# **Annual Information Form**

**Aurinia Pharmaceuticals Inc.** 

For the year ended December 31, 2013



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## **BASIS OF PRESENTATION**

The information in this annual information form ("AIF") is as of March 31, 2014, unless otherwise stated or where information in documents incorporated by reference has a different date.

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

On October 23, 2013, the outstanding common shares were consolidated on a 50:1 basis. Accordingly, all share and per share references in this AIF are on a post-conversion basis, unless otherwise noted.

References to the "Company" in this AIF refer to Aurinia Pharmaceuticals Inc. ("Aurinia") 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.

All dollar figures are in Canadian dollars, unless stated otherwise.

## FORWARD-LOOKING INFORMATION

A statement is forward-looking when it uses what we know and expect today to make a statement about the future. Forward-looking statements may include words such as "anticipate", "believe", "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 products 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 may include, without limitation, plans to fund the Company's operations, statements concerning strategic alternatives and include partnering activities. These statements also may include, without limitation, summary statements relating to results of the past voclosporin trials, plans to advance the development of voclosporin, statements concerning partnership activities and health regulatory discussions, strategy, future operations, future financial position, future revenues, projected costs, plans and objectives of management. This AIF contains forward-looking statements about the Company's objectives, strategies, financial condition, and results of operations, cash flows and businesses. These statements are forward-looking because they are based on our current expectations, estimates and assumptions. It is important to know that:

- Forward-looking statements in this AIF describe our expectations as of March 31, 2014;
- Actual results could be materially different from what we expect if known or unknown risks affect our business,
  or if our estimates or assumptions turn out to be inaccurate. As a result, we cannot guarantee that any
  forward-looking statement will materialize and, accordingly, you are cautioned not to place undue reliance on
  these forward-looking statements;
- Forward-looking statements do not take into account the effect that transactions or non-recurring or other special items announced or occurring after the statements are made may have on our business. For example, they do not include the effect of mergers, acquisitions, other business combinations or transactions, dispositions, sales of assets, asset write-downs or other charges announced or occurring after the forward-looking statements are made. The financial impact of such transactions and non-recurring and other special items can be complex and necessarily 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 our business;

• We disclaim any intention and assume no obligation to update any forward-looking statements even if new information becomes available, as a result of future events or for any other reason.

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.

Specifically, this AIF and the documents incorporated by reference in this AIF contain forward-looking information regarding:

- The Company's plan to continue the clinical development of voclosporin;
- The Company's intention to seek regulatory approvals in the United States and Europe for voclosporin; and
- The Company's intention to seek additional corporate alliances to support the commercialization of our products.

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 in the longer term 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;
- 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 products.

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. The forward-looking statements are made as of the date hereof and we disclaim 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**

## Name, Address and Incorporation

Aurinia Pharmaceuticals Inc. (formerly Isotechnika Pharma Inc.) or the "**Company**" is a biopharmaceutical company with its registered office located at 5120 – 75 Street, Edmonton, Alberta T6E 6W2. The Company's head office is located at #1203-4464 Markham Street, Victoria, British Columbia and incorporates the clinical, regulatory and business development functions of the Company.

Aurinia Pharmaceuticals Inc. is incorporated pursuant to the Business Corporations Act (Alberta).

The Company is a reporting issuer in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador.

The Company's common shares are currently listed and traded on the TSX Venture Exchange ("**TSXV**") under the symbol "AUP". The Company's primary business is the development of a therapeutic drug to treat autoimmune diseases, in particular lupus nephritis ("**LN**").

The Company has the following wholly owned subsidiaries: Aurinia Pharma Corp. (formerly Aurinia Pharmaceuticals Inc.), Aurinia Pharmaceuticals, Inc. (Delaware incorporated), and Aurinia Pharma Limited (UK incorporated). Aurinia Pharma Corp. has one wholly owned inactive subsidiary, Aurinia Holdings Corp. (Barbados), which in turn has one wholly owned inactive subsidiary, Aurinia Development Corp. (Barbados).

#### Summary Description of Business

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

The Company has rebranded, restructured and refocused itself over the past year and modified its strategy to focus on the development of voclosporin for the treatment of LN. The mechanism of action of voclosporin, a calcineurin inhibitor ("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, 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 status for the treatment of LN outside of Japan.

# GENERAL DEVELOPMENT OF THE BUSINESS AND RECENT DEVELOPMENTS

## **Private Placement Financing**

On February 14, 2014 the Company completed a US\$52 million private placement (the "**Offering**") The Company intends to use the net proceeds from the Offering to advance the clinical and nonclinical development of its lead drug candidate, voclosporin, as a therapy for LN and for general corporate 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 Life Science Co., Ltd. ("ILJIN") and Difference Capital.

Under the terms of the Offering, the Company issued 18.92 million units (the "Units") at a subscription price of US\$2.7485 (C\$3.038) per Unit, with each Unit consisting of one common share and one-quarter (0.25) of a common share purchase warrant (each full purchase warrant, a "Warrant"), exercisable for a period of five years from the date of issuance at an exercise price of US\$3.2204 (C\$3.56). In addition, in the event that the Company does not reduce the size of its board of directors (the "Board") to seven directors within 90 days following the closing of the Offering, an additional 0.1 Warrants will be issued for each Unit purchased by a subscriber for every additional 90-day period delay, up to a maximum of 0.35 Warrants per Unit. This represents a maximum of 6.62 million additional Warrants. If the Company does not obtain approval to list its common shares on NASDAQ within 12 months following the closing of the Offering, the Company has agreed to issue an additional 0.1 Warrants for each Unit purchased by a subscriber for every 90-day period delay, up to a maximum of 0.35 Warrants per Unit. This represents a maximum of 6.62 million additional Warrants. All securities issued in connection with the Offering will be subject to a four-month hold period from the date of issuance in accordance with applicable securities law, which expires on June 15, 2014 for the securities issued at closing.

A Canadian dollar translation of U.S. dollar amounts is provided using the Bank of Canada closing exchange rate on February 10, 2014, which, for the Offering was C\$1.00:US\$0.9046.

#### **CORPORATE DEVELOPMENTS IN 2013**

## Plan of Arrangement and Acquisition of Aurinia Pharma Corp.

On February 5, 2013 the Company 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 in the Company for securities of Aurinia Pharma Corp. resulting in an estimated 65:35 post merger ownership split, on a warrant diluted basis, between the Company 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 Life Science Co., Ltd. ("ILJIN") pursuant to which, upon the successful completion of the proposed merger, the combined company would re-acquire the 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 warrant diluted basis, which is calculated to give effect to the dilution by the exercise of warrants but excluding the exercise of stock options. On June 11, 2013, a draft arrangement agreement was prepared implementing the arrangement (the "Arrangement Agreement"), the terms of which were subsequently negotiated by the parties. The Arrangement was intended to implement the terms of the Settlement Agreement, whereby ILJIN would receive a further ownership interest in the Company 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 (International) AG ("Vifor"); and
- (ii) suspending all of its current or contemplated legal or financial claims against the Company, Aurinia Pharma Corp. or Vifor.

Upon closing of the plan of arrangement on September 20, 2013 the Company 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 US\$10.0 million, plus up to US\$1.6 million upon the merged company reaching certain financing milestones.

The Company also acquired all of the issued and outstanding common shares of Aurinia Pharma Corp. at a ratio of approximately 19.83 Common Shares for each Aurinia Pharma Corp. share held by an Aurinia Pharma Corp. shareholder.

## a) Settlement with ILJIN

The estimated fair value of the contract settlement with ILJIN at September 20, 2013 was \$8.88 million and has been determined to represent reacquired license rights in the amount of \$4.40 million and a loss on contract settlement of \$4.48 million. Consideration paid or payable to ILJIN is as follows: the Company's 10% interest in Aurinia Pharma Corp. of \$670,000, \$3.81 million in common shares (by issuance of 1.69 million common shares at a deemed price of \$2.25 per share), \$1.64 million in financial milestones payable and \$2.75 million in clinical and sales milestones payable based on the estimated fair value of the pre-defined future milestone payments.

