ongoing or future trials of our product may not support the conclusion that LUPKYNIS has an acceptable safety profile or the FDA may disagree with our or clinical trials 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. During our clinical trials we noted the following adverse effects using LUPKYNIS. The most common adverse reactions to LUPKYNIS demonstrated in our Pahse 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. 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 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.

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 do not have 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 **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 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 LUPKYNIS, 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 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 the FDA and, depending on the scope of a potential product issue that the FDA 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. FDA may also require or request the withdrawal of the product from the market. Any of these post-marketing regulatory actions could materially affect our sales and, therefore, have the potential to adversely affect our business, financial condition, results of operations and cash flows.

Risks Related to Our Reliance on Third Parties and Partners

We are dependent on international third-party licensees for the development and commercialization of* LUPKYNIS *in several countries outside the United States. The failure of these licensees to meet their 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 entirely dependent on this third party to achieve 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 the licensee. We also depend on this third party 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 this licensee and have limited ability to terminate this agreement if the licensee does not perform as anticipated. The failure of the licensee to devote sufficient time and effort to the development and commercialization of LUPKYNIS, or the failure of this licensee to meet their obligations to us, including for future royalty and milestone payments; to adequately deploy business continuity plans in the event of a crisis; and/or satisfactorily resolve significant disagreements with us or address other factors, could harm our financial results and operations.

If this third party 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.

We have limited experience in drug formulation or manufacturing and rely exclusively on third parties 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, encapsulation, and packaging:

- Lonza is currently the sole source manufacturer of voclosporin (API); 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, we could experience delays in commercialization and development efforts as we locate and qualify new manufacturers. Our reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify 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 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 contract 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 contract manufacturers to manufacture LUPKYNIS must be approved by the FDA.
- If any third-party manufacturer makes improvements in the manufacturing process for LUPKYNIS, we may not own, or may have to share, the intellectual property rights to the innovation. Each of these risks could delay the commercialization of LUPKYNIS, or result in higher costs or deprive us of potential product revenue.

Any disruption or loss of these relationships could delay our development and commercialization efforts and our business could be harmed.

We rely on third parties for the supply and manufacture of* LUPKYNIS*, which can be unpredictable in terms of quality, cost, timing, and availability. If we encounter any such difficulties, our ability to supply* LUPKYNIS *for commercial sale could be delayed or halted entirely.

Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, stability, quality control and assurance, and shortages of qualified personnel, as well as compliance with strictly enforced federal, provincial, state, and foreign regulations. We rely on a limited number of third parties to manufacture and supply raw materials for LUPKYNIS. The third parties we choose to manufacture and supply raw materials for LUPKYNIS are not under our control and may not perform as agreed or may terminate their agreements with us, and we may not be able to find other third parties to manufacture and supply raw materials

on commercially reasonable terms, or at all. If any of these events were to occur, our operating results and financial condition would be adversely affected.

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

The process of manufacturing LUPKYNIS is extremely susceptible to product loss due to a variety of factors, including but not limited to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product or in the manufacturing facilities in which our product are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any adverse developments affecting manufacturing operations for our product may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives.

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.

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 any 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*, or 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*, or 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, or 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, or 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 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 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, as a result, we may not be able to attract and retain such individuals on acceptable terms, or at all. In addition, because we do not maintain "key person" life insurance on any of our officers, employees, or consultants, any delay in replacing such persons, or an inability to replace them with persons of similar expertise, could harm our business, financial condition, and results of operations.

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

Incentive provisions for our key executives include the granting of stock options that vest over time, designed to encourage such individuals to stay with us. However, a low share price, whether as a result of disappointing progress in our development programs or as a result of market conditions generally, 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 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 will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research, commercialization, and product development without a corresponding increase in our operational, financial and management systems could harm our business, financial condition and results of operations.

As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize LUPKYNIS and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development and commercialization efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

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

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

malfunction, or to prevent data from being stolen or corrupted in the event of a security breach. Any such loss or breach could harm our business, operating results, and financial condition.

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

We rely upon a variety of Internet service providers, third-party hosting facilities and cloud computing platform providers to support our business. With our offices closed due to the COVID-19 pandemic, 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, cybersecurity attacks, terrorist attacks, power outages and similar events or acts of misconduct. In addition, any changes in our cloud service providers service levels may harm our ability to meet our requirements and operate our business.

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

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

Risks Related to Our Industry

Unstable markets and economic conditions may have harmful consequences to business, financial condition, and trading price of our Common Shares.

Our results of operations could be harmed by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our approved product and our ability to raise additional capital when needed on acceptable terms, if at all. Weak global economic conditions could decrease the number of clinical trials sites available to us and hinder our ability to conduct trials required by the FDA. A weak or declining economy could also strain our supplies, partners or third-parties, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell LUPKYNIS profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the U.S, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the ACA. While it is difficult to assess the impact of the ACA in isolation, either in general or on our business specifically, it is widely thought that the ACA increases downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, LUPKYNIS. Further, the U.S. and foreign governments regularly consider reform measures that affect healthcare coverage and costs. Such reforms may include changes to the coverage and reimbursement of healthcare services and products. In particular, there have been recent judicial

and Congressional challenges to the ACA, which could have an impact on coverage and reimbursement for healthcare services covered by plans authorized by the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. Most recently, the *U.S. Tax Cuts and Jobs Act* was enacted, which, among other things, removes the penalties for not complying with the ACA's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the *U.S. Tax Act,* the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. Additionally, the United States Supreme Court is currently reviewing the constitutionality of the ACA, but it is unclear when a decision will be made. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, 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. 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 new Biden administration has indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take or whether such steps will be successful. We cannot predict all of the ways in which future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

We anticipate that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for LUPKYNIS, and could harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize LUPKYNIS.

We may face substantial competition, which may result in others discovering, developing, or commercializing products before, or more successfully than we do.

The industry in which we operate is highly competitive and we have numerous potential domestic and foreign competitors, including major pharmaceutical and chemical companies, universities, academic institutions, government agencies, public and private research organizations and large, fully-integrated pharmaceutical companies which have extensive resources and experience in research and development, process development, clinical evaluation, manufacturing, regulatory affairs, distribution and marketing. Many of our potential competitors possess substantially greater research and development skills, financial, technical and marketing expertise and human resources than we do, and may be better equipped to develop, manufacture and market products. There is a risk that new products and technologies may be developed which may be more

effective or commercially viable than the product being developed or marketed by us, thus making LUPKYNIS non-competitive or obsolete. There may also be market resistance to the acceptance of our new product in any indication and a risk that LUPKYNIS, even though clinically effective, is not economically viable.

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

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

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

While we take substantial precautions such as laboratory and clinical testing, toxicology studies, quality control and assurance testing and controlled production methods, the health and safety risks associated with producing a product for human ingestion cannot be eliminated. Products produced by us may be found to be, or to contain substances that are harmful to the health of our patients and customers and which, in extreme cases, may cause serious health conditions or death. This sort of finding may expose us to substantial risk of litigation and liability. Further, we would be forced to discontinue production of LUPKYNIS, which would harm our profitability. We maintain product liability insurance coverage; however, there is no guarantee that our current coverage will be sufficient or that we can secure insurance coverage in the future at commercially viable rates or with the appropriate limits.

Risks Related to Our Common Shares

There is no assurance of a sufficient liquid trading market for our Common Shares in the future.

Our shareholders may be unable to sell significant quantities of Common Shares into the public trading markets without a significant reduction in the price of their Common Shares, or at all. There can be no assurance that there will be sufficient liquidity of our Common Shares on the trading market, and that we will continue to be listed on the TSX or the 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 patent or other proprietary rights of competitors; concern as to the safety of LUPKYNIS; period-to-period fluctuations in operating results; changes in estimates of our performance by securities analysts; market conditions for biotechnology stocks in general; global or local political, economic, social and health crises; 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.

We may be a passive foreign investment company for U.S. tax purposes, which may result in adverse tax consequences for U.S. investors.

If we are characterized as a passive foreign investment company (PFIC), there may be adverse tax consequences for U.S. investors. Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of the average quarterly value of our assets are held for the production of, or produce, passive income, we would be characterized as a PFIC

for U.S. federal income tax purposes. Based on the nature of our income and the value and composition of our assets, we do not believe we were a PFIC during 2020. While we also do not believe we will be a PFIC for the current taxable year, because PFIC status is determined on an annual basis and generally cannot be determined until the end of the taxable year, there can be no assurance that we will not be a PFIC for the current or future taxable years. If we are characterized as a PFIC, our shareholders who are U.S. holders may suffer adverse tax consequences, including the treatment of gains realized on the sale of our Common Shares as ordinary income, rather than as capital gain, the loss of the preferential rate applicable to dividends received on our Common Shares by individuals who are U.S. holders, and the addition of interest charges to the tax on such gains and certain distributions. A U.S. shareholder of a PFIC generally may mitigate these adverse U.S. federal income tax consequences by making a "qualified electing fund" election, or, to a lesser extent, a "mark to market" election.

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

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

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

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

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

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. We may become the target of securities litigation in the future. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of such suits, and we may not prevail. Monitoring and defending against legal actions is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with any such litigation. We have not established any reserves for any potential liability relating to any such potential lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. We currently maintain insurance coverage for some of these potential liabilities. Other potential liabilities may not be covered by insurance, insurers may dispute coverage or the amount of insurance may not be enough to cover damages awarded. In addition, certain types of damages may not be covered by insurance, and insurance coverage for all or certain forms of liability may become unavailable or prohibitively expensive in the future. A decision adverse to our interests on one or more legal matters or litigation could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our reputation, financial condition and results of operations.

Our ability to use our net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be subject to certain limitations. We may also be subject to other potential tax consequences.

Under the provisions of the applicable tax legislation, our net operating loss and tax credit carryforwards are subject to review and possible adjustment by applicable tax regulatory authorities. In addition, proposed or actual changes to applicable tax

legislation may significantly impact our ability to utilize our net operating losses to offset taxable income in the future. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of a company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. We may not be able to use some or all of our net operating loss and tax credit carryforwards, even if we attain profitability. Additionally, should an event occur that causes or is deemed to cause a change in the residency of Aurinia Pharmaceuticals Inc. from Canada to the United States, for example, we may be subject to certain tax rules that could cause a deemed disposition of our assets for tax purposes. Should that occur, we may be subject to a material amount of tax owing, without corresponding revenue from any actual disposition of our assets. Our Common Shares could fall or may not increase.

General Business Risks

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

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

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

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

An investment in our Common Shares may result in the loss of an investor's entire investment.

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

Future issuances of equity securities by us or sales by our existing shareholders 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 sales by our existing shareholders in the market, or the perception that these sales could occur. Sales of Common Shares by shareholders might also make it more difficult for us to issue Common Shares at a time and price that we deem appropriate. With an additional sale or issuance by us of Common Shares, investors will suffer dilution of their voting power and may experience dilution in earnings per share.

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

We have never declared or paid any dividends on the Common Shares. We intend, for the foreseeable future, to retain our future earnings, if any, to finance our commercial activities and further research and the expansion of our business. As a result, the return on an investment in Common Shares will likely depend upon any future appreciation in value, if any, and on a shareholder's ability to sell Common Shares. The payment of future dividends, if any, will be reviewed periodically by our board of directors and will depend upon, among other things, conditions then existing including earnings, financial conditions, cash on hand, financial requirements to fund our commercial activities, development and growth, and other factors that our board of directors may consider appropriate in the circumstances.

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

Our management has broad discretion to use our cash and cash equivalents to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our Common Shares. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the trading price of our Common Shares to decline and delay 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, the Nasdaq and the TSX have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly.

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease an approximately 13,206 square foot facility in Victoria, British Columbia, which is used primarily as our headquarters as well as for research and development and administrative purposes. We lease approximately 2,248 square feet of space in Edmonton, Alberta, which is used for general and administrative purposes. We lease approximately 30,531 square feet of space in Rockville, Maryland, which serves as our commercial office and is used for marketing as well as general and administrative purposes. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional or alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

Information pertaining to legal proceedings can be found under Part IV, Note 13 Commitments and Contingencies to the "Index to Consolidated Financial Statements" in this Annual Report and is incorporated by reference herein.

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" and on the TSX under the symbol "AUP". The following graph shows the value of an investment of $100 from December 31, 2015 through December 31, 2020, 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.

