# **Annual Information Form**

**Aurinia Pharmaceuticals Inc.** 

For the year ended December 31, 2015



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# BASIS OF PRESENTATION

Unless otherwise stated, the information in this AIF is as of March 18, 2016.

References to "Aurinia" in this AIF refer to Aurinia Pharmaceuticals Inc. after October 22, 2013 and to Isotechnika Pharma Inc. ("Pharma") prior to October 22, 2013. Pharma changed its name to Aurinia on October 23, 2013. References to the "Company" refer to Aurinia or Pharma, as applicable, together with its subsidiaries on a consolidated basis.

This AIF describes the Company and its operations, its prospects, risks and other factors that affect its business.

All references herein to "dollars" and "\$" are to United States dollars, unless otherwise indicated. All references to CDN\$ are to Canadian dollars. On March 18, 2016 the exchange rate for conversion of US dollars into Canadian dollars was US\$1.00 = CDN\$1.2982 based upon the Bank of Canada noon rate.

Capitalized terms that are not otherwise defined in this AIF have the meanings attributed thereto in Schedule 3 to this AIF.

# FORWARD-LOOKING STATEMENTS

A statement is forward-looking when it uses what the Company knows and expects 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", "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 the Company's product and the timing or magnitude of those events, as they are inherently risky and uncertain.

Securities laws encourage companies to disclose forward-looking information so that investors can get a better understanding of the Company's future prospects and make informed investment decisions. These statements made in this AIF may include without limitation:

- the Company's expected corporate strategy;
- plans to fund the Company's operations;
- statements concerning strategic alternatives and future operations;
- partnering activities;
- summary statements relating to results of the past voclosporin trials or plans to advance the development of voclosporin;
- statements concerning partnership activities and health regulatory discussions;
- the timing of the release of the primary end-point results of the Company's AURA study;
- the timing of the analysis and review of the AURA data with the FDA;
- the timing of commencement and completion of clinical trials;
- the Company's intention to seek regulatory approvals in the United States and Europe for voclosporin;
- the Company's intention to seek additional corporate alliances and collaborative agreements to support the commercialization and development of its product;
- the Company's intention to demonstrate that voclosporin possesses pharmacologic properties with the potential to demonstrate best-in-class differentiation with first-in-class status for the treatment of LN outside of Japan;
- the Company's intention to use the LN Phase 2b clinical trial program to gain a clearer understanding of voclosporin's time to onset of action in patients suffering from LN;
- the Company's belief that recent granted formulation patents regarding the delivery of voclosporin to the ocular surface for conditions such as dry eye have the potential to be of therapeutic value;
- the Company's belief that voclosporin has further potential to be of therapeutic value in other autoimmune indications and in the prevention of transplant rejection;
- the Company's intention to seek regulatory approval in other jurisdictions in the future and initiate clinical studies;
- the Company's anticipated future financial position, future revenues and projected costs;
- plans and objectives of management;
- the Company's belief that utilizing a multi-targeted approach with voclosporin may help LN patients;
- the expected agreement with the FDA on further clinical development requirements.

Such statements reflect the Company's 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 the Company, as at the date of such statements, are inherently subject to significant business, economic, competitive, political, scientific and social uncertainties and contingencies, many of which, with respect to future events, are subject to change. The factors and assumptions used by the

Company to develop such forward-looking statements include, but are not limited to: the assumption that the Company will be able to reach agreements with regulatory agencies on executable development programs; the assumption that recruitment to clinical trials will occur as projected; the assumption that the Company will successfully complete its clinical programs on a timely basis, including the Phase 2b LN clinical trial currently in progress, to enable the Company to proceed to conduct the required Phase 3 LN clinical trials and meet regulatory requirements for approval of marketing authorization applications and new drug approvals; the assumption that the regulatory requirements will be maintained; the assumption that the Company will be able to manufacture and secure a sufficient supply of voclosporin to successfully complete the development and commercialization of voclosporin; the assumption that the Company's patent portfolio is sufficient and valid; the assumption that there is a potential commercial value for other indications for voclosporin; the assumption that market data and reports reviewed by the Company are accurate; the assumption that the Company's current good relationships with its suppliers, service providers and other third parties will be maintained; the assumptions relating to the availability of capital on terms that are favourable to the Company; the assumption that the Company will be able to attract and retain skilled staff; the assumption that general business and economic conditions will be maintained, and the assumptions relating to the feasibility of future clinical trials.

#### It is important to know that:

- Actual results could be materially different from what the Company expects if known or unknown risks affect its business, or if the Company's estimates or assumptions turn out to be inaccurate. As a result, the Company cannot guarantee that any forward-looking statement will materialize and, accordingly, you are cautioned not to place undue reliance on these forward-looking statements.
- 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 the Company's 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 depends 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 the Company's business.
- The Company disclaims any intention and assumes no obligation to update any forward-looking statements even if new
  information becomes available, as a result of future events, new information, or for any other reason except as required by
  law.

The factors discussed below and other considerations discussed in the "Risk Factors" section of this AIF could cause the Company's actual results to differ significantly from those contained in any forward-looking statements.

Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the Company's actual results, performance, or achievements to differ materially from any further results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause such differences include, among other things, the following:

- the need for additional capital to fund the Company's development programs and the effect of capital market conditions and other factors on capital availability;
- difficulties, delays, or failures the Company may experience in the conduct of and reporting of results of its clinical trials for voclosporin, and in particular its current LN Phase 2b clinical trial;
- difficulties, delays or failures in obtaining regulatory approvals for the initiation of clinical trials;
- difficulties, delays or failures in obtaining regulatory approvals to market voclosporin;
- difficulties the Company may experience in completing the development and commercialization of voclosporin;
- insufficient acceptance of and demand for voclosporin;
- difficulties, delays, or failures in obtaining appropriate reimbursement of voclosporin; and/or
- difficulties that the Company may experience in identifying and successfully securing appropriate corporate alliances to support the development and commercialization of its product.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance or achievements. These forward-looking statements are made as of the date of this AIF, and the Company disclaims any intention and have no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

# **OVERVIEW**

# **CORPORATE STRUCTURE**

Aurinia is a clinical stage biopharmaceutical company with its head office located at #1203-4464 Markham Street, Victoria, British Columbia V8Z 7X8 where clinical, regulatory and business development functions of the Company are conducted. Aurinia has its registered office located at #201, 17904-105 Avenue, Edmonton, Alberta T5S 2H5 where the finance function is performed. The office of the CEO is located in Bellevue, Washington.

Aurinia is organized under the *Business Corporations Act* (Alberta). Aurinia's By-Law No. 2 was amended at a shareholder's meeting held on August 15, 2013 to include provisions requiring advance notice for any nominations of directors by shareholders.

Aurinia's Common Shares are currently listed and traded on the NASDAQ under the symbol "AUPH" and on the TSX under the symbol "AUP". The Company's primary business is the development of a therapeutic drug to treat autoimmune diseases, in particular LN.

Aurinia has the following wholly-owned subsidiaries: Aurinia Pharma Corp. (British Columbia incorporated), Aurinia Pharmaceuticals, Inc. (Delaware incorporated) and Aurinia Pharma Limited (UK incorporated).

#### RECENT DEVELOPMENTS

# AURA-LV (AURA) Phase 2b Clinical Trial Update - Patient Enrolment Completed

On January 19, 2016, the Company announced completion of patient enrollment of its AURA (<u>Aurinia Urinary protein Reduction in Active lupus nephritis or AURA</u>) clinical trial at 265 patients (the target number of patients was 258). This Phase 2b clinical trial, is a randomized, controlled, double-blind study comparing the efficacy of voclosporin as a component of multi-targeted therapy against placebo in achieving remission in patients with active LN. AURA is one of the largest prospective registration-quality studies ever conducted within this specific disease area.

The AURA trial has been designed to demonstrate that voclosporin can induce a rapid and sustained reduction of proteinuria with extremely low steroid exposure. The placebo-controlled study assesses two doses of voclosporin, with all patients receiving background therapy of MMF coupled with an aggressive oral corticosteroid taper. There will be a primary analysis to determine complete remission at week 24 (confirmed at 26 weeks) and various secondary analyses at both 24 and 48 weeks which include biomarkers and markers of non-renal lupus. This disease has shown to be particularly difficult to treat with fewer than 20% of patients achieving clinical remission at six months on existing regimens which often require unacceptably high steroid exposure in this predominantly young, female population.

Un-blinding and disclosure of the primary trial data is scheduled within approximately one month of the last enrolled patient completing 24 weeks of active treatment. Therefore, the Company expects that the primary end-point results of the AURA trial will be released in the third quarter ended September 30, 2016 of this year.

#### **AURION Study Update**

On February 8, 2016 the Company announced that it had completed a preliminary analysis of its AURION (<u>A</u>urinia early <u>U</u>rinary protein <u>Reduction</u> Predicts Response) study. In the first seven patients that have reached at least eight weeks of therapy in the AURION study, 100% (7/7) have achieved at least a 25% reduction in proteinuria compared to study entry. A 25% reduction in proteinuria has been shown to be predictive of a positive clinical response at 24 weeks. All of the other pre-specified eight week biomarkers of active LN have also improved and are trending towards normalization. These biomarkers have also been shown to be predictive of positive clinical response rates at 24 weeks.

In the first eight weeks of a 48 week regimen of multi-target therapy including voclosporin in the AURION study, an overall mean reduction of proteinuria of 72% compared to pre-treatment levels was observed, and 57% (4/7) of these patients achieved complete remission as defined by a urinary protein creatinine ratio of  $\leq 0.5$ mg/mg. Overall renal function as measured by eGFR in these patients has remained stable.

The AURION study is an open label, single arm, exploratory study assessing the ability of biomarkers at eight weeks to predict clinical response rates at 24 and 48 weeks in subjects taking voclosporin 23.7mg twice daily in combination with standard of care, MMF and corticosteroids, in patients with active LN. It is the first ever trial with voclosporin in this patient population and supports the Company's hypothesis that utilizing a multi-targeted approach with voclosporin may help LN patients.

#### Fast Track

On March 2, 2016 the Company announced that the FDA granted Fast Track designation for voclosporin, the Company's next generation CNI, for the treatment of LN.

The Fast Track program was created by the FDA to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address significant unmet medical needs. Compounds that receive this FDA designation benefit from more frequent meetings and communications with the FDA to review the drug's development plan including the design of clinical trials and the use of biomarkers to support approval. Additionally, Fast Track designation allows the Company to submit parts of the NDA on a rolling basis for review as data becomes available. The Company expects to analyze and review the AURA data with the FDA late in 2016 in order to reach agreement on further clinical development requirements.

## **BUSINESS OF THE COMPANY**

The Company has, since September 20, 2013, rebranded, restructured and refocused itself around a strategy that focuses on the development of voclosporin for the treatment of LN.

Aurinia is focused on the development of voclosporin, a novel therapeutic immunomodulating drug candidate which is a second generation CNI. It has been previously studied in kidney rejection following transplantation, psoriasis and in various forms of uveitis (an ophthalmic disease).

The mechanism of action of voclosporin, a CNI, has been validated with certain first generation CNIs for the prevention of rejection in patients undergoing solid organ transplants and in several autoimmune indications, including dermatitis, keratoconjunctivitis sicca (Dry Eye Syndrome), psoriasis, rheumatoid arthritis, and for LN in Japan. The Company believes that voclosporin possesses pharmacologic properties with the potential to demonstrate best-in-class differentiation with first-in-class regulatory approval status for the treatment of LN outside of Japan.

# Strategy

The Company's business strategy is to optimize the clinical and commercial value of voclosporin, its late stage clinical candidate. In particular, the Company is focused on the development of voclosporin as an add-on therapy to the current standard of care, CellCept®, which was developed by the Aurinia Pharma Corp. management team during its tenure at Aspreva.

The key elements of the Company's corporate strategy include:

- Focusing the Company's resources on advancing voclosporin through a robust LN Phase 2b clinical trial.
- Mitigate development risk by leveraging the ALMS database and management team's experience the Company has certain rights to utilize the ALMS database including its use in planning, designing and informing the LN Phase 2b clinical trial.
- Upon successful completion of the Phase 2b clinical trial, plan to initiate the required Phase 3 clinical program for LN.
- Evaluate other voclosporin indications while the Company intends to deploy its operational and financial resources to develop voclosporin for LN, the Company believes that recent granted formulation patents regarding the delivery of voclosporin to the ocular surface for conditions such as dry eye have the potential to be of therapeutic value. The Company will explore its strategic options to exploit shareholder value from this intellectual property. The Company also believes that voclosporin has further potential to be of therapeutic value in other autoimmune indications and in the prevention of transplant rejection. Management will consider strategic opportunities for these other potential indications on an ongoing basis.
- Consider other business development opportunities including potentially in-licensing other suitable clinical compounds that would be a strategic fit for the Company under the right circumstances and timing.

# LN Clinical Development Program

In June 2014, Aurinia announced the initiation of its planned global 258 patient LN Phase 2b clinical trial to evaluate the safety and efficacy of voclosporin as a treatment for LN. LN is an inflammation of the kidney that if untreated or inadequately treated can lead to end-stage renal disease and the requirement for life-long dialysis, or even death.

The AURA trial is being conducted in 20 countries and is a randomized, controlled, double-blind study comparing the efficacy of voclosporin against placebo in achieving remission in patients with active LN. The AURA trial is designed to demonstrate that voclosporin can induce a rapid and sustained reduction of proteinuria in the presence of extremely low steroid exposure and fulfill specific regulatory requests. It will compare two dosage groups of voclosporin (23.7mg and 39.5mg) administered with MMF vs.

MMF alone. All patients will also receive oral corticosteroids as background therapy. There will be a primary analysis to determine complete remission at week 24 and various secondary analyses at week 48 which include biomarkers and markers of non-renal SLE.

The Company's clinical strategy involves layering voclosporin on top of the current standard of care (CellCept®/MMF and steroids) as a MTT approach to induce and maintain remission in patients suffering from active LN. In 2012, the Company gained alignment with both the Cardio-Renal and Pulmonary, Allergy, and Rheumatology Products divisions of the FDA on its proposed Phase 2b protocol. The Company has an open IND with the FDA.

With the existing evidence that supports the utility of CNIs in combination with MMF in treating LN, the robust safety data base of voclosporin generated in other disease states and the fact that CellCept®/MMF in combination with the other CNIs is the standard of care in solid organ transplant patients, it is reasonable to consider that voclosporin is a risk-mitigated clinical asset for the treatment of LN.

In support of this large, randomized, LN Phase 2b clinical trial, the Company announced on February 9, 2015 the initiation of an open label, exploratory study to assess short term predictors of response using voclosporin in combination with MMF, in patients with active LN. The AURION study being conducted at two sites in Malaysia will examine biomarkers of disease activity at eight weeks and their ability to predict response at 24 and 48 weeks.

#### **About Lupus Nephritis**

The Lupus Foundation of America ("**LFA**") estimates that approximately 1.5 million people in the United States and up to 5.0 million people worldwide suffer from SLE. Approximately 90% of patients suffering from SLE are women of child-bearing age. The disease causes severe impairments on quality of life and wellbeing. Of the patients suffering from SLE, 40-60% experience renal manifestations of the disease resulting in inflammation of the kidney. These patients are considered to have LN and have a high probability of advancing to end stage renal disease and dialysis if left untreated.

Based on the work performed by the former Aspreva team, the ALMS data has been reported in several respected journals, including, the New England Journal of Medicine (*Dooley MA, Jayne D, Ginzler EM, Isenberg D, Olsen NJ, Wofsy D, Solomons, N et al; ALMS Group. Mycophenolate versus azathioprine as maintenance therapy for lupus nephritis. N Engl J Med. 2011 Nov 17;365(20):1886-95) and the Journal of the American Society of Nephrology (<i>Appel GB, Contreras G, Dooley MA, Ginzler EM, Isenberg D, Jayne D, Solomons N et al; Aspreva Lupus Management Study Group. Mycophenolate mofetil versus cyclophosphamide for induction treatment of lupus nephritis. J Am Soc Nephrol. 2009 May;20(5):1103-12. Epub 2009 Apr 15.)* These publications and subsequent alterations in treatment strategies by physicians caring for patients suffering from LN have established CellCept®/MMF as the standard of care for the treatment of LN. This shift in the treatment paradigm for LN and the establishment of CellCept® use as a relatively uniform treatment approach for these patients has, in the view of the Company, caused the LN market to evolve into an attractive and mature market opportunity.