## b) Acquisition of Aurinia Pharma Corp.

The Company determined that the transaction with Aurinia Pharma Corp. represented a business combination with the Company identified as the acquirer. The Company began consolidation of the operating results, cash flows and net assets of Aurinia Pharma Corp. on September 20, 2013. Had the Company consolidated the results of Aurinia Pharma Corp. from January 1, 2013, the revenue and net loss of the Company would have been \$1.01 million and \$2.90 million, respectively.

The table below presents the allocation of the purchase price to the assets and liabilities acquired, as well as the settlement of pre-existing balances between the parties to the Arrangement Agreement prior to acquisition.

	Carrying value \$ (in thousands)	Settle Pre- existing items \$ (in thousands)	Fair value adjustments \$ (in thousands)	Fair Value of Acquisition \$ (in thousands)
Cash Prepaid expenses and deposits Inventory	4 123 80	- - -	- - -	4 123 80
Intangibles	207 2,448	(577)	13,629	207 15,500
	2,655	(577)	13,629	15,707
Accounts payable Note payable Deferred income taxes	185 528	(49) (528)	- - 4,106	136 - 4,106
	713	( 577)	4,106	4,242
Net assets acquired	1,942	-	9,523	11,465

Consideration provided by the Company for the acquisition of Aurinia Pharma Corp. was 3.68 million common shares of the Company with a fair value of \$8.28 million, less \$495,000 of deferred revenue that was effectively settled as a result of the business combination. The fair value of the shares issued was determined by the trading price on September 20, 2013. The \$3.67 million difference between the fair value of net consideration of \$7.79 million and the fair value of net assets acquired of \$11.46 million is recorded as a gain in other income.

The fair value of the reacquired rights and intellectual know-how, including the Aspreva Lupus Management Study (ALMS) database, was determined to be \$15.5 million. The fair value was determined using a differential income

approach. Management attributes the gain recognized on the purchase to the fact that the consideration provided was determined by the trading price of the Company's shares on the measurement date, and that the share price would not have fully reflected the value of the transaction.

## **Second Unit Offering**

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

ILJIN participated in the Second Unit Offering for 667,000 Second Units.

## Listing on the TSX Venture Exchange

The arrangement transaction described above was determined by the Toronto Stock Exchange ("TSX") to constitute a "backdoor listing" under the rules of the TSX due to the significant increase in the ownership position in the Company by ILJIN. The result of that determination was that the Company was required to meet the TSX's original listing requirements following completion of the arrangement. The Company 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. The Company 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.

## Share consolidation and name change

On October 23, 2013, the Company proceeded with a consolidation of its Common Shares on a 50:1 basis. In conjunction with the share consolidation, the Company 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 the Company at its shareholder meeting held on August 15, 2013. In connection with its name change, the Company's trading symbol on the TSX Venture Exchange was changed to "AUP".

## **Management Change**

On November 6, 2013 the Company announced the appointment of Stephen W. Zaruby as the Company's President and Chief Executive Officer. 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 US\$885 million in 2010. Mr. Zaruby joined ZymoGenetics 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.

#### **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 LN care, CellCept®, which was developed by the Aurinia Pharma Corp. management team during its tenure at Aspreva Pharmaceuticals Inc. ("Aspreva").

• Focus the Company's resources on advancing voclosporin through a robust Phase 2b LN study. There is currently an open Investigational New Drug ("IND") with the United States Federal Drug Administration (the

"FDA") for the Company to begin treating patients with voclosporin for the treatment of LN. Aurinia plans to execute on this clinical plan as soon as practicably possible.

- Mitigate development risk by leveraging the ALMS database and the new management team's experience. The Company has certain rights to utilize the ALMS database including its use in planning, designing and informing the Phase 2b LN study.
- Evaluate future voclosporin indications. While the Company intends to deploy its operational and financial resources to develop voclosporin for LN, the Company believes that voclosporin has the potential to be of therapeutic value in a number of autoimmune indications and the prevention of transplant rejection.
- Further develop the Company as an attractive acquisition target. Management of the Company believes that should the planned clinical studies be successful, maintaining broad rights to the Company's technology through the completion of the clinical program will increase the Company's potential to be an attractive acquisition target.

## **About Lupus Nephritis**

The Lupus Foundation of America ("**LFA**") estimates that approximately 1.5 million people in the United States of America and up to five million people worldwide suffer from systemic lupus erythematosus ("**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 or under-treated.

Based on the work performed by the former Aspreva team, 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® (mycophenolate mofetil (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 suggest 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 In., 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 marketed CNIs available, cyclosporine and tacrolimus. Cyclosporine was introduced in the early 1980's and tacrolimus was first

marketed in the mid-1990's. Both cyclosporine and tacrolimus have lost key patent protection and have not been approved for the treatment of lupus in Europe or North America. For the past 20 years these products, in combination with CellCept® 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.

In 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 calcineurin inhibitor tacrolimus. In addition to this approval, a substantial amount of recent data has been generated, primarily from investigator initiated trials that support 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 multi-targeted therapeutic ("MTT") approach to treating LN as 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. (<i>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 its CNI, 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 mycophenolic acid ("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, pharmacokinetic and pharmacodynamics ("**PK-PD**") analysis indicate lower PK-PD variability for voclosporin versus tacrolimus or cyclosporine, to the extent that the Company believes flat-dosing 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 the fact that most LN 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.

## **Voclosporin Development History**

More than 2,600 patients have been administered voclosporin. 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 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 ("**PASI**"), 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 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 the incidence of new onset diabetes after transplantation ("NODAT"). 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 longer and 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 a 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 BioSciences, Inc. ("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.

## 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 multitargeted 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.

## Status of the Company's Development Program in LN

The Company's clinical strategy involves layering voclosporin on top of the current standard of care (CellCept®/MMF and steroids) as MTT 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 active IND and plans to initiate this international multi-center study as soon as practicably possible.

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

## **Transplant Indication**

The Company applied for, and received, positive Scientific Advice ("SA") from the European Medicines Agency ("EMA") in October 2011 for a Phase 3 renal transplant protocol. Similarly, the FDA sent a letter agreement to the Company on a Special Protocol Assessment ("SPA") in March 2012. Receipt of the SA and SPA has cleared the regulatory pathway for the Phase 3 renal transplant protocol. The Phase 3 protocol contemplated a study of 1,200 renal transplant patients, divided into two separate Phase 3 trials. Each of the two studies would be comprised of 600 patients, of which half (n=300 patients) would be randomized to voclosporin and the other half (n=300 patients) would receive the market leading drug, tacrolimus. The primary endpoint of the studies would be driven primarily by BPAR. Secondary endpoints included New Onset Diabetes ("NODAT") and other measures of safety.

For a variety of reasons the Company has decided to pursue the LN indication as the lead indication, as voclosporin would be the only commercially approved CNI for this indication, outside Japan. However, the Company is willing to exploit the transplant indication with a development and commercialization partner, should such a partner be interested in the entire nephrology franchise (i.e., both LN and renal transplantation). At this point, the Company feels that it is best not to split the drug's indications in order to offer shareholders the best value.

## Termination and Assignment Agreement with Lux Biosciences, Inc.

On May 24, 2006, the Company signed a distribution and license agreement ("**DLA**") with Lux Biosciences, Inc. ("**Lux**") granting Lux worldwide rights to develop and commercialize voclosporin for the treatment and prophylaxis of all ophthalmic diseases. Under the terms of the agreement, Lux made an upfront payment, and was to make further milestone payments, assuming development milestones were achieved. Lux was also to pay royalties based on a percentage of net sales. Lux was responsible for the clinical development, registration, and marketing of voclosporin for all ophthalmic indications.

In February 2010, Lux filed a new drug application ("NDA") with the FDA and a marketing authorization application ("MAA") with the EMA for voclosporin for the treatment of noninfectious uveitis. In August 2010, Lux received a Complete Response Letter ("CRL") from the FDA regarding their NDA for voclosporin. A CRL is issued by the FDA when the review of a file is completed and questions remain that prevents the approval of the NDA in its current form. The FDA requested additional information and recommended that an additional clinical trial be conducted in order to consider future approval of voclosporin for this indication. In February, 2011, Lux commenced the required additional pivotal Phase 3 trial. The study was a six-month randomized trial of voclosporin versus placebo in 155 patients in North America and Europe with active non-infectious intermediate, posterior, or pan-uveitis. In January of 2013 Lux released results of this Phase 3 study, whereby the study drug failed to achieve statistical significance vs. placebo. During the fourth quarter of 2013 the Company received notification from Lux that it would be ceasing business activity and therefore returning the license to the Company.

