



# AEQUUS PHARMACEUTICALS INC.

## // ANNUAL INFORMATION FORM

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2019

APRIL 28, 2020

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## TERMS OF REFERENCE

In this annual information form, a reference to the “Company”, “Aequus”, “we”, “us”, “our” and similar words refer to Aequus Pharmaceuticals Inc. and its subsidiary, Aequus Pharma (Canada) Ltd., formerly TeOra Health Ltd. (“TeOra”), or either one of them, as the context requires.

This annual information form includes references to trade names and trade-marks of other companies, which trade names and trade-marks are the property of their respective owners.

Statistical information and other data relating to the pharmaceutical and biotechnology industry included in this annual information form are derived from industry reports published by industry analysts, industry associations and/or independent consulting and data compilation organizations. Market data and industry forecasts used throughout this annual information form were obtained from various publicly available sources. Although we believe that these independent sources are generally reliable, the accuracy and completeness of such information is not guaranteed and has not been independently verified.

The information set forth in this annual information form is as of December 31, 2019, unless another date is indicated. All references to dollars (\$) in this document are expressed in Canadian funds, unless otherwise indicated.

## CAUTION REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS

Certain statements and information in this annual information form contain forward-looking statements or forward-looking information under applicable Canadian securities legislation that may not be based on historical fact, including, without limitation, statements containing the words “believe”, “may”, “plan”, “will”, “estimate”, “continue”, “anticipate”, “intend”, “expect”, “predict”, “project”, “potential”, “continue”, “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words and similar expressions.

Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as the factors we believe are appropriate. Forward-looking statements in this annual information form include, but are not limited to, statements relating to:

- our ability to obtain funding for our operations, including funding for research and commercial activities;
- our ability to promote and market third party products and the anticipated timing thereof, including our ability to successfully market tacrolimus immediate-release (“Tacrolimus IR”), Vistitan™ and Evolve® in Canada;
- our anticipated regulatory submissions and commercial activities in Canada in respect of Topiramate XR, Oxcarbazepine XR and Evolve®;
- the expected benefits of Tacrolimus IR, Vistitan™, Topiramate XR, and Evolve®;
- our estimates of the size and characteristics of the potential markets for Tacrolimus IR, Vistitan, Topiramate XR, Evolve® and our internal product candidates;
- the Company’s development of its cannabinoid programs (AQS1304);
- the initiation, timing, cost, progress and success of our research and development programs, pre-clinical studies and clinical trials;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit sufficient numbers of patients for our future clinical trials;
- our ability to achieve profitability;

- our ability to establish and maintain relationships with collaborators with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts;
- whether our third-party collaborators will maintain their intellectual property rights in the technology we license;
- the manufacturing capacity of third-party manufacturers for our product candidates;
- the implementation of our business model and strategic plans;
- our ability to develop and commercialize product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, provincial and foreign regulatory requirements;
- whether we will receive, and the timing and costs of obtaining a development and commercial partner for our product candidates;
- the therapeutic benefits, effectiveness and safety of our product candidates;
- the rate and degree of market acceptance and clinical utility of our future products, if any;
- the timing of, and our ability and our collaborators' ability, if any, to obtain and maintain regulatory approvals for our product candidates;
- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- our ability to engage and retain the employees or consultants required to grow our business;
- the compensation that is expected to be paid to employees and consultants of the Company;
- our future financial performance and projected expenditures;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available; and
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing.

Such forward-looking statements reflect our current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Aequus as of the date of such statements, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements. In making the forward looking statements included in this annual information form, the Company has made various material assumptions, including but not limited to: (i) obtaining positive results of clinical trials; (ii) obtaining regulatory approvals; (iii) general business and economic conditions; (iv) the Company's ability to successfully out-license or sell its current products and in-license and develop new products; (v) the assumption that our current good relationships with our manufacturer and other third parties will be maintained; (vi) the availability of financing on reasonable terms; (vii) the Company's ability to attract and retain skilled staff; (viii) market competition; (ix) the products and technology offered by the Company's competitors; (x) the Company's ability to protect patents and proprietary rights; and (xi) the Company's ability to integrate acquired or licensed products into the Company's existing pipeline and sales infrastructure.

By their very nature, forward-looking statements or information involve known and unknown risks, uncertainties and other factors that may cause our actual results, events or developments, or industry results, to be materially different from any

future results, events or developments expressed or implied by such forward-looking statements or information. In evaluating these statements, current and prospective shareholders should specifically consider various factors, including the risks outlined herein, under the heading “*Risk Factors*”. Some of these risks and assumptions include, without limitation, risks related to:

- Aequus having a limited history of generating revenue by promoting third party products;
- Aequus currently generating revenue from a limited number of promotional or distribution services agreements;
- Aequus being subject to potential product liability claims relating to third-party products it markets;
- Aequus having continued access to skilled contractors and consultants;
- Aequus’ third-party products potentially being subject to sales quotas and additional regulatory approvals;
- third-party products not achieving market acceptability;
- third parties that Aequus is reliant on may not meet their commitments with respect to their products;
- Aequus not having reached profitability to date and the risk that the Company may never become profitable;
- Aequus having incurred operating losses since its inception and expecting to incur losses for the foreseeable future;
- Aequus being unable to complete the development or commercialization of its product candidates or obtain their regulatory approval if it fails to obtain the necessary capital to fund its operations;
- Aequus raising additional capital, which may restrict operations or cause dilution to Aequus’ existing shareholders;
- Aequus’ business to date and future viability being hard for investors to evaluate due to Aequus having a limited history with marketed drug products produced by third parties;
- Aequus having a history of negative operating cash flow, which may continue into the future;
- Aequus not having obtained regulatory approval in any country for any of its internal product candidates;
- Aequus never having submitted, and the potential that it may never be able to submit, an investigational new drug application or NDA (as defined below) in the United States for any of its internal product candidates;
- Aequus potentially being required to abandon development of a product if clinical trials are not successful;
- Aequus conducting clinical trials in sites outside the U.S. and the potential that the FDA (as defined below) may not accept such data;
- further clinical trials for Topiramate XR and Oxcarbazepine XR potentially being required, since Health Canada may require different data packages than the FDA;
- regulatory approval of Aequus’ products being delayed or unobtainable if additional time or studies are required;
- regulatory approval or sales being affected if Aequus’ product candidates or promoted third party products cause adverse effects;
- the success of AQS1303 partially depending on data not developed by Aequus, but which the FDA may rely on when reviewing Aequus’ NDA;
- the commercial success of Aequus’ product candidates being substantially dependent on forming a third-party partnership;