Despite CellCept® being the current standard of care for the treatment of LN, it remains far from adequate with fewer than 20% of patients on therapy actually achieving disease remission after six months of therapy. Data suggests that a LN patient who does not achieve rapid disease remission upon treatment is more likely to experience renal failure or require dialysis at 10 years (*Chen YE, Korbet SM, Katz RS, Schwartz MM, Lewis EJ; the Collaborative Study Group. Value of a complete or partial remission in severe lupus nephritis. Clin J Am Soc Nephrol.* 2008;3:46-53.). Therefore, it is critically important to achieve disease remission as quickly and as effectively as possible. The data suggests that the majority of patients in the United States suffering from LN will not achieve complete remission and are not adequately treated (BioTrends® Research Group Inc., ChartTrends® SLE, December 2010).

#### **CNIs and Lupus Nephritis**

Aurinia's lead drug, voclosporin, belongs to a class of drugs called CNIs. There are only two other oral marketed CNIs available, cyclosporine and tacrolimus. Cyclosporine was introduced to the marketplace in the early 1980s while tacrolimus was first marketed in the mid-1990s. Both cyclosporine and tacrolimus have lost key patent protection and have not been approved for the treatment of LN outside of Japan. For the past 20 years these products, in combination with CellCept®/MMF and steroids have been the cornerstone for the prevention of renal transplant rejection with greater than 90% of all renal transplant patients leaving hospital on lifelong CNI plus MMF therapy (UNOS database).

In late 2008, the Japanese Health Authority became the first major jurisdiction in 50 years to approve a pharmaceutical agent for the treatment of LN. This product was the CNI tacrolimus. In addition to this approval, a substantial amount of recent data has been generated, primarily from investigator initiated trials that supports the use of either cyclosporine or tacrolimus for the treatment of various forms of lupus including LN. The addition of tacrolimus, layered on top of MMF and steroids akin to the widely accepted and utilized transplantation regimen, appears to dramatically improve complete response/remission rates in LN (*Bao H, Liu ZH, Xie* 

HL, Hu WX, Zhang HT, Li LS. Successful treatment of class V+IV lupus nephritis with multitarget therapy. J Am Soc Nephrol. 2008 Oct;19(10):2001-10. Epub 2008 Jul 2 and .Liu, Zhi-Hong et al., 2012 ASN Abstract SA-OR097). This approach to treatment can be considered a MTT approach to treating LN as it is routinely used in transplantation. Complete remission rates of up to 50% have been reported utilizing this approach. Long term follow-up studies in LN suggest that the early reduction in proteinuria as seen in complete remission leads to improved renal outcome at ten years. (Houssiau FA, Vasconcelos C, D'Cruz D, Sebastiani GD, de Ramon Garrido E, Danieli MG, et al. Early response to immunosuppressive therapy predicts good renal outcome in lupus nephritis. Lessons from long-term followup of patients in the Euro-lupus nephritis trial. Arthritis Rheum. 2004 Dec;50(12):3934-40).

The Company plans to utilize this MTT approach to treating LN patients with voclosporin.

#### **About Voclosporin**

Voclosporin is an oral drug, administered twice daily. It is structurally similar to cyclosporine A ("CsA"), but is chemically modified on the amino acid-1 residue. This modification leads to a number of advantages the Company believes offer relevant clinical benefits as compared to the older off-patent CNIs.

#### **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 (Faul C, et al. The actin cytoskeleton of kidney podocytes is a direct target of the antiproteinuric effect of cyclosporine A. Nat Med. 2008 Sep;14(9):931-8. doi: 10.1038/nm.1857). 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.

#### **Potential Voclosporin Clinical Benefits**

The Company believes that voclosporin has shown a number of key clinical benefits over the existing commercially available CNIs (tacrolimus & cyclosporine). Firstly, CNI assay results have indicated that voclosporin is approximately four times more potent than its parent molecule cyclosporine, which would indicate an ability to give less drug and produce fewer potentially harmful metabolites. Secondly, cyclosporine inhibits the enterohepatic recirculation of MPA, the active metabolite of MMF. The net effect of co-administration of CsA with MMF is reduced MPA systemic exposure by as much as 50% (*D. Cattaneo et al. American Journal of Transplantation, 2005:12(5);2937-2944.*). This drug interaction has not been observed with voclosporin and it is not expected that MPA blood exposure levels will be reduced with voclosporin co-administration. This is an extremely important fact to consider as most patients being treated with voclosporin for LN will already be taking MMF. Furthermore, PK-PD analysis indicate lower PK-PD variability for voclosporin versus tacrolimus or cyclosporine, to the extent that the Company believes flatdosing can be achieved for voclosporin. The currently available CNIs require extensive therapeutic drug monitoring which can often be costly, confusing and time consuming for treating physicians.

In a head-to-head study comparing voclosporin against cyclosporine in the treatment of psoriasis, cyclosporine was shown to cause significant increases in lipid levels as compared to voclosporin. The difference was statistically significant. This is important considering most lupus patients die of cardiovascular disease. In another study comparing voclosporin against tacrolimus in patients undergoing renal transplantation, the voclosporin group experienced a statistically significantly lower incidence of glucose intolerance and diabetes than tacrolimus treated patients. Additionally, in the Japanese tacrolimus study that led to the approval of this drug in Japan, almost 15% of tacrolimus patients experienced glucose intolerance (Miyasaka N, Kawai S, Hashimoto H. Efficacy and safety of tacrolimus for lupus nephritis: a placebo-controlled double-blind multicenter study. Mod Rheumatol. 2009;19(6):606-15. Epub 2009 Aug 18). This is a major limitation for physicians wanting to use this agent in LN and is a well described side effect of tacrolimus.

The Company believes that voclosporin can be differentiated from the older CNIs and thus possess a unique position with the market.

#### Scientific Rationale for Treatment of LN with Voclosporin

SLE, including LN, is a heterogeneous autoimmune disease with often multiple organ and immune system involvement. 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.

The use of voclosporin in combination with the current standard of care for the treatment of LN provides a multi-targeted approach to treating this heterogenous disease (similar to the standard approach in preventing kidney transplant rejection). Voclosporin 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 cytoskeletion 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 patients have been in voclosporin clinical trials including studies where voclosporin was compared to placebo or active control. The safety and tolerability profile of the drug therefore is well characterized. Phase 2 or later clinical studies that have been completed include studies in the following indications:

**Psoriasis:** To date, 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 the Company has decided not to pursue further Phase 3 development.

**Renal Transplantation:** A Phase 2b clinical trial in de novo renal transplant recipients was completed. Study ISA05-01, the PROMISE Study (Busque S, Cantarovich M, Mulgaonkar S, Gaston R, Gaber AO, Mayo PR, et al; PROMISE Investigators. The PROMISE study: a phase 2b multicenter study of voclosporin (ISA247) versus tacrolimus in de novo kidney transplantation. Am J Transplant. 2011 Dec;11(12):2675-84) 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, but superior to tacrolimus with respect to the incidence of new onset diabetes after transplantation. In 2010, tacrolimus lost its exclusivity in most world markets and as a result, the competitive pricing environment for voclosporin for this indication has come into question. Additionally, the more expensive development timelines for this indication has made it a less attractive business proposition as compared to the LN indication, even when considering the fact that a special protocol assessment has been agreed to by the FDA for this indication.

**Uveitis:** Multiple studies in various forms of non-infectious uveitis have been completed over the past several years by Lux, a former licensee of the Company, 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 as expected. The Company has now successfully terminated its licensing agreement with Lux. In conjunction with this termination the Company has retained a portfolio of additional patents that Lux had been prosecuting that are focused on delivering effective concentrations of voclosporin to various ocular tissues. The Company will continue to evaluate these patents and make strategic recommendations on how they fit into the ongoing strategic directives of the Company.

# THREE YEAR HISTORY

#### **CORPORATE DEVELOPMENTS IN 2015**

Filing of Base Shelf Prospectus - October 19, 2015

The Company received a final receipt from the British Columbia Securities Commission on October 19, 2015 for the Short Form Base Shelf Prospectus (the "**Shelf Prospectus**") of Aurinia dated October 16, 2015.

The Shelf Prospectus and corresponding shelf registration statement allows Aurinia to offer common shares of Aurinia, warrants to purchase common shares of Aurinia and subscription receipts that entitle the holder to receive upon satisfaction of certain release conditions, and for no additional consideration, common shares of Aurinia or any combination thereof during the 25-month period that the Shelf Prospectus is effective, with a total offering price, in the aggregate, of up to US\$250 million. The Shelf Prospectus is intended to give Aurinia the capability to access new capital from time to time. The amount and timing of any future offerings will be based on the Company's financial requirements and market conditions at the time.

The specific terms of any future offering under the Shelf Prospectus will be established at the time of such offering. At the time any of the securities covered by the Shelf Prospectus are offered for sale, a prospectus supplement containing specific information about the terms of such offering will be filed with applicable Canadian securities regulatory authorities and the SEC.

#### **CORPORATE DEVELOPMENTS IN 2014**

#### Listing on NASDAQ - September 2, 2014

Aurinia received approval from the NASDAQ Listing Qualifications Department to list its common shares on the NASDAQ and commenced trading on September 2, 2014 under the trading symbol "AUPH".

#### Listing on the TSX - June 2, 2014

Aurinia applied to the TSX for the relisting of its common shares and subsequently the common shares were listed on the TSX as of the open of trading on June 2, 2014. The common shares of Aurinia continue to trade on the TSX under the trading symbol "AUP".

# Private Placement Financing - February 14, 2014

On February 14, 2014, Aurinia completed a \$52 million private placement (the "**Offering**"). The proceeds from the Offering are being used for the LN Phase 2b clinical trial currently underway, general corporate and working capital purposes.

The financing was led by venBio, New Enterprise Associates, Redmile Group, RA Capital Management, Great Point Partners, and Apple Tree Partners, with participation from various other institutional investors, including existing shareholders Lumira Capital, ILJIN and Difference Capital.

Under the terms of the Offering, Aurinia issued 18.92 million units (the "**Units**") at a subscription price per Unit of \$2.7485, each Unit consisting of one common share and one-quarter (0.25) of a common share purchase warrant (a "**Warrant**"), exercisable for a period of five years from the date of issuance at an exercise price of \$3.2204. All securities issued in connection with the Offering were subject to a four-month hold period from the date of issuance in accordance with applicable securities law, which expired on June 15, 2014 for the securities issued at closing.

Leerink Partners LLC acted as lead placement agent and Canaccord Genuity Inc. acted as co-placement agent for the Offering. The placement agents were paid a 7.5% cash commission on subscriptions excluding those from existing shareholders for a total commission of \$3.86 million.

## Termination of Distribution and License Agreement with Lux – February 27, 2014

On February 27, 2014 Aurinia signed a Termination and Assignment Agreement (the "Lux Agreement") with Lux which returned worldwide rights to develop and commercialize voclosporin for the treatment and prophylaxis of all ophthalmic diseases back to the Company. The return of this license further consolidates the intellectual property related to voclosporin which was a key consideration in the acquisition of Aurinia Pharma Corp. by the Company in 2013. Coincident with the termination of the Lux Agreement the Company has retained a portfolio of patents focused around delivering voclosporin in high concentrations to various tissues of the eye. The Company will evaluate this intellectual property and define its role as it relates to the defined corporate strategy of the Company.

# **CORPORATE DEVELOPMENTS IN 2013**

#### Management Change - November 6, 2013

On November 6, 2013 the Company announced the appointment of Stephen W. Zaruby as Aurinia's President and CEO. Mr. Zaruby has an accomplished history of strategic operations, sales and marketing, research and development, and general management success in the global biotechnology and pharmaceutical industries. Previously, he was President of Seattle-based ZymoGenetics Inc., which was acquired by Bristol-Myers Squibb for \$885 million in 2010. Mr. Zaruby joined ZymoGenetics Inc. from Bayer. There, his 20 years of progressive leadership experience included executive roles managing Bayer's domestic and international anti-infectives, quinolone and hospital/surgical business franchises.

# Share Consolidation and Name Change - October 23, 2013

On October 23, 2013, Aurinia proceeded with a consolidation of its common shares on a 50:1 basis. In conjunction with the share consolidation, Aurinia changed its name from Isotechnika Pharma Inc. to Aurinia Pharmaceuticals Inc. Both the name change and the share consolidation were approved by the shareholders of Aurinia at its shareholder meeting held on August 15, 2013. In connection with its name change, Aurinia's trading symbol on the TSXV was changed to "AUP".

#### Plan of Arrangement and Acquisition of Aurinia Pharma Corp. - September 20, 2013

On February 5, 2013 Aurinia announced that it had signed a binding term sheet (the "**Term Sheet**") with Aurinia Pharma Corp. for the merger of the two companies, creating a clinical development stage pharmaceutical company focused on the global nephrology market. The Term Sheet set forth the main criteria to be incorporated into a definitive merger agreement under which the Company would acquire 100% of the outstanding securities of Aurinia Pharma Corp. The merger was expected to be effected by the exchange of shares of Aurinia for securities of Aurinia Pharma Corp. resulting in an estimated 65:35 post merger ownership split, on a warrant diluted basis, between Aurinia and Aurinia Pharma Corp. shareholders, respectively.

On April 3, 2013, the Company and Aurinia Pharma Corp. negotiated a tripartite settlement agreement (the "Settlement Agreement") with ILJIN pursuant to which, upon the successful completion of the proposed merger, the combined company would re-acquire the voclosporin license previously granted to ILJIN and therefore obtain full rights to voclosporin for autoimmune indications including lupus, and transplantation in the United States, Europe and other regions of the world, outside of Canada, Israel, South Africa, China, Taiwan and Hong Kong. In return, ILJIN would be entitled to receive certain predefined future milestone payments and would also own approximately 25% of the issued and outstanding shares of the merged company on a diluted basis, calculated to give effect to the dilution by the exercise of Warrants but excluding the exercise of stock options. On August 6, 2013, an arrangement agreement (the "Arrangement Agreement") was prepared implementing the arrangement. The Arrangement Agreement was intended to implement the terms of the Settlement Agreement, whereby ILJIN would receive a further ownership interest in Aurinia in exchange for:

- (i) returning to the Company and terminating:
  - (a) all of its rights, licenses and obligations under the DDLA; and
  - (b) all other licenses and sublicenses between ILJIN and any of the Company, Aurinia Pharma Corp. or Vifor; and
- (ii) suspending all of its current or contemplated legal or financial claims against the Company, Aurinia Pharma Corp. or Vifor.

The Company completed the merger and related transactions (the "**Plan of Arrangement**") on September 20, 2013 that its shareholders had approved on August 15, 2013.

Upon closing of the Plan of Arrangement on September 20, 2013, Aurinia issued common shares to ILJIN. In addition, ILJIN is entitled to receive certain predefined future success based clinical and marketing milestone payments in the aggregate amount of up to \$10 million, plus up to \$1.6 million upon the merged company reaching certain financing milestones.

Aurinia also acquired all of the issued and outstanding common shares of Aurinia Pharma Corp. at a ratio of approximately 19.83 pre-consolidated common shares for each Aurinia Pharma Corp. share held by an Aurinia Pharma Corp. shareholder.

## Second Unit Offering

Immediately following the completion of the transaction described above, Aurinia completed a second private placement (the "Second Unit Offering") of 2.67 million units ("Second Offering Units") at a price of CDN\$2.25 per Second Offering Unit for gross proceeds of CDN\$6.0 million. Each Second Offering Unit is comprised of one common share and one-half of a whole Warrant (each a "Second Offering Warrant"), with each whole Second Offering Warrant exercisable for one common share at a price of CDN\$2.50 per common share for a period of three years from their date of issuance.

#### Listing on the TSXV

The arrangement transaction among the Company, ILJIN and Aurinia Pharma Corp. was determined by the TSX to constitute a "backdoor listing" under the rules of the TSX due to the significant increase in the ownership position in Aurinia by ILJIN. The result of that determination was that Aurinia was required to meet the TSX's original listing requirements following completion of the arrangement. Aurinia did not meet the TSX's original listing requirements and, as a result, the common shares were delisted from the TSX as of the end of trading on September 27, 2013. Aurinia applied to the TSXV for listing of the common shares on that exchange and subsequently the common shares were listed on the TSXV as of the open of trading on September 30, 2013.

# Management Restructuring

Upon the completion of the Plan of Arrangement, the Company made changes to its management team which included the appointments of Dr. Richard Glickman as interim CEO, Dr. Neil Solomons as CMO, and Michael Martin as COO which resulted in either the termination or position change of certain previous officers and employees.