Holders

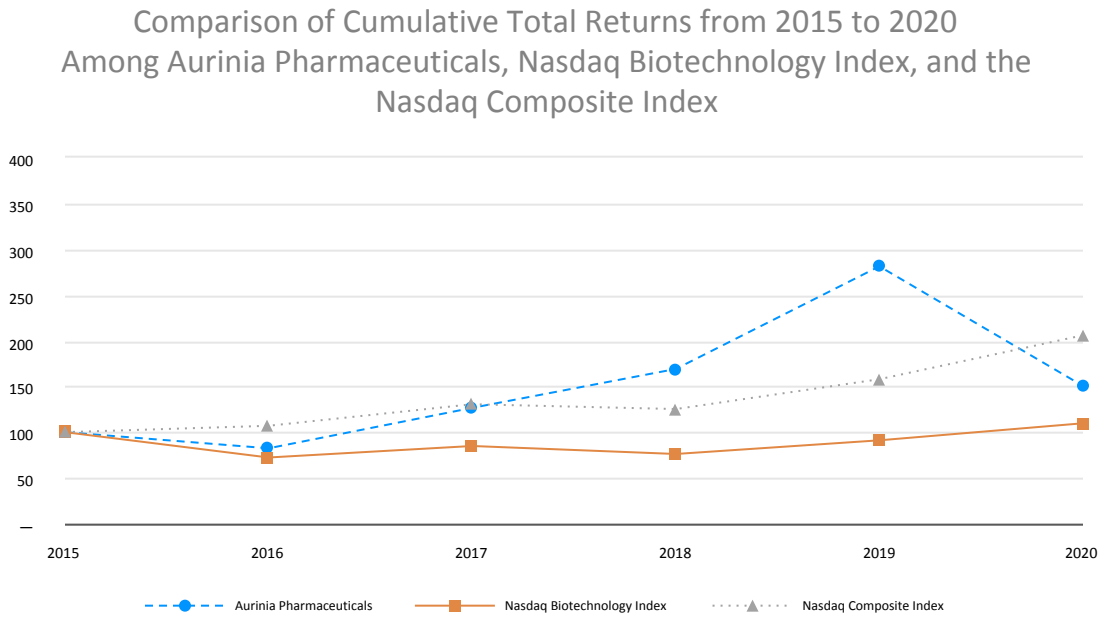
As of February 18, 2021 there were approximately 39 registered holders of record of our Common Shares.

Dividends

We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business and operations, including the commercialization of LUPKYNIS, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, 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.

Performance Graph

The following graph shows the value of an investment of $100 from December 31, 2015 through December 31, 2020, 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.



	Cumulative Total Return Date Ended					
	2015	2016	2017	2018	2019	2020
Aurinia Pharmaceuticals	$100.00	$82.38	$126.57	$169.07	$281.23	$150.48
Nasdaq Biotechnology Index	$100.00	$72.31	$84.89	$76.16	$91.10	$109.72
Nasdaq Composite Index	$100.00	$106.98	$130.54	$125.26	$157.89	$205.87

The Performance Graph is not deemed to be "soliciting material" or "filed" with the SEC or subject to Regulation 14A or 14C under the Exchange Act, or to the liabilities of Section 18 of the Exchange Act, and is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date of this Annual Report and irrespective of any general incorporation language in those filings.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

None.

Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and with our consolidated financial statements and related notes included in Part IV, Item 15 "Exhibits, Financial Statements and Schedules." Our historical results are not necessarily indicative of the results that can be expected in the future.

	Years Ended December 31,				
Consolidated Statements of Operations (in thousands, except per share data)	**2020**	**2019**	**2018**	**2017**	**2016**
Revenues:					
Licensing revenue	**$ 50,118**	$ 318	$ 118	$ 418	$ 118
Contract revenue	**—**	—	345	—	55
Total revenues	**50,118**	318	463	418	173
Operating expenses:					
Research and development	**50,327**	52,866	41,382	33,930	14,534
General and administrative	**95,983**	22,338	13,694	12,118	6,992
Amortization of intangible assets	**1,289**	1,138	1,293	1,182	642
Other expenses (income), net	**6,809**	14,919	(666)	5	3,504
Total operating expenses	**154,408**	91,261	55,703	47,235	25,672
Loss from operations	**(104,290)**	(90,943)	(55,240)	(46,817)	(25,499)
Interest income	**1,516**	2,702	2,234	702	27
Net loss before income taxes	**(102,774)**	(88,241)	(53,006)	(46,115)	(25,472)
Income tax benefit (expense)	**94**	(144)	(73)	—	—
Net loss and comprehensive loss	**$ (102,680)**	$ (88,385)	$ (53,079)	$ (46,115)	$ (25,472)
Basic and diluted loss per common share	**$ (0.87)**	$ (0.95)	$ (0.63)	$ (0.60)	$ (0.72)
Weighted-average Common Shares outstanding used in computation of basic and diluted loss per share	**118,473**	93,024	84,782	76,918	35,285

	As of December 31,				
	2020	2019	2018	2017	2016
Balance Sheet Data: (in thousands)					
Cash and equivalents, short-term investments	**$ 398,329**	$ 306,019	$ 125,856	$ 173,462	$ 39,649
Working capital[(1)]	**$ 387,430**	$ 303,842	$ 125,659	$ 167,175	$ 33,359
Total assets	**$ 463,661**	$ 324,301	$ 143,230	$ 186,963	$ 53,862
Total liabilities	**$ 55,911**	$ 25,701	$ 7,513	$ 9,119	$ 9,219
Total shareholders' equity	**$ 407,750**	$ 298,600	$ 135,717	$ 177,844	$ 44,643

[(1)] Working capital is computed as current assets less current liabilities

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

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with "Selected Financial Data" and the consolidated financial statements and the notes thereto included in the "Index to Consolidated Financial Statements" in Part IV on pages F-1 through F-21 of this Annual Report. This 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. 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."

Overview

Aurinia is a biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. We have commercially launched LUPKYNIS in the United States for the treatment of adult patients with active LN, and continue to conduct pre-clinical, clinical, and regulatory advancement to support the voclosporin development program.

On January 22, 2021, the FDA approved LUPKYNIS in combination with a background immunosuppressive therapy regimen to treat adult patients with active LN.

LUPKYNIS is a CNI immunosuppressant, that has the potential to improve near and long-term outcomes in LN when used in combination with MMF, the current standard of care for LN (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.

Earlier generation CNIs have demonstrated efficacy for a number of conditions, including transplant and other autoimmune diseases; however, side effects exist which can limit their long-term use and tolerability. Some clinical complications of earlier generation CNIs include hypertension, hyperlipidemia, diabetes, and both acute and chronic nephrotoxicity.

Based on published data, we believe the key potential benefits of LUPKYNIS in the treatment of adult patients with active LN versus marketed CNIs include:

- increased potency compared to cyclosporine A, allowing for lower dosing requirements and potentially fewer off target effects;
- limited inter and intra patient variability, allowing for easier dosing without the need for monitoring blood levels for therapeutic drug monitoring;
- less cholesterolemia and triglyceridemia than cyclosporine A; and
- limited incidence of glucose intolerance and diabetes at therapeutic doses compared to tacrolimus.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table sets forth our results of operations for the years ended December 31, 2020 and 2019.

	Years Ended December 31,		
(in thousands)	**2020**	**2019**	**Change**
Revenues:			
Licensing revenue	$ 50,118	$ 318	$ 49,800
Total revenues	50,118	318	49,800
Operating expenses:			
Research and development	50,327	52,866	(2,539)
General and administrative	95,983	22,338	73,645
Amortization of intangible assets	1,289	1,138	151
Other expenses (income), net	6,809	14,919	(8,110)
Total operating expenses	154,408	91,261	63,147
Loss from operations	(104,290)	(90,943)	(13,347)
Interest income	1,516	2,702	(1,186)
Net loss before income taxes	(102,774)	(88,241)	(14,533)
Income tax benefit (expense)	94	(144)	238
Net loss and comprehensive loss	$ (102,680)	$ (88,385)	$ (14,295)

Revenues

Revenues were $50.1 million and $318 thousand for the years ended December 31, 2020 and 2019, respectively. The increase of $49.8 million in 2020 was primarily due to the upfront payment from Otsuka of $50.0 million recorded as licensing revenue.

Research and Development Expenses

R&D expenses decreased to $50.3 million for the year ended December 31, 2020 compared to $52.9 million for the year ended December 31, 2019. R&D expenses consisted of the following:

	Years Ended December 31,	
Research and development (in thousands)	**2020**	**2019**
Contract research organizations (CRO) and third party clinical trial expenses	$ 23,534	$ 29,102
Drug supply and distribution	7,954	13,328
Salaries, incentive pay and employee benefits	11,094	5,906
Share-based compensation expense	3,729	2,693
Travel, insurance, patent annuity fees, legal fee and other	4,016	1,837
	$ 50,327	$ 52,866

The primary drivers for the decrease of $2.5 million in R&D spend in 2020 (as detailed in the table above) were a decrease in drug manufacturing and supply costs, due to inventory capitalization of pre-launch inventory, lower CRO expenses and other third party clinical trial expenses, partially offset by an increase in regulatory related costs as we prepared for FDA approval.

General and Administrative Expenses

Corporate, administration and business development expenses increased to $96.0 million for the year ended December 31, 2020 compared to $22.3 million for the year ended December 31, 2019.

The primary driver for the increase of $73.6 million in corporate, administrative and business development spend in 2020 was an increase of $32.8 million in salaries and employee benefits, $8.9 million in share compensation expense, $7.1 million in

insurance, rent and other facilities costs and $24.1 million for professional fees for activities such as strategic review, recruiting, legal, audit, market research and other pre-commercial activities undertaken during the year as we developed our commercial capabilities across the organization including the expansion of the commercial team headed by our new Chief Commercial Officer.

Amortization of Acquired Intellectual Property and Other Intangible Assets

Amortization of acquired intellectual property and other intangible assets increased slightly to $1.3 million for the year ended December 31, 2020 compared to $1.1 million for the year ended December 31, 2019.

Other Expenses (Income), Net

Other expenses were $6.8 million for the year ended December 31, 2020 compared to $14.9 million for the year ended December 31, 2019.

The primary driver for the decrease of $8.1 million in other expenses during 2020 was the higher expense related to a settlement to ILJIN that was recorded in 2019.

Comparison of the Years Ended December 31, 2019 and 2018

The following table sets forth our results of operations for the years ended December 31, 2019 and 2018.

	Years Ended December 31,		
(in thousands)	**2019**	**2018**	**Change**
Revenues:			
Licensing revenue	$ 318	$ 118	$ 200
Contract revenue	—	345	(345)
Total revenues	318	463	(145)
Operating expenses:			
Research and development	52,866	41,382	11,484
General and administrative	22,338	13,694	8,644
Amortization of intangible assets	1,138	1,293	(155)
Other expenses (income), net	14,919	(666)	15,585
Total operating expenses	91,261	55,703	35,558
Loss from operations	(90,943)	(55,240)	(35,703)
Interest income	2,702	2,234	468
Net loss before income taxes	(88,241)	(53,006)	(35,235)
Income tax benefit (expense)	(144)	(73)	(71)
Net loss and comprehensive loss	$ (88,385)	$ (53,079)	$ (35,306)

Revenues

Revenues were $318 thousand and $463 thousand for the years ended December 31, 2019 and 2018, respectively.

Research and Development Expenses

R&D expenses increased to $52.9 million for the year ended December 31, 2019 compared to $41.4 million for the year ended December 31, 2018. R&D expenses consisted of the following:

	Years Ended December 31,	
Research and development (in thousands)	**2019**	**2018**
Contract research organizations (CRO) and third party clinical trial expenses	$ 29,102	$ 27,924
Drug supply and distribution	13,328	4,858
Salaries, incentive pay and employee benefits	5,906	4,260
Share-based compensation expense	2,693	2,696
Travel, insurance, patent annuity fees, legal fee and other	1,837	1,644
	$ 52,866	$ 41,382

The primary drivers for the increase of $11.5 million in R&D spend in 2019 (as detailed in the table above) were an increase in drug supply and distribution costs which reflected the increased manufacturing of voclosporin for future commercial and investigational use combined with higher CRO expenses and other third party clinical trial expenses incurred for the AURORA 2 extension study and preparation costs associated with the planned NDA submission for voclosporin for the treatment of adult patients with active LN, offset by lower AURORA clinical trial costs.

General and Administrative Expenses

Corporate, administration and business development expenses increased to $22.3 million for the year ended December 31, 2019 compared to $13.7 million for the year ended December 31, 2018.

The primary driver for the increase of $8.6 million in corporate, administrative and business development spend in 2019 was an increase of $2.8 million in salaries and employee benefits and $4.1 million in higher fees for activities such as strategic review, recruiting, legal, audit, market research and other pre-commercial activities undertaken during the year.

Amortization of Acquired Intellectual Property and Other Intangible Assets

Amortization of acquired intellectual property and other intangible assets decreased slightly to $1.1 million for the year ended December 31, 2019 compared to $1.3 million for the year ended December 31, 2018.

Other Expenses (Income), Net

Other expenses were $14.9 million for the year ended December 31, 2019 compared to other income of $666 thousand for the year ended December 31, 2018.

The primary driver for the increase of $15.6 million in other expense during 2019 was the recognition of the royalty obligation which is the result of a resolution of our board of directors dated March 8, 2012 whereby certain executive officers at that time were provided with future potential retention benefits for remaining with the Company as further detailed in Note 14 coupled with an increased expense related to a settlement to ILJIN.

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 accounting principles generally accepted in the United States, or 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.