- the difficulty of profitably selling Aequus' product candidates or promoted third party products if their coverage and reimbursement is limited;
- third party agreements to market and sell Aequus' product candidates outside of Canada potentially being unobtainable;
- Aequus' potential international business relationships adversely affecting its business;
- Aequus' sales and marketing infrastructure potentially being unable to generate enough revenue to cover commercial expenses;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available;
- potential legislation increasing the difficulty and cost for Aequus to obtain marketing approval of and to commercialize product candidates;
- Aequus' product candidate being subject to labeling and other restrictions;
- third party coverage, reimbursement, cost containment initiatives, and treatment guidelines potentially constraining Aequus' future revenue;
- Aequus' reliance on third party manufacturing for their clinical and commercial supply;
- Aequus being subject to penalties if it fails to comply with regulatory requirements or experiencing unanticipated problems with its product candidates;
- Aequus' future collaboration arrangements potentially adversely affecting the development and commercialization of Aequus' product candidates;
- Aequus being subject to extensive regulatory review and potentially expensive ongoing obligations even if marketing approval for its product candidates is obtained;
- receiving marketing approval for AQS1303 or AQS1304 in other countries not being guaranteed, even if these product candidates receive marketing approval in the U.S.;
- adverse effects on Aequus' business if Aequus fails to obtain FDA or Health Canada approval for any proposed product candidates;
- Aequus' relationships with physicians, customers and payors being subject to various laws and regulations, which could expose Aequus to various adverse consequences that could diminish profits and future earnings;
- Aequus potentially not being able to protect its proprietary technology in the marketplace;
- Aequus' intellectual property portfolio being comprised of pending patent applications, which may turn out to be unsuccessful or limited in scope;
- Aequus potentially not being able to enforce its intellectual property rights throughout the world;
- Patent reform legislation in the U.S. increasing the uncertainty and cost of prosecuting and defending patents;
- obtaining and maintaining patent protection being contingent on ongoing compliance with various requirements imposed by governmental patent agencies;
- Aequus or its consultants or contractors potentially infringing, or facing claims it infringed on, third party intellectual property rights, including know-how or trade secrets;
- Aequus potentially being unable to adequately prevent disclosure of trade secrets and other proprietary information;

- potential lawsuits relating to infringement of intellectual property rights, which could be costly, time consuming, and adversely impact the price of Common Shares;
- potential intellectual property disputes distracting Aequus' personnel and causing diversion of substantial resources;
- Aequus' growth and profitability being contingent on successfully maintaining and building additional third party partnerships or commercializing its internal products;
- Aequus being unable to license or acquire additional product candidates or technologies from third parties;
- potential changes in laws, regulations and guidelines relating to marijuana impacting the business, results of operations and financial condition of the company;
- Aequus' acquired cannabinoid transdermal patch (AQS1304) potentially attracting negative publicity or consumer perception;
- the future success of AQS1304 being dependent in part on additional states in the U.S. legalizing medical marijuana;
- the fact that marijuana remains illegal under United States federal law;
- Aequus potentially having difficulty accessing the service of U.S. banks due to AQS1304;
- Aequus' business activities potentially being adversely impacted by the recent outbreak of the novel coronavirus (COVID-19);
- successful implementation of Aequus' business strategy being dependent on attracting and retaining highly qualified personnel;
- potential product liability lawsuits being brought against Aequus and any liabilities incurred potentially limiting commercialization of product candidates;
- any potential benefits of the collaboration with Sandoz or Medicom (as defined below) or any further strategic alliances that Aequus enters into not being realized;
- Aequus' business being affected by macroeconomic conditions;
- Aequus incurring significant costs and devoting substantial time to compliance initiatives;
- potential business interruptions delaying development of Aequus' product candidates and disrupting sales;
- Aequus' business and operations suffering in the event of system failures;
- Aequus' business potentially being significantly harmed by misconduct perpetrated by non-arm's length parties;
- the directors and officers of Aequus being subject to conflicts of interest;
- future sales or issuances of Aequus' securities causing the market price of Aequus' equity securities to decline;
- the Common Share price fluctuating significantly;
- Aequus potentially being subject to securities litigation, which is expensive and could divert management attention;
- Aequus' existing shareholders, officers, and directors being able to exert significant control over matters submitted to Aequus' shareholders for approval due to their substantial equity ownership;
- potential future sales of Common Shares by existing shareholders causing the Common Share price to decline;

- Aequus not being required to make representations relating to the establishment and maintenance of disclosure controls and procedures and internal control over financial reporting due to its status as a venture issuer;
- Aequus never having paid, and not anticipating paying, dividends on its Common Shares;
- the price of Common Shares potentially declining due to equity research analysts publishing negatively about Aequus' business, or not publishing about Aequus' business at all; and
- anti-takeover provisions in Aequus constating documents potentially discouraging third parties from making takeover bids that could benefit Aequus' shareholders.

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined herein under the heading "*Risk Factors*". Should one or more of these risks or uncertainties, or a risk that is not currently known to us materialize, or should assumptions underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this annual information form and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by applicable securities laws. Investors are cautioned that forward-looking statements are not guarantees of future performance and are inherently uncertain. Accordingly, investors are cautioned not to put undue reliance on forward-looking statements.

## CORPORATE STRUCTURE

The Company was incorporated under the name "Aequus Pharmaceuticals Inc." pursuant to the *Business Corporations Act* (British Columbia) (the "BCBCA") on January 3, 2013. The Company's registered and records office is located at Suite 2600, 595 Burrard Street, Vancouver, British Columbia, Canada V7X 1L3 and its head office is located at Suite 2820, 200 Granville Street, Vancouver, British Columbia, Canada V6C 1S4.

In July 2015, the Company acquired a 100% interest in TeOra, a company incorporated under the BCBCA on October 6, 2014. Subsequent to the acquisition, TeOra changed its name to Aequus Pharma (Canada) Ltd. ("Aequus Canada"). Aequus Canada is the Company's only subsidiary.

The Company's outstanding common shares (the "Common Shares") trade on the TSX Venture Exchange (the "TSX-V") under the symbol "AQS" and on the OTCQB® Venture Marketplace in the United States under the symbol "AQSZF".

## GENERAL DEVELOPMENT OF THE BUSINESS

Aequus is a specialty pharmaceutical company, with a focus on commercializing value-add products in specialty therapeutic areas in the Canadian market. Aequus' sales force currently markets third party products for which the Company receives revenues based on agreed upon percentages of net sales. The Company continues to build its pipeline in ophthalmology and has recently added a number of near-commercial stage products through in-licensing agreements.

Our commercial infrastructure is Canadian-based, with specialty sales representatives currently promoting two specialty medicines to physicians. We leverage the unique demographics in Canada, such as a highly-concentrated population, to have an efficient sales force with diverse product offerings grown through promotional partnership agreements, asset acquisitions, and in-licenses.

Our commercial programs are supported and validated by insights from patients, physicians and payers to ensure there is a realizable benefit for them from our work in advancing these products. Aequus' management team has a proven track record of successfully managing the required clinical development, regulatory approval processes and marketing of products either directly or through collaborations. We continue to leverage our internal capabilities and know-how to execute an efficient commercial strategy and development plan to drive shareholder value.