# REGULATORY AND BUSINESS MATTERS

# REGULATORY REQUIREMENTS

The development, manufacturing and marketing of voclosporin 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. The Company would require regulatory approval in the United States and Europe where activities would be conducted by the Company or on the Company's behalf. Depending upon the circumstances surrounding the clinical evaluation of the product candidate, the Company itself may undertake clinical trials, contract clinical trial activities to contract research organizations, or rely upon corporate partners for such development. The Company believes this approach will allow the Company to make cost effective developmental decisions in a timely fashion. The Company 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 and Europe are discussed in this section, the Company also intends to seek regulatory approval in other jurisdictions in the future and will initiate clinical studies where appropriate.

#### **United States**

In the United States, all drugs are regulated under the Code of Federal Regulations and are enforced by the FDA. The regulations are similar to those in Canada and require that non-clinical and clinical studies be conducted to demonstrate the safety and effectiveness of products before marketing, and that the manufacturing be conducted according to certain "Good Manufacturing Practice" standards development by the FDA.

Subsequent to the initial proof-of-concept and preliminary safety studies, the application submitted to the FDA prior to conducting human clinical trials of new drugs is referred to as an IND application. This application contains similar information to the Canadian CTA, and the FDA has 30 days in which to notify the Company if the application is unsatisfactory. If the application is deemed satisfactory, then the Company may proceed with the clinical trials. As in Canada, before a clinical trial can commence at each participating clinical trial site, the site's IRB/IEC must approve the clinical protocol and other related documents.

After completing all required non-clinical and clinical trials, and prior to selling a novel drug in the United States, the Company must also comply with NDA procedures required by the FDA. The NDA procedure includes the submission of a package containing similar information as to that required in the new drug submission in Canada to demonstrate safety and efficacy of the novel drug and describe the manufacturing processes and controls. FDA approval of the submission is required prior to commercial sale or commercial distribution of the product in the United States. Pre- and/or post-approval inspections of manufacturing and testing facilities are necessary. The FDA may also conduct inspections of the clinical trial sites and the non-clinical laboratories conducting pivotal safety studies to ensure compliance with good clinical practice and good laboratory practice requirements. The FDA has the authority to impose certain post-approval requirements, such as post-market surveillance clinical trials. In addition, FDA approval can be withdrawn for failure to comply with any post-marketing requirements or for other reasons, such as the discovery of significant adverse effects.

#### **Europe**

In Europe, the evaluation of new products is coordinated by the EMA. The regulations are similar to those in Canada and the United States and require that non-clinical and clinical studies be conducted to demonstrate the safety and effectiveness of products before marketing, and that the manufacturing be conducted according to good manufacturing practice.

Subsequent to the initial proof-of-concept and preliminary safety studies, and prior to conducting human clinical trials, a CTA must be submitted to the competent authority in the country where the clinical trial will be conducted. This application contains similar information to the Canadian CTA and United States IND. In Europe, the clinical trials are regulated by the European Clinical Trial Directive (2001/20/EC). As in Canada and the United States, before a clinical trial can commence at each participating clinical trial site, the site's IRB/IEC must approve the clinical protocol and other related documents.

A major difference in Europe, when compared to Canada and the United States, is with the approval process. In Europe, there are different procedures that can be used to gain marketing authorization in the EU. The first procedure is referred to as the centralized procedure and requires that a single application be submitted to the EMA and, if approved, allows marketing in all countries of the EU. The centralized procedure is mandatory for certain types of medicines and optional for others. The second procedure is referred to as national authorization and has two options; the first is referred to as the mutual recognition procedure and requires that approval is gained from one member state, after which a request is made to the other member states to mutually recognize the approval, whilst the second is referred to as the decentralised procedure which requires a member state to act as the reference member state through a simultaneous application made to other member states.

#### DRUG DEVELOPMENT PROCESS

Clinical trials involve the administration of an investigational pharmaceutical product to individuals under the supervision of qualified medical investigators. Clinical studies are conducted in accordance with protocols that detail the objectives of a study, the parameters to be used to monitor safety, and the efficacy criteria to be evaluated. Each protocol is submitted to the appropriate regulatory body and to a relevant IRB/IEC prior to the commencement of each clinical trial. Clinical studies are typically conducted in three sequential phases which may overlap in time-frame.

In summary, the following steps must be completed prior to obtaining approval for marketing in the United States and Europe:

- Nonclinical Animal Studies These studies evaluate the safety and potential efficacy of a therapeutic product and form
  part of the application which must be reviewed by the appropriate regulatory authority prior to initiation of human clinical
  trials.
- 2. **Phase 1 Clinical Trials** These trials test the product in a small number of healthy volunteers to determine toxicity (safety), maximum dose tolerance, and pharmacokinetic properties.
- 3. **Phase 2 Clinical Trials** These trials are conducted in the intended patient population and include a larger number of subjects than in Phase 1. The primary goal is to determine the safety of a product in a larger number of patients and ultimately in the intended patient population. These trials may also provide early information on the potential effectiveness of a product.
- 4. **Phase 3 Clinical Trials** These trials are conducted in an expanded patient population at multiple sites to determine longer-term clinical safety and efficacy of the product. It is from the data generated in these trials that the benefit/risk relationship of a product is established and the final drug labelling claims are defined.

In the course of conducting clinical trials for a drug candidate, a company may conduct more than one trial of a particular phase in order to evaluate the drug against a variety of indications or in different patient populations. In such a case, industry practice is to differentiate these trials by way of designations such as "Phase 2a" or "Phase 2b".

A key factor influencing the rate of progression of clinical trials is the rate at which patients can be recruited to participate in the research program. Patient recruitment is largely dependent upon the incidence and severity of the disease and the alternative treatments available.

Even after marketing approval for a drug has been obtained, further trials may be required (referred to as Phase 4 trials). Post-market trials may provide additional data on safety and efficacy necessary to gain approval for the use of the product as a treatment for clinical indications other than those for which the product was initially tested. These trials may also be used for marketing purposes.

Aurinia expects that it will be required to conduct additional studies for the LN clinical program in order to submit for marketing approval in the United States and Europe. The costs and timing of the program will be dependent on a number of variables including the results of the AURA clinical trial, and the number and size of the additional studies. The additional studies will be determined subsequent to the AURA primary endpoint data results based on meetings with the regulators. The costs of conducting the additional studies are expected to be at least as much as those required for the current AURA clinical trial.

# MANUFACTURING, ENCAPSULATING AND PACKAGING OF VOCLOSPORIN

Drug supply costs are comprised of third party charges for manufacturing, encapsulating and packaging of voclosporin.

Lonza Ltd., a Swiss-based contract drug manufacturer, manufactured the API for the Company's LN Phase 2b clinical trial currently underway. It is the Company's intention that Lonza Ltd. will manufacture the API required for future clinical and commercial voclosporin supply needs.

Voclosporin, requires a specialized manufacturing process. Lonza Ltd. is currently the Company's sole manufacturer of voclosporin. Pricing for clinical supply is determined through negotiations between Lonza Ltd. and the Company and is based on the size of specific API production runs and the cost of the raw materials used in the API manufacturing process. As at the date of this AIF, the Company has not experienced any difficulty in obtaining the raw materials required with respect to the manufacturing of voclosporin.

The Company has contracted Catalent Pharma Solutions to encapsulate and package voclosporin for its LN Phase 2b clinical trial program. It is the Company's intention that Catalent Pharma Solutions will provide services with respect to encapsulating and

packaging the voclosporin required for future clinical and commercial supply needs. Catalent Pharma Solutions is currently the sole supplier for encapsulating and packaging the Company's clinical drug supply. Pricing for these services is determined by negotiations between Catalent Pharma Solutions and the Company and is based on the specific production run size. As at the date of this AIF, the Company has not experienced any difficulty in obtaining the raw materials used in the encapsulating and packaging process.

# INTELLECTUAL PROPERTY RIGHTS

Patents and other proprietary rights are essential to the Company's business. The Company's policy has been to file patent applications to protect technology, inventions, and improvements to its inventions that are considered important to the development of its business.

The Company owns the patents and patent applications related to voclosporin in the United States, Europe and in other jurisdictions around the world except for Canada, South Africa and Israel which belong to Paladin. As at March 18, 2016 there are 177 granted patents for voclosporin worldwide. These patents cover composition of matter, method of use, formulation and synthesis. The composition of matter patents, with accompanying patent term adjustments and extensions, will provide product exclusivity in the major markets until at least late 2027 with the potential to extend to 2029. In addition to patent rights, the Company also expects to receive certain periods of New Chemical Entity (NCE) exclusivity which range between five to 10 years beyond the date of regulatory approval in the major markets.

The Company also has 16 granted ophthalmic formulation patents with eight patent applications pending as of March 18, 2016. These granted patents, with accompanying patent term adjustments and extensions, provide product exclusivity in the major markets until at least 2031.

#### **COMPETITIVE ENVIRONMENT**

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 the Company. Many of these companies have substantially greater financial and other resources, larger research and development staff, and more extensive marketing and manufacturing organization than the Company does. Many of these companies have significant experience in preclinical 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. 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 institutions also compete with the Company in recruiting and retaining highly qualified scientific personnel.

#### **EMPLOYEES**

	As at December 31, 2015	As at December 31, 2014	As at December 31, 2013
Total Number of Employees	16	11	13

As at December 31, 2015 the Company employed 16 employees, 12 of whom held advanced degrees in science and business, including one with a Ph.D. degree and one with an MD.

Of the Company's total 15.1 full-time equivalent employees as at December 31, 2015, 7.5 full-time equivalent employees were engaged in, or directly support, clinical trial activities; and 7.6 full-time equivalent employees were engaged in corporate, administration and business development activities.

The Company's employees are not governed by a collective agreement. The Company has not experienced a work stoppage and believes its employee relations are satisfactory given the current economic conditions.

# **FACILITIES**

The Company entered into an agreement, effective June 1, 2014, to sublease 4,418 square feet of office and storage space at its head office location in Victoria, British Columbia. The sublease is for a term of five years, with the Company having the right to terminate after the third year at no cost. The estimated base rent plus operating costs on a monthly basis for the period January 1, 2016 to May 31, 2017 is approximately \$9,000 per month.

The Company entered into an agreement on November 14, 2014 to lease 1,247 square feet of office space for the Edmonton, Alberta registered office where the Company's finance group is located. The lease is for a term of two years commencing on January 1, 2015 at a cost of approximately \$1,300 per month.

The Company also entered into an 18 month agreement to rent offices in a shared office facility in Bellevue, Washington commencing April 1, 2015 at a cost of approximately \$5,000 per month.

On October 1, 2013, the Company reduced its leased lab premises cost in Edmonton, Alberta by entering into a three-year sublease with the head lessee for approximately 9,000 square feet while vacating the remaining 16,318 square feet it had previously been leasing. The cost of the subleased space for the remainder of term (January 1, 2016 to September 30, 2016) is approximately \$16,000 monthly and includes base rent, utilities and operating costs. The Company paid the head lessee a deposit of \$145,000 for approximately the last 7 months of rent.

The Company in turn, effective October 15, 2014 subleased out this 9,000 square feet space for approximately \$6,000 per month for the remaining term of the sublease as it no longer required this space.

# **RISK FACTORS**

Investing in the Company's securities involves a high degree of risk. You should carefully consider the following risks in addition to the other information included in this AIF, the Company's historical consolidated financial statements and related notes, before you decide to purchase the Company's common shares. The risks and uncertainties described below are those that the Company currently believes may materially affect the Company and are set out in no particular order. Additional risks and uncertainties that the Company is unaware of or that it currently deems immaterial may also become important factors that materially and adversely affect its business, financial condition and results of operations. If any of the following events were to actually occur, the Company's business, operating results or financial condition could be adversely affected in a material manner.

#### RISKS RELATING TO AURINIA'S BUSINESS

The Company's financial statements for the year ended December 31, 2015 contain a going concern note which may have an adverse effect on its relationships with current and future collaborators, contract suppliers and investors

Since its inception, the Company has experienced recurring operating losses and negative cash flows, and expects to continue to generate operating losses and consume significant cash resources for the foreseeable future. At December 31, 2015, the Company had net working capital of \$12,917,000 compared to \$30,715,000 at December 31, 2014. For the year ended December 31, 2015, the Company reported a loss of \$18,607,000 (2014 - \$19,421,000) and a cash outflow from operating activities of \$17,766,000 (2014 - \$16,908,000). As at December 31, 2015 the Company had an accumulated deficit of \$257,753,000 (2014 - \$239,146,000)

Management believes that the Company has sufficient working capital to reach the 24 week primary endpoint for its AURA clinical trial which completed enrollment on January 18, 2016. The Company expects to release the 24 week primary endpoint data in the third quarter of 2016. However, in order to complete the remainder of the 48 week AURA clinical trial and be able to undertake further development and commercialization of voclosporin, the Company will need to raise additional funds within the next 12 months.

These conditions raise substantial doubt about its ability to continue as a going concern without raising these additional funds.

As a result, the Company's consolidated financial statements for the year ended December 31, 2015 contain a going concern note (note 2) with respect to this uncertainty. Substantial doubt about the Company's ability to continue as a going concern may materially and adversely affect the price the Company's common shares, and it may be more difficult for the Company to obtain financing. The going concern note in the Company's consolidated financial statements may also adversely affect its relationships with current and future collaborators, contract manufacturers and investors, who may grow concerned about its ability to meet our ongoing financial obligations. If potential collaborators decline to do business with the Company or potential investors decline to participate in any future financings due to such concerns, the Company's ability to increase its financial resources may be limited. The Company has prepared its financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company's consolidated financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

#### Clinical Trial Progress and Results – Heavy Dependence on Voclosporin

The Company has invested a significant portion of its time and financial resources in the development of voclosporin. Voclosporin is currently the Company's only product. The Company anticipates that its ability to generate revenues and meet expectations will depend on the successful development and commercialization of voclosporin. The successful development and commercialization of voclosporin will depend on several factors, including the following:

- successful completion of clinical programs, and in particular, the Phase 2b LN clinical trial currently in progress;
- receipt of marketing approvals from the FDA and other regulatory authorities with a commercially viable label;
- securing and maintaining partners with sufficient expertise and resources to help in the continuing development and eventual commercialization of voclosporin for autoimmune indications and/or transplant;
- maintaining suitable manufacturing and supply agreements to ensure commercial quantities of the product through validated processes; and
- acceptance and adoption of the product by the medical community and third-party payors.

It is possible that the Company may decide to discontinue the development of voclosporin at any time for commercial, scientific, or regulatory reasons. If voclosporin is developed, but not marketed, the Company will have invested significant resources and its future operating results and financial conditions would be significantly adversely affected. If the Company is not successful in commercializing voclosporin, or significantly delayed in doing so, its business will be materially harmed and the Company may need to curtail or cease operations.

#### **Product Development Goals and Time Frames**

The Company sets goals for, and makes public statements regarding, timing of the accomplishment of objectives material to its success, such as the commencement and completion of clinical trials, anticipated regulatory approval dates, and time of product launch. The actual timing of these events can vary dramatically due to factors such as delays or failures in clinical trials, the uncertainties inherent in the regulatory approval process, and delays in achieving product development, manufacturing, or marketing milestones necessary to commercialize its product. There can be no assurance that the Company's clinical trials will be completed, that regulatory submissions will be made or receive regulatory approvals as planned, or that the Company will be able to adhere to the current schedule for the validation of manufacturing and launch of its product. If the Company fails to achieve one or more of these milestones as planned, the price of the Company's common shares could decline.

#### No Assurance of Successful Development

The Company has not completed the development of any therapeutic products and in particular, voclosporin, and therefore there can be no assurance that any product will be successfully developed. The Company's therapeutic product has not received regulatory approval for commercial use and sale for any indication, in any jurisdiction. The Company cannot market a pharmaceutical product in any jurisdiction until it has completed thorough preclinical testing and clinical trials in addition to that jurisdiction's extensive regulatory approval process. In general, significant research and development and clinical studies are required to demonstrate the safety and effectiveness of its products before submission of any regulatory applications. The Company may never obtain the required regulatory approvals for its product in any indication. Product candidates require significant additional research and development efforts, including clinical trials, prior to regulatory approval and potential commercialization, however, there can be no assurance that the results of all required clinical trials will demonstrate that these product candidates are safe and effective or, even if the results of all required clinical trials do demonstrate that these product candidates are safe and effective, or even if the results of the clinical trials are considered successful by the Company, that the regulatory authorities will not require the Company to conduct additional clinical trials before they will consider approving such product candidates for commercial use. Approval or consent by regulatory authorities to commence a clinical trial does not indicate that the device, drug, or treatment being studied can or will be approved. Preparing, submitting, and advancing applications for regulatory approval is complex, expensive, time intensive and entails significant uncertainty.