Revenue Recognition: Pursuant to Accounting Standards Codification 606, *Revenue from Contracts with Customers* (ASC 606), we recognize revenue when a customer obtains control of promised goods or services. We record 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. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, we assess 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.

License, Collaboration and Other Revenues

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

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our agreements, we perform 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) we satisfy each performance obligation. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use 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 our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize 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, we utilize 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. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the licensee exercises these options, any additional payments are recorded in license, collaboration and other revenues when the licensee obtains control of the goods, which is typically upon delivery.

Milestone Payments: At the inception of each arrangement that includes development or commercial sales milestone payments, we evaluate 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 we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate 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. Any consideration related to sales-based royalties (and sales-based milestones) will be recognized when the related sales occur.

Research and development costs: Research and development costs, are accounted for in accordance with ASC Topic 730, *Research and Development*, (ASC 730) and are expensed as incurred. Research and development costs consist primarily of the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, subcontractors and materials used for research and development activities, including nonclinical studies, clinical trials, manufacturing costs and professional services. The costs of services performed by others in connection with our R&D activities, including R&D conducted by others on our behalf, shall be included in research and development costs and expensed as the contracted work is performed. We accrue for costs incurred as the services are being provided by monitoring the status of the trial or project and the invoices received from its external service providers. Where contingent milestone payments are due to third parties under research and development arrangements or license agreements, the milestone payment obligations are expensed when the milestone results are probable to be achieved.

Inventory: We capitalize inventory costs related to products to be sold in the ordinary course of business. We make 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. Pre-launch inventory is held as an asset when there is a high probability of regulatory approval for the product.

Inventories are valued under a standard costing method and are stated at the lower of cost or net realizable value. We measure inventory, which include the direct purchase cost of materials and supplies and manufacturing overhead costs, by approximating actual cost under a first-in, first-out basis. We assess recoverability of inventory each reporting period to determine any write down to net realizable value resulting from excess or obsolete inventories.

Share-based compensation: We follow 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. We record compensation expense associated with service and performance-based stock options in accordance with provisions of authoritative guidance. The estimated fair value of service-based awards is determined using option pricing models that use unobservable inputs and is generally amortized on a straight-line basis over the requisite service period and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. 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.

Royalty obligation: We have recorded a royalty obligation in liabilities for estimated future employee benefits relating to applicable historical employment arrangements. Pursuant to ASC Topic 710, we recognize future royalty benefits provided by employee retention arrangements, as a royalty obligation, which is recognized when we determine that it is probable we will have to make future payments.

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 us or changes in assumptions are recognized in the consolidated statement of operations.

We are required to use judgment to determine the most appropriate model to use to measure the obligation and is required to use significant judgment and estimates in determining the inputs into the model. The royalty obligation is based on an income approach using an internal risk-adjusted net present value of the future royalty payments to be made to the former executive officers which are based on the future net revenues for voclosporin. The royalty rates applied to the net revenue are dependent on the type of net revenue earned. There are multiple unobservable inputs. The determination of this royalty obligation is subject to significant judgments and estimates in determining the significant assumptions including:

- Net pricing - this includes the established WAC pricing of the product and estimates of payor and channel mix (which include government rebates, customer discounts and co-payment programs) and annual price escalations of the product.
- Number of patients being treated - this includes various inputs including the number of patients receiving treatment, market penetration, time to peak market penetration, speed of response to treatment, duration of treatment, patient adherence,dosing adjustments according to the approved product labeling and the timing of generics and competitors entering the market.

- Discount rate - the rate used to derive the present value of future cash flows based on the company's estimated cost of equity rate.

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 us and research papers as sources to develop their inputs. 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 result in a material change to the obligation.

Contingencies: In the normal course of business, we may be subject to loss contingencies, such as legal proceedings, amounts arising from contractual arrangements and claims arising out of our 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), we record accruals for such loss contingencies when it is probable that a liability will be incurred, and the amount of loss can be reasonably estimated. In accordance with this guidance, we do not recognize gain contingencies until realized.

Income taxes: We account for income taxes under the asset and liability method in accordance with ASC 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. Our policy is to record interest and penalties on uncertain tax positions as a component of income tax expense.

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" of the Notes to Consolidated Financial Statements included in Item 15.

Liquidity and Capital Resources

At December 31, 2020, we had cash and cash equivalents of $272.4 million and short term investments of $126.0 million compared to cash and cash equivalents of $306.0 million at December 31, 2019. Cash and cash equivalents and our investments are primarily held in U.S. dollars. As of December 31, 2020 and 2019, we had working capital of $387.4 million and $303.8 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. For the years ended December 31, 2020 and December 31, 2019, we reported a loss of $102.7 million and $88.4 million respectively. Cash used in operating activities was $69.9 million and $63.6 million for years ended December 31, 2020 and December 31, 2019, respectively. As of December 31, 2020 and 2019, we had an accumulated deficit of $575.2 million and $472.5 million, respectively.

Taking into consideration the cash and cash equivalents and short term investments balance as of December 31, 2020, we believe that our cash position is sufficient to fund our current plans which include conducting our planned R&D programs, funding pre-commercial and launch activities, manufacturing and packaging of commercial drug supply required for launch, and funding our supporting corporate and working capital for at least the next 12 months.

Sources and Uses of Cash

The following table summarizes our cash flows for December 31, 2020, 2019 and 2018:

	Years Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Net cash (used in) provided by:			
Operating activities	$ (69,858)	$ (63,585)	$ (51,611)
Investing activities	(158,186)	7,783	(65)
Financing activities	194,375	243,854	4,014
Net change in cash and cash equivalents	$ (33,669)	$ 188,052	$ (47,662)

Cash used in operating activities in December 31, 2020 was $69.9 million, an increase of $6.3 million, from cash used in operating activities of $63.6 million from 2019. While we had a net loss of $102.7 million in 2020, non-cash components included $17.5 million of share-based compensation and $6.8 million of royalty expense. Operating cash flows included a net increase in working capital of $4.5 million. Net change in working capital during 2020 was largely impacted by changes in inventory, prepaid expenses and deposits, accounts payable and accrued liabilities and changes in our non-current assets and liabilities. Cash used in operating activities during the year ended December 31, 2019 was $63.6 million compared to $51.6 million from 2018. The increase was primarily related to the increase in royalty expense of $8.2 million.

Cash used in investing activities during 2020 was $158.2 million compared to cash provided by investing activities of $7.8 million during 2019. Investing activities in 2020 consisted primarily of $203.0 million for purchases of investments of commercial paper and corporate bonds as discussed in Note 4 of the audited consolidated financial statements for the year ended December 31, 2020. Cash provided by investing activities during 2019 increased compared to cash used in 2018 of $65 thousand mainly from our proceeds of short-term debt securities.

Cash provided by financing activities for the year ended December 31, 2020 was $194.4 million compared to cash provided by financing activities of $243.9 million for the year ended December 31, 2019. Cash provided by financing activities for the year ended December 31, 2020 decreased mainly due to the net proceeds of $187.7 million from our underwritten public offering of common shares (the "July 2020 Offering") compared to 2019, which included $223.1 million net proceeds from the December 2019 Offering and the September 2019 Offering (each described below). Cash provided by financing activities for the year ended December 31, 2019 of $243.9 million compared to $4.0 million for the year ended December 31, 2018 increased due to the December 2019 and September 2019 Offering. Additionally, during 2019 and 2018, we had an increase of $12.8 million and $3.9 million of proceeds from the exercise of stock options and warrants, respectively.

Use of Financing Proceeds

July 2020 Offering

On July 27, 2020, we completed an underwritten public offering of 13.33 million Common Shares, for net proceeds of $187.7 million. The net proceeds are being used for pre-commercialization and launch activities, R&D activities, working capital and general corporate purposes.

December 2019 Offering

On December 12, 2019, we completed an underwritten public offering of 12.78 million Common Shares, which included 1.67 million Common Shares issued pursuant to the full exercise of the underwriters' over allotment option to purchase additional Common Shares, for net proceeds of $179.9 million (the "December 2019 Offering"), which were to be used for pre-commercialization and launch activities, working capital and general corporate purposes.

September 2019 ATM

On September 13, 2019 we entered into an open market sale agreement with Jefferies LLC pursuant to which Aurinia would be able to, from time to time, sell, through at the market (ATM) offerings, Common Shares that would have an aggregate offering price of up to $40.0 million (the "2019 ATM"). On December 9, 2019 we terminated the agreement with Jefferies LLC related to the 2019 ATM. We received net proceeds of $14.4 million from the 2019 ATM. The net proceeds were used for working capital and corporate purposes. The last of such funds were utilized in 2020.

November 2018 ATM

On November 30, 2018 we entered into an open market sale agreement with Jefferies LLC pursuant to which Aurinia would be able to, from time to time, sell, through ATM offerings, Common Shares that would have an aggregate offering price of up to $30.0 million (the 2018 ATM). As of the first quarter of 2019, the agreement terminated as the maximum dollar amount of Common Shares were sold under the 2018 ATM. We received net proceeds of $28.8 million from the 2018 ATM. The net proceeds were used for working capital and corporate purposes. The last of such funds were utilized in 2020.

March 2017 Offering

On March 20, 2017, we completed an underwritten public offering of 25.64 million Common Shares, which included 3.35 million Common Shares issued pursuant to the full exercise of the underwriters' over allotment option to purchase additional Common Shares, for net proceeds of $162.3 million, which were used for R&D activities and for working capital and corporate purposes. The last of such funds were utilized in 2020.

A summary of the anticipated and actual use of net proceeds used to date from the above financings is set out in the table below.

Allocation of net proceeds	Total net proceeds from financings (in thousands)	Net proceeds used to date (in thousands)
March 20, 2017 Offering		
R&D Activities	$ 123,400	$ 123,400
Working capital and corporate purposes	38,924	38,924
	162,324	162,324
November 30, 2018 ATM facility	28,830	28,830
September 2019 ATM facility	14,371	14,371
December 2019 Public Offering:		
Pre-commercial and launch activities, working capital and corporate purposes	179,918	44,181
July 2020 Public Offering:		
Pre-commercial and launch related activities	$117,000 to $143,000	—
R&D activities	$28,000 to $34,000	—
Working capital and corporate purposes	$10,500 to $42,500	—
	187,700	—
Total	$ 573,143	$ 249,706

As of December 31, 2020, there have been no material variances from how we disclosed we were going to use the proceeds from the above noted offerings and thus no material impact on its ability to achieve our business objectives and milestones.

Contractual Obligations and Commitments

We have the following contractual obligations and commitments as of December 31, 2020:

	Payments due by period				
(in thousands)	Total	Less than one year	One to three years	Four to five years	More than five years
Operating leases	$ 16,028	$ 536	$ 1,962	$ 3,222	$ 10,308
Contractual obligations	144,058	19,741	24,992	31,784	67,541
Royalty obligation	15,000	294	3,113	2,269	9,324
Total contractual obligations	$ 175,086	$ 20,571	$ 30,067	$ 37,275	$ 87,173

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and with vendors for preclinical studies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancellable contracts and not included in the table above.

Off-Balance Sheet Arrangements

As of December 31, 2019 and 2020, we did not have any off-balance sheet arrangements, as such term is defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Act.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

Our activities can expose us to market risks which include foreign currency risk and interest rate 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. Our investment portfolio includes cash and cash equivalents and investments that earn interest at market rates. Our investments held during the year were comprised of bonds and commercial paper with a maturity of less than two years. Accounts receivable, accounts payable and accrued liabilities bear no interest. We do not believe that the results of operations or cash flows would be affected to any significant degree by a sudden change in market interest rates relative to our investment portfolio.

Foreign currency risk

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

A 10% increase of the Canadian dollar would have increased the net loss by $0.5 million assuming all other variables remained constant. An assumed 10% weakening of the Canadian dollar would have had an equal but opposite effect to the amounts shown above, on the basis all other variables remain constant.

Credit risk

Our exposure to credit risk generally consists of cash and cash equivalents, restricted cash, investments and receivables. We place our cash, cash equivalents and restricted cash with what we believe to be highly rated financial institutions and invest the excess cash in highly rated investments. Our investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restriction on maturities and concentrations by asset class and issuer.

ITEM 8. Financial Statements and Supplementary Data

The consolidated financial statements required in this item are set forth beginning on page F-1 of this Annual Report on Form 10-K.

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, 2020, 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, 2020.

The effectiveness of our internal control over financial reporting has been audited by PricewaterhouseCoopers LLP (PwC) 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, 2020, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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 2021 Annual Meeting of Shareholders to be filed with the SEC by April 30, 2021 (our Proxy Statement) and is incorporated in this Annual Report by reference.