## Three Year Development

### Recent developments subsequent to December 31, 2019

On January 10, 2020, the Company advanced the filings for provincial reimbursement in both Quebec and British Columbia for its lead product, Vistitan™ (bimatoprost 0.03%). If successful, this additional coverage would advance sales in the second and third largest markets in Canada and would trigger an increase in the percentage of total revenue that Aequus receives from its partner, Sandoz.

In February 2020, Aequus added Stu Fowler to its team. Mr Fowler is one of the most experienced commercial ophthalmology executives in Canada and has joined the Company in an operational role as a Strategic Commercial Advisor and has been appointed to Aequus' Board of Directors. Mr. Fowler has an impressive background of operational and leadership experience in ophthalmology and is the immediate past General Manager of Alcon in Canada, and past President and General Manager of Allergan Canada, two of the largest ophthalmology companies in Canada and globally. Ian Ball, Chief Commercial Officer of the Company, transitioned to a full-time senior management role with the Company's partner, Medicom Healthcare Ltd. ("Medicom"), as of February 1, 2020.

### Year ended December 31, 2019 Developments

#### Commercial Activities

As of November 4, 2019, a major health authority in the province of British Columbia announced a change to their dispensing formulary for tacrolimus and mandated that Sandoz tacrolimus, co-promoted by Aequus, is to be dispensed for all new patients requiring tacrolimus for prophylaxis of organ rejection in the province of British Columbia.

On July 29, 2019, the Company signed an exclusive distribution agreement with Medicom with terms consistent to the term sheet that was previously announced in March 2019. Under the distribution agreement, Aequus will receive commercial rights to novel portions of Medicom's portfolio of ophthalmology products including the Evolve® line of preservative free dry eye products which contains five commercial stage products, an undisclosed preservative free ophthalmic medication, and the diagnostic eye drop Fluosine for Canada.

The Company has made the decision to terminate the agreement with Mynosys for further promotion of the Zepto Precision Capsulotomy System (the "Zepto System") while modifications to the handpieces are being made by the manufacturer. This decision is not expected to have a material impact on our current 2020 revenue forecast.

On January 1, 2019, Aequus' profit sharing royalty for Tacrolimus and Vistitan was reduced in accordance with the tiered royalty structure in the Sandoz agreement. This change impacts the royalty revenue to Aequus from these products, which is the main factor in the decrease in revenue seen in the first quarter of 2019 compared to previous quarters. This was the final royalty step-down of the agreement. Aequus is eligible to increase the royalty for the duration of the agreement with Sandoz based on milestones tied to market access and product sales.

#### Corporate Activities

The Company issued convertible debenture units (each, a "Convertible Debenture Unit") for gross proceeds of \$2,348,000. Each Convertible Debenture Unit consists of one 9.5% unsecured convertible debenture of the Company in the principal amount of \$1,000 (each, a "Convertible Debenture") and 2,380 common share purchase warrants (each, a "Warrant"). Each Convertible Debenture will be convertible at the option of the holder into common shares of the Company (each, a "Debenture Share") at a conversion price of \$0.21 per Debenture Share, with interest payable semi-annually in arrears on June 30 and December 31 of each year and maturing May 2, 2022. Each Warrant entitles the holder thereof the right to

purchase one common share of the Company (a "Warrant Share") at an exercise price of \$0.22 per Warrant Share at any time up to May 2, 2022. The offering of Convertible Debenture Units was led by Mackie Research Capital Corporation as the lead agent and sole bookrunner (the "Agent") pursuant to the terms and conditions of an agency agreement dated April 25, 2019 between the Agent and the Company (the "Agency Agreement"). The Convertible Debentures and Warrants are governed by a debenture indenture (the "Debenture Indenture") and warrant indenture (the "Warrant Indenture"), respectively, each dated May 2, 2019 and between the Corporation and Computershare Trust Company of Canada.

#### Year ended December 31, 2018 Developments

On January 11, 2018, Aequus announced a collaboration with CannaRoyalty Corp. ("CannaRoyalty") to advance a suite of cannabis-based therapies targeting neurological disorders into clinical trials in Canada, in collaboration with Canadian physicians and opinion leaders. CannaRoyalty is expected to contribute its 10% equity stake in Bodhi Research & Development Inc. into the collaboration in exchange for an initial ownership position in the collaboration, subject to satisfaction of certain conditions and approvals.

On January 31, 2018, the Company closed a public offering of 1,000,000 units (the "January 2018 Units") at a price of \$0.30 per January 2018 Unit, for aggregate gross proceeds to the Company of \$300,000 (the "January 2018 Offering"), pursuant to the terms of a subscription agreement between the Company and a single subscriber. Each January 2018 Unit issued under the January 2018 Offering is comprised of one Common Share and one common share purchase warrant (each, a "January 2018 Warrant"). Each January 2018 Warrant is exercisable to acquire one Common Share for a period of two years following the closing date of the January 2018 Offering at an exercise price of \$0.50 per Common Share, subject to adjustment in certain events. In the event that the volume weighted average trading price of the Company's Common Shares on the TSX-V is greater than \$0.85 per Common Share for a period of 10 consecutive trading days, the Company may accelerate the expiry date of the January 2018 Warrants by giving notice to the holders thereof by way of press release and in such case the January 2018 Warrants will expire on the 30<sup>th</sup> day after such notice is given.

On March 5, 2018, Aequus entered into a collaboration agreement with Ehave, Inc. ("Ehave") on terms consistent with the August 28, 2017 Ehave LOI (as defined below), whereby Aequus will incorporate Ehave's bioinformatics platform to enhance and streamline data management process for Aequus-sponsored clinical trials studying specific cannabinoid-rich formulations for treating a number of neurological disorders. Aequus will pay Ehave a per-patient fee for trials, and Aequus will receive patient assessment, diagnostic and therapeutic outcomes and side-effect profile content from formal and informal studies. Aequus will also own all clinical results and data generated from trials using the Ehave platform.

On March 19, 2018, Aequus announced that it had been awarded a three-year contract, effective as of May 2018, with Sigma Santé for its partnered product, tacrolimus IR, an immunosuppressive therapy used concomitantly with adrenal corticosteroids to prevent or treat rejection following organ transplant and for the reduction of symptoms experienced by patients with rheumatoid arthritis.

On April 12, 2018, Aequus announced that it had entered into a commercial agreement (the "Mynosys Agreement") with Mynosys Cellular Devices ("Mynosys") for the Canadian distribution, sales and marketing of the Zepto System for cataract surgery. The Mynosys Agreement had an initial term of three years, with automatic and continuous renewal for additional three-year terms, provided that Aequus meets minimum sales targets. In 2019, the Company made the decision to terminate the Mynosys Agreement. See "*Year ended December 31, 2019 Developments*" above.