On February 27, 2014, the Company signed a termination and assignment 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.

## THREE YEAR HISTORY

The Company, in 2013 and prior years, had signed licensing agreements and partnerships to further the advancement of its lead drug, voclosporin as noted below:

## ILJIN Life Science Co., Ltd.

Effective January 28, 2011 (the "Effective Date") the Company completed a Development, Distribution and License Agreement (the "DDLA") with ILJIN for the further clinical and commercial development of voclosporin for use in transplant indications applicable to voclosporin. The Company granted to ILJIN an exclusive license to voclosporin for transplant and autoimmune indications for the United States and other regions outside of Europe, Canada, Israel, South Africa, China, Taiwan and Hong Kong. The Company retained the rights over voclosporin in Europe for future development and commercialization.

Pursuant to the DDLA, the Company was to receive a total license fee of US\$5.0 million. In addition, ILJIN was to purchase 90.7 million common shares (pre-consolidation) of the Company for gross proceeds of US\$19.87 million in three tranches.

The Company was obligated under the terms of the agreement to complete a single Phase 3 clinical trial for the prevention of kidney transplant rejection. The Company received \$4.5 million (US\$4.5 million) of the license fee and the first private placement tranche of \$2.38 million (US\$2.37 million) on January 28, 2011 which was the Effective Date of the Agreement. The Company issued 11.5 million common shares (pre-consolidation) at a price of \$0.207 per share (US\$0.207) to ILJIN pursuant to the subscription agreement for securities. On or before January 28, 2012 ILJIN was to pay US\$500,000 to the Company as the Second Development Payment and purchase 39.6

million common shares (pre-consolidation) of the Company issued from treasury for an aggregate subscription price of US\$8.5 million. On or before January 28, 2013, ILJIN was to purchase the final tranche of 39.6 million common shares (pre-consolidation) of the Company issued from treasury for an aggregate subscription price of US\$9.0 million.

Prior to the January 28, 2012 date, ILJIN verbally indicated their intent to alter the economics of the DDLA. Consequently, payment under the DDLA was not received as required per the agreement of January 28, 2011. The Company on January 30, 2012 notified ILJIN that it was terminating the DDLA. At that time the Company believed that the termination of the original DDLA was valid.

The Company received notification in March, 2012 that ILJIN submitted a request for arbitration to the International Chamber of Commerce ("ICC") Court of Arbitration relating to the Company's termination of the DDLA. The Arbitration hearing to determine the Company's right to terminate the agreement was held early in the fourth quarter of 2012. In November, 2012 the Company received notification from the ICC that a Partial Award regarding its right to terminate the DDLA with ILJIN had been issued to the parties. In the result, the Partial Award provided that the DDLA had not been terminated and, therefore, the Company's contractual relationship with ILJIN still existed. As such the Partial Award rejected the Company's interpretation of the DDLA's termination provision. In January of 2013, ILJIN formally notified the Company and the arbitral tribunal that ILJIN had withdrawn all claims for damages in the parties' pending arbitration.

On September 20, 2013, the Company, ILJIN and Aurinia Pharma Corp. completed a plan of arrangement whereby the DDLA was terminated as more fully described in the "Corporate Developments for 2013" section above.

#### Licensing and Collaboration Agreement with Aurinia Pharmaceuticals Inc.

The Company signed a global Licensing and Collaboration Agreement ("LCA") effective December 30, 2011 with Vifor. The agreement granted Vifor an exclusive license for voclosporin, for the treatment of lupus and all proteinuric nephrology indications (the "Vifor License"). The Vifor License was for the United States and other regions outside of Canada, South Africa, Israel, China, Taiwan and Hong Kong (the "Vifor Territory"). Under the terms of the Agreement, the Company was to receive milestone payments, as well as royalties on commercial sales. In connection with this agreement, Vifor was to purchase voclosporin active pharmaceutical ingredient ("API") from the Company. Vifor was to carry the burden of the costs associated with these clinical trials. On December 13, 2012, the LCA was assigned to Aurinia Development Corp. by Vifor. Aurinia Development Corp. is a subsidiary of Aurinia Pharma Corp.

ILJIN had provided a License Back for the field of lupus and proteinuric kidney diseases for the Territory defined in the ILJIN DDLA of certain rights to the Company in order for these rights to be licensed to Vifor specifically for the indications of lupus and proteinuric kidney disease, in return for certain milestones and royalties to be paid by Vifor.

On December 10, 2012 pursuant to this agreement, the Company received as a milestone payment, an investment in Aurinia Pharma Corp. Aurinia Pharma Corp. issued the Company a share certificate representing 10% of the common shares of Aurinia Pharma Corp. Aurinia Pharma Corp. had the option of granting the Company these shares or \$592,000 in cash (US\$600,000). The Company determined that the fair value of the shares in Aurinia Pharma Corp. approximated \$592,000 and therefore recorded the value of the investment in Aurinia Pharma Corp. shares at \$592,000. The Company has recorded this milestone payment as deferred revenue upon receipt. Under the LCA, the primary substantive obligations of the Company were to maintain the patent portfolio and pay for drug supply if costs exceed a certain amount.

On April 3, 2013, the Company entered into a term sheet to merge with Aurinia and a tripartite settlement agreement between the Company, ILJIN and Aurinia Pharma Corp.

The Company's investment in Aurinia Pharma Corp. was carried at fair value, with changes in fair value recognized in other comprehensive income ("OCI"). Since Aurinia Pharma Corp.'s shares did not trade in a public market, the Company used a form of company valuation approach to determine fair value, categorized as level 3 in

the fair value hierarchy. Due to the unique nature of Aurinia Pharma Corp's primary assets, being its license agreement with the Company and its intellectual property related to lupus nephrology research, management does not believe there are any comparable companies that trade publicly for which an indicative value could be obtained. As a result, it compared the value of Aurinia Pharma Corp. to the value of the Company based on the merger of the entities and the relative valuation formula agreed to by the parties and approved by the shareholders. Without providing for any adjustments for lack of liquidity or non-controlling interests, this approach resulted in a fair value of the investment of \$670,000 at September 20, 2013. Pursuant to the plan of arrangement the Company transferred its ownership interest in Aurinia Pharma Corp. to ILJIN. The Company recorded a gain of \$78,000 on the statement of operations and comprehensive loss upon disposal of this investment.

See the "Corporate Developments in 2013" section earlier in this document regarding the Plan of Arrangement.

## 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 Canada, 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 Good Manufacturing Practice.

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 clinical trial application ("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 Institutional Review Board/Research Ethics Board ("IRB/REB") 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 indicate 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 shipment 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 European Medicines Agency ("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/REB 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 European Union ("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/REB 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 Canada, the United States and Europe:

- 1. **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.

#### MANUFACTURING

#### Voclosporin

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

On June 8 2004, Isotechnika Inc. signed a manufacturing agreement with Lonza Ltd. ("Lonza") to manufacture voclosporin for clinical trial and regulatory purposes.

In December 2007 Lonza completed the manufacture of the API validation batches of voclosporin required for regulatory approval. Lonza has completed the manufacture of the API required for the Company's Phase 3 kidney transplant program. It will also manufacture the API required for commercial supply purposes. Lonza manufactures the API in Switzerland.

Paladin is responsible for the API drug supply function with the Company until December 31, 2014. Pursuant to the Supply Agreement Paladin shall supply the Company's required API for use in clinical studies and for commercial purposes until this date. The purchase price of the API shall be the fully allocated supply costs, including allocable overhead, plus 5%.

## 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 31, 2014 there are 219 granted patents for voclosporin worldwide. These patents cover synthesis, composition of matter, method of use and formulation.

The Company also has three ophthalmic patents acquired upon the return of the ophthalmic indications of voclosporin as result of the Company signing a Termination and Assignment Agreement with Lux on February 27, 2014.

## 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**

	December 31, 2013	December 31, 2012	<b>December 31, 2011</b>
Total	13	21	26

As at December 31, 2013 the Company employed 13 employees, 11 of whom held advanced degrees in science and business, including 6 with Ph.D. degrees.