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

Item 11. Executive Compensation

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

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

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

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

Item 13. Certain Relationships and Related Transactions and Director Independence

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

Item 14. Principal Accountant Fees and Services

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

PART IV

Item 15. Financial Statement Schedules and Exhibits

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

1. Consolidated Financial Statements.

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

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

2. Financial Statement Schedules

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

3. Exhibits

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

		Incorporation by Reference			
Exhibit Number	**Description**	**Form**	**SEC File No.**	**Exhibit**	**Filing Date**
3.1*	Articles of Amalgamation, as amended, as currently in effect				
3.2	By Law No. 2, as currently in effect	S-8	333-239048	4.2	6/9/2020
4.1*	Form of Common Shares Certificate of the Company				
4.2	Reference is made to Exhibits 3.1 and 3.2				
4.3*	Description of the Registrant's Common Shares				
10.1+*	Form of Indemnity Agreement between the Registrant and each of its Directors and Executive Officers				
10.2+	Form of Option Commitment under the Stock Option Plan	S-8	333-216447	99.2	3/3/2017
10.3+	Equity Incentive Plan	S-8	333-239048	99.1	06/09/20
10.4**#	Collaboration and Licensing Agreement between the Registrant and Otuska Pharmaceutical Co. Ltd. dated December 17, 2020	6-K	001-36421	99.2	12/30/20
10.5*#	Manufacturing Services Agreement between the Registrant and Lonza Ltd. dated November 16, 2020				
10.6#	Lease agreement for space at 77 Upper Rock Circle, Rockville, MD between BOF II MD 77 Upper Rock LLC and Aurinia Pharma U.S. Inc. dated March 12, 2020				
10.7*#	Lease agreement for space at 2615-2629 Douglas Street, Victoria, BC between TC Evolution Limited Partnership and the Registrant dated August 12, 2020				
10.8*#	Lease agreement for space at Suite No. 1203 and No. 1201 Building No. 100, 4464 Markham Street Victoria, BC between University of Victoria Properties Investments, Inc. and the Registrant dated October 30, 2020				

10.9*#	Softgel Commercial Supply Agreement between the Registrant and Catalent Pharma Solutions, LLC dated August 28, 2020
10.10*	Settlement Agreement among ILJIN Life Science Co. Ltd., Isotechnika Pharma Inc., and Aurinia Pharmaceuticals Inc., dated April 3, 2013
10.11+*#	Employment Agreement between Aurinia Pharma U.S., Inc. and Peter Greenleaf dated April 11, 2019
10.12+*#	Employment Agreement between Aurinia Pharma U.S. Inc. and Max Colao dated February 10, 2020
10.13+*#	Employment Agreement between Aurinia Pharma U.S. Inc. and Max Donley dated July 15, 2019
10.14+*#	Employment Agreement between the Registrant and Robert Huizinga dated October 1, 2017
10.15+*#	Employment Agreement between the Registrant and Michael Martin dated October 1, 2017
10.16+*#	Employment Agreement between Aurinia Pharma U.S. Inc. and Joe Miller dated April 8, 2020
10.17+*#	Employment Agreement between the Registrant and Stephen Robertson dated September 29, 2020
10.18+*#	Employment Agreement between the Registrant and Neil Solomons dated October 1, 2017
10.19+*#	Separation Agreement between Aurinia Pharma U.S., Inc. and Erik Eglite dated October 26, 2020
10.20+*	Form of Inducement Grant Option Commitment
21.1*	List of Subsidiaries of Registrant
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
24.1*	Power of Attorney (contained in signature page of this report)
31.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

**	Furnished herewith. Exhibit 32.1 is 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 have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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 24, 2021

By: /s/ Peter Greenleaf

Peter Greenleaf
Chief Executive Officer
(Principal Executive Officer)

SIGNATURES AND POWER OF ATTORNEY

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

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

Name	Title	Date
/s/ Peter Greenleaf Peter Greenleaf	Chief Executive Officer, Director *(Principal Executive Officer)*	February 24, 2021
/s/ Joseph Miller Joseph Miller	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 24, 2021
/s/ George M. Milne, Jr. Ph.D. George M. Milne, Jr., Ph.D.	Chairman	February 24, 2021
/s/ Daniel Billen, Ph.D. Daniel Billen, Ph.D.	Director	February 24, 2021
/s/ R. Hector MacKay-Dunn, J.D., Q.C. R. Hector MacKay-Dunn, J.D., Q.C.	Director	February 24, 2021
/s/ Joseph P. Hagan Joseph P. Hagan	Director	February 24, 2021
/s/ Michael Hayden, C.M., OBC, MB, ChB, Ph.D., FRCP(C), FRSC Michael Hayden, C.M., OBC, MB, ChB, Ph.D., FRCP(C), FRSC	Director	February 24, 2021
/s/ David R.W. Jayne, M.D., FRCP, FRCPE, FMedSci David R.W. Jayne, M.D., FRCP, FRCPE, FMedSci	Director	February 24, 2021
/s/ Jill Leversage Jill Leversage	Director	February 24, 2021
/s/ Timothy P. Walbert Timothy P. Walbert	Director	February 24, 2021

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, 2020 and 2019, 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, 2020, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 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, 2020, 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 the accompanying Management's Annual Report on Internal Control over Financial Reporting. 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 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

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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 the royalty obligation

As described in Notes 2 and 14 to the consolidated financial statements, the royalty obligation is the result of a resolution of the board of directors of the Company dated March 8, 2012 whereby certain executive officers at that time (former executive officers) were provided with future potential employee benefit obligations for remaining with the Company, for a certain period of time, and this obligation was also contingent on the occurrence of uncertain future events. The obligation was recorded once the specified events were deemed probable to occur. The royalty obligation amounted to $15 million as of December 31, 2020. The royalty obligation is based on an income approach using an internal risk-adjusted net present value of the future royalty payments to be made to the former executive officers

which are based on the future net revenues for voclosporin (the model). The royalty rates applied to the net revenue are dependent on the type of net revenue earned. Significant judgments and estimates are used in determining the royalty obligation which include the determination of significant assumptions with respect to net pricing, number of patients being treated, and discount rate. Management developed the net pricing, number of patients being treated, and discount rate 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 royalty obligation is a critical audit matter are (i) the significant judgment by management, including the use of management's specialists, when determining the significant assumptions, which in turn led to; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating the reasonableness of the significant assumptions used by management and management's specialists in determining the royalty obligation; 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 royalty obligation, including controls over management's development of the net pricing, number of patients being treated, and discount rate assumptions utilized in the measurement of the royalty obligation. These procedures also included, among others (i) evaluating and testing management's process for determining the royalty obligation; (ii) evaluating the appropriateness of the model used; and (iii) testing the completeness and accuracy of underlying data used in the determination of the royalty obligation. The work of management's specialists was used in performing the procedures to evaluate the reasonableness of the significant assumptions relating to net pricing and number of patients being treated. 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 net pricing and number of patients being treated 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

Edmonton, Canada
February 24, 2021

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)	Note	As of December 31, 2020	2019
Assets			
Current assets:			
Cash and cash equivalents	(2)	**$ 272,350**	$ 306,019
Short term investments	(4)	**125,979**	—
Accrued interest and other receivables	(6)	**1,018**	368
Inventories	(2)	**13,927**	—
Prepaid expenses and deposits		**6,153**	8,750
Total current assets		**419,427**	315,137
Non-current assets:			
Long term investments	(4)	**24,380**	—
Other non-current assets		**247**	209
Property and equipment, net	(7)	**4,786**	93
Acquired intellectual property and other intangible assets, net	(8)	**9,332**	8,862
Right of use asset	(15)	**5,489**	—
Total assets		**$ 463,661**	$ 324,301
Liabilities and Shareholders' Equity			
Current liabilities:			
Accounts payable and accrued liabilities	(9)	**24,797**	11,177
Other current liabilities (of which $6,000 due to related party in 2020)	(19)	**6,118**	118
Operating lease liability	(15)	**788**	—
Royalty obligation	(14)	**294**	—
Total current liabilities		**31,997**	11,295
Non-current liabilities:			
Other non-current liabilities (of which $6,000 due to related party in 2019)		**1,589**	6,206
Operating lease liability	(15)	**7,619**	—
Royalty obligation	(14)	**14,706**	8,200
Total liabilities		**55,911**	25,701
Commitments and Contingencies	(13)		
Shareholders' Equity:			
Common shares - no par value, unlimited shares authorized, 126,725 and 111,798 shares issued and outstanding at December 31, 2020 and 2019, respectively	(16)	**944,328**	746,487
Additional paid-in capital	(16)	**39,383**	25,394
Accumulated other comprehensive loss	(16)	**(805)**	(805)
Accumulated deficit	(16)	**(575,156)**	(472,476)
Total shareholders' equity		**407,750**	298,600
Total liabilities and shareholders' equity		**$ 463,661**	$ 324,301

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

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)	Note	Years ended December 31, 2020	2019	2018
Revenues:				
Licensing revenue	**(2)**	**$ 50,118**	$ 318	$ 118
Contract revenue	**(2)**	**—**	—	345
Total revenues		**50,118**	318	463
Operating expenses:				
Research and development	**(2)**	**50,327**	52,866	41,382
General and administrative	**(2)**	**95,983**	22,338	13,694
Amortization of intangible assets	**(2)**	**1,289**	1,138	1,293
Other expenses (income), net	**(2)**	**6,809**	14,919	(666)
Total operating expenses		**154,408**	91,261	55,703
Loss from operations		**(104,290)**	(90,943)	(55,240)
Interest income		**1,516**	2,702	2,234
Net loss before income taxes		**(102,774)**	(88,241)	(53,006)
Income tax benefit (expense)	**(12)**	**94**	(144)	(73)
Net loss and comprehensive loss		**(102,680)**	(88,385)	(53,079)
Basic and diluted loss per common share	**(18)**	**$ (0.87)**	$ (0.95)	$ (0.63)
Weighted-average Common Shares outstanding used in computation of basic and diluted loss per share	**(18)**	**118,473**	93,024	84,782

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

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(in thousands)	Note	Common Shares		Additional Paid-In Capital	Accumulated other comprehensive loss	Accumulated Deficit	Total Shareholders' Deficit
		Shares	Amount				
Balance - January 1, 2018		84,052	$ 483,294	$ 26,445	$ (805)	$ (331,012)	$ 177,922
Exercise of warrants	**(16)**	1,172	3,977	(906)	—	—	3,071
Exercise of stock options	**(17)**	276	1,473	(530)	—	—	943
Stock-based compensation	**(17)**	—	—	6,860	—	—	6,860
Net loss		—	—	—	—	(53,079)	(53,079)
Balance - December 31, 2018		85,500	$ 488,744	$ 31,869	$ (805)	$ (384,091)	$ 135,717
Issue of common shares	**(16)**	19,735	236,747	—	—	—	236,747
Share issue costs	**(16)**	—	(13,629)	—	—	—	(13,629)
Exercise of warrants	**(16)**	2,983	12,428	(5,440)	—	—	6,988
Exercise of stock options	**(17)**	3,580	22,197	(8,449)	—	—	13,748
Stock-based compensation	**(17)**	—	—	7,414	—	—	7,414
Net loss		—	—	—	—	(88,385)	(88,385)
Balance - December 31, 2019		111,798	$ 746,487	$ 25,394	$ (805)	$ (472,476)	$ 298,600
Issuance of common shares	**(16)**	**13,333**	**200,000**	**—**	**—**	**—**	**200,000**
Share issue costs	**(16)**	**—**	**(12,268)**	**—**	**—**	**—**	**(12,268)**
Exercise of warrants	**(16)**	**1**	**2**	**(1)**	**—**	**—**	**1**
Exercise of stock options	**(17)**	**1,593**	**10,107**	**(3,464)**	**—**	**—**	**6,643**
Stock-based compensation	**(17)**	**—**	**—**	**17,454**	**—**	**—**	**17,454**
Net loss		**—**	**—**	**—**	**$ —**	**(102,680)**	**(102,680)**
Balance - December 31, 2020		**126,725**	**$ 944,328**	**$ 39,383**	**(805)**	**$ (575,156)**	**$ 407,750**

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

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Note	Years ended December 31, 2020	2019	2018
Cash flows from operating activities:				
Net loss		(102,680)	(88,385)	(53,079)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:				
Depreciation of property and equipment	**(7)**	**82**	33	20
Amortization of intangible assets	**(8)**	**1,289**	1,138	1,293
Royalty obligation expense	**(14)**	**6,800**	8,200	—
Share-based compensation	**(17)**	**17,454**	7,414	6,860
Other, net		**2,677**	5,986	(706)
Net changes in operating assets and liabilities:				
Accrued interest and other receivables		**(650)**	(151)	(108)
Inventories	**(2)**	**(13,927)**	—	—
Prepaid expenses and deposits		**2,559**	(1,826)	(5,004)
Right of use assets	**(15)**	**(5,489)**	—	—
Accounts payable and accrued liabilities	**(9)**	**13,620**	4,006	(887)
Lease liabilities	**(15)**	**8,407**	—	—
Net cash used in operating activities		**(69,858)**	(63,585)	(51,611)
Cash flows from investing activities:				
Proceeds on disposal/maturity of short-term debt securities	**(4)**	**52,108**	7,884	36,093
Purchase of short-term debt securities	**(4)**	**(202,951)**	—	(36,084)
Purchase of long-lived assets		**(5,584)**	(85)	(74)
Purchase of cloud based arrangements		**(1,675)**	—	—
Capitalized patent costs		**(84)**	(16)	—
Net cash used in investing activities		**(158,186)**	7,783	(65)
Cash flows from financing activities:				
Proceeds from issuance of common shares pursuant to Public Offering, net of issuance costs	**(16)**	**187,732**	223,118	—
Proceeds from exercise of share options	**(16)**	**6,642**	13,748	943
Proceeds from exercise of warrants	**(16)**	**1**	6,988	3,071
Net cash provided by financing activities		**194,375**	243,854	4,014
Net (decrease) increase in cash and cash equivalents during the year		**(33,669)**	188,052	(47,662)
Cash and cash equivalents, beginning of the year		**306,019**	117,967	165,629
Cash and cash equivalents, end of the year		**$ 272,350**	$ 306,019	$ 117,967
Supplemental cash flow information:				
Non-cash investing and financing activities:				
Cash paid for legal settlement		**$ —**	$ 100	$ —
Cash received for interest		**$ 1,884**	$ 2,619	$ 2,148
Cash paid for taxes		**$ 261**	$ 59	$ —

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

1. Organization and Description of Business

Aurinia Pharmaceuticals Inc. (Aurinia) or the Company is a commercial-stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. The Company has developed LUPKYNIS, an investigational drug, for the treatment of adult patients with active LN and continues to conduct pre-clinical, clinical, and regulatory advancement to support the voclosporin development program.