On May 2, 2018, Aequus received positive feedback from the United States Food and Drug Administration (the "FDA") on the Company's pre-Investigational New Drug submission ("Pre-IND") for the Company's long-acting anti-nausea transdermal patch, AQS1303. Through the pre-IND feedback, the Company has received clear regulatory guidance for AQS1303. The FDA confirmed that the planned Section 505(b)(2) abbreviated regulatory pathway, which allows for the

Company to reference safety and efficacy data of the original oral tablet Diclegis®, is appropriate for submission in a New Drug Application (“NDA”) for the program in the United States.

On June 19, 2018 Aequus expanded its relationship with Corium International, Inc. (“Corium”) to include the Company’s long-acting transdermal patch, AQS1303, for the treatment of nausea and vomiting in pregnancy. Under the terms of the collaboration agreement between the Company and Corium dated April 28, 2015 (the “Corium Collaboration Agreement”), Corium will use its Corplex™ technology to improve the clinical performance of AQS1303 and will be the exclusive clinical and commercial manufacturer for the product.

On July 15, 2018 Aequus extended the term and improved the economics for its promotional service agreement with Sandoz for Vistitan™ (“Vistitan™”). Aequus began promotional efforts in May 2016 for Vistitan™ (bimatoprost 0.03%, ophthalmic solution), which is approved in Canada for the reduction of elevated intraocular pressure (“IOP”) in patients with open angle glaucoma or ocular hypertension. Under the previous agreement, Aequus and Sandoz split revenues based upon an agreed to tiered structure over the term. The term has been extended to June 2021, with an option for renewal if mutually agreed to.

On July 30, 2018, the Company closed a public offering of 4,000,000 units (the “July 2018 Units”) at a price of \$0.20 per July 2018 Unit, for aggregate gross proceeds to the Company of \$800,000 (the “July 2018 Offering”), pursuant to the terms of a subscription agreement between the Company and a single subscriber. Each July 2018 Unit issued under the July 2018 Offering is comprised of one Common Share and one-half share purchase warrant (a “July 2018 Warrant”) where one whole warrant is exercisable at a price of \$0.30 for a period of 48 months under the prospectus supplement to the Company’s base shelf prospectus.

On August 8 and 10, 2018, the Company closed, in two tranches, a non-brokered private placement of 3,875,000 units (the “August 2018 Units”) at a price of \$0.20 per August 2018 Unit, for aggregate gross proceeds to the Company of \$775,000 (the “August 2018 Financing”). Each August 2018 Unit issued under the August 2018 Financing is comprised of one Common Share and one-half share purchase warrant (a “August 2018 Warrant”) where one whole warrant is exercisable at a price of \$0.30 for a period of 48 months under the prospectus supplement to the Company’s base shelf prospectus. The Company paid a fee to certain arm’s length finders in connection with the Units issued to investors introduced to the Company by the Finders, consisting of (i) a 7% cash payment on certain subscriptions in the aggregate amount of \$33,250 and (ii) issued an aggregate of 166,250 Common Share purchase warrants.

On November 4, 2018, Aequus formed a Strategic Advisory Board in ophthalmology to assist in assessing and rationalizing the many ophthalmology pipeline opportunities, both in therapeutics and medical devices, available to the Company. The Advisory Board will help Aequus in determining whether a product can improve patient outcomes, integrate into a clinician’s workflow, and navigate the Canadian reimbursement and commercial landscape.

On December 16, 2018 Aequus signed a term sheet with Medicom in December for an undisclosed preservative-free therapeutic in ophthalmology. The preservative free therapeutic is a prescription product, currently approved in certain countries in Europe. Aequus has previously met with Health Canada to receive regulatory guidance regarding this therapeutic and expects to submit an application for regulatory approval in the second half of 2019 for this product, with minimal additional analytical data required to complete the data package.

#### Year ended December 31, 2017 Developments

On January 9, 2017, the Company received approval from Health Canada to initiate a multi-dose POC study to evaluate the bioavailability and safety of the Company’s once-weekly transdermal patch in healthy volunteers for aripiprazole, AQS1301. The study completed dosing on February 14, 2017 with positive results announced on April 3, 2017. As was predicted, steady state of aripiprazole, AQS1301 was reached in week three of dosing, with relative concentrations of

aripiprazole and its active metabolite, comparable to oral dosing. There were no serious adverse events or safety concerns. Following the results of this study, the Company anticipates meeting with the FDA for a pre-IND meeting to define the clinical strategy for regulatory approval in the United States.

On February 1, 2017, Aequus announced that it will receive funding from the National Research Council of Canada Industrial Research Assistance Program to support the multi-dose POC study of its lead product candidate, AQS1301. Aequus expects the final amount of the funding to be approximately \$90,000.

On March 2, 2017, in connection with the Company's previously announced Research Service Contract (as defined below) with Transdermal Research Pharm Laboratories LLC ("TRPL"), the Company entered into a term sheet to acquire an exclusive world-wide license to a transdermal patch containing cannabinoids for use in the treatment of epilepsy, Multiple Sclerosis and certain other neurological disorders.

On March 13, 2017, the Company closed a public offering of 17,250,000 units (the "2017 Units") at a price of \$0.30 per 2017 Unit, for aggregate gross proceeds to the Company of \$5,175,000 (the "2017 Offering"), pursuant to the terms of an underwriting agreement (the "Underwriting Agreement") dated March 6, 2017 between the Company and Canaccord Genuity Corp. (the "Underwriter").

Each 2017 Unit issued under the 2017 Offering was comprised of one Common Share and one-half of one common share purchase warrant (each whole common share purchase warrant, a "2017 Warrant"). Each 2017 Warrant was exercisable to acquire one Common Share for a period of two years following the closing date of the 2017 Offering at an exercise price of \$0.45 per share, subject to adjustment in certain events. In addition, Aequus issued to the Underwriter a total of 862,500 broker warrants (the "Broker Warrants") in connection with the 2017 Offering. Each such Broker Warrant entitled the holder to acquire a 2017 Unit at an exercise price of \$0.30 per 2017 Unit for a period of two years following the closing of the 2017 Offering.

On April 3, 2017, Aequus announced results from its second POC study designed to evaluate pharmacokinetics, safety and tolerability following repeat exposure of its once-weekly aripiprazole transdermal patch, AQS1301, for the treatment of certain psychiatric disorders. The study demonstrated that steady state was achieved in week three of dosing in healthy volunteers, with comparable plasma concentrations to the orally delivered form of aripiprazole, Abilify®.