Of the Company's total 12.1 full-time equivalent employees as at December 31, 2013, 7.1 employees were engaged in, or directly support, research and development activities; and 5 were engaged in corporate and administration activities.

Subsequent to December 31, 2013, four employees engaged in research and development activities were terminated as a result of the early-stage NICAM program being divested.

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**

Until September 30, 2013 the Company was leasing 25,318 square feet of lab and office space (6 bays) in Edmonton, Alberta. On October 1, 2013 the Company significantly reduced its leased premises costs 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 sublease is \$22,000 monthly and includes base rent, utilities and operating costs. In turn, the Company subleases out, on a month-to-month basis, a portion of the 9,000 square feet, and receives rental proceeds of approximately \$10,000 per month. The Company entered into the sublease to avoid the costs of converting the premises back to its original state if the premises had been turned back to the landlord. The Company is exploring options to sublease additional space as it no longer requires lab space after divesting of the NICAM project on February 14, 2014. The Company also continues to lease from the landlord two adjoining office bays on a short term month-to-month basis at \$10,000 per month as it transitions its administration and finance operations from Edmonton, Alberta to Victoria, British Columbia. The Company is currently in lease negotiations regarding the rental of office space in Victoria.

#### ENVIRONMENTAL PROTECTION

The Company believes it is in material compliance with applicable environmental protection laws, and believes that ongoing compliance with applicable environmental protection laws will not have a material effect on the business. Expenditures for environmental compliance have not been, and are not anticipated to be, material. The Company is unable to predict what changes may be made to environmental laws in the jurisdictions in which it operates and may operate in the future, although it anticipates that such laws will likely become more stringent.

## **RISK FACTORS**

The risks and uncertainties described below are those that we currently believe may materially affect us. Additional risks and uncertainties that we are unaware of or that we currently deem immaterial may also become important factors that affect us. If any of the following events were to actually occur, our business, operating results or financial condition could be adversely affected in a material manner.

## RISKS RELATED TO THE COMPANY'S BUSINESS

#### DEPENDENCE ON VOCLOSPORIN

The Company has invested a significant portion of its time and financial resources in the development of voclosporin. 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;
- > 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.

#### 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. None of the Company's therapeutic products have received regulatory approval for commercial use and sale 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 any of its products. 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, and time intensive and entails significant uncertainty.

The results of our 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 products.

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 any of the Company's products 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 its products. 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 one of the Company's products 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 equity 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 products and regulatory approval for these products. Future success of commercialization of any product is also dependant on the ability of the Company to obtain patents, enforce such patents and avoid patent infringement. There can be no assurance that the Company will successfully develop such products, or these products will be developed in a timely manner or that the Company will achieve significant revenues from such products if they are successfully developed.

#### DEPENDENCE ON KEY PERSONNEL

The Company is highly dependent upon certain members of its senior management team, the loss of whose services might impede the achievement of the Company's business objectives and have an adverse effect on the Company's operating results and prospects.

#### SUPPLY AND MANUFACTURE OF RAW MATERIALS

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

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 products 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, 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 products. The third parties the Company chooses to manufacture and supply raw materials for its products 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.

## USE OF HAZARDOUS MATERIALS

The Company's discovery and development processes involve the controlled use of hazardous materials. The Company is subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although the Company believes that its safety procedures for handling and disposing of such materials 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. Although the Company believes that it is in compliance in all material respects with applicable environmental laws and regulations and currently does not expect to make material capital expenditures for environmental control facilities in the near-term, there can be no assurance that the Company will not be required to incur significant costs to comply with environmental laws and regulations in the future, or that its

operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

#### ANTICIPATED REVENUES MAY BE DERIVED FROM LICENSING ACTIVITIES

The Company anticipates that its revenues in the foreseeable future may be derived primarily 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 products. There can be no assurance that it will have earnings or positive cash flow in the future.

As at December 31, 2013, the Company had an accumulated deficit of \$212.70 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 products. 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.

#### 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 maintains director and officer liability insurance coverage of \$5 million to reduce the exposure of the Company.

#### 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 any products being developed or marketed by the Company, thus making the Company's products non-competitive or obsolete. There may also be market resistance to the acceptance of any of the Company's new products and a risk that a product, even though clinically effective, is not economically viable in the commercial production stage.

#### 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; or
- the patents issued do not infringe the patents or intellectual property of others.

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 products of the Company.

The Company may need to obtain additional licenses for the development of its products. If available, these licenses may obligate the Company to exercise diligence in the development of technology and may obligate the Company to make minimum guarantees, milestone payments or purchases from specific suppliers. These diligence and milestone payments may be costly and affect the business of the Company. The Company may be obligated to make royalty payments on the sales, if any, of products resulting from licensed technology and may be responsible for the costs of filing and prosecuting patent applications.

#### RELIANCE ON PARTNERS AND OTHER THIRD PARTIES

#### **Partners**

The Company's strategy and success for the research, development, and commercialization of voclosporin in China (partner - 3SBio, Inc.), Canada, South Africa and Israel (partner - Paladin) is dependent upon these partners performing their respective contractual responsibilities. The amount and timing of resources such third parties 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 and research and development agreements with the third parties 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.

The Company intends to seek additional collaborative arrangements to develop and commercialize voclosporin for the transplant indication. There can be no assurance that the Company will be able to negotiate collaborative arrangements on favorable terms, or at all, in the future, or that current or future collaborative arrangements will be successful.

#### Other Third Parties

For some products, 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 products. The Company does not anticipate any difficulties in obtaining required components or products or any difficulties in the validation and clinical testing of its products 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. All of the Company's 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 an arrangement for the supply of voclosporin through Paladin Labs Inc. until January 1, 2015, at which time the Company will have all supply rights for voclosporin returned.

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. The Company's dependence upon third parties for the manufacturing of its therapeutic products may adversely affect the Company's profit margins and its ability to develop and deliver such products on a timely and competitive basis.

#### 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 any of its products 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 products, 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.

#### 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 products. 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 any of its products. If the Company fails to achieve one or more of these milestones as planned, the price of the Company's common shares could decline.

#### **MARKET ACCEPTANCE**

Even if the Company's products are approved for sale, they may not be successful in the marketplace. Market acceptance of any of the Company's products will depend upon a number of factors, including demonstration of clinical effectiveness and safety; the potential advantages of its products over alternative treatments; the availability of acceptable pricing and adequate third party reimbursement; and the effectiveness of marketing and distribution methods for the products. If the Company's products do not gain market acceptance among physicians, patients, and others in the medical community, the Company's ability to generate significant revenues from its products would be limited.

#### HEALTH CARE REIMBURSEMENT

In both domestic and foreign markets, sales of the Company's products, 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 products 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 products on a profitable basis.

#### **GOVERNMENT REGULATION**

The production and marketing of the Company's products 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 products. 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 in the United States, 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 products 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.

#### DEPENDENCE ON SUPPLY AGREEMENT

The Company is dependent upon Paladin until January 1, 2015 for the timely supply of API for the Company's use and clinical studies or for other research and development uses pursuant to the terms of the supply agreement. There can be no assurance that Paladin will be able to supply the API in the quantities and timeframes required by the Company. Any prolonged delays in supply of API may adversely affect the Company's business, results of operations and financial condition.

#### ADDITIONAL FUNDING MAY NOT BE AVAILABLE ON FAVORABLE TERMS

While the Company believes it has sufficient funding to conduct the planned Phase 2b LN clinical trial as a result of completing the US\$52 million private placement on February 14, 2014, the Company's longer term funding needs may vary depending upon a number of factors including progress on the Company's voclosporin development program (s), the costs associated with completing future clinical trials and the regulatory process, the Company potential decision to in-license or acquire additional products for development and defending or enforcing the Company's patent claims and other intellectual property rights. There can be no assurance that such funds will be available on favorable terms or at all.

#### RISKS RELATED TO THE COMPANY'S SECURITIES

#### **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 our 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 TSXV. Investors may not be able to sell their shares quickly or at the latest market price if the trading in our 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 31% of the Company's outstanding common shares as at March 31, 2014. 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.

## **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.

Each common share entitles the holder thereof to one vote at any meeting of the shareholders of the Company.

As at March 31, 2014, the Company had 32,354,082 common shares issued and outstanding.