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

Aurinia is incorporated pursuant to the Business Corporations Act (Alberta). The Company's common shares are currently listed and traded on the Nasdaq Global Market (Nasdaq) under the symbol AUPH and on the Toronto Stock Exchange (TSX) under the symbol AUP.

These consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Aurinia Pharma U.S., Inc. (Delaware incorporated) and Aurinia Pharma Limited (UK incorporated).

2. Summary of Significant Accounting Policies

Basis of presentation: The Company follows accounting standards established by the Financial Accounting Standards Board (FASB) to ensure consistent reporting of financial condition, results of operations, and cash flows. References to generally accepted accounting principles (GAAP) or U.S. GAAP in these footnotes are to the FASB Accounting Standards Codification (ASC or the Codification). Previously, the Company prepared its consolidated financial statements under International Financial Reporting Standards (IFRS) as permitted by securities regulators in Canada, as well as in the United States under the status of a Foreign Private Issuer as defined by the United States Securities and Exchange Commission (SEC). At the end of the second quarter of 2020, the Company determined that it no longer qualified as a Foreign Private Issuer under the SEC rules. As a result, beginning January 1, 2021 the Company is required to report with the SEC on domestic forms and comply with domestic company rules in the United States. The transition to U.S. GAAP was made retrospectively for all periods from the Company's inception. New accounting standards implemented subsequent to January 1, 2018 were adopted on their required adoption date.

Principles of consolidation: These financial statements present the consolidated financial position of the Company and its wholly owned subsidiaries as of December 31, 2020 and 2019, and the results of operations and cash flows for the three years ended December 31, 2020, 2019 and 2018. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of estimates: The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. 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 license, contract and product revenues. Operating segments are defined as components of an enterprise where separate financial information is evaluated regularly by the chief operating decision maker, the chief executive officer, in deciding how to allocate resources and assessing performance. The chief operating decision maker allocates resources and assesses performance based upon discrete financial information at the consolidated level.

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

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

Concentration of credit risk: Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents and short term investments. The Company attempts to minimize the risks related to cash and cash equivalents and investments by investing in a broad and diverse 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 corporate debt securities, and places restrictions on maturities and concentration by type and issuer. The Company may at times maintain cash balances in excess of amounts insured by the Federal 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 United States dollar and foreign currencies, primarily with the Canadian dollar, will affect the Company's operating and financial results. The Company holds the majority of its cash and cash equivalents in US dollars and the majority of its expenses, including clinical trial costs are also denominated in US dollars, which mitigates the risk of material foreign exchange fluctuations.

The Company currently anticipates to have 3 main customers and 1 rest of world partner for sales of LUPKYNIS. 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, including their payment plans and obtains positive confirmation of the validity of the receivables. An allowance against accounts receivable is established when it is probable they will not be collected. Global economic conditions and customer-specific factors may require the Company to periodically re-evaluate the collectability of its receivables and the Company could potentially incur credit losses.

COVID-19: U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the annual consolidated financial statements and accompanying notes. The annual consolidated financial statements reflect all adjustments of a normal, recurring nature that are, in the opinion of management, necessary for a fair presentation of results for these interim periods. The full extent to which the novel coronavirus (COVID-19) pandemic will directly or indirectly impact the Company's estimates related to income taxes (Note 12), royalty obligation (Note 14), leases (Note 15), share based compensation (Note 17) or results of operations will depend on future developments that are uncertain at this time. As events continue to evolve and additional information becomes available, the Company's estimates may change materially in future periods.

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 money market funds and bank money market accounts and are stated at cost, which approximate fair value. Cash and cash equivalents totaled $272.4 million as of December 31, 2020. The Company has invested its cash reserves in short term U.S. dollar denominated, fixed rate, highly liquid and highly rated financial instruments such as treasury notes, banker acceptances, bank bonds, and term deposits.

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

Accounts receivable: Accounts receivables are stated at their net realizable value. Estimates of the Company's allowance for doubtful accounts are determined based on existing contractual payment terms, historical payment patterns of our customers and individual customer circumstances. Historically, the amounts of uncollectible accounts receivable that have been written off have been insignificant. The allowance for doubtful accounts was $0 as of December 31, 2020, 2019 and 2018.

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 translation is recorded in the income statement. All assets and liabilities denominated in a foreign currency are translated into U.S. dollars at the exchange rate on the balance sheet date. Revenues and expenses are translated at the average exchange rate during the period. Equity transactions are translated using historical exchange rates. 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.

Intangible assets: Intangible assets are amortized over their useful lives using methods that correlate to the pattern in which the economic benefits are expected to be realized. All intangible assets are amortized on a straight-line basis. Implementation costs related to a hosting arrangement that is a service contract will be amortized over the term of the hosting arrangement, beginning when the module or component of the hosting arrangement is ready for its intended use. The Company evaluates the estimated remaining useful life of its intangible assets and whether events or changes in circumstances warrant a revision to the remaining period of amortization. The carrying amounts of these assets are periodically reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. Refer to the long-lived assets section below for impairment considerations.

Acquired intellectual property and patents

External patent costs specifically associated with preparing, filing, obtaining and protecting patents are capitalized and amortized straight-line over the shorter of the estimated useful life and the patent life, commencing in the year of the grant of the patent. Other intellectual property expenditures are recorded as research and development expenses on the consolidated statements of operations as incurred. Patents do not contain the option to extend or renew.

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

Implementation costs of a hosting arrangement that is a service contract

The Company’s costs associated with implementing cloud computing arrangements have been capitalized as implementation costs of hosting arrangements that are service contracts. Costs capitalized include external direct costs of materials and services consumed in developing or obtaining the internal-use software, including fees paid to third parties for services to develop software during the application development stage, costs incurred to obtain software from third parties and travel expenses directly associated with developing the enterprise resource planning system. Subsequent development costs incurred are capitalized to the extent that they provide additional functionality or a new territory to the existing software and hosting arrangement.

Property, plant and equipment: Property, plant and equipment are recorded at cost. Expenditures for additions and betterments are capitalized. 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. Property, plant and equipment is depreciated using the straight-line method over the following estimated useful lives:

Office equipment and furniture	5 years
Computer equipment and software	3 years

Leasehold improvements are amortized over the lesser of the expected lease term or the estimated useful life of the improvement.

Recoverability and impairment of long-lived assets: ASC Topic 360 requires long-lived assets, including definite-lived intangible assets, to be evaluated for impairment when events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The judgments made related to the expected useful lives of long-lived assets, definitions of lease terms and the Company's ability to realize undiscounted cash flows in excess of the carrying amounts of these assets are affected by factors such as the ongoing maintenance and improvements of the assets, changes in economic conditions, changes in usage or operating performance and other factors. If indicators are present, assets are grouped to the lowest level for which identifiable cash flows are largely independent of other asset groups and cash flows are estimated for each asset group over the remaining estimated life of each asset group. If the undiscounted cash flows estimated to be generated by the asset group are less than the asset's carrying amount, impairment is recognized in the amount of excess of the carrying value over the fair value. The Company recorded no asset impairment charges during the years ended December 31, 2020, 2019 and 2018.

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. Certain leases have lease and non-lease components, which are accounted for as a single lease component.

The Company leases office space under operating leases that typically provide for the payment of minimum annual rentals and may include scheduled rent increases. The Company also entered into a manufacturing agreement that contained an embedded lease of a dedicated manufacturing facility that will be accounted for as a financing lease once lease commencement begins (see Note 15).

The Company adopted ASC Topic 842 on January 1, 2019, which requires lessees to recognize the following for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (2) a right-of-use asset (ROU asset), which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. ASC 842 also requires lessees to classify leases as either finance or operating leases based on whether or not the lease is effectively a financed purchase of the leased asset by the lessee. This classification is used to evaluate whether the lease expense should be recognized based on an effective interest method or on a straight-line basis over the term of the lease.

The Company elected, for all asset classes, 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 sheet, and fixed costs associated with these arrangements are disclosed in Note 15 of the financial statements.

The Company has elected to recognize lease incentives, such as tenant improvement allowances, at the lease commencement date as a reduction of the ROU asset and lease liability until paid to the Company by the lessor, to the extent that the lease provides a specified fixed or maximum level of reimbursement, and the Company is reasonably certain to incur reimbursable costs at least equaling such amounts.

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

The table in Note 15 provides supplemental balance sheet information related to the operating lease ROU assets and lease liabilities.

Royalty obligation: The Company has recorded a royalty obligation in liabilities for estimated future employee benefits relating to applicable historical employment arrangements. Pursuant to ASC Topic 710, the Company recognizes future royalty benefits provided by employee retention arrangements, as a royalty obligation, which is recognized when the Company determines that it is probable to make future payments.

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.

The Company is required to use judgment to determine the most appropriate model to use to measure the obligation and is required to use significant judgment and estimates in determining the inputs into the model. The royalty obligation is based on an income approach using an internal risk-adjusted net present value of the future royalty payments to be made to the former executive officers which are based on the future net revenues for voclosporin. The royalty rates applied to the net revenue are dependent on the type of net revenue earned. There are multiple unobservable inputs. The determination of this royalty obligation is subject to significant judgments and estimates in determining the significant assumptions including:

- Net pricing - this includes the established WAC pricing of the product and estimates of payor and channel mix (which include government rebates, customer discounts and co-payment programs) and annual price escalations of the product.
- Number of patients being treated - this includes various inputs including the number of patients receiving treatment, market penetration, time to peak market penetration, speed of response to treatment, duration of treatment, patient adherence, dosing adjustments according to the approved product labeling and the timing of generics and competitors entering the market.
- Discount rate - the rate used to derive the present value of future cash flows based on the Company's estimated cost of equity rate.

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 and research papers as sources to develop their inputs. 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 result in a material change to the obligation.

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.

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 specialty pharmacies and specialty distributors. These customers subsequently resell the Company's products to health care providers and patients. Revenues from product sales are recognized when the customer obtains control of 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). The Company's estimates of reserves established for variable consideration are calculated based upon utilizing the expected value method. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjust these estimates, which could have an effect on earnings in the period of adjustment.

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 a G&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 made on the Company's behalf by the Specialty Pharmacies.

License, Collaboration and Other Revenues

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

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the

transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

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

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the licensee exercises these options, any additional payments are recorded in license, collaboration and other revenues when the licensee obtains control of the goods, which is typically upon delivery.

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. Any consideration related to sales-based royalties (and sales-based milestones) will be recognized when the related sales occur.

Research and development costs: Research and development costs are accounted for in accordance with ASC Topic 730, *Research and Development*, (ASC 730) and are expensed as incurred. Research and development costs consist primarily of the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, subcontractors and materials used for research and development activities, including nonclinical studies, clinical trials, manufacturing costs and professional services. The costs of services performed by others in connection with the research and development activities of the Company, including research and development conducted by others on behalf of the Company, shall be included in research and development costs and expensed as the contracted work is performed. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or project and the invoices received from its external service providers. Where contingent milestone payments are due to third parties under research and development arrangements or license agreements, the milestone payment obligations are expensed when the milestone results are probable to be achieved.

Research and development expenses for the years ended December 31, 2020, 2019 and 2018 were $50.3 million, $52.9 million and $41.4 million, respectively, and are included in total costs and expenses on the accompanying consolidated statements of operations.

Inventory: 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. Pre-launch inventory is held as an asset when there is a high probability of regulatory approval for the product.

Inventories are valued under a standard costing method and are stated at the lower of cost or net realizable value. The Company measures inventory, which include the direct purchase cost of materials and supplies and manufacturing overhead costs, by

approximating actual cost under a first-in, first-out basis. The Company assesses recoverability of inventory each reporting period to determine any write down to net realizable value resulting from excess or obsolete inventories.