The results of the Company's completed preclinical studies and clinical trials may not be indicative of future clinical trial results. A commitment of substantial resources to conduct time-consuming research, preclinical studies, and clinical trials will be required if the Company is to complete the development of its product.

There can be no assurance that unacceptable toxicities or adverse side effects will not occur at any time in the course of preclinical studies or human clinical trials or, if any products are successfully developed and approved for marketing, during commercial use of its products. The appearance of any such unacceptable toxicities or adverse side effects could interrupt, limit, delay, or abort the development of the Company's product or, if previously approved, necessitate their withdrawal from the market. Furthermore, there can be no assurance that disease resistance or other unforeseen factors will not limit the effectiveness

of the Company's product. Any products resulting from the Company's programs are not expected to be successfully developed or made commercially available in the near term and may not be successfully developed or made commercially available at all. Should the Company's product prove to have insufficient benefit and/or have an unsafe profile, its development will likely be discontinued.

The future performance of the Company will be impacted by a number of important factors, including, in the short-term, its ability to continue to generate cash flow from financings, and in the longer term, its ability to generate royalty or other revenues from licensed technology and bring new products to the market. The Company's future success will require efficacy and safety of its product and regulatory approval for the product. Future success of commercialization of any product is also dependant on the ability of the Company to obtain patents, enforce such patents, avoid patent infringement, and obtain patent extensions where applicable.

# The Company will have significant additional future capital needs and there are uncertainties as to the Company's ability to raise additional funding.

The Company will require significant additional capital resources to expand the Company's business, in particular the further development of the Company's product candidate, voclosporin. Advancing the Company's product candidate, market for the Company's product, or acquisition and development of any new products or product candidates will require considerable resources and additional access to capital markets. In addition, the Company's future cash requirements may vary materially from those now expected. For example, the Company's future capital requirements may increase if:

- the Company experiences unexpected or increased costs relating to preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, or other lawsuits, brought by either the Company or its competition;
- the Company experiences scientific progress sooner than expected in its discovery, research and development projects, if the Company expands the magnitude and scope of these activities, or if the Company modifies the Company's focus as a result of its discoveries;
- the Company is required to perform additional pre-clinical studies and clinical trials; or
- the Company elects to develop, acquire or license new technologies, products or businesses.

The Company 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 the Company, are unfavourable, the Company's ability to obtain significant additional funding on acceptable terms, if at all, will be negatively affected. Additional financing that the Company may pursue may involve the sale of Common Shares which could result in significant dilution to the Company's shareholders. If sufficient capital is not available, the Company may be required to delay the Company's research and development projects, which could have a material adverse effect on the Company's business, financial condition, prospects or results of operations.

#### Patents and Proprietary Technology

Patents and other proprietary rights are essential to the Company's business. The Company's policy has been to file patent applications to protect technology, inventions, and improvements to its inventions that are considered important to the development of its business.

The Company's success will depend in part on its 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 biopharmaceutical 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 by third parties;
- the patents issued do not infringe the patents or intellectual property of others; or
- that the Company will be able to obtain any extensions of the patent term.

A number of pharmaceutical, biotechnology, 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 the business of the Company. Some of these technologies, applications or patents may conflict with or adversely affect the technologies or

intellectual property rights of the Company. Any conflicts with the intellectual property of others could limit the scope of the patents, if any, that the Company may be able to obtain or result in the denial of patent applications altogether.

Further, there may be uncertainty as to whether the Company may be able to successfully defend any challenge to its patent portfolio. Moreover, the Company may have to participate in interference proceedings in the various jurisdictions around the world. An unfavorable outcome in an interference or opposition proceeding could preclude the Company or its collaborators or licensees from making, using or selling products using the technology, or require the Company 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 the business of the Company. If such licenses are not available, the Company could encounter delays or prohibition of the development or introduction of the product of the Company.

## Clinical trials for the Company's product candidates are expensive and time-consuming, and their outcome is uncertain.

Before the Company can obtain regulatory approval for the commercial sale of any product candidate currently under development, the Company is required to complete extensive clinical trials to demonstrate its safety and efficacy. Clinical trials are very expensive and difficult to design and implement. The clinical trial process is also time-consuming. If the Company finds a collaboration partner for the development of voclosporin, the clinical trials are expected to continue for several years, although costs associated with voclosporin may well be shared with the Company's collaboration partner. The timing of the commencement, continuation and completion of clinical trials may be subject to significant delays relating to various causes, including:

- the Company's inability to find collaboration partners;
- the Company's inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- delays in obtaining regulatory approvals to commence a study, or government intervention to suspend or terminate a study;
- delays, suspension, or termination of the clinical trials imposed by the IRB/IEC responsible for overseeing the study to protect research subjects at a particular study site;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- slower than expected rates of patient recruitment and enrollment;
- uncertain dosing issues;
- inability or unwillingness of medical investigators to follow the Company's clinical protocols;
- variability in the number and types of subjects available for each study and resulting difficulties in identifying and enrolling subjects who meet trial eligibility criteria;
- scheduling conflicts with participating clinicians and clinical institutions;
- difficulty in maintaining contact with subjects after treatment, which results in incomplete data;
- unforeseen safety issues or side effects;
- lack of efficacy during the clinical trials;
- the Company's reliance on clinical research organizations to conduct clinical trials, which may not conduct those trials with good clinical or laboratory practices; or
- other regulatory delays.

# The results of pre-clinical studies and initial clinical trials are not necessarily predictive of future results, and the Company's current product candidate may not have favourable results in later trials or in the commercial setting.

Pre-clinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in pre-clinical or animal studies and early clinical trials does not ensure that later large scale efficacy trials will be successful nor does it predict final results. Favourable results in early trials may not be repeated in later trials.

A number of companies in the life sciences industry have suffered significant setbacks in advanced clinical trials, even after positive results in earlier trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be repeated or terminated. Pre-clinical data and the clinical results the Company has obtained for voclosporin may not predict results from studies in larger numbers of subjects drawn from more diverse populations or in a commercial setting, and also may not predict the ability of the Company's product to achieve its intended goals, or to do so safely.

The Company will be required to demonstrate in Phase 3 clinical trials that voclosporin is safe and effective for use in a diverse population before the Company can seek regulatory approvals for its commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical and post-approval trials. If voclosporin fails to demonstrate sufficient safety and efficacy in ongoing or future clinical trials, the Company could experience potentially significant delays in, or be required to abandon development of, the Company's product candidate currently under development.

# The Company's industry is subject to health and safety risks.

The Company produces a product for human ingestion. While the Company takes substantial precautions such as laboratory and clinical testing, toxicology studies, quality control and assurance testing and controlled production methods, the associated health and safety risks cannot be eliminated. Products produced by the Company may be found to be, or to contain substances that are harmful to the health of the Company's patients and customers and which, in extreme cases, may cause serious health conditions or death. This sort of finding may expose the Company to substantial risk of litigation and liability.

Further, the Company would be forced to discontinue production of the Company's product, which would harm the Company's profitability. Aurinia maintains product liability insurance coverage; however, there is no guarantee that the Company's current coverage will be sufficient or that the Company can secure insurance coverage in the future at commercially viable rates or with the appropriate limits.

The Company's product may not achieve or maintain expected levels of market acceptance, which could have a material adverse effect on the Company's business, financial condition and results of operations and could cause the market value of the Company's Securities to decline.

Even if the Company is able to obtain regulatory approvals for the Company's product, the success of the product is dependent upon achieving and maintaining market acceptance. New product candidates 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 the Company's product could be impacted by several factors, many of which are not within the Company's control, including but not limited to:

- safety, efficacy, convenience and cost-effectiveness of the Company's product compared to products of the Company's competitors;
- scope of approved uses and marketing approval;
- timing of market approvals and market entry;
- difficulty in, or excessive costs to, manufacture;
- infringement or alleged infringement of the patents or intellectual property rights of others;
- availability of alternative products from the Company's competitors;
- acceptance of the price of the Company's product; and
- ability to market the Company's product effectively at the retail level.

In addition, by the time any products are ready to be commercialized, what the Company believes to be the market for these products may have changed. The Company's estimates of the number of patients who have received or might have been candidates to use a specific product may not accurately reflect the true market or market prices for such products or the extent to which such products, if successfully developed, will actually be used by patients. The Company's failure to successfully introduce and market its product that are under development would have a material adverse effect on its business, financial condition, and results of operations.

# The Company is dependent upon the Company's key personnel to achieve the Company's business objectives.

As a technology-driven company, intellectual input from key management and personnel is critical to achieve the Company's business objectives. Consequently, the Company's ability to retain these individuals and attract other qualified individuals is critical to the Company's success. The loss of the services of key individuals might significantly delay or prevent achievement of the Company's business objectives. In addition, because of a relative scarcity of individuals with the high degree of education and scientific achievement required for the Company's business, competition among life sciences companies for qualified employees is intense and, as a result, the Company may not be able to attract and retain such individuals on acceptable terms, or at all. In addition, because the Company does not maintain "key person" life insurance on any of the Company's officers, employees, or consultants, any delay in replacing such persons, or an inability to replace them with persons of similar expertise, would have a material adverse effect on the Company's business, financial condition, and results of operations.

The Company also has relationships with scientific collaborators at academic and other institutions, some of whom conduct research at the Company's request or assist the Company in formulating its research and development strategies. These scientific collaborators are not the Company's employees and may have commitments to, or consulting or advisory contracts

with, other entities that may limit their availability to the Company. In addition, even though the Company's collaborators are required to sign confidentiality agreements prior to working with the Company, they may have arrangements with other companies to assist such other companies in developing technologies that may prove competitive to the Company.

Incentive provisions for the Company's key executives include the granting of stock options that vest over time, designed to encourage such individuals to stay with the Company. However, a low share price, whether as a result of disappointing progress in the Company's development programs or as a result of market conditions generally, could render such agreements of little value to the Company's key executives. In such event, the Company's key executives could be susceptible to being hired away by the Company's competitors who could offer a better compensation package. If the Company is unable to attract and retain key personnel the Company's business, financial conditions and results of operations may be adversely affected.

# The Company is exposed to risks relating to the write-down of intangible assets, which comprises a significant portion of the Company's total assets.

A significant amount of the Company's total assets relate to the Company's intellectual property. As of December 31, 2015, the carrying value of the Company's intangible assets was approximately US\$17.0 million. In accordance with IFRS, the Company is required to review the carrying value of the Company's 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 have a material adverse effect on the Company's business, financial condition, and results of operations.

# If the Company were to lose the Company's foreign private issuer status under U.S. federal securities laws, the Company would likely incur additional expenses associated with compliance with the U.S. securities laws applicable to U.S. domestic issuers.

As a foreign private issuer, as defined in Rule 3b-4 under the *Exchange Act*, the Company is exempt from certain of the provisions of the U.S. federal securities laws. For example, the U.S. proxy rules and the Section 16 reporting and "short swing" profit rules do not apply to foreign private issuers. However, if the Company were to lose the Company's status as a foreign private issuer, these regulations would immediately apply and the Company would also be required to commence reporting on forms required of U.S. companies, such as Forms 10-K, 10-Q and 8-K, rather than the forms currently available to the Company, such as Forms 40-F and 6-K. Compliance with these additional disclosure and timing requirements under these securities laws would likely result in increased expenses and would require the Company's management to devote substantial time and resources to comply with new regulatory requirements. Further, to the extent that the Company was to offer or sell the Company's Securities outside of the United States, the Company would have to comply with the more restrictive Regulation S requirements that apply to U.S. companies, and the Company would no longer be able to utilize the multijurisdictional disclosure system forms for registered offerings by Canadian companies in the United States, which could limit the Company's ability to access the capital markets in the future.

# Legislative actions, potential new accounting pronouncements, and higher insurance costs are likely to impact the Company's future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect the Company's 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 of these uncertainties are leading generally toward increasing insurance costs, which may adversely affect the Company's business, results of operations and the Company's ability to purchase any such insurance, at acceptable rates or at all, in the future.

# The Company relies on third parties for the supply and manufacture of voclosporin, which can be unpredictable in terms of quality, cost, timing and availability.

The Company's drug, voclosporin, requires a specialized manufacturing process. Lonza Ltd. is currently the sole source manufacturer of voclosporin.

The Company has contracted Catalent Pharma Solutions to encapsulate and package voclosporin for its LN Phase 2b clinical trial program. It is the Company's intention that Catalent Pharma Solutions will provide services with respect to encapsulating and packaging the voclosporin required for future clinical and commercial supply needs. Catalent Pharma Solutions is currently the sole supplier for encapsulating and packaging the Company's clinical drug supply.

The FDA and other regulatory authorities require that drugs be manufactured in accordance with the current good manufacturing practices regulations, as established from time to time. Accordingly, in the event the Company receives marketing approvals for

voclosporin, it may need to rely on a limited number of third parties to manufacture and formulate voclosporin. The Company may not be able to arrange for its product to be manufactured on reasonable terms or in sufficient quantities.

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 and foreign regulations. The Company relies on a limited number of third parties to manufacture and supply raw materials for its product. The third parties the Company chooses to manufacture and supply raw materials for its product are not under its control, and may not perform as agreed or may terminate their agreements with the Company, and the Company may not be able to find other third parties to manufacture and supply raw materials on commercially reasonable terms, or at all. If either of these events were to occur, the Company's operating results and financial condition would be adversely affected.

In addition, drug and chemical manufacturers are subject to various regulatory inspections, including those conducted by the FDA, to ensure strict compliance with good manufacturing practices ("GMP") and other government regulations. While the Company is obligated to audit the performance of the Company's third-party contractors, the Company does not have complete control over their compliance. The Company could be adversely impacted if the Company's third-party manufacturers 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 drugs, or cause delays, suspension or withdrawal of approvals, product seizures or recalls, operating restrictions, facility closures and criminal prosecutions. Any of this will have a material adverse impact on the Company's business, financial condition, and results of operations.

# Anticipated Revenues may be derived from Licensing Activities

The Company anticipates that its 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 the Company's 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 the Company's control, including:

- changes in economic conditions;
- changes in the regulatory environment, including governmental pricing controls affecting health care and health care providers;
- pricing pressures; and
- other factors affecting research and development spending.

## Lack of Operating Profits

The Company has incurred losses and anticipates that its losses will increase as it continues its development and clinical trials and seeks regulatory approval for the sale of its therapeutic product. There can be no assurance that it will have earnings or positive cash flow in the future.

As at December 31, 2015, the Company had an accumulated deficit of \$257.75 million. The net operating losses over the near-term and the next several years are expected to continue as a result of initiating new clinical trials and activities necessary to support regulatory approval and commercialization of its product. There can be no assurance that the Company will be able to generate sufficient product revenue to become profitable at all or on a sustained basis. The Company expects to have quarter-to-quarter fluctuations in expenses, some of which could be significant, due to research, development, and clinical trial activities, as well as regulatory and commercialization activities.

#### Negative Cash Flow

The Company had negative operating cash flow for the financial year ended December 31, 2015. The Company anticipates that it will continue to have negative cash flow as it continues its development of voclosporin. To the extent that the Company has negative operating cash flow in future periods, it may need to allocate a portion of its cash reserves to fund such negative cash flow. The Company may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that the Company will be able to generate a positive cash flow from its operations, that additional capital or other types of financing will be available when needed or that these financings will be on terms favourable to the Company.

#### The Company's business depends heavily on the use of information technologies.

Several key areas of the Company's business depend on the use of information technologies, including production, manufacturing and logistics, as well as clinical and regulatory matters. Despite the Company's best efforts to prevent such behavior, third parties may nonetheless attempt to hack into the Company's systems and obtain data relating to the Company's pre-clinical studies, clinical trials, patients using the Company's product or the Company's proprietary information on voclosporin. If the Company fails to maintain or protect the Company's information systems and data integrity effectively, the Company could lose existing customers, have difficulty attracting new customers, have problems in determining product cost estimates and establishing appropriate pricing, have difficulty preventing, detecting, and controlling fraud, have disputes with customers, 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. While the Company has invested in the protection of data and information technology, there can be no assurance that the Company's efforts or those of the Company's 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 have a material adverse effect on the Company's business, operating results and financial condition.