On May 15, 2017, Aequus announced results from a medical cannabis needs assessment survey it deployed involving 410 physicians in Canada and the United States. Aequus sought to understand the current attributes and therapeutic use of cannabis in the medical community including the delivery of cannabis, the limitations of use, the perceived benefits and risks in specific indications, and the gaps in knowledge in the field from a prescriber's perspective. Findings from the survey highlighted the medical need for improved clinical trial data to support safety and efficacy of medical cannabis, reliability of dose delivery systems, high quality data collection tracking real world clinical outcomes, physician education and quality-controlled ingredients.

On June 1, 2017, Aequus entered into a broad research collaboration with the Centre for Drug Research and Development to establish pre-clinical safety and efficacy of select cannabinoid-based therapeutics targeting neurological movement disorders including epilepsy, Multiple Sclerosis, Parkinson's disease and Huntington's disease.

On July 4, 2017, Aequus announced that it had received approval from Health Canada to initiate a POC clinical trial to evaluate the bioavailability and safety of Aequus' long-acting transdermal anti-nausea patch, AQS1303. The Company plans to initiate a single-dose cross-over comparative bioavailability study versus the currently approved oral version, in nine healthy volunteers.

On August 1, 2017, Aequus entered into a non-binding term sheet with Scientus Pharma, Inc. ("Scientus") on a collaboration to develop, assess clinical performance and commercialize a cannabinoid containing transdermal formulation designed and optimized to address both acute and chronic treatment of Resistant Epilepsy and certain other neurological disorders.

On August 24, 2017, Aequus announced that it had received positive feedback from the FDA to pursue the abbreviated Section 505(b)(2) clinical pathway for the Company's once-weekly transdermal aripiprazole patch, AQS1301. Upon review of the Company's pre-investigated New Drug Application submission, the FDA agreed that AQS1301 is a suitable candidate for the Section 505(b)(2) regulatory pathway for approval in the United States.

On August 28, 2017, Aequus entered into a collaboration with Ehave (the "Ehave LOI") whereby Aequus gained access to Ehave's bioinformatics platform for use in Aequus' anticipated clinical trials for its portfolio products, with an initial focus in neurology. Aequus will pay Ehave a per-patient fee for trials conducted using Ehave's platform. bioinformatics platform and will receive patient assessment, diagnostic and therapeutic outcomes and side-effect profiles content from formal and informal studies conducted using the Ehave platform, subject to standard patient consent and clinical research and ethics approvals. Aequus will own all clinical results and data generated from trial using the Ehave platform.

On September 7, 2017, Aequus announced positive results from an initial POC clinical study for AQS1303. This single-dose crossing-over comparative bioavailability study versus the currently approved oral version was successfully completed in nine healthy female volunteers. The results suggested that sustained delivery of therapeutic levels of active ingredients through the skin over a multi-day period is possible with the current formulation. The formulation was tolerated with no adverse events reported.

On October 10, 2017, Aequus announced that the State Intellectual Property Office of the People's Republic of China had granted a Chinese patent to Aequus' once-weekly transdermal patch containing aripiprazole, in development for the treatment of certain psychiatric disorders. This expands the patent portfolio for AQS1301 with a patent issued/allowed in six other major countries or regions to date, namely the United States, Russia, Mexico, Japan, Australia, and Canada.

On November 16, 2017, Aequus announced that the European Patent Office had issued an intention to grant a European patent for AQS1301. AQS1301 is in development for the treatment of certain psychiatric disorders and is intended to provide patients with a long-acting dosing alternative that is comfortable, convenient and easy-to-use in an effort to promote medication adherence. This patent covers 37 nations across Europe and provides intellectual property protection in the second largest antipsychotic market globally.

## DESCRIPTION OF THE BUSINESS

### Aequus' Business Strategy

Aequus is a revenue-generating, specialty pharmaceutical company with commercial activities in Canada. Aequus looks to leverage its core capabilities, commercial infrastructure and existing product portfolio to continue on the Company's current growth trajectory. The Company's near-term growth strategy includes the following key components:

- Progressive build-out of the Company's commercial platform, including leveraging its specialty sales force in Canada to enable Aequus to continue to in-license and sell high-value, branded products in Canada.
- Advance near commercial stage programs through Health Canada required studies.

Aequus has launched promotional activities for three third-party products in the Canadian market. Aequus has also in-licensed two near commercial stage neurology programs, and in July 2019, Aequus announced a deal with Medicom for

nine additional ophthalmology products for Canada, with a number of these products expected to receive Health Canada approval and be commercially launched in 2020. These activities support the key areas of Aequus' growth strategy.

Aequus expects to continue to make select investments aimed at expanding and improving the efficiency of its sales channel in Canada through a combination of in-licensing and the acquisition of high-quality, differentiated products in specialty therapeutic areas.

#### Key Strategic Collaborations

##### *SANDOZ CANADA, INC.*

In October 2015, Aequus became the exclusive promotional and marketing partner for the first to market generic form of Tacrolimus IR. This product had already been approved by Health Canada. Aequus began promoting Tacrolimus IR for the treatment and prevention of acute rejection following organ transplantation in December 2015.

In April 2016, Aequus launched promotional efforts in Canada for Vistitan™, a treatment for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension. Aequus obtained multiple provincial formulary listings within the first six months of Vistitan's launch, including a Limited-Use drug designation on the Ontario Drug Benefit Plan. In July 2018, Aequus and Sandoz agreed to extend the term of the agreement with improved economics for its promotional service agreement with Sandoz for Vistitan.

##### *MEDICOM HEALTHCARE LTD.*

In July of 2019, Aequus signed an exclusive distribution agreement with Medicom, a United Kingdom based pharmaceutical company with a focus on preservative free therapies in ophthalmology. Under the distribution agreement, Aequus will receive commercial rights to novel portions of Medicom's portfolio of ophthalmology products including the Evolve® line of preservative free dry eye products which contains five commercial products, an undisclosed preservative free ophthalmic medication, and the diagnostic eye drop Fluosine, within Canada.

##### *SUPERNUS PHARMACEUTICALS, INC.*

In February 2016, Aequus entered into an agreement with Supernus which was amended on June 15, 2016 for certain licensing fees ("Supernus Agreement"), whereby the Company acquired the Canadian commercial rights to Topiramate XR and Oxcarbazepine XR. Both products are branded, once-daily, extended-release anti-epileptic drugs ("AEDs"), and have been successfully marketed by Supernus in the U.S. since 2013 under the tradenames Trokendi XR® and Oxtellar XR®, respectively.

Under the terms of the Supernus Agreement, Aequus will be responsible for the regulatory submission and commercial activities for both products in Canada. Supernus is eligible to receive milestone payments and royalties from product sales in Canada. Aequus has since had on-going dialogue with Health Canada around the acceptability of the FDA clinical package and foreign market experience and expects to initiate a small clinical study to support a non-new active substance new drug submission (non-NAS NDS).