## MARKET FOR SECURITIES

#### TRADING PRICE AND VOLUME OF AURINIA SHARES

The Company is a reporting issuer in the provinces of British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador.

Aurinia's Common Shares were traded on the TSX until September 27, 2013 under the symbol "ISA". Starting September 30, 2013, the Company's common shares commenced trading on the TSXV under the symbol "ISA" for the period September 30, 2013 to October 22, 2013. Effective October 22, 2013, the Company's common shares were consolidated on a 50:1 basis and commenced trading under the symbol "AUP". The following table sets out the high

and low trading prices as well as the trading volume for Aurinia's common shares for the 12-month period indicated, as reported on the TSX and the TSXV.

## <u>TSX</u>

Month	Price :	Total Volume	
Month	High	Low	Total Volume
2013			
January *	\$4.25	\$2.50	37,232
February *	\$3.25	\$1.50	68,544
March *	\$2.50	\$1.50	28,606
April *	\$2.00	\$1.50	65,699
May *	\$2.00	\$1.50	27,593
June *	\$1.75	\$1.50	4,835
July *	\$2.75	\$1.50	30,834
August*	\$2.75	\$1.75	36,906
September 1-27*	\$2.75	\$1.75	72,072

## **TSXV**

Month	Price	Total Volume		
Month	High Low		Total Volume	
2013				
September 30*	\$2.25	\$2.25	1,731	
October*	4.19	3.21	62,276	
November	3.84	2.36	112,871	
December	4.19	3.21	81,415	

<sup>\*</sup>After giving effect to the 50:1 share consolidation on October 23, 2013.

## **PRIOR SALES**

The following table summarizes the distribution of securities other than our 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
June 26, 2013	Warrants	\$2.50	453,111	June 26, 2018
June 26, 2013	<b>Broker Warrants</b>	\$2.25	19,273	June 26, 2018
September 20, 2013	Warrants	\$2.50	1,333,333	September 20, 2016
September 20, 2013	<b>Broker Warrants</b>	\$2.25	112,067	September 20, 2016
September 20, 2013	Warrants	\$2.00	13,997	December 31, 2018

<sup>\*</sup> After giving effect to the 50:1 share consolidation on October 23, 2013

## 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 31, 2014, 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 and Municipality of Residence	Position with the Company	Director/Officer since	Principal Occupation for Five Preceding Years
Stephen W. Zaruby  Woodinville, WA, U.S.A.	President and Chief Executive Officer	November 2013	Chief Executive Officer 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	Chief Financial Officer	CFO since May 1998	Chief Financial Officer of the Company since May, 1998.
Michael R. Martin Victoria, British Columbia Canada	Chief Operating Officer	Director since August 2013; COO since September, 2013	Chief Operating Office 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 Pharmaceuticals.
Neil Solomons Victoria, British Columbia Canada	Chief Medical Officer	September 2013	Chief Medical Officer of the Company since September 2013; prior thereto was Vice President, Research and Development at Vifor Pharma, formerly Aspreva Pharmaceuticals.
Robert Huizinga St. Albert, Alberta, 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 Pharmaceuticals.
Richard Glickman Victoria, British Columbia Canada	Director; Chairman of the Board	August 2013	Chairman of the Board Aurinia Pharmaceuticals Inc.; Chairman of the Board Aspreva Pharmaceuticals Inc.; CEO Aspreva Pharmaceuticals Inc.; CEO StressGen Pharmaceuticals Inc.
Peter Wijngaard Basel, Switzerland	Director	February 2011	February 2011 to present – Vice President, Innovation Leader Research & Development, The Medicines Company (Schweiz) GmbH, a global pharmaceutical company; prior thereto Senior Director Medical Affairs at ViroPharma Inc. and Global Alliance Director in Transplantation at Hoffman-La Roche.

Kurt von Emster Belmont, California U.S.A.	Director	February 2014	Chartered Financial Analyst, Founding member of venBio since 2009.
Daniel S. Park Seoul, South Korea	Director	August 2013	January 1, 2014 to present - President of ILJIN Group; Executive Vice President of ILJIN Group 2010-2013; prior thereto was Senior Vice President of ILJIN Group.
Benjamin Rovinski Thornhill, Ontario Canada	Director	September 2013	Managing Director, Lumira Capital.
Chris Kim Seoul, South Korea	Director	August 2013	2008 to present, Chief Executive Officer, Lumirich Co. and ILJIN Semicon Co. of Seoul, Korea.
Donald W. Wyatt  Seattle, Washington  U.S.A.	Director	December 2011	From 2009 to present – Principle, The Wyatt Group, LLC, an Intellectual Property Consulting firm; 2005 to 2009 – Vice President of Legal Affairs and Corporate Secretary for Cell Therapeutics, Inc., a biopharmaceutical company.

Directors and officers of the Company, as of March 31, 2014, beneficially own, directly or indirectly, 2,276,255 common shares representing 7.26% of the outstanding common shares of the Company.

#### **EXECUTIVE OFFICERS AND DIRECTORS**

The following are brief biographies of our senior management team and directors.

## Stephen W. Zaruby, President and Chief Executive Officer

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. Stephen 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. Stephen remains active within the industry, with board membership in discovery-stage biotechnology companies.

## Dennis Bourgeault, C.A., Chief Financial Officer

Dennis Bourgeault has been the Chief Financial Officer of the Company since 1998 and is responsible for the financial operations of the Company. Prior to joining Isotechnika he was the controller for a private industrial distribution company for six years and was a senior manager in public accounting at KPMG. Mr. Bourgeault obtained his chartered accountant designation in 1984.

#### Michael R. Martin, Chief Operating Officer

Michael Martin was formerly CEO, director and co-founder of the privately held Aurinia Pharmaceuticals Inc. which was acquired in 2013 by the former Isotechnika Pharma Inc. In his current role with Aurinia, Mr. Martin is responsible for managing company functions such as corporate and business development, alliance management, marketing, finance and internal company operations. Mr. Martin is a biotech/pharmaceutical executive with over 18

years industry experience and offers a solid mix of strategic planning, marketing, commercial operations, business development, licensing and people management skills. 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. Most recently, Mr. Martin has spent time in Europe where he was responsible for the rheumatology business unit for Remicade® in France. There, Mr. Martin had full profit and loss responsibilities and had direct responsibility for the sales team, the marketing team and the infusion access team. In addition while at Schering-Plough, Mr. Martin was the brand manager responsible for the Canadian launch of Remicade (infliximab), which ultimately became the most successful product launch in Canadian history. Mr. Martin started his career in the industry in the sales organization of Schering-Plough where he received multiple awards and recognition while rapidly progressing towards the prior mentioned roles.

## Neil Solomons, M.D., Chief Medical Officer

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 15 years of clinical development and medical affairs experience in both big pharma and biotech. He is a recognized expert in raredisease drug development and is widely published in this field. Dr. Solomons joins Aurinia from Vifor Pharma, formerly Aspreva Pharmaceuticals (NASDAQ:ASPV) 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 the 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 Aspreva Lupus Management Study (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. His research interests included sepsis and chronic pain.

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

Mr. Huizinga has been with the Company since 2002, and most recently served as Senior Director, Clinical Affairs, focused on managing the global clinical development of voclosporin. Before joining Isotechnika, 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. Over the years, Mr. Huizinga has established and nurtured close relationships in the nephrology and transplant communities, and has fostered strong connections with transplant investigators and clinical trial sites.

Mr. Huizinga has numerous articles published in leading medical journals, including the *New England Journal of Medicine, Lancet*, and the *American Journal of Transplantation*. Mr. Huizinga is a member of many professional societies related to nephrology, transplantation and nursing, has served on many nephrology and transplantation committees, and is the founder of RenalPro, a moderated forum for renal professionals. 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 Regulatory and Quality, Mr. Mandt is responsible for regulatory strategy, as well as implementation of the Company's regulatory projects. Most recently, he led the effort to write, compile and publish the new IND permitting human clinical testing of *voclosporin* in LN patients, which was accepted by FDA. Mr. Mandt brings 30+ years' experience in global regulatory affairs, in large and small companies, across a variety of therapeutic areas. During his career, he has operated at the executive level for 10+ years.

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 Pharmaceuticals 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 CellCeptÒ 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, he 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 QLT, Mr. Mandt led the regulatory and medical affairs function for CIBA Vision Opthalmics (ultimately became Novartis Ophthalmics) for eight years, gaining approval of the 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.