As of December 31, 2020 and 2019, there was $13.9 million and $nil pre-launch inventory recognized on the consolidated balance sheets that was classified as work in process.

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 associated with service and performance-based stock options in accordance with provisions of authoritative guidance. The estimated fair value of service-based awards is determined using option pricing models that use unobservable inputs and is generally amortized on a straight-line basis over the requisite service period and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. 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 to estimate forfeitures based on historical forfeiture experience.

Warrants: The Company classifies issued warrants to purchase shares of its common stock as equity on its consolidated balance sheets. The Company uses the Black-Scholes model to measure the grant date fair value of the warrants at issuance. The grant date fair value of the warrants is included as a component of equity and is transferred from warrants to common shares upon exercise.

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.

3. Recent Accounting Pronouncements

Recently adopted accounting pronouncements:

On January 1, 2019, the Company adopted ASC 842, *Leases*, using the modified retrospective transition approach as of the period of adoption. The Company's financial statements prior to January 1, 2019 were not modified for the application of the new lease standard. Upon adoption of ASC 842, the Company elected the "package of practical expedients," which allowed the Company to not reassess (a) whether expired or existing contracts as of January 1, 2019 are or contain leases, (b) the lease classification for any expired or existing leases as of January 1, 2019, and (c) the treatment of initial direct costs relating to any existing leases as of January 1, 2019. The package of practical expedients was made as a single election and was consistently applied to all leases that commenced before January 1, 2019. As part of the transition, the Company completed a comprehensive review of its lease portfolio, including significant leases by geography and by asset type that were impacted by the new guidance, and enhanced its controls around leasing. Furthermore, management reviewed all of the Company's non-facility contracts to determine whether any agreements will impact the Company's consolidated financial statements. The adoption of ASC 842 did not result in a material change to the statement of financial position, as majority of the Company's leases as of January 1, 2019 had a term of less than 12 months, with the exception of the Victoria office lease that did not result in a material adjustment to the statement of financial position.

In June 2018, the FASB issued ASU 2018-07*, Improvements to Nonemployee Share-Based Payment Accounting (Topic 718)*. ASU 2018-07 simplifies the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Some of the areas of simplification apply only to nonpublic entities. For public business entities, the amendments in ASU 2018-07 are effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods. Upon adoption, this was applied to certain awards held by

a former Chairman of the Board and Chief Executive Officer. The impact of the adoption of this standard on the Company's consolidated financial statements as of January 1, 2019 is not material.

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

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

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40)-Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the accounting for implementation costs incurred in a hosting arrangement that is a service contract with the accounting for implementation costs incurred to develop or obtain internal-use software under ASC 350-40, in order to determine which costs to capitalize and recognize as an asset and which costs to expense. ASU 2018-15 is effective for annual reporting periods, and interim periods within those years, beginning after December 15, 2019, and can be applied either prospectively to implementation costs incurred after the date of adoption or retrospectively to all arrangements. The Company adopted ASU 2018-15 effective January 1, 2020 and applied the standard prospectively to implementation costs incurred in its cloud computing arrangements, resulting in capitalized costs of $1.7 million in 2020.

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

Recently issued accounting pronouncements not yet adopted:

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

4. Investments

At December 31, 2020, the Company had $126.0 million and $24.4 million of short and long term investments, respectively, mainly of commercial paper and bonds as summarized below. The Company had no investments as of December 31, 2019. These instruments are carried at fair market value which is approximately equal to amortized cost.

	December 31,	
(in thousands)	**2020**	**2019**
Cashable Guaranteed Investment Certificate (GIC)	2,000	—
Corporate Bond	40,372	—
Commercial Paper	67,747	—
Treasury Bill	7,999	—
Treasury Bond	5,045	—
Yankee Bond	2,816	—
Total short term investments	$ 125,979	$ —
Corporate Bonds - total long term investments	24,380	—
Total investments	$ 150,359	$ —

5. Fair Value Measurement

The Company's financial instruments consist primarily of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued liabilities. The 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. 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 Company's Level 1 instruments include cash and cash equivalents and short-term investments that are valued using quoted market prices. Level 2 instruments include the Company's short and long term investments that are valued through third-party pricing services that use verifiable observable market data.

There were no transfers between Level 1, Level 2 and Level 3 in the periods presented.

The following tables summarize the types of assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

	December 31, 2020			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and cash equivalents:				
Deposits held with banks	**$ 130,807**	**$ —**	**$ —**	$ 130,807
Short-term highly liquid investments	**141,543**	—	—	141,543
Investments	**69,746**	**80,613**		150,359
	342,096	**80,613**	—	422,709

	December 31, 2019			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and cash equivalents:				
Deposits held with banks	$ 286,019	$ —	$ —	286,019
Short-term highly liquid investments	20,000	—	—	20,000
Investments	—			—
	306,019	—	—	306,019

6. Accrued interest and other receivables

(in thousands)	**Dec 31, 2020**	**Dec 31, 2019**
Other receivables	$ 51	$ 163
Accrued interest receivable	486	205
Income taxes recoverable	481	—
	$ 1,018	$ 368

7. Property, Plant and Equipment

Property, plant and equipment as of December 31, 2020 and 2019 are as follows:

(in thousands)	**Estimated Useful Life (in years)**	**2020**	**2019**
Construction in progress	—	$ 4,467	$ —
Leasehold improvements	Shorter of term of the lease or estimated useful life	34	34
Office equipment and furniture	5	83	41
Computer equipment and software	3	381	175
		4,965	250
Less accumulated depreciation		(179)	(157)
Property and equipment, net		**$ 4,786**	$ 93

Construction in progress assets relate to leasehold improvements and office equipment and furniture for the Company's Rockville, MD office, which are not available for use at December 31, 2020.

Depreciation expense for the years ended December 31, 2020, 2019 and 2018, was $82 thousand, $33 thousand and $20 thousand, respectively, which is included in general and administrative within operating expenses on the consolidated statements of operations.

8. Intangible Assets

Intangible assets are amortized over their useful lives on a straight-line basis. The following table summarizes the Company's intangible assets as of December 31, 2020 and 2019:

	December 31, 2020			
(in thousands)	**Weighted Average Life (in years)**	**Gross Carrying Value**	**Accumulated Amortization**	**Net Carrying Amount**
Patents	11	$ 1,651	$ (1,203)	$ 448
Acquired intellectual property and reacquired rights	11	15,126	(7,770)	7,356
Cloud computing arrangements	3	1,675	(147)	1,528
	11	$ 18,452	$ (9,120)	$ 9,332

	December 31, 2019			
(in thousands)	**Weighted Average Life (in years)**	**Gross Carrying Value**	**Accumulated Amortization**	**Net Carrying Amount**
Patents	12	$ 1,568	$ (1,097)	$ 471
Acquired intellectual property and reacquired rights	12	15,126	(6,735)	8,391
	12	$ 16,694	$ (7,832)	$ 8,862

Amortization expense recognized by the Company related to intangible assets was $1.3 million, $1.1 million and $1.3 million for the years ended December 31, 2020, 2019 and 2018, respectively. Amortization expense as it relates to the amortization of acquired intellectual property and other intangible assets resides within amortization on the consolidated statements of operations. The estimated aggregate amortization expense for intangible assets over the next five fiscal years ending December 31, 2021 through December 31, 2025 is approximately $7.0 million.

9. Accounts payable and accrued liabilities

	2020	**2019**
Trade payables	$ 2,635	$ 4,153
Other accrued liabilities	10,855	3,281
Employee accruals	11,307	3,743
Total accrued liabilities	$ 24,797	$ 11,177

10. License and Contract Revenue

Licensing Revenue

Otsuka Contract

On December 17, 2020, the Company entered into a collaboration and license agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka) for the development and commercialization of oral LUPKYNIS for the treatment of adult patients with active LN in the European Union (EU), Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine.

As part of the agreement, Aurinia received an upfront cash payment of $50.0 million for the license agreement, and has the potential to receive up to $50.0 million in regulatory milestones. Aurinia will receive tiered royalties on future sales ranging from 10 to 20 percent (dependent on achievement of sale milestones) on net sales upon commercialization, along with additional milestone payments based on the attainment of certain annual sales by Otsuka. In addition, a supply agreement will be negotiated in the future.

The Company evaluated the Otsuka Agreement under ASC 606. Based on that evaluation, the license transferred was determined to be functional intellectual property (IP) that has significant standalone functionality. That is, the treatment of lupus nephritis and other diseases provides significant benefit to Otsuka at the point of transfer, and it is not expected that the utility of the IP will substantively change as a result of any remaining clinical trials or ongoing activities of Aurinia. The Company determined the upfront fee of $50.0 million is fixed consideration for the transfer of the license and is recognized upon transfer of the license in December 2020.

The remaining forms of consideration are variable because they are dependent on achieving milestones or are based on aggregate future net sales for the regions. None of the regulatory milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including the magnitude of a potential reversal of revenue, uncertainty about if or when the milestone related performance obligations might be achieved and that receipt of the milestones are outside the control of the Company since they are dependent on efforts to be undertaken by Otsuka and regulatory approval by various foreign government agencies. Any consideration related to sales-based royalties (and sales-based milestones) will be recognized when the related sales occur.

Other Licensing Revenue

The Company also recorded licensing revenue of $118 thousand in 2020 (2019 - $118 thousand; 2018 - $118 thousand) related to the upfront license payment of $1.5 million received in 2010 pursuant to the 3SBio Inc. license agreement. Under the agreement, the primary substantive obligations of the Company were to grant the license and transfer intellectual knowledge to 3SBio. Under the agreement, the Company was also required to maintain the patent portfolio in China, Taiwan and Hong Kong, and to provide further support and cooperation to 3SBio over the life of the agreement. Any additional assistance provided to 3SBio was to be performed on a full cost recovery basis. The deferred licensing fee revenue is recognized on a straight-line basis as the Company satisfies the performance obligations over the life of the patents and the benefit to the customer transfers ratably throughout the patent life, which expires in 2022. As at December 31, 2020, $207 thousand (2019 - $324 thousand; 2018 - $442 thousand) of deferred revenue remains relating to this payment.

On April 17, 2017, the Company entered into an agreement with Merck Animal Health (MAH) whereby the Company granted them worldwide rights to develop and commercialize its patented nanomicellar LUPKYNIS ophthalmic solution (VOS) for the treatment of Dry Eye Syndrome in dogs. The Company received a milestone payment of $200 thousand in 2019. This agreement provided MAH with a right to use intellectual property. MAH was able to direct the use of and obtain substantially all of the benefits from the license at the time that control of the rights were transferred and therefore, this $200 thousand milestone payment was recognized as revenue in the year ended December 31, 2019. The Company is eligible to receive further payments based on certain development and sales milestones and receive royalties based on global product sales.

Contract Revenue

In 2018 the Company earned a contract milestone of $345 thousand (CA$450,000) pursuant to a purchase and sale agreement dated February 14, 2014 between Ciclofilin Pharmaceuticals Corp. (now Hepion Pharmaceuticals, Inc.) and Aurinia Pharmaceuticals Inc. under which the Company sold the Non-Immunosuppressive Cyclosporine Analogue Molecules (NICAMs) early stage research and development asset to Ciclofilin. The Company is eligible to receive further payments based on certain development and sales milestones and to receive royalties based on global product sales. The Company has no obligations under this agreement.

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. There was one customer that accounted for the majority of revenues at December 31, 2020 and two customers that accounted for all of the revenues in 2019 and 2018, respectively.

Revenues by Geographic Location

The following geographic information reflects revenue based on customer location:

(in thousands)	**2020**	**2019**	**2018**
Revenue			
Japan	**$ 50,000**	$ —	$ —
China	**118**	118	118
United States	**—**	200	345
Total	**$ 50,118**	$ 318	$ 463

Long-lived Assets by Location

Long-lived assets by location consist of property plant and equipment:

(in thousands)	**2020**	**2019**
Long-lived assets		
Canada	**$ 298**	$ 93
United States	**4,488**	—
Total	**$ 4,786**	$ 93

12. Income Taxes

The components of pre-tax (losses) income before income taxes for the years ended December 31, 2020, 2019 and 2018 are as follows:

(in thousands)	**2020**	**2019**	**2018**
Canada	$ (61,024)	$ (88,694)	$ (53,290)
Foreign	(41,750)	453	284
	$ (102,774)	$ (88,241)	$ (53,006)

Income tax (benefit) expense for the years ended December 31, 2020, 2019 and 2018 are as follows:

(in thousands)	2020	2019	2018
Current:			
Canada	**$ —**	$ —	$ —
Foreign	**(94)**	144	73
	(94)	144	73
Deferred:			
Canada	**—**	—	—
Foreign	**—**	—	—
Total deferred	**—**	—	—
Income tax (benefit) expense	**$ (94)**	$ 144	$ 73

The provision for income taxes varied from the income taxes provided based on the Canadian statutory rate of 26.8%, 25.4%, and 27.0% in the years ending December 31, 2020, 2019 and 2018, respectively.