## Competition and Technological Change

The industry in which the Company operates is highly competitive and the Company has numerous domestic and foreign competitors, including major pharmaceutical and chemical companies, specialized biotechnology 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 the Company's potential competitors possess substantially greater research and development skills, financial, technical and marketing expertise and human resources than the Company, 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 the Company, thus making the Company's product non-competitive or obsolete. There may also be market resistance to the acceptance of the Company's new product in any indication and a risk that the product, even though clinically effective, is not economically viable in the commercial production stage.

# Reliance on Partners

The Company's strategy and success for the research, development, and commercialization of voclosporin in China, Canada, South Africa and Israel is dependent upon the Company's partners performing their respective contractual responsibilities. The Company has partnered with 3SBio in China and Paladin in Canada, South Africa and Israel. The amount and timing of resources such partners will devote to these activities may not be within the Company's control. There can be no assurance that its partners will perform their obligations as expected.

The license, research and development agreements with the partners noted above include indemnification and obligation provisions that are customary in the industry. These guarantees generally require the Company to compensate the other party for certain damages and costs incurred as a result 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 the Company from making a reasonable estimate of the maximum potential amount it could be required to pay.

#### Reliance on Other Third Parties

The Company depends on third parties for the sourcing of components or for the product itself. Furthermore, as with other pharmaceutical companies, the Company relies on medical institutions for testing and clinically validating its prospective product. The Company does not anticipate any difficulties in obtaining required components or products or any difficulties in the validation and clinical testing of its product but there is no guarantee that they will be obtained.

The Company currently relies on contract research organizations ("CROs") for the conduct of its clinical trials. These CROs operate in accordance with good clinical management practices mandated by the regulatory authorities and are subject to regular audits by regulatory authorities and by the Company.

The Company also has arrangements for the encapsulation, packaging and labeling of voclosporin through a third party supplier. Contract manufacturers must operate in compliance with regulatory requirements. Failure to do so could result in, among other things, the disruption of product supplies.

#### Marketing and Distribution

The Company has limited experience in the sales, marketing, and distribution of pharmaceutical products. There can be no assurance that the Company will be able to establish sales, marketing, and distribution capabilities or make arrangements through collaborations, licensees, or others to perform such activities, or that such efforts would be successful. If the Company decides to market its product directly, the Company must either acquire or internally develop a marketing and sales force with technical expertise and provide supporting distribution capabilities. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of management and key personnel, and have a negative impact on product development. If the Company contracts with third parties for the sales and marketing of its product, the Company's revenue will be dependent on the efforts of these third parties, whose efforts may not be successful. If the Company fails to establish successful marketing and sales capabilities or to make arrangements with third parties, the business, financial condition and results of operations will be materially adversely affected.

#### Health Care Reimbursement

In both domestic and foreign markets, sales of the Company's product, if any, will be dependent in part on the availability of reimbursement from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. There can be no assurance that the Company's product will be considered cost effective by these third party payors, that reimbursement will be available or if available that the payor's reimbursement policies will not adversely affect the Company's ability to sell its product on a profitable basis.

## Government Regulation

The production and marketing of the Company's product and its ongoing research and development activities are subject to regulation by numerous federal, provincial, state and local governmental authorities in Canada, the United States and any other countries where the Company may test or market its product. These laws require the approval of manufacturing facilities, including adhering to "good manufacturing" and/or "good laboratory" practices during production and storage, the controlled research and testing of products, governmental review and approval of submissions requiring manufacturing, pre-clinical and clinical data to establish the safety and efficacy of the product for each use sought in order to obtain marketing approval, and the control of marketing activities, including advertising and labeling. The process of obtaining required approvals (such as, but not limited to, the approval of the FDA, the EMA, and Health Canada) can be costly and time consuming and there can be no assurance that future products will be successfully developed, proven safe and effective in clinical trials or receive applicable regulatory approvals. Potential investors should be aware of the risks, problems, delays, expenses and difficulties which may be encountered by the Company in view of the extensive regulatory environment which controls its business.

In addition, there can be no assurance that the Company will be able to achieve or maintain regulatory compliance with respect to all or any part of its current or future products or that the Company will be able to timely and profitably produce its product while complying with applicable regulatory requirements. If the Company fails to maintain compliance, regulatory authorities may not allow the continuation of the drug development programs, or require the Company to make substantial changes to the drug. Any such actions could have a material adverse effect on the business, financial condition, and results of operations.

#### Unauthorized Disclosure of Confidential Information

There may be an unauthorized disclosure of the significant amount of confidential information under the Company's control. The Company maintains and manages confidential information relating to its technology, research and development, production, marketing and business operations and those of its collaborators, in various forms. Although the Company has 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 the Company to complaints or lawsuits for damages or could otherwise have a negative impact on its business, financial condition, results of operations, reputation and credibility.

# Use of Hazardous Materials

Drug manufacturing processes involve the controlled use of hazardous materials. The Company and its third party manufacturing contractors are subject to regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although the Company believes that its 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, the Company could be held liable for any damages that result and such liability could exceed the Company's resources.

#### Liability and Insurance

The testing, marketing and sale of human pharmaceutical products involves unavoidable risks. If the Company succeeds in developing new pharmaceutical products, the sale of such products may expose the Company to potential liability resulting from the use of such products. Such liability might result from claims made directly by consumers or by regulatory agencies, pharmaceutical companies or others. The obligation to pay any product liability claim in excess of whatever insurance the Company is able to acquire, or the recall of any of its products, could have a material adverse effect on the business, financial condition and future prospects of the Company.

The Company entered into indemnification agreements with its officers and directors. The maximum potential amount of future payments required under these indemnification agreements is unlimited. However, the Company currently maintains director and officer liability insurance coverage of US\$20 million to reduce the exposure of the Company.

## RISKS RELATED TO THE COMPANY'S SECURITIES

#### The adverse capital market conditions could continue to affect the Company's liquidity.

Adverse capital market conditions could continue to affect the Company's ability to meet its liquidity needs, as well as its access to capital and cost of capital. The Company needs additional funding to continue development of its internal pipeline and collaborations. The Company's results of operations, financial condition, cash flows and capital position could be materially affected by continued disruptions in the capital markets.

Raising additional capital may cause dilution to the Company's shareholders, restrict its operations or require the Company to relinquish rights to its technologies or drug candidate.

In order to meet its financing needs, the Company may issue a significant amount of additional common shares and warrants to purchase common shares. The precise terms of any future financing will be determined by the Company and potential investors and such future financings may significantly dilute its shareholders' percentage ownership in the Company. Additionally, if the Company raises additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or drug candidate or grant licenses on terms that may not be favourable to the Company and/or that may reduce the value of its common shares.

# Volatility of Share Price

The trading price of the Company's common shares has been highly volatile and could continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond the Company's control, including:

- > actual or anticipated period-to-period fluctuations in financial results;
- Failure to achieve, or changes in, financial estimates by securities analysts;
- > announcements regarding new or existing products or services or technological innovations by competitors;
- > comments or opinions by securities analysts or major shareholders;
- conditions or trends in the pharmaceutical, biotechnology and life science industries;
- > announcements by the Company of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- > announcements by the Company of results of, and developments in, its research and development efforts, including results and adequacy of, and development in, clinical trials and applications for regulatory approval;
- additions or departures of key personnel;
- > economic and other external factors or disasters or crises;
- limited daily trading volume;
- if any of the Company's products do not become commercially viable for any reason, including the failure of preclinical studies and clinical trials, the Company may not achieve profitability and the Company's share price would likely decline; and
- > developments regarding the Company's licensed intellectual property or that of the Company's competitors.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been significant volatility in the market prices of securities of biotechnology companies. Factors such as the results and adequacy of the Company's preclinical studies and clinical trials, as well as those of its collaborators, or its competitors; other evidence of the safety or effectiveness of the Company's products or those of its competitors; announcements of technological innovations or new products by the Company or its competitors; governmental regulatory actions; developments with collaborators; developments (including litigation) concerning patent or other proprietary rights of the Company or competitors; concern as to the

safety of the Company's products; period-to-period fluctuations in operation results; changes in estimates of the Company's performance by securities analysts; market conditions for biotechnology stocks in general; and other factors not within the control of the Company could have a significant adverse impact on the market price of the Company's securities, regardless of its 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 the Company could result in substantial costs, potential liabilities and the diversion of management's attention and resources.

There is no guarantee that an active trading market for the Company's common shares will be maintained on the TSX and/or NASDAQ. Investors may not be able to sell their shares quickly or at the latest market price if the trading in the Company's common shares is not active.

The Company expects to issue common shares in the future. Holders of stock options may elect to exercise their options into common shares depending on the stock price. Future issuances of common shares, or the perception that such issuances are likely to occur, could affect the prevailing trading prices of the common shares. Future issuances of the Company's common shares could result in substantial dilution to its shareholders. In addition, the existence of Warrants may encourage short selling by market participants.

Sales of common shares could cause a decline in the market price of the Company's common shares. Two of the Company's major shareholders (venBio and ILJIN) own an aggregate of approximately 30% of the Company's outstanding common shares as at March 18, 2016. Any sales of common shares by these shareholders or other existing shareholders or holders of options may have an adverse effect on the Company's ability to raise capital and may adversely affect the market price of its common shares.

# Aurinia may be a "Passive Foreign Investment Company"

Aurinia may be a "passive foreign investment company" under the U.S. Internal Revenue Code, which may result in material adverse U.S. federal income tax consequences to investors in common shares that are U.S. taxpayers. Investors in common shares that are U.S taxpayers should be aware that Aurinia believes that it was not for the financial year ended December 31, 2015, a "passive foreign investment company" under Section 1297(a) of the U.S. Internal Revenue Code (a "PFIC"). However, there is no certainty that taxation authorities in the United States would agree with the Company's determination, and there is no certainty that the Company will not be a PFIC at some point in the future. If Aurinia is determined to be or becomes a PFIC, generally any gain recognized on the sale of the common shares and any "excess distributions" (as specially defined) paid on the common shares must be ratably allocated to each day in a U.S. taxpayer's holding period for the common shares. The amount of any such gain or excess distribution allocated to prior years of such U.S taxpayer's holding period for the common shares generally will be subject to U.S federal income tax at the highest tax applicable to ordinary income in each such prior year, and the U.S. taxpayer will be required to pay interest on the resulting tax liability for each such prior year, calculated as if such tax liability had been due in each such prior year.

Alternatively, a U.S taxpayer that makes a "qualified electing fund" (a "QEF") election with respect to Aurinia generally will be subject to U.S. federal income tax on such U.S. taxpayer's pro rata share of Aurinia's "net capital gain" and "ordinary earnings" (as specifically defined and calculated under U.S. federal income tax rules), regardless of whether such amounts are actually distributed by Aurinia. U.S. taxpayers should be aware, however, that there can be no assurance that Aurinia will satisfy record keeping requirements under the QEF rules or that Aurinia will supply U.S. taxpayers with required information under the QEF rules, in the event that Aurinia is a PFIC and a U.S. taxpayer wishes to make a QEF election. As a second alternative, a U.S. taxpayer may make a "mark-to-market election" if Aurinia is a PFIC and the common shares are "marketable stock" (as specifically defined). A U.S. taxpayer that makes a mark-to-market election generally will include in gross income, for each taxable year in which Aurinia is a PFIC, an amount equal to the excess, if any, of (a) the fair market value of the common shares as of the close of such taxable year over (b) such U.S. taxpayer's adjusted tax basis in the common shares.

The above paragraphs contain only a brief summary of certain U.S. federal income tax considerations. Investors should consult their own tax advisor regarding the PFIC rules and other U.S. federal income tax consequences of the acquisition, ownership, and disposition of common shares.

# DIVIDEND POLICY

The Company has not paid dividends on its outstanding common shares in the past and has no established dividend policy for its common shares. The Company plans to use future earnings, if any, to finance further research and development and the expansion of its business and does not anticipate paying out dividends on its common shares in the foreseeable future. The payment of dividends in the future will depend upon the earnings and financial condition of the Company and such other factors as the Board considers appropriate.

# CAPITAL STRUCTURE

The Company's authorized share capital consists of an unlimited number of common shares, all without nominal or par value.

The holders of common shares are entitled to receive notice of and attend all meetings of shareholders, with each common share held entitling the holder to vote on any resolution to be passed at such shareholder meetings. The holders of common shares are entitled to dividends if, as and when declared by the Board. The common shares are entitled upon liquidation, dissolution or winding up of Aurinia, to receive the remaining assets of Aurinia available for distribution to shareholders. There are no preemptive, redemption, purchase or conversion rights attached to the Company's common shares.

As at March 18, 2016, the Company had 32,287,419 common shares issued and outstanding.

In addition as of March 18, 2016 there were 2,713,192 common shares issuable upon the exercise of outstanding stock options and 515,550 common shares reserved for future grant or issuance under the Company's stock option plan.

The Company also has 5,916,114 Warrants outstanding as at March 18, 2016.

For additional information on stock options and warrants, please see note 13 to the Company's annual consolidated financial statements for the year ended December 31, 2015 which can be retrieved under the Company's profile on either of the SEDAR or EDGAR websites.

# TRADING PRICE AND VOLUME OF AURINIA SHARES

The Company's common shares are listed and posted for trading on the NASDAQ under the symbol "AUPH", and on the TSX under the symbol "AUP".

The following table sets forth, for the periods indicated, the reported high and low prices (in United States dollars) and the volume of shares traded for each month on NASDAQ.

#### **NASDAQ**

	Price Ran	Total Volume	
	High	Low	Total Volume
January, 2015	\$3.96	\$3.08	523,951
February, 2015	\$4.86	\$3.03	769,165
March, 2015	\$5.65	\$4.11	2,895,790
April, 2015	\$4.52	\$3.66	1,096,718
May, 2015	\$4.37	\$3.44	1,049,840
June, 2015	\$3.60	\$2.99	662,465
July, 2015	\$3.78	\$3.00	2,455,759
August, 2015	\$4.30	\$2.91	961,414
September, 2015	\$3.59	\$2.78	545,100
October, 2015	\$3.34	\$2.82	376,036
November, 2015	\$3.05	\$2.34	672,961
December, 2015	\$2.68	\$2.09	570,074

The following table sets forth, for the 12 month period ended December 31, 2015, the reported high and low prices (in Canadian dollars) and volume on shares traded for each month on the TSX.

# **TSX**

Month	Price Rang	Total Volume	
MOUTH	High	Low	1 otai voiume
January, 2015	\$4.44	\$4.00	626,833
February, 2015	\$5.90	\$3.86	557,449
March, 2015	\$7.00	\$5.11	394,125
April, 2015	\$5.60	\$4.42	194,198
May, 2015	\$5.12	\$4.18	147,577
June, 2015	\$4.50	\$3.70	107,458
July, 2015	\$4.94	\$3.80	316,426
August, 2015	\$5.34	\$3.51	148,626
September, 2015	\$4.66	\$3.75	44,178
October, 2015	\$4.29	\$3.66	164,049
November, 2015	\$3.94	\$3.13	98,699
December, 2015	\$3.79	\$2.85	84,729

# **ESCROWED SECURITIES**

There are no securities of the Company subject to escrow.

# **PRIOR SALES**

The following table summarizes the distribution of securities other than common shares that were issued during the most recently completed financial year, identifying the type of security, the price per security, the number of securities issued, expiry date and the date on which the securities were issued.

Date	Type of Security	Price per Security	Number of Securities	Expiry Date
January 6, 2015	Options	CDN\$4.25	959,943	January 6, 2020
April 7, 2015	Options	CDN\$5.19	48,000	April 7, 2020
June 2, 2015	Options	CDN\$4.31	60,000	June 2, 2020
August 17, 2015	Options	CDN\$4.45	323,149	August 17, 2020
December 18, 2015	Options	CDN\$3.39	65,000	December 18, 2020

# **DIRECTORS AND OFFICERS**

The directors of the Company are elected by the shareholders at each annual meeting and typically hold office until the next annual meeting, at which time they may be re-elected or replaced. The officers are appointed by the Board and hold office pursuant to individual contractual obligations.

As at March 18, 2016, the names and municipalities of residence of the directors and officers of the Company and their principal occupations within the five preceding years are set forth below:

Name, province or state, and country of residence	Position with the Company	Director/Officer since	Principal Occupation for Five Preceding Years
Stephen W. Zaruby Woodinville, Washington, US	President and CEO	November 2013	President and CEO of the Company since November 6, 2013; prior thereto was President of ZymoGenetics Inc.; Vice President, Global Head, Hospital Surgical Business Unit at Bayer Schering Pharma.
Dennis Bourgeault Edmonton, Alberta, Canada	CFO	May 1998	CFO of the Company since May, 1998.