## Richard M. Glickman, L.L.D. (Hon), Chairman of the Board

Dr. Glickman was a co-founder and has served as an Interim Executive Chairman of the Company and presently serves as its Chairman of the Board. He was a co-founder, Chairman and Chief Executive Officer of Aspreva Pharmaceuticals ("Aspreva"). Prior to establishing Aspreva, Dr. Glickman was the co-founder and Chief Executive Officer 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 and as Chairman of the Board of Essa Pharmaceuticals Inc. Dr. Glickman was also the founder and a director of Ontario Molecular Diagnostics, a diagnostic facility that evolved into the largest molecular diagnostic laboratories in Canada. He co-founded Probtec Corporation, a rational drug design and molecular genetics firm, where he established and introduced the first licensed DNA-based forensic and paternity testing services in Canada. He has served on numerous biotechnology and community boards including roles as Chairman of Life Sciences B.C. (formerly the British Columbia Biotechnology Alliance), 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. Dr. Glickman received the Ernst & Young Entrepreneur of the Year 2004 Award for the Pacific Region Life Sciences Group and has received both Canada's and British Columbia's Top 40 under 40 Award for Entrepreneurs and has been the recipient of 2006 BC Biotech Leadership Award.

# Daniel Park, Chairman of the Compensation Committee

Mr. Park is currently the President of ILJIN Group. He started his management career with ETEX Corp, an advanced biomaterials company focusing on products that promote bone repair and enable controlled delivery therapies in 1988. ETEX is one of the subsidiaries of ILJIN Group, and Mr. Park has since worked in numerous ILJIN Group companies including ILJIN Display Co., Ltd. and ILJIN Diamond Co., Ltd. in senior management positions. He is presently in the Planning Office of ILJIN Group which contains multiple sub companies ranging from the Jeonju Television Co., Ltd. to ILJIN Electricity Co., Ltd.

Mr. Park holds Masters of Business Administration (University of California at Los Angeles), along with a Masters and a Bachelor's degree in Economics from Seoul National University.

#### Chris Kim, Ph.D., Director

Dr. Kim is currently CEO, Lumirich Co., and ILJIN Semicon Co., of Seoul, Korea dating from 2008 to present. Prior to that, from 2006 to 2008, Dr. Kim was CEO, ILJIN Display Co., Korea. From 2000 to 2006, Dr. Kim was Vice-president, Sales and Marketing at Samsung SDI Co, Korea, where he was in charge of Samsung SDI's worldwide plasma display panel sales and marketing. During his tenure with Samsung SDI Co., Dr. Kim gained considerable commercial experience with CE related products to OEM customers including, for example, Philips Consumer Electronics, Sony, Dell, and Hewlett-Packard. From 2001 to 2005, Dr. Kim was able to increase revenue growth from approximately \$0.7 million to \$1.7 billion. Dr. Kim had increasing responsibilities from 1986 to 1999 while at companies including NSF Polymer Research Center, VPI, in Blacksburg, Virginia, USA; Exxon-Mobil Corp., in Rochester, NY, USA; Corning Inc., in Corning, NY, USA; Lam Research Corp., in Fremont, California, USA, and Fujitsu Inc., in San Jose, California, USA. Dr. Kim has an undergraduate science degree in chemical engineering from Seoul National University (1985) and a PhD in chemical engineering (1989) from Virginia Tech., Blacksburg, Virginia, USA. He also has more than ten technical publications, one book chapter, and numerous worldwide patents, and is fluent in three languages.

## Kurt von Emster, Director

Mr. von Emster has been an institutional biotechnology and health care analyst and portfolio manager for over 20 years. Mr. von Emster is a Managing Partner of venBio. He is a member of the board of directors of Cytos AG and CymaBay Therapeutics, Inc., a former member of the board of Somaxon Pharmaceuticals Inc. (sold to Pernix Therapeutics in 2013) and Facet Biotech Corporation (sold to Abbott Laboratories in 2010), and a former board observer of Acceleron Pharma. Mr. von Emster's investment career started in 1989 at Franklin Templeton where he founded and managed several health and biotechnology funds in the 1990s, each achieving a 5-star Morningstar ranking. In 2000, he was managing over \$2B in biotech and health care funds for Franklin Templeton. In 2001, Mr. von Emster became a General Partner at MPM Capital, a leading biotechnology private equity firm, and launched the MPM BioEquities Fund, a cross over public and private biotechnology hedge fund. He was the portfolio manager of this fund from inception in 2001 until his departure in 2009. He also co-founded the MPM Biogen Idec Strategic Fund during his tenure at MPM. Mr. von Emster is located in the San Francisco office.

## 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.

## Peter Wijngaard, Ph.D., Director, Chair of the Audit Committee

Dr. Peter Wijngaard is the Vice President, Innovation Leader Research & Development for The Medicines Company (Schweiz) GmbH. Prior to this he served as the Senior Director Medical Affairs at ViroPharma Incorporated, and as the Global Alliance Director, Life Cycle Leader in Transplantation, International Medical Manager in Transplantation, and Country Medical Manager Transplantation at Hoffmann-La Roche. He brings extensive experience in the areas of Global Project Leadership, Business Development, Medical Affairs, and Pharmaceutical Marketing. Dr. Wijngaard has a B.Sc. in Clinical Chemistry, and his Ph.D. in Transplantation Immunology from Utrecht University examining the immunological aspects of human heart transplantation. He conducted his Postdoctoral Fellowships at Pharmacia Diagnostics, Inselspital Bern, and Sandoz. He has published extensively in the area of transplant immunology and immunosuppression, with emphasis on the use of mycophenolate mofetil (CellCept ®). From 2005 to 2008, Dr. Wijngaard was a member of the Board of Trustees of the Roche Organ Transplant Research Foundation, which supports important and innovative clinically oriented research projects in organ transplantation. During his tenure, the Foundation managed a total of 67.5 million Swiss Francs donated by F. Hoffmann-La Roche Ltd.

## Donald W. Wyatt, B.S., J.D., Director

Donald Wyatt has over 20 years of experience in the pharmaceutical industry, including research and legal representation. He has worked in research in large pharmaceutical companies, as an attorney in a law firm, and as inhouse patent and general legal counsel. Mr. Wyatt is founder of The Wyatt Group, a consulting firm serving companies worldwide in strategic transactions, relationships and intellectual property strategies. Donald Wyatt was appointed to the Board on December 7, 2011 as the nominee of 3SBio, Inc. pursuant to the terms of a development, distribution and license agreement among the Company and 3SBio, Inc. dated August 6, 2010.

## COMMITTEES OF THE BOARD

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

Committee	Members	
	Dr. Peter Wijngaard (Chair)	
Audit Committee (1)	Donald W. Wyatt	
Audit Committee	Daniel S. Park	
	Kurt Von Emster	
	Daniel S. Park (Chair)	
Compensation Committee	Dr. Peter Wijngaard	
	Dr. Benjamin Rovinski	
	Kurt Von Emster	

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

# CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

Unless otherwise disclosed in this AIF, 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, chief executive officer or chief financial officer 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, chief executive officer or chief financial officer; 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, chief executive officer or chief financial officer and which resulted from an event that occurred while he was acting in the capacity of a director, chief executive officer or chief financial officer; or
- (b) is, or has been within 10 years before the date of this AIF, a director, chief executive officer or chief financial officer 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

The Company is not aware of, as of March 31, 2014, 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 in 2013, 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 ended December 31, 2013. 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 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 *Corporate Update - Recent Developments – Development, Distribution and License Agreement with ILJIN Life Science Co., Ltd.* 

## TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar for the common shares of Aurinia Pharmaceuticals Inc. is Computershare Trust Company of Canada located at 100 University Avenue, Toronto, Ontario, Canada M5J 2Y1.

## **INTERESTS OF EXPERTS**

PricewaterhouseCoopers LLP are the auditors who prepared the auditors' report and the report on Canadian generally accepted audit standards for the Company's consolidated financial statements for the period ended December 31, 2013. PricewaterhouseCoopers LLP is "independent" from the Company in accordance with the relevant professional standards.