	2020	2019	2018
Canada statutory income tax benefit	**26.8 %**	25.4 %	27.0 %
Effect of tax rates on foreign jurisdictions	**(2.4)**	—	—
Impact of future rates and tax rate changes	**6.1**	(0.9)	—
Non-deductible share-based compensation	**(4.5)**	(2.1)	(3.5)
Change in valuation allowance	**(26.0)**	(22.3)	(23.0)
Other	**0.1**	(0.3)	(0.6)
Effective tax rate	**0.1 %**	(0.2)%	(0.1)%

The tax effects of the temporary differences giving rise to the Company's net deferred tax assets as of December 31, 2020 and 2019 are summarized as follows:

(in thousands)	2020	2019
Deferred tax assets:		
Loss carry-forwards	$ 80,087	$ 56,533
Share issue costs	6,295	4,734
Intangible assets	2,718	1,710
SRED (Scientific Research and Experimental Development)	4,808	3,938
Royalty obligation	4,006	2,005
Other	5,243	2,553
Total deferred tax assets	103,157	71,473
Valuation allowance	(101,792)	(71,459)
Net deferred tax assets	1,365	14
Deferred tax liabilities:		
Right of use asset	(1,173)	—
Property and equipment	(192)	(14)
Deferred tax liabilities	(1,365)	(14)
Net deferred tax assets (liabilities)	$ —	$ —

The Company’s valuation allowance increased by $30.3 million in 2020 as compared to 2019 as a result of the additional pre-tax book losses that the Company has determined are not more likely than not realizable.

At December 31, 2020, the Company had $307.8 million in total net operating loss (NOL) carryforwards which included $31.4 million for the U.S. and $272.4 million for Canada. The NOLs in the U.S. have an indefinite carryforward period. The NOLs in Canada will expire beginning 2029. As of December 31, 2020, the Company has approximately $3.9 million of Canada Investment Tax Credits and British Columbia Scientific Research and Experimental Development (SRED) with an expiration period of 2029-2040.

The Company is open to examinations with the applicable tax authorities prior to the expiration of statute of limitations, which ranges from tax years 2017 through 2019. The Company is currently under audit by the Canadian Revenue Agency for years 2017 and 2018.

13. Commitments and Contingencies

Purchase obligations: The Company has entered into contractual obligations for services and materials required for its drug manufacturing, clinical trial programs and other operational activities.

The future minimum amounts to exit the Company's purchase obligations are as follows:

(in thousands)	**Purchase Obligations**
Years Ending December 31:	
2021	$ 2,233
2022	65
2023	—
	$ 2,298

Litigation: 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 position of the Company.

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 is 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, a CNI immunosuppressant ophthalmic solution, prior to the expiration of our United States Patent No. 10,265,375. In our action, we request relief in the form of an order confirming Sun has infringed our patent, an injunction preventing Sun from manufacturing, using or selling CEQUA, and monetary relief (including costs). Sun has not yet responded to the claim, other than to waive service on the two international Sun entities. Sun has 90 days from the initiation of our claim to file a statement of defense.

14. Royalty Obligation

The royalty obligations 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 (former executive officers) were provided with future potential employee benefit obligations for remaining with the Company, for a certain period of time, and this obligation was also contingent on the occurrence of uncertain future events. The obligation was recorded once the specified events were deemed probable to occur.

As a result of the completion of the Phase 3 AURORA trial, and the results obtained from the trial in the fourth quarter of 2019, the Company re-assessed the probability of royalty obligation payments being required in the future, and recorded the royalty obligation at December 31, 2019. Until one of the triggering events occur, no royalty payments are required to be paid. Royalties on sales or licensing expected in the next twelve months have been classified as short term. The total balance of the royalty obligation at December 31, 2020 and December 31, 2019 was estimated to be $15 million and $8.2 million, respectively.

During the year ended December 31, 2020 the Company re-assessed the royalty obligation and reduced the discount rate from 12.0% at December 31, 2019 to 10.3% at December 31, 2020. The reduction was primarily attributable to the decline in interest rates caused by the global coronavirus (COVID-19) pandemic. The change in discount rate, FDA approval of LUPKYNIS on January 22, 2021 and passage of time, on revaluation, resulted in an increase in the royalty obligation of $6.8 million for the year ended December 31, 2020.

15. Leases

All of the Company's existing leases as of December 31, 2020 are classified as operating leases. The Company's leases have a remaining term of 11 years and have an option to extend for two five-year periods after the 11 years elapsed and an option to terminate after 7 years. As of December 31, 2020, no such options have been recognized as part of the right-of-use assets and liabilities. For the twelve months ended December 31, 2020 the Company incurred $944 thousand rent expenses, respectively. This is compared to $297 thousand of rent expense for the twelve months ended December 31, 2019. The company did not incur any variable rent expense for the years ended December 31, 2020 or 2019.

Short-term leases are leases having a term of twelve months or less. The Company recognizes the short term leases on a straight-line basis and does not record a related lease asset or liability for such leases. During the quarter ended December 31, 2020, the Company entered into an agreement to lease premises at #201, 17873 - 106A Avenue, Edmonton, Alberta, consisting of 2,248 square feet of office space, for a term commencing October 1, 2020 to September 30, 2021 at a cost of approximately $2,200 per month.

During March 2020, the Company entered into a lease for its U.S. commercial office in Rockville, Maryland (MD lease) for a total space of 30,531 square feet of office space. The Company recognized a $5.8 million ROU asset and a $5.8 million lease liability related to the lease. 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.

During August 2020, the Company entered into a binding letter of intent to lease 18,615 square feet of commercial office space in Victoria, British Columbia. The lease term is expected to begin in 2022 and the present value of the minimum lease payments for this lease are $3.1 million. As of December 31, 2020 there has been no accounting recognition associated with this lease, as the Company has not been granted access to the building.

During October 2020, the Company entered into a lease for its head office located in Victoria, British Columbia for a total space of 13,206 square feet of office space. The lease term commencing January 1, 2021 to August 31 2022 at a cost of approximately $19 thousand per month.

As of December 31, 2020, the Company received reimbursement for tenant leasehold improvements by the landlord in the amount of $2.3 million for the MD lease. The Company recorded these leasehold improvement incentives as additions to the lease liability and construction in process.

As of December 31, 2020, the Company had an operating lease right of use asset of $5.5 million and lease liability of $8.4 million on the balance sheet.

The following table provides supplemental balance sheet information related to the operating lease ROU asset and lease liabilities:

(in thousands, except for lease term and discount rate)	Balance Sheet Classification	December 31, 2020	December 31, 2019
Assets			
Operating lease right of-use assets	Property and equipment, net	$ 5,489	$ —
Total leased assets		5,489	—
Liabilities			
Current			
Operating lease liabilities	Current maturities of operating lease liabilities	788	—
Non-current			
Operating lease liabilities	Operating lease liabilities	7,619	—
Total lease liabilities		$ 8,407	$ —
Weighted average remaining lease term - operating leases (in years)		10.67	—
Weighted average discount rate - operating leases		5.2 %	—

The adoption of ASC 842 had no effect on retained earnings as of January 1, 2019.

The following provides a summary of the components of leasing costs and rent for the years ended December 31, 2020 and December 31, 2019:

(in thousands)	Consolidated Statement of Operations	December 31, 2020	December 31, 2019
Operating lease costs	General and administrative	$ 909	$ 229
Short-term lease costs	General and administrative	35	68
Total lease costs		$ 944	$ 297

Cash flow and supplemental information is presented below:

(in thousands)	Years ended December 31, 2020	2019	2018
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows used in operating leases	$ 232	$ 114	$ 151
Operating cash flows used in short-term leases	$ 35	$ 68	$ 72

The following table provides a summary of lease liability maturities for the next five years and thereafter:

(in thousands)	Operating Lease Payments
2021	$ 287
2022	968
2023	1,061
2024	1,085
2025	1,109
Thereafter	6,773
Total lease payments	11,283
Less imputed interest	(2,876)
Total	$ 8,407

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

Upon completion of the monoplant, the Company will have the right to maintain unobstructed use of the monoplant by paying a quarterly fixed facility fee. The first capital expenditure payment was made in February 2021.

The Company expects to account for the arrangement as a finance lease under ASC 842. As of December 31, 2020, construction of the underlying asset of the lease has yet to commence. The present value of the minimum lease payments total approximately $94 million, beginning February 2021 and expiring in 2030, and are not included in the above table.

16. Shareholders' Equity

Common shares: The Company has authorized an unlimited number of shares of common shares, no par value. As of December 31, 2020, 2019 and 2018, 126.7 million, 111.8 million and 85.5 million Common Shares, respectively, were issued and outstanding. Each 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.

The common share activity for 2020, 2019 and 2018 is as follows:

	Common Shares	
	Number of Shares (in thousands)	Amount (in thousands)
Balance at December 31, 2017	84,052	$ 483,294
Issued pursuant to exercise of warrants	1,172	3,977
Issued pursuant to exercise of stock options	276	1,473
Balance at December 31, 2018	85,500	488,744
Issued pursuant to Public Offering	12,782	191,737
Issued pursuant to At-the-Market (ATM) Facilities	6,953	45,010
Share issue costs	—	(13,629)
Issued pursuant to exercise of warrants	2,983	12,428
Issued pursuant to exercise of stock options	3,580	22,197
Balance at December 31, 2019	111,798	746,487
Issued pursuant to Public Offering	13,333	200,000
Share issue costs	—	(12,268)
Issued pursuant to exercise of warrants	1	2
Issued pursuant to exercise of stock options	1,593	10,107
Balance at December 31, 2020	**126,725**	**$ 944,328**

July 27, 2020 public offering

On July 27, 2020 the Company completed a public offering of 13.3 million Common Shares at a price of $15.00 per share. Gross proceeds from this offering were $200.0 million and the share issue costs totaled an estimated $12.3 million which included a 6% underwriting commission of $12.0 million and professional fees of $268 thousand.

December 12, 2019 public offering

On December 12, 2019 the Company completed a public offering of 12.8 million common shares at a price of $15.00 per share. Gross proceeds from this offering were $191.7 million and the share issue costs totaled $11.8 million which included a 6% underwriting commission of $11.5 million and professional fees of $315 thousand.

September 13, 2019 ATM facility

On September 13, 2019 the Company entered into an Open Market Sale Agreement (the "Sale Agreement") with Jeffries 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 $40.0 million. Aurinia filed a prospectus supplement with securities regulatory authorities in Canada in the provinces of British Columbia, Alberta and Ontario, and with the United States Securities and Exchange Commission, which supplements Aurinia's short form base shelf prospectus dated March 29, 2018, and Aurinia's shelf registration statement on Form F-10 dated March 26, 2018, declared effective on March 29, 2018. Sales from the ATM offering were only conducted in the United States through Nasdaq at market prices.

Pursuant to this agreement the Company issued 2.3 million common shares at a weighted average price of $6.40 resulting in gross proceeds of $15.0 million. The Company incurred share issue costs of $640 thousand including a 3% commission of $450 thousand paid to the agent and professional fees of $190 thousand directly related to the ATM. On December 9, 2019, the Company terminated the September 13, 2019 Sale Agreement with Jefferies LLC related to the 2019 ATM.

November 30, 2018 ATM facility

On November 30, 2018 the Company entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company sold, through at-the-market (ATM) offerings, common shares that would have an aggregate offering price of up to $30.0 million. Aurinia filed a prospectus supplement with securities regulatory authorities in Canada in the provinces of British Columbia, Alberta and Ontario, and with the United States Securities and Exchange Commission, which supplements Aurinia's short form base shelf prospectus dated March 26, 2018, and Aurinia's shelf registration statement on Form F-10 dated March 26, 2018, declared effective on March 29, 2018. Sales from the ATM offering were only conducted in the United States through Nasdaq at market prices.

Pursuant to this agreement the ATM Facility was fully utilized resulting in gross proceeds of $30.0 million upon the issuance of 4.6 million common shares at a weighted average price of $6.51. The Company incurred share issue costs of $1.2 million including a 3% commission of $900 thousand paid to the agent and professional and filing fees of $270 thousand directly related to the ATM.

A summary of the anticipated and actual use of net proceeds used to date from the above financings is set out in the table below.

Allocation of net proceeds	Total net proceeds from financings (in thousands)	Net proceeds used to date (in thousands)
March 20, 2017 Offering		
R&D Activities	$ 123,400	$ 123,400
Working capital and corporate purposes	38,924	38,924
	162,324	162,324
November 30, 2018 ATM facility	28,830	28,830
September 2019 ATM facility	14,371	14,371
December 2019 Public Offering:		
Pre-commercial and launch activities, working capital and corporate purposes	179,918	44,181
July 2020 Public Offering:		
Pre-commercial and launch related activities	$117,000 to $143,000	—
R&D activities	$28,000 to $34,000	—
Working capital and corporate purposes	10,500 to 42,500	—
	187,700	—
Total	$ 573,143	$ 249,706

Warrants:

Warrant related to February 14, 2014 private placement offering: On February 14, 2014, the Company completed a $52.0 million private placement (2014 Private Offering). Under the terms of the 2014 Private Offering, a Unit consisted of one common share and one-quarter (0.25) of a common share purchase price warrant (2014 Warrant). The Company issued 18.9 million Units at a subscription price per Unit of $2.7485, exercisable for a period of five years from the date of issuance, at an exercise price of $3.2204. These February 2014 Warrants meet the scope exceptions provided in ASC 815, *Derivatives and Hedging*, as they are indexed to the Company's own shares, and therefore are accounted for under ASC 505, *Equity*.