Name, province or state, and country of residence	Position with the Company	Director/Officer since	Principal Occupation for Five Preceding Years
Michael R. Martin Victoria, British Columbia Canada	COO	September, 2013	COO of the Company since September 2013; prior thereto was CEO of privately-held Aurinia Pharmaceuticals Inc.; Director, Global Business Development & Licensing at Vifor Pharma, formerly Aspreva.
Neil Solomons Victoria, British Columbia Canada	СМО	September 2013	CMO of the Company since September 2013; prior thereto was Vice President, Research and Development at Vifor Pharma, formerly Aspreva.
Robert Huizinga North Saanich, British Columbia, Canada	Vice President, Clinical Affairs	August 2011	Vice President, Clinical Affairs of the Company since August 2011, prior thereto was Senior Director of Clinical Affairs of the Company.
Lawrence D. Mandt Qualicum Beach, British Columbia Canada	Vice President, Regulatory and Quality	September 2013	Vice President Regulatory and Quality of the Company since September 2013; independent regulatory consultant from 2010-2013; Senior Vice President, Global Regulatory Affairs at Vifor Pharma; Vice President Regulatory Affairs at Aspreva.
Rashieda Gluck Bellevue, Washington US	Vice President, Clinical Operations	January 2016	Vice President, Clinical Operations of the Company since January 1, 2016; Lead of Clinical Operations for the Company from April 2015 to December 2015; prior thereto was an independent clinical trial consultant for the Company from May 2014 to March 2015; prior thereto was Vice President Clinical Operations at Qu Biologics; Vice President and Head of Global Clinical Operations at Vifor Pharmaceuticals, Zurich; Vice President Clinical Operations at Aspreva.
Richard Glickman Victoria, British Columbia Canada	Director; Chair of the Board	August 2013	Chair of the Board at the Company; Corporate Director.
Benjamin Rovinski Toronto, Ontario Canada	Director	September 2013	Managing Director at Lumira Capital, a North American health care and life science venture capital firm.
Charles A. Rowland, Jr. Furlong, Pennsylvania US	Director	July 2014	Corporate Director; Vice President and CFO of Viro-Pharma Incorporated, an international biopharmaceutical company, from 2008 to 2014.
David R.W. Jayne Cambridge, UK	Director	May 2015	Certified nephrologist, Director of the Vasculitis and Lupus Clinic and Reader at The University of Cambridge, UK.

Name, province or state, and country of residence	Position with the Company	Director/Officer since	Principal Occupation for Five Preceding Years
Gregory M. Ayers Eastsound, WA US	Director	May 2015	Consultant to device and biopharmaceutical industry providing clinical and regulatory advice to various companies; prior thereto was CMO of Heart Metabolics, Ltd., a clinical stage pharmaceutical company.
Hyuek Joon Lee Seoul, South Korea	Director	May 2015	Director of New Business Development for ILJIN Group, a Korean industrial conglomerate.

Directors and officers of the Company, as of March 18, 2016, beneficially own, directly or indirectly, 2,347,006 common shares representing 7.27% of the outstanding common shares of the Company.

# **EXECUTIVE OFFICERS AND DIRECTORS**

The following are brief biographies of the Company's executive officers and directors.

## Stephen W. Zaruby, President and CEO

Stephen Zaruby has over 20 years' experience in the highly complex biopharmaceutical industry. Expertise has been demonstrated in the executive general management of fully-integrated biotechnology and pharmaceutical corporations in both the U.S. and Europe, with over-sight including business development, finance, product development, regulatory affairs, manufacturing, various general and administrative functions, and global commercial operations incorporating sales, marketing, and product distribution. Mr. Zaruby was president of ZymoGenetics Inc., a publically-traded, Seattle-based biotechnology company, until the time of its acquisition by Bristol-Myers Squibb. Prior to this he worked within the pharmaceutical division of Bayer Healthcare for many years, holding several different positions with leadership of one of their global strategic business units as his last operational posting.

# Dennis Bourgeault, CPA-CA, CFO

Dennis Bourgeault has been the CFO of the Company since 1998 and is responsible for the financial operations of the Company. He was the controller for a private industrial distribution company for six years from 1992 to 1998 and prior to this time he was a senior manager in public accounting at KPMG. Mr. Bourgeault obtained his Chartered Accountant designation in 1984 and earned a Bachelor of Commence Degree from the University of Alberta.

#### Michael R. Martin, COO

Michael Martin was formerly CEO, director and co-founder of the privately held Aurinia Pharma Corp. which was acquired in 2013 by the Company. In his current role with Aurinia, Mr. Martin is responsible for managing company functions such as corporate and business development, alliance management, investor relations, intellectual property and pre-commercial market planning. Mr. Martin is a biotech/pharmaceutical executive with over 19 years industry experience. Mr. Martin joined Aurinia from Vifor Pharma where he held the position of Director, Global Business Development & Licensing. Prior to Vifor, Mr. Martin was a key member of the business development team that saw Aspreva sold to Galenica for \$915M. Upon joining Aspreva in 2004, Mr. Martin initiated the strategic launch planning process for CellCept® in "less-common" autoimmune diseases. These included such indications as pemphigus vulgaris, myasthenia gravis, and LN. Prior thereto, Mr. Martin held a variety of progressively senior commercial positions at Schering-Plough. Mr. Martin spent time in Europe where he was responsible for the rheumatology business unit for Remicade® in France. In addition while at Schering-Plough, Mr. Martin was the brand manager responsible for the Canadian launch of Remicade (infliximab).

#### Neil Solomons, MD, CMO

Dr. Neil Solomons is responsible for managing, developing, guiding and coordinating Aurinia's clinical development group and its activities. He is also Aurinia's senior medical spokesperson to investigators, scientific advisors and investors. Dr. Solomons is an experienced pharmaceutical physician with more than 15 years of clinical development and medical affairs experience in both big pharma and biotech. He is a recognized expert in rare-disease drug development and is widely published in this field. Prior to Aurinia Dr. Solomons worked at Vifor Pharma, formerly Aspreva, where he held the position of Vice President, Research and Development being the lead clinician in the development of CellCept® in rare diseases. Dr. Solomons led CellCept Clinical Development teams of over 50 people that saw the completion, reporting and publication of studies in pemphigus vulgaris,

myasthenia gravis, both industry firsts, and the successful landmark LN study called the ALMS. He was responsible for all clinical development activities from Phases 1 to 3, as well as participating in the formulation of R&D strategy, portfolio management, and due diligence efforts. Prior to Vifor & Aspreva, Dr. Solomons held a variety of positions at Roche in both Global Clinical Development and Medical Affairs in transplantation, virology and auto-immune diseases. While at Roche, Dr. Solomons led a diverse team in the development and implementation of post-marketing studies with a budget exceeding \$15 million for its transplantation (CellCept® and Zenapax®) and virology (Cytovene®) franchises. Dr. Solomons qualified in medicine in 1991 receiving his MB BS (MD) at Guys Hospital Medical School, London. He subsequently worked as a physician in London UK, completing specialist training in anesthesia and intensive care.

# Robert B. Huizinga, RN NNC, MSc(Epi), CNeph(C), Vice President, Clinical Affairs

Mr. Huizinga has been with the Company since 2002, focused on managing the global clinical development of voclosporin. Before joining the Company, Mr. Huizinga was a Nephrology and Transplantation nursing specialist with 14 years of clinical and research experience where he was involved in more than 60 clinical trials from Phase I through Phase IV. He has acted as a consultant to nephrology and transplantation pharmaceutical companies, and has lectured extensively. Mr. Huizinga holds a M.Sc. in medicine (epidemiology) from the University of Alberta, is a registered nurse, certified in nephrology, and a member of Sigma Theta Tau (Honor Society of Nursing).

# Lawrence D. Mandt, Vice President Regulatory and Quality

As Vice President Quality & Regulatory Affairs, Mr. Mandt is responsible for regulatory strategy, as well as implementation of the Company's regulatory projects. Mr. Mandt brings over 30 years' experience in global regulatory affairs, in large and small companies, across a variety of therapeutic areas. Prior to Aurinia, Mr. Mandt worked as an independent regulatory consultant after leaving Vifor Pharma as Senior Vice President, Global Regulatory Affairs in 2010. During his time with Vifor Pharma, he served as a member of the Leadership Team (LST) and successfully led the consolidation of the regulatory affairs function after the acquisition of Aspreva where he was Vice President, Regulatory Affairs. While with Aspreva, Mr. Mandt was a key contributor to the regulatory strategies, tactics and operational activities associated with the CellCept® autoimmune programs, conducted in collaboration with Roche. Before joining Aspreva in 2004, Mr. Mandt was Senior Vice President, Regulatory and Quality Affairs at QLT, Inc. During his time with QLT, QLT gained approval of Visudyne, the first drug ever approved for the treatment of age related macular degeneration. Approvals were obtained in the USA, the EU and 70+ other countries. Prior to OLT, Mr. Mandt led the regulatory and medical affairs function for CIBA Vision Opthalmics (ultimately became Novartis Ophthalmics) for eight years, gaining approval of that company's first entirely internally developed new drug, Zaditor, for the treatment of ocular allergies. In addition to the development activities underway, applications for 25 ANDA/NDA products were effectively managed to extend life cycle and meet the needs of the business. Previous to his time at CIBA/Novartis, Mr. Mandt worked in research and development and regulatory positions of increasing responsibilities at Bausch & Lomb Inc, first in the SOFLENS division and then in the pharmaceuticals division of the company, eventually becoming Director, Regulatory Affairs. Highlights during his career at Bausch include launching major new OTC and Rx products and gaining approval for a new state of the art manufacturing facility. Mr. Mandt began his career as a microbiologist at Merck, Sharp and Dohme, at their vaccine facility in West Point, PA, USA.

# Rashieda Gluck, Vice President Clinical Operations

Ms. Gluck has over 20 years of industry experience with proven success in the strategic planning and delivery of high quality clinical programs and extensive experience in building and leading high performing, cross functional global teams. Most recently, Ms. Gluck served as Vice President Clinical Operations for Qu Biologics, a clinical stage biopharmaceutical company developing a novel class of immunotherapies for the treatment of autoimmune disease and advanced cancer. In her role Ms. Gluck was responsible for leading their clinical programs and providing strategic direction for the clinical development of their platform immunotherapeutic treatments in multiple disease indications. Previously, Ms. Gluck held the position of Vice President of Clinical Operations at Aspreva in New Jersey and was responsible for the successful integration of the global clinical operations department post acquisition by Zurich-based Vifor Pharmaceuticals. At Vifor, as Vice President and Head of Global Clinical Operations, she was a member of the Research, Development and Leadership team and continued to build and lead the clinical research department in Zurich and hold overall accountability for the execution and delivery of all global clinical programs. Earlier in her career, Ms. Gluck served in increasingly senior positions at major pharmaceutical companies including Novartis, Organon, and GSK. Ms. Gluck holds a B.Sc. in Nursing from the University of British Columbia and is a Registered Nurse.

#### Richard M. Glickman, LLD (Hon), Director, Chairman of the Board

Dr. Glickman presently serves as the Company's Chairman of the Board. He previously served as the Interim Executive Chairman of the Company for the period September 20, 2013 to February 28, 2014 and as Acting Interim CEO for the period October 22, 2013 to November 5, 2013. He was a co-founder of the privately held Aurinia Pharma Corp. which was acquired by the Company. He was a co-founder, Chairman and CEO of Aspreva. Prior to establishing Aspreva, Dr. Glickman was the co-founder

and CEO of StressGen Biotechnologies Corporation. Since 2000, Dr. Glickman has served as the Chairman of the Board of Vigil Health Solutions Inc., a healthcare services company, as Lead Director for Cardiome Pharma Corp., as founding Chairman of the Board of Essa Pharmaceuticals Inc., and as Chairman of the Board of Engene Inc. He has served on numerous biotechnology and community boards including roles as Chairman of B.C Biotech., Director of the Canadian Genetic Disease Network, a member of the federal government's National Biotechnology Advisory Committee, a member of the British Columbia Innovation Council and as a Director for the Vancouver Aquarium.

# Benjamin Rovinski, Ph.D., Director

Dr. Benjamin Rovinski has 27 years of investment, operational, managerial and research experience in the healthcare sector. He joined Lumira Capital in 2001, where he is a Managing Director, with an investment focus on mid-to late-stage private and public life sciences companies. Prior to joining Lumira Capital, Dr. Rovinski held several senior management positions in the biotechnology sector, including 13 years at Sanofi Pasteur where he was a senior scientist and director of molecular virology. He led global R&D programs in the areas of HIV/AIDS and therapeutic cancer vaccines, bringing several of them through to clinical-stage. Dr. Rovinski received a PhD in biochemistry from McGill University in Montréal and did post-doctoral studies in molecular oncology and retrovirology at the Ontario Cancer Institute in Toronto. He obtained his undergraduate degree from Rice University in Houston. Dr. Rovinski's current and past board roles and investment responsibilities include several private and public companies, including KAI Pharmaceuticals (acquired by Amgen); Morphotek (acquired by Eisai); Cervelo Pharmaceuticals; Health Hero Network (acquired by Bosch); Avalon Pharmaceuticals (NASDAQ: AVRX; acquired by Clinical Data, Inc.); Inovise Medical, Inc.; Protana; Signature Biosciences; and SGX Pharmaceuticals (NASDAQ: SGXP; acquired by Eli Lilly). He also serves on the board of directors of Life Sciences Ontario. Dr. Rovinski is fluent in English, French and Spanish. He has published over 25 scientific articles and reviews and is the recipient of 29 issued patents.

#### Charles A. Rowland, Jr., Director, Chair of the Audit Committee

Charles A. Rowland, Jr., CPA, MBA, was most recently the Vice President and Chief Financial Officer of ViroPharma Incorporated, an international biopharmaceutical company, until it was acquired by Shire plc in January 2014. He has 35 years of diversified experience across a broad field of financial areas. Prior to joining ViroPharma in 2008, Mr. Rowland was the Executive Vice President and Chief Financial Officer, as well as the interim Co-Chief Executive Officer, for Endo Pharmaceuticals Inc., a specialty pharmaceutical company with a primary focus in pain management, where he served from 2006 to 2008. Mr. Rowland previously held positions of increasing responsibility at Biovail Corporation, Breakaway Technologies, Inc., Pharmacia Corporation, Novartis AG and Bristol-Myers Squibb Co. He is a member of the board of directors and chairs the audit committee of Bind Therapeutics, Inc., as of May 2014, Aurinia Pharmaceuticals Inc., as of July 2014, Vitae Pharmaceuticals, Inc., as of September 2014, and Blueprint Medicines Corporation, as of March 2015. He is also a member of the supervisory board and chairs the audit committee of Nabriva Therapeutics, AG as of January 2015. He is the chair and member of the compensation committee at Blueprint Medicines and Nabriva Therapeutics, respectively. Previously, he served on the board of Idenix Pharmaceuticals until its acquisition by Merck. Mr. Rowland holds an M.B.A. with a finance concentration from Rutgers University and a B.S. in Accounting from Saint Joseph's University.

## David R.W. Jayne, MD FRCP FRCPE FMedSci, Director

Dr. David R.W. Jayne is Director of the Vasculitis and Lupus Clinic and Reader in Vasculitis at The University of Cambridge, UK. Dr. Jayne received his bachelor of surgery degree and medical degree from Cambridge University, Cambridge, England. He received postgraduate training at several London hospitals and Harvard University. He is a fellow of the Royal Colleges of Physicians of London and Edinburgh, and the Academy of Medical Science. He is a certified nephrologist and an Honorary Consultant Physician at Addenbrooke's Hospital, Cambridge UK. Dr. Jayne is a medical advisor to UK, US, and EU regulatory bodies, patient groups, and professional organizations. He has published more than 250 peer-reviewed journal articles, book chapters, and reviews. He was elected the first President of the European Vasculitis Society in 2011 and is a member of the ERA-EDTA immunopathology working group. Dr. Jayne's research includes investigator-initiated international trials and the introduction of newer therapies in vasculitis and SLE with collaborators in five continents.