## MATERIAL CONTRACTS

The Company currently has two material contracts, each of which was entered into in connection with the Offering. Under the terms of the subscription agreement for the Offering, if the Company does not reduce the size of its Board to seven directors within 90 days following the closing of the Offering, an additional 0.1 Warrants will be issued for each Unit purchased by a subscriber for every additional 90-day period delay, up to a maximum of 0.35 Warrants per Unit. This represents a maximum of 6.62 million additional Warrants. The Company will issue and deliver such additional Warrants to each subscriber in accordance with the registration instructions provided by the subscriber in the subscription agreement for no additional consideration within five business days after the commencement of each applicable 90-day period.

The Company has also granted the subscribers, in the aggregate, the right to nominate two persons for election to the Company's board of directors.

Under the terms of the registration rights agreement for the Offering (the "Registration Rights Agreement"), the Company has agreed to use its commercially reasonable efforts to cause its common shares to be approved for listing on NASDAQ within 12 months following the closing of the Offering and to provide each shareholder with notice of such listing. If the Company does not obtain approval to list its common shares on NASDAQ within 12 months following the closing of the Offering, the Company has agreed to issue an additional 0.1 Warrants for each Unit purchased by a subscriber for every 90-day period delay, up to a maximum of 0.35 Warrants per Unit. This represents a maximum of 6.62 million additional Warrants. The Company will issue and deliver such additional Warrants to each subscriber in accordance with the registration instructions provided by the subscriber in the subscription agreement for no additional consideration within five business days after the commencement of each applicable 90-day period.

Under the terms of the Registration Rights Agreement, at any time following the date that is six months after the listing of the Company's common shares on NASDAQ, the holders of a majority of the securities purchased under the Offering may request that the Company effect the registration under the Securities Act of 1933 of an amount of common shares with a market value of at least \$10,000,000 (a "Registration Request"). If the Company receives a Registration Request, it must, within 10 days of receipt, provide written notice of such request to all shareholders describing the terms of such registration; and, as soon as practicable, cause to be prepared and filed with the U.S. Securities and Exchange Commission a registration statement providing for the resale of all securities purchased under the Offering which shareholders request to be registered.

## ADDITIONAL INFORMATION

Additional information with respect to the Company, including directors' and officers' compensation, principal holders of the Company's common shares and securities authorized for issuance under equity compensation plans is contained in the Company's information circular for its most recent annual and special meetings of the shareholders that involved the election of directors. The Company's financial information is also provided in the management discussion and analysis and comparative consolidated financial statements for the financial year ended December 31, 2013.

Additional information regarding the Company is available on the SEDAR website located at <a href="www.sedar.com">www.sedar.com</a>, the Company's corporate website located at <a href="www.auriniapharma.com.com">www.auriniapharma.com.com</a> or upon request addressed to Michael Martin, Chief Operating Officer, at #1203, 4464 Markham Street, Victoria, British Columbia V8Z 7X8. Except when the Company's securities are in the process of distribution pursuant to a prospectus, the Company may charge reasonable fees if the request is from a person who does not hold any of the Company's securities.

# **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 1A to this AIF.

## 2. Composition of the Audit Committee

Name	Independent	Financially Literate
Dr. Peter Wijngaard (Chair)	Yes	Yes
Daniel S. Park	Yes	Yes
Donald W. Wyatt	Yes	Yes
Kurt von Emster	Yes	Yes

## 3. Relevant Education and Experience

## Peter Wijngaard, Ph.D.

Dr. Peter Wijngaard is the Vice President, Innovation Leader Research & Development for The Medicines Company (Schweiz) GmbH. Prior to this he served as the Senior Director Medical Affairs at ViroPharma Incorporated, and as the Global Alliance Director, Life Cycle Leader in Transplantation, International Medical Manager in Transplantation, and Country Medical Manager Transplantation at Hoffmann-La Roche. He brings extensive experience in the areas of Global Project Leadership, Business Development, Medical Affairs, and Pharmaceutical Marketing. Dr. Wijngaard has a B.Sc. in Clinical Chemistry, and his Ph.D. in Transplantation Immunology from Utrecht University examining the immunological aspects of human heart transplantation. He conducted his Postdoctoral Fellowships at Pharmacia Diagnostics, Inselspital Bern, and Sandoz. He has published extensively in the area of transplant immunology and immunosuppression, with emphasis on the use of mycophenolate mofetil (CellCept ®). From 2005 to 2008, Dr. Wijngaard was a member of the Board of Trustees of the Roche Organ Transplant Research Foundation, which supports important and innovative clinically oriented research projects in organ transplantation. During his tenure, the Foundation managed a total of 67.5 million Swiss Francs donated by F. Hoffmann-La Roche Ltd.

## Daniel Park

Mr. Park is currently the President of ILJIN Group. He started his management career with ETEX Corp, an advanced biomaterials company focusing on products that promote bone repair and enable controlled delivery therapies in 1988. ETEX is one of the subsidiaries of ILJIN Group, and Mr. Park has since worked in numerous ILJIN Group companies including ILJIN Display Co., Ltd. and ILJIN Diamond Co., Ltd. in senior management positions. He is presently in the Planning Office of ILJIN Group which contains multiple sub companies ranging from the Jeonju Television Co., Ltd. to ILJIN Electricity Co., Ltd.

Mr. Park holds Masters of Business Administration (University of California at Los Angeles), along with a Masters and a Bachelor's degree in Economics from Seoul National University.

## Donald W. Wyatt, B.S., J.D.

Donald Wyatt has over 20 years of experience in the pharmaceutical industry, including research and legal representation. He has worked in research in large pharmaceutical companies, as an attorney in a law firm, and as in-house patent and general legal counsel. Mr. Wyatt is founder of The Wyatt Group, a consulting firm serving companies worldwide in strategic transactions, relationships and intellectual property strategies.

#### Kurt von Emster

Mr. von Emster has been an institutional biotechnology and health care analyst and portfolio manager for over 20 years. Mr. von Emster is a Managing Partner of venBio. He is a member of the board of directors of Cytos AG and CymaBay Therapeutics, Inc., a former member of the board of Somaxon Pharmaceuticals Inc. (sold to Pernix Therapeutics in 2013) and Facet Biotech Corporation (sold to Abbott Laboratories in 2010), and a former board observer of Acceleron Pharma. Mr. von Emster's investment career started in 1989 at Franklin Templeton where he founded and managed several health and biotechnology funds in the 1990s, each achieving a 5-star Morningstar ranking. In 2000, he was managing over \$2B in biotech and health care funds for Franklin Templeton. In 2001, Mr. von Emster became a General Partner at MPM Capital, a leading biotechnology private equity firm, and launched the MPM BioEquities Fund, a cross over public and private biotechnology hedge fund. He was the portfolio manager of this fund from inception in 2001 until his departure in 2009. He also co-founded the MPM Biogen Idec Strategic Fund during his tenure at MPM. Mr. von Emster is located in the San Francisco office.

## **External Auditor Service Fees (By Category)**

The aggregate fees recorded for professional services rendered by PricewaterhouseCoopers LLP for the Company and its subsidiaries for the years ended December 31, 2013 and 2012, respectively are as follows:

Fiscal year ended	2013	2012
Audit fees (for audit of the Company's annual financial statements and services provided in connection with statutory and regulatory filings) <sup>(1)</sup>	\$79,380	\$24,893
Audit related fees, including review of the Company's quarterly financial Statements <sup>(2)</sup>	\$46,725	\$15,645
Tax fees (tax compliance, tax advice and planning) <sup>(3)</sup>	\$5,250	\$5,145
All other fees <sup>(4)</sup>	\$26,775	\$1,260
Total fees	\$158,130	\$46,943

- (1) These fees include professional services provided by the external auditor for the statutory audits of the annual financial statements.
- (2) These fees relate to consulting on financial accounting and reporting standards and issues and performing review engagement services on the Company's quarterly financial statements.
- (3) These fees include professional services for tax compliance, tax advice, tax planning and advisory services relating to the preparation of corporate tax, capital tax and commodity tax returns.
- (4) These fees include professional services for reporting and fling requirements related to the Plan of Arrangement with Aurinia Pharma Corp.

## SCHEDULE 1A - AUDIT COMMITTEE CHARTER

## AURINIA PHARMACEUTICALS INC.

## **AUDIT COMMITTEE CHARTER**

The term "Company" refers to Aurinia Pharmaceuticals Inc., the term "Board" refers to the board of directors of the Company.