In 2019, certain holders of these 2014 Warrants elected the cashless exercise option and the Company issued 0.7 million common shares in lieu of 1.3 million 2014 Warrants, which was recorded through an increase in equity (common shares) and decrease in additional paid-in capital. One holder of 464 thousand 2014 Warrants exercised these 2014 Warrants for cash and received 464 thousand common shares. The Company received cash proceeds of $1.5 million and recorded an increase in cash and additional paid in capital. In 2018, no holders of the 2014 Warrants elected the cashless exercise option. As a result, the Warrants related to the February 14, 2014 private placement offering have been extinguished upon the exercise of the aforementioned warrants, at December 31, 2019.

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

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

In 2020, a holder exercised 500 Warrants at $3.00 per share for gross proceeds of $2 thousand which was recorded through an increase in cash and equity. In 2019, certain holders of these Warrants exercised at $3.00 per share for gross proceeds of $5.5 million. In 2018, no holders of these Warrants exercised.

A summary of the outstanding warrants as of December 31, 2020 is presented below:

	Number of Warrants (in Thousands)	Weighted-Average Exercise Price $
Expiry date:		
December 28, 2021	1,690	3.00
	1,690	3.00

The warrant activity for 2019 and 2018 is as follows:

	Number of Warrants (in thousands)
Balance at December 31, 2018	3,523
Warrants exercised	(1,832)
Balance at December 31, 2019	1,691
Warrants exercised	(1)
Balance at December 31, 2020	1,690

17. Shared-Based Compensation

The Equity Incentive Plan (the Plan) was adopted and approved in 2012 and re-approved in May 2014. The Plan was amended as to Section 2.2 by the shareholders of the Company in June 2016 and amended and restated in June 2020. The purpose of the Plan is to advance the interest of the Company by encouraging equity participation in the Company through the acquisition of Common Shares.

The Plan requires the exercise price of each option to be determined by the Board of Directors and not to be less than the closing market price of the Company's stock on the day immediately prior to the date of grant. Any options which expire may

be re-granted. 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

As of December 31, 2020 and 2019, 126.7 million and 111.8 million, common shares were issued and outstanding, resulting in a maximum of 15.8 million and 14.0 million, respectively, options available for issuance under the Plan. An aggregate total of 12.0 million and 6.2 million, options are presently outstanding in the Plan, representing 9.4% and 5.5%, respectively, of the issued and outstanding shares of the Company.

Stock Options

The following table summarizes the number of options outstanding under the Plan and inducement grants outside of the Plan for the years ended December 31, 2020, 2019 and 2018.

	Number of Shares (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2017	4,864	$ 3.87		
Granted	3,003	$ 5.29		
Exercised/released	(276)	$ 3.53		
Outstanding at December 31, 2018	7,591	$ 4.44	4.17	$ 18,076
Granted	2,520	$ 6.00		
Granted inducement	1,600	$ 6.28		
Exercised/released	(3,578)	$ 4.03		
Cancelled/forfeited	(311)	$ 5.40		
Outstanding at December 31, 2019	7,822	$ 5.47	6.64	$ 115,655
Granted	7,568	$ 15.61		
Inducement grants	925	$ 14.36		
Exercised/released	(1,593)	$ 4.39		
Balance as of Cancelled/forfeited	(236)	$ 11.82		
Outstanding at December 31, 2020	14,486	$ 11.35	7.51	$ 35,891
Vested and expected to vest at December 31, 2020	3,246	$ 8.03		
Exercisable - Options at December 31, 2020	5,063	$ 6.94		

On November 20, 2020, the Company's Compensation Committee granted the newly appointed Executive Vice President, General Counsel, Corporate Secretary & Chief Compliance Officer, a non-qualified stock option to purchase an aggregate of 298,924 common shares on November 16, 2020. The option has a per share exercise price of $13.40, the closing trading price on November 13, 2020. One-third of the shares underlying the option vest in November 2021, and the balance of the shares vest in a series of 24 equal monthly installments thereafter.

On October 2, 2020, the Company's Compensation Committee granted 9 new employees non-qualified stock options to purchase an aggregate of 96,000 common shares, at a per share exercise price of $14.73, the closing trading price on September 30, 2020. One-third of the options vest in October 2021, and the balance of the options vests in a series of 24 equal monthly installments thereafter.

On September 4, 2020 the Company granted 105 new employees non-qualified stock options to purchase an aggregate of 530,000 common shares, at a per share exercise price of $14.83, the closing trading price on August 31, 2020. One-third of the options vest in September 2021, and the balance of the options vests in a series of 24 equal monthly installments thereafter.

On April 29, 2019, the Company granted 1.6 million inducement stock options to the new Chief Executive Officer pursuant to Section 613(c) of the TSX Company Manual at a price of $6.28. The first 25% of these options vest on the one year anniversary of the grant, and the remaining 75% vest in equal amounts over 36 months following the one year anniversary date and are exercisable for a term of ten years.

On May 2, 2016, the Company granted 200 thousand inducement stock options to a new employee pursuant to Section 613(c) of the TSX Company Manual at a price of $2.92. These options vest in equal amounts over 36 months and are exercisable for a term of five years. The employee had exercised 150 thousand of these options as of December 31, 2019. There are zero options remaining at December 31, 2020.

The inducement options noted above were granted as an inducement material to the new employees entering into employment with Aurinia in accordance with Nasdaq Listing Rule 5635(c)(4). The inducement stock options also have a ten-year term and are subject to the terms and conditions of the stock option agreement pursuant to which the option was granted. The inducement options are recorded outside of the Plan.

Dr. Richard Glickman and the Company entered into a transition agreement whereby upon his retirement as Chairman of the Board and Chief Executive Officer of the Company, Dr. Glickman would continue to provide substantive services as an adviser to the Company for a period of 12 months commencing May 6, 2019. Management applied judgment, at that time, in assessing if the services to be provided were substantive. Unvested stock options at May 6, 2019 were modified such that they vest in equal installments over the next 12 months, subject to Dr. Glickman remaining an adviser to the Company at each of the vesting dates.

The transition agreement resulted in 100 thousand stock options that would have been forfeited at May 6, 2020 vesting on an accelerated timeline. Therefore, the Company considered that the amount expensed for such awards to date should be reversed. The Company recognized these 100 thousand stock options as a new grant based on the fair value at the date of the transition agreement which will be expensed as they vest over the transition period. The Company also revised the allocation over the remaining vesting period to reflect the graded nature of the vesting over the transition period.

The Company used the Black-Scholes option pricing model to estimate the fair value of the options granted in 2020, 2019 and 2018. The expected life is based upon the contractual term, taking into account expected employee exercise and expected post-vesting employment termination behavior. The Company considers historical volatility of its Common Shares in estimating its future stock price volatility. 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.

The following weighted average assumptions were used to estimate the fair value of the options granted during the years ended December 31, 2020, 2019 and 2018:

	2020	2019	2018
Expected term (in years)	**3 years**	4 years	4 years
Volatility	**52 %**	52 %	55 %
Risk-free interest rate	**0.55 %**	1.61 %	2.04 %
Dividend yield	**0.0 %**	0.0 %	0.0 %

The weighted average grant date fair value of stock options granted during the years ended December 31, 2020, 2019 and 2018 was $5.58, $2.56 and $2.33, respectively. The total fair value of options vested during the years ended December 31, 2020, 2019 and 2018 was $14.9 million, $8.5 million and $10.7 million, respectively. As of December 31, 2020, there was $51.5 million of unrecognized share-based compensation expense related to unvested stock options granted. The expense is expected to be recognized over a weighted-average period of approximately 1.4 years.

Performance Awards

The Company also granted 439 thousand performance awards (PAs) to officers of the Company, which will vest as the performance milestones are met.

Compensation Expense

Share-based compensation expense before taxes for the years ended December 31, 2020, 2019 and 2018 totaled approximately $17.5 million, $7.4 million and $6.9 million, respectively, as shown in the table below.

(in thousands)	**2020**	2019	2018
Share-based compensation expense			
Research and development	**$ 3,729**	$ 2,693	$ 2,697
General and administrative	**13,616**	4,721	4,163
Capitalized under inventories	**109**	—	—
Share-based compensation expense	**$ 17,454**	$ 7,414	$ 6,860

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 for the year. In determining diluted net loss per Common Share, the weighted average number of Common Shares outstanding is adjusted for stock options and warrants eligible for exercise where the average market price of Common Shares for the years ended December 31, 2020, 2019 and 2018 exceeds the exercise price. Common Shares that could potentially dilute basic net loss per Common Share in the future that could be issued from the exercise of stock options and warrants were not included in the computation of the diluted loss per Common Share for the years ended December 31, 2020, 2019 and 2018, because to do so would be anti-dilutive. Therefore, the weighted average number of Common Shares outstanding used to calculate both basic and diluted net loss per share attributable to Common Shareholders is the same.

The numerator and denominator used in the calculation of basic and diluted net loss amounts per Common Share are as follows:

	2020	**2019**	**2018**
Net loss for the year	**$ (102,680)**	$ (88,385)	$ (53,079)
Weighted average number of Ccommon Shares outstanding	**118,473**	93,024	84,782
Net loss per Common Share (expressed in $ per share)	**$ (0.87)**	$ (0.95)	$ (0.63)

The outstanding number and type of securities that would potentially dilute basic loss per Common Share in the future and which were not included in the computation of diluted loss per share, because to do so would be anti-dilutive for the years presented, are as follows:

	2020	**2019**	**2018**
Stock options	**14,486**	7,822	7,591
Warrants	**1,690**	1,691	5,261
	16,176	9,513	12,852

19. Related-Party Transactions

The outstanding amount payable to ILJIN, an affiliated shareholder, is the result of a settlement completed on September 20, 2013 between ILJIN and the Company. Per the terms of the settlement agreement, payments of up to $10.0 million may be payable and are based on the achievement of pre-defined clinical milestones related to LUPKYNIS and marketing milestones related to DES. During 2019, Aurinia paid ILJIN $100 thousand, upon the achievement of a specific milestone. Previously, in 2017 the Company paid ILJIN $2.2 million upon the achievement of two specific milestones. These payments reduced the original $10.0 million contingent consideration to $7.8 million. A liability was recorded in the amount of $6.0 million on December 31, 2019 related to these milestones as it was determined that achievement of regulatory approval and sales

milestones were probable. The remaining milestones of $1.8 million are related to the discontinued DES program and are not considered probable of achieving.

The amount payable to ILJIN was $6.0 million recorded in other liabilities for the years ended December 31, 2020 and December 31, 2019 and $600 thousand for the year ended December 31, 2018.

Stephen P. Robertson, a partner at Borden Ladner Gervais (BLG) acted as our corporate secretary through October 2020. We incurred legal fees in the normal course of business to BLG of $392 thousand for the year ended December 31, 2020 compared to $473 thousand for the same period in 2019. For the year ended December 31, 2020, we had no ongoing contractual or other commitments as a result of engaging Mr. Robertson to act as our corporate secretary and Mr. Robertson received no additional compensation for acting as the corporate secretary. On November 2, 2020 we announced the appointment of Stephen Robertson as our Executive Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer.

20. Selected Quarterly Financial Information (unaudited)

The following condensed quarterly financial information is for the years December 31, 2020 and 2019:

(in thousands, except per share data)	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Revenues	$ 30	$ 29	$ 29	$ 50,030
Operating expenses	27,090	26,892	42,344	58,082
Loss from operations	(27,060)	(26,863)	(42,315)	(8,052)
Net loss and comprehensive loss	$ (25,932)	$ (26,544)	$ (42,130)	$ (8,074)
Basic and diluted loss per Common Share	$ (0.23)	$ (0.24)	$ (0.34)	$ (0.05)

	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Revenues	$ 30	$ 29	$ 230	$ 29
Operating expenses	14,921	17,172	24,298	34,870
Loss from operations	(14,891)	(17,143)	(24,068)	(34,841)
Net loss and comprehensive loss	$ (14,097)	$ (16,375)	$ (23,454)	$ (34,459)
Basic and diluted loss per Common Share	$ (0.16)	$ (0.18)	$ (0.25)	$ (0.36)

21. Subsequent Events

The Company has evaluated subsequent events through the date on which the consolidated financial statements were available for issuance and noted that, other than the matters described below, the Company has not identified any significant events for which it needs to provide disclosure.

On January 22, 2021, the U.S. Food and Drug Administration (FDA) approved LUPKYNIS in combination with a background immunosuppressive therapy regimen to treat adult patients with active lupus nephritis (LN).