During the year ended December 31, 2019, the Company recognized an impairment on the Supernus Agreement of \$478,940 due to the Company's limited ability to pay the future milestone payments in the short term. If management subsequently assesses that the recoverable amount exceeds its carrying value, then the Company would reverse the impairment and the asset will be adjusted to its fair value.

## MYNOSYS CELLULAR DEVICES

In April 2018, Aequus entered into a commercial agreement with Mynosys, an ophthalmology focused medical device company based in Fremont, California, for the Canadian distribution, sales and marketing of Zepto® for cataract surgery. Zepto was approved for sale in Canada by the Therapeutic Products Directorate in February 2018, and through this agreement was launched in Canada by Aequus in the second quarter of 2018.

The Company has made the decision to terminate the agreement with Mynosys for further promotion of the Zepto Capsulotomy System while modifications to the handpieces are being made by the manufacturer. This decision is not expected to have a material impact on our current 2020 revenue forecast.

## Commercial Products & Pipeline



<sup>1</sup> Aequus carries out the Canadian promotional activity for products owned by Sandoz Canada.

Figure 1. Aequus' Canadian commercial pipeline

### TACROLIMUS IR

Aequus began promotional activities for Tacrolimus IR in December, 2015 and receives a tiered revenue split on incremental sales of the product over the established baseline set prior to promotion.

Tacrolimus immediate release is an immunosuppressant used for the treatment and prevention of acute rejection following organ transplantation. Tacrolimus is part of a patient's immunosuppressive therapy prescribed chronically in their lifelong management to prevent graft rejection. Tacrolimus is recommended as a first line calcineurin inhibitor treatment by the BC Transplant consensus guidelines and is prescribed in >90% of new kidney transplant patients (OPTN/SRTR 2014).

Due to the chronic risk of graft rejection, tacrolimus has been classified as a Critical Dose Drug with a Narrow Therapeutic Index. In Canada, tacrolimus is available in an immediate release form, marketed under the brand name of Prograf® in Canada, and in an extended-release form, marketed under the brand name of Advagraf® in Canada. Aequus is promoting the first to market and only currently available generic version of Prograf®.

Aequus has been successful in growing market share for Tacrolimus IR in Canada since the initiation of its promotional efforts, and in March 2018, was awarded a three-year contract with Sigma Santé, one of the largest healthcare group purchasing organizations ("GPO") in Quebec and the final GPO in the province to list this first-to-market, generic version of Tacrolimus IR. Most recently, a major health authority in the province of British Columbia announced a change to their dispensing formulary for tacrolimus mandating that Sandoz tacrolimus, co-promoted by Aequus, is to be dispensed for all



new patients requiring tacrolimus for prophylaxis of organ rejection in the province of British Columbia.

*PRVISTITAN™*

*(bimatoprost 0.03%, ophthalmic solution)*

Aequus' ophthalmology focused salesforce markets a branded ophthalmology product, Vistitan™ (bimatoprost 0.03%, ophthalmic solution). Commercial activities for this product commenced in May 2016. Aequus splits revenues of this product with its partner, Sandoz, in a tiered structure.

Bimatoprost 0.03% is a prostaglandin approved by Health Canada for the reduction of elevated IOP in patients with open angle glaucoma or ocular hypertension. It is estimated that there are over 350,000 people living with glaucoma or ocular hypertension in Canada. The disease is the second leading cause of blindness worldwide. The incidence of glaucoma is highest in patients above the age of 80, but onset may be as early as 40 years of age. IOP-lowering drugs are prescribed as soon as the disease is diagnosed and must be taken chronically to prevent vision loss. Prostaglandins are the first-line approach among IOP-lowering agents, in 2015 bimatoprost accounted for 42% of all prostaglandin prescription volume in Canada (IMS Health).

Vistitan™, which was approved by Health Canada in 2014, is currently the only marketed version of 0.03% bimatoprost ophthalmic solution in Canada for this indication. Since its launch, and with the support of Aequus' promotional efforts, Vistitan™ has been successfully listed among 90% of private payor groups as well as a benefit under key provincial formularies, including the Ontario Drug Benefit Plan, Alberta Health and Manitoba Health.

In a recent study assessing the comparative efficacy of latanoprostene bunod to other treatments for intraocular pressure reduction – the main indicator of glaucoma risk – bimatoprost 0.03%, currently only available in Vistitan™, was found to be the most successful<sup>1</sup>. This study adds to a growing body of evidence that Vistitan™ is the most effective product available for treating glaucoma in Canada.

*EVOLVE DRY EYE PRODUCTS*

Launched in 2015 in Europe, the Evolve® brand has grown to five products across 35 countries with two additional products in development. With an array of products, the brand can address the various symptoms involved with dry eye disease and blepharitis including discomfort, stinging, burning, and dryness. Currently in Canada, the dry eye market is estimated at over \$90M, which includes both prescription and over-the-counter products.

Aequus and Medicom are currently working with Health Canada to review Medicom's manufacturing facility prior to submitting the regulatory package for the Evolve® line of products. Aequus expects to promote these products with the existing commercial infrastructure that details ophthalmologists, optometrists, and pharmacists, allowing for effective and efficient use of resources, and a seamless launch into the Canadian marketplace.

*PRESERVATIVE FREE PRESCRIPTION DRUG*

In July 2019, Aequus completed the formal agreement with Medicom for the promotion of an undisclosed prescription preservative free ophthalmic product in Canada. Under the terms of the agreement Medicom will supply the product while

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1. Harasymowycz PJ, Royer C, Jobin Gervais K, et al. Effectiveness of latanoprostene bunod in treating OAG and OHT: network meta-analysis. Presented at: The American Academy of Ophthalmology (AAO) 2019 Annual Meeting; October 12-15, 2019; San Francisco, California. Abstract PO176.



Aequus will be responsible for marketing, distribution, and sales in Canada upon approval of the product by Health Canada. The Company has previously met with Health Canada to receive regulatory guidance regarding this therapeutic.

### Product Development Pipeline

The Company is committed to focusing on the commercial activities and growing revenues in 2020. The key efforts supported at this time for the Company's product development pipeline is through business development activities, and will continue discussions around advancing Topiramate XR and Oxcarbazepine XR to meet the requirements of Health Canada. An overview of the Company's product development pipeline is provided below. At this time, the Company does not expect to progress AQS1301, a once-weekly transdermal formulation of aripiprazole, in 2020.

### *AQS1303 – LONG-ACTING TRANSDERMAL PYRIDOXINE / DOXYLAMINE*

#### *Key Highlights*

- The combination of pyridoxine / doxylamine currently approved is first-line therapy and the only on-label intervention for nausea and vomiting of pregnancy ("NVP") dosed several times per day;
- Aequus' transdermal alternative provides a non-oral and long-acting alternative to the oral form;
- Initial Proof of Concept clinical study successfully completed in healthy volunteers;
- FDA pre-IND completed in early 2018 with positive feedback confirming approval via the 505(b)(2) accelerated approval pathway in the United States; and
- Corium will utilize its Corplex™ transdermal technology to optimize the product presentation for clinical testing and will be the exclusive clinical and commercial manufacturer for AQS1303.