#### **PURPOSE**

The Audit Committee (the "Committee") is a standing committee appointed by the Board to assist the Board in fulfilling its oversight responsibilities with respect to the Company's financial reporting including responsibility to:

- oversee the integrity of the Company's consolidated financial statements and financial reporting process, including the audit process and the Company's internal accounting controls and procedures and compliance with related legal and regulatory requirements;
- oversee the qualifications and independence of the Company's external auditors;
- oversee the work of the Company's financial management and external auditors in these areas; and
- provide an open avenue of communication between the external auditors, and the Board and the officers (collectively, "Management") of the Company.

In addition, the Committee will review and/or approve any other matter specifically delegated to the Committee by the Board.

## COMPOSITION AND PROCEDURES

In addition to the procedures and powers set out in any resolution of the Board, the Committee will have the following composition and procedures:

## 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.

## 4. Separate Executive Meetings

The Committee will endeavour to meet at least once every quarter, if required, and more often as warranted, with the Chief Financial Officer and the external auditors in separate executive sessions to discuss any matters that the Committee or each of these groups believes should be discussed privately.

#### **5.** Professional Assistance

The Committee may retain special legal, accounting, financial or other consultants to advise the Committee at the Company's expense.

#### 6. Reliance

Absent actual knowledge to the contrary (which will be promptly reported to the Board), each member of the Committee shall be entitled to rely on (i) the integrity of those persons or organizations within and outside the Company from which it receives information, (ii) the accuracy of the financial and other information provided to the Committee by such persons or organizations and (iii) representations made by the Chief Financial Officer, the Company, senior management and the external auditors, as to any information, technology, internal audit and other non-audit services provided by the external auditors to the Company and its subsidiaries.

#### 7. Review of Charter

The Committee will periodically review and reassess the adequacy of this Charter as it deems appropriate and recommend changes to the Board. The Committee will evaluate its performance with reference to this Charter. The Committee will approve the form of disclosure of this Charter, where required by applicable securities laws or regulatory requirements, in the annual proxy circular or annual report of the Company.

# 8. Delegation

The Committee may delegate from time to time to any person or committee of persons any of the Committee's responsibilities that lawfully may be delegated.

# 9. Reporting to the Board

The Committee will report through the Committee Chair to the Board following meetings of the Committee on matters considered by the Committee, its activities and compliance with this Charter.

## SPECIFIC MANDATES OF THE COMMITTEE

The Committee will:

# I. In Respect of the Company's External Auditors

- (a) review the performance of the external auditors of the Company who are accountable to the Committee and the Board as the representatives of the shareholders of the Company, including the lead partner of the independent auditor team and make recommendations to the Board as to the reappointment or appointment of the external auditors of the Company to be proposed in the Company's proxy circular for shareholder approval and shall have authority to terminate the external auditors;
- (b) review the reasons for any proposed change in the external auditors of the Company which is not initiated by the Committee or Board and any other significant issues related to the change, including the response of the incumbent auditors, and enquire as to the qualifications of the proposed replacement auditors before making its recommendation to the Board;
- (c) approve the terms of engagement and the compensation to be paid by the Company to the Company's external auditors;
- (d) review the independence of the Company's external auditors, including a written report from the external auditors respecting their independence and consideration of applicable auditor independence standards;
- (e) approve in advance all permitted non-audit services to be provided to the Company or any of its affiliates by the external auditors or any of their affiliates, subject to any *de minimus* exception allowed by applicable law; the Committee may delegate to one or more designated members of the Committee the authority to grant pre-approvals required by this subsection;
- (f) review the disclosure with respect to its pre-approval of audit and non-audit services provided by the Company's external auditors;
- (g) approve any hiring by the Company or its subsidiaries of employees or former employees of the Company's external auditors;
- (h) review a written or oral report describing:
  - (i) critical accounting policies and practices to be used in the Company's annual audit,
  - (ii) alternative treatments of financial information within generally accepted accounting principles that have been discussed with Management and that are significant to the Company's consolidated financial statements, ramifications of the use of such alternative disclosures and treatments, and the treatment preferred by the external auditors, and
  - (iii) other material written communication between the Company's external auditors and Management, such as any management letter or schedule of unadjusted differences;
- (i) review with the external auditors and Management the general audit approach and scope of proposed audits of the consolidated financial statements of the Company, the objectives, staffing, locations, co-ordination and reliance upon Management in the audit, the overall audit plans, the audit procedures to be used and the timing and estimated budgets of the audits;
- (j) if a review engagement report is requested of the external auditors, review such report before the release of the Company's interim consolidated financial statements;

(k) discuss with the external auditors any difficulties or disputes that arose with Management during the course of the audit, any restrictions on the scope of activities or access to requested information and the adequacy of Management's responses in correcting audit-related deficiencies;

## II. In Respect of the Company's Financial Disclosure

- (a) review with the external auditors and Management:
  - (i) 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 Chairman of the Board, 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;
  - (ii) the Company's interim consolidated financial statements and the notes and Managements' Discussion and Analysis relating to such consolidated financial statements, the recommendations for approval of each of the foregoing from each of the Chairman of the Board, 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;
  - (iii) the quality, appropriateness and acceptability of the Company's accounting principles and practices used in its financial reporting, changes in the Company's accounting principles or practices and the application of particular accounting principles and disclosure practices by Management to new transactions or events;
  - (iv) all significant financial reporting issues and judgments made in connection with the preparation of the Company's consolidated financial statements, including the effects of alternative methods in respect of any matter considered significant by the external auditor within generally accepted accounting principles on the consolidated financial statements and any "second opinions" sought by Management from an independent or other audit firm or advisor with respect to the accounting treatment of a particular item:
  - (v) the effect of regulatory and accounting initiatives on the Company's consolidated financial statements and other financial disclosures;
  - (vi) any reserves, accruals, provisions or estimates that may have a significant effect upon the consolidated financial statements of the Company;
  - (vii) the use of special purpose entities and the business purpose and economic effect of off balance sheet transactions, arrangements, obligations, guarantees and other relationships of the Company and their impact on the reported financial results of the Company;
  - (viii) any legal matter, claim or contingency that could have a significant impact on the consolidated financial statements, the Company's compliance policies and any

- material reports, inquiries or other correspondence received from regulators or governmental agencies and the manner in which any such legal matter, claim or contingency has been disclosed in the Company's consolidated financial statements;
- review the treatment for financial reporting purposes of any significant transactions that are not a normal part of the Company's operations;
- (x) the use of any "pro forma" or "adjusted" information not in accordance with generally accepted accounting principles;
- (b) review and resolve disagreements between Management and the Company's external auditors regarding financial reporting or the application of any accounting principles or practices;
- (c) review earnings press releases, as well as financial information and earnings guidance provided to analysts and ratings agencies, it being understood that such discussions may, in the discretion of the Committee, be done generally (i.e., by discussing the types of information to be disclosed and the type of presentation to be made) and that the Committee need not discuss in advance each earnings release or each instance in which the Company gives earning guidance;
- (d) establish and monitor procedures for the receipt and treatment of complaints received by the Company regarding accounting, internal accounting controls or audit matters and the anonymous submission by employees of concerns regarding questionable accounting or auditing matters and review periodically with the Management these procedures and any significant complaints received; and
- (e) review and discuss the Company's major financial risk exposures and the steps taken to monitor and control such exposures, including the use of any financial derivatives and hedging activities.

## **III.** In Respect of Insurance

(a) review periodically insurance programs relating to the Company and its investments;

## IV. In Respect of Internal Controls

- (a) review the adequacy and effectiveness of the Company's internal accounting and financial controls based on recommendations from Management and the external auditors for the improvement of accounting practices and internal controls;
- (b) oversee compliance with internal controls and the Code of Business Conduct;

## V. In respect of Other Items

- (a) on an annual basis review and assess committee member attendance and performance and report thereon to the Board and review this Charter and, if required implement amendments to this Charter;
- (b) on a quarterly basis review compliance with the Disclosure Policy of the Company; and
- (c) on a quarterly basis review any related-party transactions.

#### **OVERSIGHT FUNCTION**

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 member who is identified as having accounting or related financial expertise, like the role of all 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.