## Gregory M. Ayers, MD, Ph.D., Director

Currently, Dr. Ayers is a consultant to the medical device and biopharmaceutical industry providing clinical and regulatory advice to various companies. He has over 25 years of experience working with medical device start-up companies. He began his career in industry at InControl, Inc., the developer of the first implantable atrial defibrillator, where he served as Vice President of Clinical Affairs. InControl was acquired by Guidant in 1999. He was a Venture Partner at MPM Capital when he founded CryoCor, Inc. (NasdaqNM: CRYO), a medical technology company headquartered in San Diego, CA that developed products using cryogenic technology to treat arrhythmias, where he also served as President & CEO until March 2006. CryoCor was sold to Boston Scientific in 2007. He served on the board of directors of Hemosense, Inc. (AMEX: HEM), where he also served as interim CEO

until April 2002. Hemosense was sold to Inverness Medical in 2008. While at MPM he served as medical director, interim CEO or member of the board of directors for 8 other portfolio companies including Alsius and ARYX pharmaceuticals (NASDAQ: ARYX). Dr. Ayers is also co-founder of IMedPro, a German based consulting company for small US companies seeking European approval or early marketing of their medical products, where he has worked with 7 additional start-up medical device companies. He has served as a medical consultant for Heartstream, a company that pioneered the use of AEDs (automatic external defibrillator). He is a founder of SonarMed, Inc. an Indianapolis based medical device company developing products for critical care medicine, where he served as Executive and Chairman of the Board until April 2008. He served as acting Medical Director of Catheter Robotics, Inc., a New Jersey based company. He was President and CEO of ViewRay, a Cleveland based oncology company. Dr. Ayers served as CMO of Heart Metabolics, Ltd., an Irish company focused on securing registration for perhexiline in the treatment of hypertropic cardiomyopathy. Dr. Ayers is a fellow of the American College of Cardiology, the American Institute of Medical and Biological Engineering and the Heart Rhythm Society. He holds 21 U.S. patents, and has published over 200 book chapters, scientific abstracts and manuscripts. Dr. Ayers received his B.S. and Ph.D. in Biomedical Engineering from Purdue University, and his M.D. from Indiana University.

#### Hyuek Joon Lee, Ph.D., Director

Dr. Hyuek Joon Lee is the Director of New Business Development for ILJIN Group and is responsible for mergers and acquisitions, and managing overseas investments, joint ventures and subsidiaries. As of October 2014 he joined the board of directors of Life Science Enterprises in Massachusetts, a privately held company focusing on advanced biomaterials that promote bone repair. Dr. Lee has over 18 years of experience in consulting, management, business development and strategic planning in a number of industries including information technology, chemical and media. Dr. Lee obtained his B.S. in Chemistry from Seoul National University, and his M.S.E. and Ph.D. in Chemical Engineering from the University of Michigan, Ann Arbor.

#### **COMMITTEES OF THE BOARD**

The Company has three standing committees: the Audit Committee, the Governance and Nomination Committee and the Compensation Committee. Current members of these committees are identified in the following table:

Committee	Members
	Charles A. Rowland, Jr. (Chair)
Audit Committee (1)	Benjamin Rovinski
	Richard Glickman
	Richard Glickman (Chair)
Governance and Nomination Committee	Gregory M. Ayers
	Hyuek Joon Lee
	Benjamin Rovinski (Chair)
Compensation Committee	Gregory M. Ayers
	Hyuek Joon Lee

<sup>(1)</sup> Detailed information on the Audit Committee is attached as Schedule 1.

# CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

To the knowledge of the directors and officers of the Company, no director or executive officer of the Company:

- is, or has been within 10 years before the date of this AIF, a director, CEO or CFO of any company that, while that person was acting in that capacity
  - (i) was subject to a cease trade order, an order similar to a cease trade order or an order that denied the relevant company access to any exemption under securities legislation, that was issued while the proposed director was acting in the capacity as a director, CEO or CFO; or
  - (ii) was subject to a cease trade order, an order similar to a cease trade order or an order that denied the relevant company access to any exemption under securities legislation, that was issued after the proposed director ceased to be a director, CEO or CFO and which resulted from an event that occurred while he was acting in the capacity of a director, CEO or CFO; or
- (b) is, or has been within 10 years before the date of this AIF, a director, CEO or CFO of any company that while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became

- bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or was subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold its assets; or
- (c) has, within 10 years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the proposed director.

No director has been subject to:

- (d) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
- (e) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable security holder in deciding whether to vote for a proposed director.

# LEGAL PROCEEDINGS AND REGULATORY ACTIONS

As of March 18, 2016, the Company is not aware of any legal proceedings against the Company that would involve a claim for damages that exceed ten per cent of the current assets of the Company.

No penalties or sanctions have been imposed against the Company by a court relating to securities legislation or any securities regulatory authority during the financial year ended December 31, 2015, nor has the Company entered into any settlement agreements with a court relating to securities legislation or with a securities regulatory authority during such financial year. No other penalties or sanctions have been imposed by a court or regulatory body against the Company which would likely be considered important to a reasonable investor in making an investment decision respecting the Company.

# INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

This section includes a description of the material interest, direct or indirect, of directors or executive officers of the Company, persons or companies that beneficially own, control, or direct more than 10% of the voting securities of the Company, or an associate or affiliate of any of such directors, executive officers, persons or companies, in the transactions conducted by the Company within the three most recently completed financial years or during the current financial year that has materially affected or is reasonably expected to materially affect the Company.

(A) The Company and ILJIN entered into the DDLA, effective January 28, 2011, for the further clinical and commercial development of voclosporin for use in transplant indications applicable to voclosporin. Mr. Chin-Kyu Huh, a representative of ILJIN, was elected a director of Pharma on December 15, 2010 at a special meeting of the shareholders. Mr. Huh was appointed Chairman of the Board on March 18, 2011 and resigned from the Board on July 28, 2011. The DDLA was terminated in connection with the Plan of Arrangement transaction which closed on September 20, 2013. For additional information on the DDLA, please see section *Three Year History* earlier in this document.

# **CONFLICTS OF INTEREST**

To the knowledge of the Company, and other than as disclosed herein, there is no known existing or potential material conflicts of interest among the Company, its directors and officers, or a subsidiary of the Company or other members of management as a result of their outside business interests, except that certain of its directors may serve as directors of other companies and therefore it is possible that a conflict may arise between their duties to the Company and their duties as a director of such other companies. See "Risk Factors - The Company is dependent upon its key personnel to achieve its business objectives".

# TRANSFER AGENT AND REGISTRAR

The co- transfer agents and co-registrars of the Company are Computershare Investor Services Inc. located at its principal offices in Calgary, Alberta and Toronto, Ontario and Computershare Trust Company, N.A. located at its principal offices in Golden, Colorado.

# MATERIAL CONTRACTS

The Company currently has the following material contracts:

- 1. Pursuant to the R&D Agreement dated June 18, 2009, between Paladin and the Company, as amended by Second Amendment to R&D Agreement dated January 17, 2011, Paladin is required to make payments to the Company equal to: (i) 20% of net sales of voclosporin, in Canada, Israel and South Africa, less manufacturing costs, until June 18, 2016; and (ii) 20% of net royalties received from third party sales, in the Paladin Territories until June 18, 2016.
- 2. Pursuant to the License Agreement dated June 18, 2009, between Paladin and the Company, as amended by Second Amendment to License Agreement dated January 17, 2011, Paladin will receive 2% of any milestone payments, development payments, royalties, and net profit splits paid to the Company, related to voclosporin outside Canada, Israel and South Africa.
- 3. Under the terms of an agreement dated February 14, 2014 between the Company and Dr. Robert Foster, whereby Dr. Robert Foster's employment as CSO was terminated by the Company, it was confirmed that effective March 8, 2012 pursuant to a resolution of the Board, Dr. Foster was entitled to receive 2% of royalty licensing revenue for royalties received on the sale of voclosporin by licensees and/or 0.3% of net sales of voclosporin sold directly by the Company, to be paid quarterly as that revenue is received by the Company. Should the Company sell substantially all of the assets of voclosporin to a third party or transfer those assets to another party in a merger in a manner such that this payment obligation is no longer operative, then Dr. Foster will be entitled to receive 0.3% of the value attributable to voclosporin in the transaction. As Dr. Foster's employment was terminated without just and sufficient "cause" as set forth in his CSO employment agreement, he is entitled to receive the royalty licensing revenues he would have been entitled to receive had his employment not been terminated.

# INTERESTS OF EXPERTS

PricewaterhouseCoopers LLP, the Company's auditor, issued an auditor's report dated March 18, 2016 in respect of the Company's Consolidated Financial Statements, which comprise the Consolidated Statements of Financial Position as at December 31, 2015 and December 31, 2014, and the Consolidated Statements of Operations and Comprehensive Loss, Consolidated Statements of Changes in Shareholders' Equity (Deficit) and Cash Flows for the years ended December 31, 2015 and December 31, 2014, and the related notes. PricewaterhouseCoopers LLP has advised the Company that they are independent with respect to the Company within the meaning of the Rules of Professional Conduct of the Chartered Professional Accountants of Alberta and the rules of the U.S. Securities and Exchange Commission.

# ADDITIONAL INFORMATION

Additional information with respect to the Company, including directors' and officers' remuneration and indebtedness, principal holders of the Company's common shares and securities authorized for issuance under equity compensation plans will be contained in the management information circular that will be prepared and filed in connection with the 2016 annual general meeting. Additional financial information is also available in the Company's comparative audited consolidated financial statements, together with the auditor's report thereon, and the related Management Discussion and Analysis for its most recently completed fiscal year ended December 31, 2015.

Additional information regarding the Company is available on the SEDAR website located at www.sedar.com, on EDGAR at <a href="www.sec.gov">www.sec.gov</a>, or on the Company's corporate website located at <a href="www.auriniapharma.com">www.auriniapharma.com</a>, or upon request addressed to Michael Martin, COO, at 1203, 4464 Markham Street, Victoria, British Columbia V8Z 7X8.

# **SCHEDULE 1 - AUDIT COMMITTEE INFORMATION**

# 1. The Audit Committee's Charter

The Company's Audit Committee Charter is available in the governance section of the Company's website at <a href="https://www.auriniapharma.com">www.auriniapharma.com</a> and is attached as Schedule 2 to this AIF.

# 2. Composition and Relevant Education and Experience

The Audit Committee is comprised of three independent directors: Charles A. Rowland, Jr. (Chair), Richard M. Glickman and Benjamin Rovinski. A description of the education and experience of each Audit Committee member that is relevant to the performance of his responsibilities as an Audit Committee member may be found above under the heading "Directors and Executive Officers".

Under the SEC rules implementing the *Sarbanes-Oxley Act of 2002*, Canadian issuers filing reports in the United States must disclose whether their audit committees have at least one audit committee financial expert. The Board has determined that Charles A. Rowland, Jr. qualifies as an audit committee financial expert under such rules. In addition, all members of the Audit Committee are considered financially literate under applicable Canadian and U.S. laws.

# 3. Pre-approval Policies and Procedures

The Audit Committee is authorized by the Board to review the performance of the Company's external auditor and approve in advance the provision of services other than auditing and to consider the independence of the external auditor, including reviewing the range of services provided in the context of all consulting services bought by the Company. Such advance approval authority may be delegated by the Audit Committee to the Chair of the Audit Committee who is "independent" and "unrelated".

All fees for audit and audit related services performed by the external auditor for the year ended December 31, 2015 were pre-approved by the Audit Committee. All fees for non-audit related services performed by the external auditor for the year ended December 31, 2015 were pre-approved by the Audit Committee and/or Audit Chair as delegated by the Audit Committee.

# 4. External Auditor Service Fees (By Category)

The aggregate fees recorded for professional services rendered by the external auditor, PricewaterhouseCoopers LLP, for the Company and its subsidiaries for the years ended December 31, 2015 and 2014, respectively are as follows:

Fiscal year ended	2015	% of Total	2014	% of Total
r iscar year chaca		Fees		Fees
Audit fees (for audit of the Company's annual financial statements				
and services provided in connection with statutory and				
regulatory filings) <sup>(1)</sup>	\$84,401	50.8%	\$167,871	57.3%
Audit related fees, including review of the Company's quarterly				
financial statements <sup>(2)</sup>	\$43,489	26.1%	\$65,445	22.4%
Tax fees (tax compliance, tax advice and planning) <sup>(3)</sup>	\$21,898	13.2%	\$19,706	6.7%
All other fees <sup>(4)</sup>	\$16,468	9.9%	\$40,028	13.6%
Total fees	\$166,256	100%	\$293,050	100%

<sup>(1)</sup> These fees include professional services provided by the external auditor for the statutory audits of the annual financial statements. The total for 2015 is comprised of \$39,375 related to interim billings for the 2015 audit and \$45,026 related to fees for the 2014 audit billed in 2015. The total for 2014 (\$167,871) consisted of \$37,916 related to interim billings for the 2014 audit and \$129,955 related to fees for the 2013 audit billed in 2014.

<sup>(2)</sup> These fees relate to performing review engagement services on the Company's quarterly financial statements and other audit related services.

<sup>(3)</sup> These fees include professional services for tax compliance, tax advice, tax planning and various taxation matters.

<sup>(4)</sup> These fees for 2015 include professional services for assistance filing the Short Form Base Shelf Prospectus dated October 16, 2015. The fees for 2014 included professional services related to the filing of Form 40-F Registration Statement as required in conjunction with obtaining the NASDAQ listing.

# **SCHEDULE 2 - AUDIT COMMITTEE CHARTER**

# AURINIA PHARMACEUTICALS INC.

# **AUDIT COMMITTEE CHARTER**

# **JANUARY 1, 2016**

#### **PURPOSE**

The purpose of the Audit Committee of the Board of Directors of Aurinia Pharmaceuticals Inc. (the "Company") shall be to assist the Board of Directors of the Company (the "Board") in its oversight of (i) the quality and integrity of the financial statements of the Company, (ii) the Company's compliance with legal and regulatory requirements, (iii) the accounting and financial management processes of the Company, and the effectiveness of the Company's internal controls over financial reporting, (iv) the quality and integrity of the annual audit of the Company's financial statements, including the independence and qualifications of the Company's independent auditor.

#### **MEMBERSHIP**

# 1. Composition

The Committee shall consist of no fewer than three (3) members. None of the members of the Committee shall be an officer or employee of the Company or any of its subsidiaries, and each member of the Committee shall be an "independent director" (in accordance with the definition of "independent director" established from time to time under the requirements or guidelines for audit committee service under applicable securities laws and the rules of any stock exchange on which the Company's shares are listed for trading).

#### 2. Appointment and Replacement of Committee Members

Any member of the Committee may be removed or replaced at any time by the Board and shall automatically cease to be a member of the Committee upon ceasing to be a director. The Board may fill vacancies on the Committee by election from among its members. The Board shall fill any vacancy if the membership of the Committee is less than three directors. If and whenever a vacancy shall exist on the Committee, the remaining members may exercise all its power so long as a quorum remains in office. Subject to the foregoing, the members of the Committee shall be elected by the Board annually and each member of the Committee shall hold office as such until the next annual meeting of shareholders after his or her election or until his or her successor shall be duly elected and qualified.

#### 3. Financial literacy

All members of the Committee should be "financially literate" (as that term is interpreted by the Board in its reasonable judgment or as may be defined from time to time under the requirements or guidelines for audit committee service under securities laws and the rules of any stock exchange on which the Company's shares are listed for trading) or must become financially literate within a reasonable period of time after his or her appointment to the Committee.

In addition, at least one member must have past employment experience in finance or accounting, requisite professional certification in accounting or any other comparable experience or background which results in the individual's financial sophistication. Unless otherwise determined by the Board, at least one member of the Audit Committee shall be an "audit committee financial expert".

# RESPONSIBILITIES AND DUTIES

The principal responsibilities and duties of the Committee in serving the purposes outlined above in this charter are set forth below. These duties are set forth as a guide with the understanding that the Committee will carry them out

in a manner that is appropriate given the Company's needs and circumstances. The Committee may supplement them as appropriate and may establish policies and procedures from time to time that it deems necessary or advisable in fulfilling its responsibilities.

#### A. INDEPENDENT AUDITOR

1. Appointment and Oversight of Independent Auditor. The Committee appoints the independent auditor to examine the Company's accounts, controls and financial statements. The Committee has sole responsibility for the appointment, compensation, retention, oversight and, if necessary, termination of any registered public accounting firm engaged (including resolution of disagreements between the Company's management and the firm regarding financial reporting) for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Company, and the independent auditor and each such registered public accounting firm will report directly to the Committee.