#### *Product Overview*

Pyridoxine/doxylamine is currently marketed as Diclegis® (United States)/Diclectin® (Canada) for the treatment of NVP, as an oral tablet dosed up to four times per day. Diclegis is the only FDA approved medication for morning sickness in pregnant women and in 2017, reached sales in the United States of approximately US\$186 million. A long-acting transdermal form of pyridoxine/doxylamine is being developed by Aequus to address the risk of missed doses due to emesis (vomiting) and provide consistent symptomatic relief.

Aequus has demonstrated the current formulation can deliver the flux profile in-vitro required for once-daily and up to seven days of therapeutic doses. Aequus completed a Proof of Concept clinical study in September 2017 with results suggesting that sustained delivery of therapeutics levels of the active ingredients through the skin over a multi-day period is possible with the current formulation. The formulation was well tolerated with no serious adverse events reported.

Aequus received positive pre-IND feedback from the FDA, confirming it will likely follow a 505(b)(2) pathway in the United States for AQS1303 approval, which would include a pharmacokinetic bridging strategy, to allow bridging to the safety and clinical pharmacology information from Diclegis®, and a single clinical efficacy study, would likely be acceptable for an NDA submission. The FDA also outlined additional standard studies required of a transdermal patch to evaluate the local safety and to ensure that consistent and predictable dosing is achieved over the dosing period.

Aequus has filed an international patent application with the USPTO that covers transdermal extended-release formulations of the combination of doxylamine and pyridoxine. During Fiscal 2017, the Company advanced the patent application for AQS1303 with PCT national stage filings in the European Region, Canada and Israel, in addition to the U.S.; Aequus owns the worldwide rights to the formulations described in the patent application.

### *AQS1304 - MEDICAL CANNABIS PROGRAM*

Aequus has initiated a research program of cannabinoid-based therapeutics targeting neurological disorders. In 2016, Health Canada provided patients in Canada the ability to access cannabis for medical purposes when recommended by their physician. There are insufficient data, however, for proper therapeutic treatment protocols regarding the proper dosage and frequency for patients dealing with a wide variety of symptoms and disease areas. Aequus has published a survey that confirms the medical need for improved clinical trial data supporting safety and efficacy of medical cannabis, reliability of dose delivery systems, high quality data collection tracking real world clinical outcomes, physician education, and quality-controlled ingredients.

Aequus has formed the following collaborations and steps forward in connection with this program:

- In March 2017, Aequus acquired an exclusive world-wide license to a transdermal patch formulation containing cannabinoids for use in the treatment of epilepsy, Multiple Sclerosis and certain other neurological disorders from TRPL;
- In May 2017, Aequus completed a needs assessment study with over four hundred physicians to validate and select a medical cannabis target product profile that is best suited for the needs of patients;
- In June 2017, Aequus and the Centre for Drug Research and Development entered into a broad research collaboration to establish pre-clinical safety and efficacy of select cannabinoid-based therapeutics targeting certain neurological movement disorders;
- In August 2017, Aequus formed a collaboration with Scientus Pharma, Inc. ("Scientus") to be the development and commercial supplier of specific cannabinoid extracts, with an option for Scientus to co-fund the development of a cannabinoid containing transdermal formulation that would be designed and optimized to address certain neurological disorders;
- In August 2017, Aequus entered into a collaboration with Ehave to access Ehave's bioinformatics platform, providing cost effective and clinically relevant data collection in Aequus' anticipated clinical trials in the medical cannabis regulatory regime.
- In January 2018, Aequus announced a collaboration with CannaRoyalty to advance a suite of cannabis-based therapies targeting neurological disorders into clinical trials in Canada, in collaboration with Canadian doctors and key opinion leaders.
- In March 2018, Aequus announced a collaboration with Ehave for comprehensive patient data management in clinical trials of medical cannabis.

#### *TOPIRAMATE XR*

*(under the tradename of Trokendi XR® in the United States)*

Topiramate XR is a once-daily topiramate product designed to improve patient compliance and to show a better pharmacokinetic profile than the currently available immediate release products, which must be taken multiple times per day. The currently approved immediate release form of topiramate in Canada is approved for use in epilepsy and prophylactic migraine. Topiramate XR's pharmacokinetic profile results in lower peak plasma concentrations, higher trough plasma concentrations, and a slower input rate. This results in smoother and more consistent blood levels of topiramate than immediate release topiramate formulations can deliver. Such a profile may mitigate blood level fluctuations that are frequently associated with many of the symptomatic side effects or breakthrough seizures that patients can suffer when taking immediate release products. Side effects can lead patients to skipping doses, whereupon the increased non-adherence could place them at higher risk for breakthrough seizures.

Aequus has had on-going dialogue with Health Canada regarding the acceptability of the FDA submission data. It is expected that Topiramate XR will be filed as a non-new active substance new drug submission (non-NAS NDS) in Canada, which will require a small pharmacokinetics bridging study. The pharmacokinetics bridging study is required to bridge the United States reference product used in the original Trokendi XR study to a Canadian equivalent reference product to validate the data under Health Canada's regulations.

## *OXCARBAZEPINE XR*

*(under the tradename of Oxtellar XR® in the United States)*

Oxcarbazepine XR is a once-daily oxcarbazepine product with a novel pharmacokinetic profile showing lower peak plasma concentrations, a slower rate of input, higher trough plasma concentrations, and a smoother, more consistent blood levels compared to immediate release products. The currently approved immediate release form of oxcarbazepine in Canada is approved for use in partial seizures in epilepsy. Oxcarbazepine XR has the potential to improve the tolerability of oxcarbazepine and thereby reduce side effects. This could enable more patients to tolerate higher doses of oxcarbazepine which would permit them to benefit from the resulting improved efficacy and greater seizure control, which has previously been reported in patients taking higher doses. Patients taking higher doses of immediate release oxcarbazepine are often unable to tolerate the increased side effects. In addition, Oxcarbazepine XR once-daily dosing regimen, is designed to improve patient compliance compared to the currently available immediate release products that must be taken multiple times per day.

The expected benefits of once-daily extended release forms of anti-epileptic drugs such as Topiramate XR and Oxcarbazepine XR include: (i) improved patient adherence with a once-daily dosing regimen, making it more probable that patients maintain sufficient level of medication in their bloodstream to protect against seizures; (ii) delivery of lower peak plasma concentrations and lower input rate over an extended time period, resulting in smooth and consistent blood levels of topiramate or oxcarbazepine during the day; and (iii) avoidance of blood level fluctuations that can be associated with symptomatic side effects or breakthrough seizures.