# 2. Auditor Independence and Qualifications

- (a) The Committee is responsible for assessing the independent auditor's qualifications, performance and independence annually, and for taking, or recommending that the full board take, appropriate action to oversee the independence of the independent auditor. In connection therewith, the Committee will make sure it reviews, on an annual basis, all relationships between the independent auditor and the Company, including those described in the formal written statement that the Committee obtains annually from the independent auditor under applicable requirements of the Canadian generally accepted auditing standards (CAS) and since the Company is registered with the U.S. Securities Exchange Commission, the Public Company Accounting Oversight Board (the "PCAOB") related to the independent auditor's communications with the Committee concerning independence, and actively engaging in a dialogue with the independent auditor with respect to any disclosed relationships or services that may impact the objectivity and independence of the independent auditor.
- (b) The Committee will obtain and review, at least annually, a report from the independent auditor describing:

i.the firm's internal quality-control procedures; and

ii.any material issues raised by the most recent internal quality-control review, peer review, Canadian Public Accountability Board (CPAB) or PCAOB review of the firm, or by any governmental or professional authority in any inquiry or investigation, within the preceding five years, regarding any independent audit carried out by the independent auditor, and any steps taken to address any such issues.

- (c) The Committee is responsible for reviewing and evaluating the lead audit partner of the independent auditor and overseeing the rotation of the lead audit partner as required by applicable law and the Commission Rules. In making its evaluation, the Committee should take into account the opinions of management and the independent auditor.
- (d) The Committee will set policies for the Company's hiring of employees or former employees of the independent auditor.

#### 3. Approval of Audit and Non-Audit Services

The Committee will review the independent auditor's audit planning, scope and staffing.

The Committee must pre-approve all audit and non-audit related services provided to the Company by the independent auditor. The Committee may establish pre-approval policies and procedures, as permitted by the Exchange Rules, Commission Rules and applicable law, for the engagement of the independent auditor to render services to the Company, including without limitation policies that would allow the delegation of pre-approval authority to one or more members of the Committee, provided that any pre-approval decision is reported to the Committee at its next scheduled meeting.

# 4. Interaction with Independent Auditor

The Committee will, to the extent warranted, discuss with the independent auditor the above referenced reports and any other matters required to be reviewed under applicable legal and regulatory requirements.

The Committee will periodically consult with the independent auditor, out of the presence of the Company's management, about the Company's internal controls, the fullness and accuracy of the Company's financial statements, the responsibilities, budget and staffing of the Company's finance function, and any other matters that the Committee or independent auditor believes should be discussed privately with the Committee.

#### B. FINANCIAL STATEMENTS AND DISCLOSURES

#### 1. Annual Financial Statements and Disclosures

- (a) The Committee will meet to review and discuss with the independent auditor and the Company's management the Company's audited consolidated financial statements and the notes and Managements' Discussion and Analysis relating to such consolidated financial statements, the annual report, the annual information form, the financial information of the Company contained in any prospectus or information circular or other disclosure documents or regulatory filings of the Company, the recommendations for approval of each of the foregoing from each of the President and Chief Executive Officer, and Chief Financial Officer of the Company and based on such recommendations provide, where applicable, its own recommendations to the Board for their approval and release of each of the foregoing to the public.
- (b) The Committee will discuss with the independent auditor and the Company's management any items appropriate or required to be discussed in accordance with applicable auditing and CPAB standards in connection with the preparation of the Company's annual financial statements, including any problems or difficulties encountered during the course of the audit, including any restrictions on the scope of work or access to required information, and any significant disagreements with management and management's response to such difficulties.

# 2. Quarterly Financial Statements and Disclosures

- (a) The Committee will meet to review and discuss with the independent auditor and the Company's management the Company's interim consolidated financial statements and the notes and Managements' Discussion and Analysis relating to such consolidated financial statements, and either, in the discretion of the Audit Committee, (A) approve and release each of the foregoing to the public, or (B) provide, where applicable, its own recommendation to the Board for their approval and release of each of the foregoing to the public.
- (b) The Committee will discuss with the independent auditor and the Company's management any items appropriate or required to be discussed in accordance with applicable auditing and CPAB standards in connection with the preparation of the Company's quarterly financial statements.
- **3.** Earnings Announcements and Guidance. The Committee will discuss generally with the Company's management and the independent auditor, as appropriate, the type of information to be disclosed and type of presentation to be made regarding the Company's earnings press releases.
- 4. **Ongoing Reviews.** In connection with the foregoing, the Committee will review the Company's financial reporting and accounting standards and principles and financial statement presentations, significant changes in the selection of such standards or principles or in their application and the key accounting decisions affecting the Company's financial statements, including alternatives to, and the rationale for, the decisions made. As part of this review, the Committee will discuss with the Company's management and the independent auditor the reasonableness of judgments and estimates used in the preparation of financial statements, and alternative accounting treatments, principles or practices that were considered or may be preferred by the independent auditor, the Committee or the Company's management.

# C. CONTROLS AND PROCEDURES

1. Review of Processes, Systems, Controls and Procedures. The Committee will periodically review and meet separately with the independent auditor, or other personnel primarily responsible for the internal control, and the Company's management to discuss their periodic reviews of the integrity, adequacy and effectiveness of the Company's accounting and financial reporting processes, systems of internal control (including any significant deficiencies and material weaknesses in their design or operation), and disclosure controls and procedures (and management's reports thereon), as well as any special audit steps adopted in light of material control deficiencies. The Audit Committee shall receive and review the required applicable annual or quarterly CEO and CFO certification reports prior to these documents being filed as required by the regulators.

# 2. Legal Matters

- (a) The Committee will periodically review with the Company's management and the Company's General Counsel, the nature and status of significant legal matters.
- (b) The Committee will review and monitor any significant pending or threatened litigation that could have a material impact on the Company's financial statements.
- **3. Risk Assessment and Risk Management.** The Committee is responsible for overseeing the management of risks associated with the Company's financial reporting, accounting and auditing matters, reviewing as required the Company's processes around the management and monitoring of such risks, including but not limited to, review and assessment of the company investment policy and performance and review and assessment of the company's insurance policies. The Committee will discuss with the Company's management the Company's major financial, accounting and reporting risk exposures and the steps management has taken to monitor and control such exposures, including the Company's risk assessment and risk management policies and guidelines.
- **4.** Whistleblower Procedures. The Committee is responsible for establishing and overseeing procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, the prompt internal reporting of violations of the Code of Business Conduct and Ethics and for the confidential, anonymous submission by Company employees of concerns regarding questionable accounting or auditing matters.

## D. OTHER DUTIES AND RESPONSIBILITIES

- 1. Code of Conduct. The Committee will periodically review and recommend to the Board any changes to the Code of Conduct applicable to the Company, including all of its directors, officers and employees. The Committee will also consider waivers of the Code of Conduct requested for executive officers and directors and retain sole authority to grant any waivers for executive officers and directors (other than where the potential waiver involves a member of the Committee, in which event such waiver shall be subject to the review of the Board). The Committee will also periodically review and recommend to the Board any changes to the Company's Insider Trading Policy and Anti-Bribery Policy, which are referenced in the Company's Code of Conduct.
- **2. Related Party Transactions.** The Committee will review and, where appropriate, approve any transaction between the Company and any related party (other than transactions that are subject to review by the Board as a whole or any other committee of the Board), as defined by applicable law, the Commission Rules and the Exchange Rules, and will periodically review the business interests and activities of members of the Board and management.
- **3.** *Review of Composition and Performance.* The Committee will evaluate the Committee's composition and performance on an annual basis and submit a report to the Board.
- **4. Review of this Charter.** The Committee will review and reassess the adequacy of this charter annually and recommend to the Board any changes the Committee determines are appropriate.
- 5. Other Actions. The Committee will perform any other activities required by applicable law, rules or regulations, including the Commission Rules and the Exchange Rules, and take such other actions and perform and

carry out any other responsibilities and duties delegated to it by the Board or as the Committee deems necessary or appropriate consistent with its purpose.

#### STUDIES AND ADVISERS

In discharging its responsibilities, the Committee may conduct, direct, supervise or authorize studies of, or investigations into, any matter that the Committee deems appropriate, with full and unrestricted access to all books, records, documents, facilities and personnel of the Company. The Committee has the sole authority to retain and terminate independent legal counsel and other consultants, accountants, experts and advisers of its choice to assist the Committee in connection with its functions, including any studies or investigations. The Committee will have the sole authority to approve the fees and other retention terms of such advisers. The Company will also provide for appropriate funding, as determined by the Committee, for:

- payment of compensation to the independent auditor and any legal and other consultants, accountants, experts and advisers retained by the Committee; and
- ordinary administrative expenses of the Committee that are necessary and appropriate in carrying out its functions.

#### MEETINGS AND ACTIONS

Meetings of the Committee shall be held at least once each quarter or more frequently, as determined to be appropriate by the Committee. The Board may appoint a member of the Committee to serve as the chairperson of the Committee (the "Chair"); if the Board does not appoint a Chair, the Committee members may designate a Chair by their majority vote. The Chair, in consultation with the other members of the Committee, will set the dates, time, places and agenda for Committee meetings. The Chair or any other member of the Committee may call meetings of the Committee by notice and the Committee may act by unanimous written consent in lieu of a meeting in accordance with the Company's Bylaws. A quorum of the Committee for the transaction of business will be a majority of its members. Meetings may be held in person or via telephone or video conference. The Committee also may act by unanimous written consent in lieu of a meeting in accordance with the Company's Bylaws. Subject to the requirements of this charter, applicable law, the Exchange Rules and the Commission Rules, the Committee and the Chair may invite any director, executive or employee of the Company, or such other person, as it deems appropriate in order to carry out its responsibilities, to attend and participate (in a non-voting capacity) in all or a portion of any Committee meeting. The Committee may meet in executive session at its discretion and may exclude from all or a portion of its meetings any person it deems appropriate in order to carry out its responsibilities. The Chair will designate a secretary for each meeting, who need not be a member of the Committee. The Company shall provide the Committee such staff support as it may require.

#### MINUTES AND REPORTS

The Committee will maintain written minutes of its meetings and copies of its actions by written consent, and will cause such minutes and copies of written consents to be filed with the minutes of the meetings of the Board. The Committee will report regularly to the Board with respect to its activities, including on significant matters related to the Committee's responsibilities and the Committee's deliberations and actions. The minutes of the Committee and actions by the unanimous written consent of the Committee members will be made available to the other members of the Board.

#### **DELEGATION OF AUTHORITY**

The Committee may from time to time, as it deems appropriate and to the extent permitted under applicable law, the Exchange Rules and the Commission Rules, and the Company's Certificate of Incorporation and Bylaws, form and delegate authority to subcommittees.

#### **COMPENSATION**

Members of the Committee will receive such fees, if any, for their service as Committee members as may be determined by the Board, which may include additional compensation for the Chair. Such fees may include retainers or per meeting fees and will be paid in such form of consideration as is determined by the Board in accordance with applicable law, the Exchange Rules and the Commission Rules.

#### **PUBLICATION**

The Company shall make this charter freely available to stockholders on request and shall publish it on the Company's web site.

#### OVERSIGHT FUNCTION

This charter sets forth the authority and responsibility of the Committee in fulfilling the purposes described herein.

While the Committee has the responsibilities and powers set forth in this Charter, it is not the duty of the Committee to plan or conduct audits or to determine that the Company's consolidated financial statements are complete and accurate or are in accordance with IFRS and applicable rules and regulations. These are the responsibilities of Management and the Company's external auditors. The Committee, its Chair and any Committee members identified as having accounting or related financial expertise are members of the Board, appointed to the Committee to provide broad oversight of the financial, risk and control related activities of the Company, and are specifically not accountable or responsible for the day-to-day operation or performance of such activities. Although the designation of a Committee member as having accounting or related financial expertise for disclosure purposes or otherwise is based on that individual's education and experience which that individual will bring to bear in carrying out his or her duties on the Committee, such designation does not impose on such person any duties, obligations or liability that are greater than the duties, obligations and liability imposed on such person as a member of the Committee and Board in the absence of such designation. Rather, the role of a Committee members, is to oversee the process, not to certify or guarantee the internal or external audit of the Company's financial information or public disclosure.

In addition, the Company's management is responsible for managing its risk function and for reporting on its processes and assessments with respect to the Company's management of risk. Each member of the Committee shall be entitled to rely on (a) the integrity of those persons and organizations within and outside of the Company from which it receives information, (b) the accuracy of the financial and other information provided to the Committee by such persons or organizations absent actual knowledge to the contrary (which shall be promptly reported to the Board) and (c) representations made by management as to any audit and non-audit services provided by the independent auditor.

The Board has formed the Committee to assist the Board in directing the Company's affairs and this charter has been adopted in furtherance of this purpose. While this charter should be interpreted in the context of all applicable laws, regulations and listing requirements, as well as in the context of the Company's Certificate of Incorporation and Bylaws, it is not intended to establish by its own force any legally binding obligations.

# SCHEDULE 3 - GLOSSARY OF TERMS AND DEFINITIONS

In this annual information form, the following capitalized words and terms shall have the following meanings:

- "AIF" means the Annual Information Form of the Company dated March 18, 2016 for the fiscal year ended December 31, 2015;
- "ALMS" means the Aspreva Lupus Management Study;
- "API" means active pharmaceutical ingredient;
- "Aspreva" means Aspreva Pharmaceuticals Inc.;
- "AURA-LV (AURA)" means a Phase 2b clinical trial. The protocol is titled A Randomized, Controlled Doubleblind Study Comparing the Efficacy and Safety of Voclosporin (23.7 mg BID, or 39.5 mg BID) with Placebo in Achieving remission in Patients with Active Lupus Nephritis;
- "AURION" means an open label exploratory study. The protocol is titled **An Exploratory study assessing the Short term Predictors of Remission of Voclosporin 23.7 mg BID in combination with standard of care in Patients with Active Lupus Nephritis.**
- "Board" means the board of directors of the Company;
- "calcineurin" means a specific enzyme (phosphatase enzyme) that can have its activity inhibited by immunosuppressive (anti-organ rejection) drugs, including, for example, cyclosporine;
- "CellCept®" means the brand name of MMF;
- "CEO" means Chief Executive Officer;
- "CFO" means Chief Financial Officer;
- "CMO" means Chief Medical Officer;
- "CNI" means calcineurin inhibitors, the cornerstone of therapy for the prevention of organ transplant rejection;
- "Company" means Aurinia Pharmaceuticals Inc. and (unless the context specifies or implies otherwise) its subsidiaries;
- "COO" means Chief Operating Officer;
- "CRO" means Contract Research Organization;
- "CSO" means Chief Scientific Officer;
- "CTA" means Clinical Trial Application;
- "cyclosporine" means a drug that suppresses the immune system and is used to prevent rejection following organ transplantation;
- "**DDLA**" means the Development, Distribution and License Agreement between the Company and ILJIN effective January 28, 2011, an agreement which granted certain development and distribution rights to voclosporin from the Company to ILJIN;
- "EMA" means the European Medicines Agency;
- "EU" means European Union;

- "FDA" means the Food and Drug Administration of the United States Government;
- "IEC" means Independent Ethics Committee;
- "ILJIN" means ILJIN Life Science Co., Ltd.;
- "IND" means investigational new drug;
- "IRB" means Institutional Review Board;
- "LN" means lupus nephritis;
- "Lux" means Lux BioSciences, Inc.;
- "MMF" means mycophenolate mofetil;
- "MPA" means mycophenolic acid, the active metabolite of MMF;
- "MTT" means multi-targeted therapeutic;
- "NASDAQ" means the NASDAQ Global Market Exchange;
- "NDA" means New Drug Application made to a regulatory agency;
- "Paladin" means Paladin Labs Inc.;
- "Paladin Territories" means Canada, Israel, Central and South America, South Africa and Mexico prior to January 28, 2011; and Canada, Israel and South Africa after January 28, 2011;
- "**Pharmacokinetics**" means the processes of drug absorption, distribution, metabolism and escretion in a living system (e.g., in humans);
- "PK-PD" means pharmacokinetic and pharmacodynamics analysis;
- "REB" means Research Ethics Board;
- "SEC" means the U.S. Securities and Exchange Commission;
- "SEDAR" means the System for Electronic Document Analysis and Retrieval;
- "SLE" means systemic lupus erythematosus;
- "TSX" means the Toronto Stock Exchange;
- "TSXV" means TSX Venture Exchange;
- "Vifor" means Vifor (International) AG; and
- "Warrants" means warrants to purchase common shares in the capital of the Company, with each whole warrant being exercisable to purchase one common share.