## *OUT-LICENSING ACTIVITIES*

Aequus continues to pursue development collaborators and marketing partners for its internal programs in markets outside of Canada, particularly for AQS1303.

## *Commercial Assessments of Market Segments with Unmet Needs*

Aequus has completed commercial and medical-needs assessments of the relevant markets for its development and commercial pipeline products and expects to complete similar assessment for any other proposed product candidates prior to devoting material resources towards the development of such product. These commercial assessments involve input from physicians, patients and payors, a comprehensive investigation of the current and future competitive landscape, pricing and reimbursement dynamics within a therapeutic category, intellectual property and the building of a target product profile that Aequus expects to use to guide clinical development to create a meaningful value proposition to provide benefits to patients, physicians and/or other stakeholders.

## *Preclinical and Clinical Development*

The development of a new dosage form for an already approved drug, such as a change from a solid oral dosage form to a transdermal patch, can rely to some extent on previous safety and/or efficacy data provided by the literature or can reference past findings of safety and effectiveness for the approved drug according to a Section 505(b)(2) NDA with the FDA. Thus, the development timelines and costs associated with the studies required to be conducted by Aequus for approval of AQS1303 as a long-acting combination of Pyridoxine/doxylamine in a transdermal patch application under the Section 505(b)(2) regulatory pathway in the U.S. (and equivalent approval pathways in other jurisdictions) could be less than what is required for a new chemical entity.

Aequus has completed pre-clinical studies to determine the feasibility and the optimal formulation for AQS1303 as a long-acting combination of Pyridoxine/doxylamine in a transdermal patch application, intended for the treatment of NVP.

## Non-IND Phase 1 Proof of Concept and Phase 1 Bioequivalence Study

On July 5, 2017, Aequus received approval from Health Canada to initiate a Proof of Concept clinical trial to evaluate the bioavailability and safety of Aequus' long-acting transdermal anti-nausea patch, AQS1303, containing the combination of pyridoxine and doxylamine (the active ingredients in Diclegis®/Diclectin®). This single-dose cross-over comparative bioavailability study versus the currently approved oral version, Diclegis®/Diclectin®, was successfully completed in nine healthy female volunteers. The results suggested that sustained delivery of therapeutic levels of the active ingredients through the skin over a multi-day period is possible with the current formulation. The formulation was well tolerated with no serious adverse events reported.

In parallel to both Proof of Concept clinical programs, Aequus engaged Camargo in October 2016 to prepare for a pre-IND meeting with the FDA, expected early 2018 for AQS1303, in an effort to further define the clinical strategy for regulatory approval in the United States. It is expected that patches with the specifications derived from both POC studies will be manufactured and a clinical trial site will be established in the U.S. or Canada to conduct a study suitable to support an NDA 505(b)(2) submission. Aequus expects to engage a third-party partner to complete the design and conduct of these trials.

## Phase 2 Clinical Study

In order to obtain regulatory approval, the Company may be required to carry out at least one clinical study with at least several hundred patients for AQS1303. The target patient population will be dependent on the advice of our clinical advisors and the results from the POC and Bioequivalence Phase 1 studies. For the Phase 2 clinical study, we anticipate patients will be exposed to AQS1303 over a 28-day period. This study is expected to take approximately one year to complete. Aequus intends to have a third-party development collaborator or commercialization partner engaged prior to initiating this study to support the funding requirements of this study.

## Clinical Development Timeline

The following table summarizes Aequus' current development plan for its product pipeline for the next year. As noted above the Company does not expect to progress AQS1301, a once-weekly transdermal formulation of aripiprazole, in 2020.

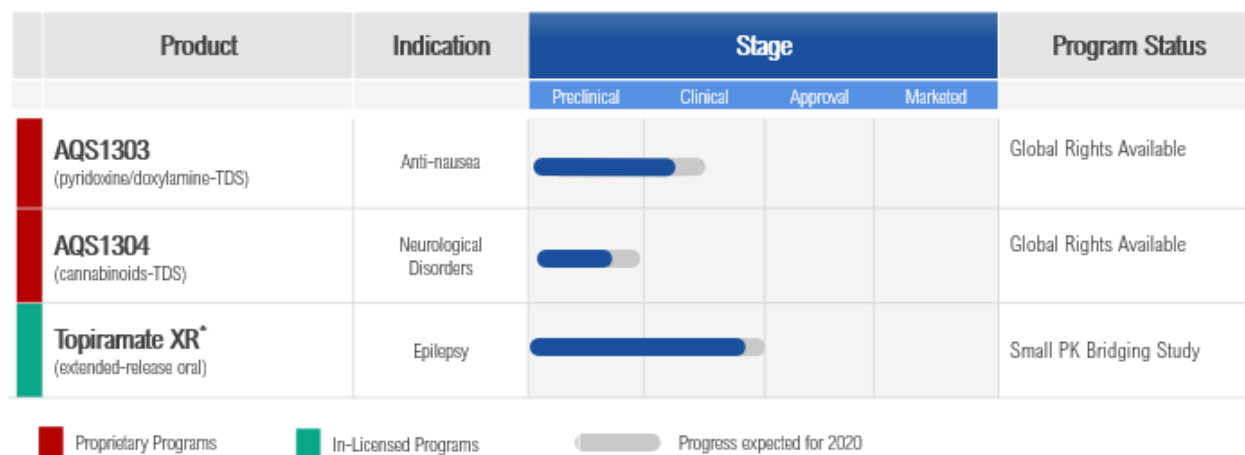


Figure 2 – Internal Product Development

The Company's product development progress is contingent upon a number of factors. See the heading "*Risk Factors*". There can be no assurances that Aequus will complete each stage of development in accordance with the timelines set out above, or at all.

#### *Steps to Reach Commercial Production*

In order for AQS1303 and AQS1304 to reach commercial production in the United States, the Company anticipates the development steps set forth below.

With respect to AQS1303, (i) formulation optimization and preclinical animal studies (completed); (ii) a POC study (completed); (iii) a Phase 1 Bioequivalence study to bridge oral Diclegis® safety and efficacy data with AQS1303; (iv) a clinical efficacy study; (v) a regulatory application via the abbreviated 505(b)(2) pathway with the FDA for commercial approval in the United States.

With respect to AQS1304, the Company also expects to conduct human POC studies with existing formulations, and to develop and optimize an initial formulation following the completion of several collaborative partnerships in this field. The Company is continuing to review the preferred path for AQS1304 to reach commercial production and the timing and cost thereof. The foregoing timeline is the Company's best estimate as of the date hereof.

The Company's actual costs, timing and steps to reach commercial development are subject to a variety of risks. See "*Risk Factors*" below.

#### **Manufacturing**

Aequus does not own manufacturing facilities. Aequus currently relies, and expects to rely, on a third party for the regulated manufacture of its product candidates for pre-clinical trials and clinical trials, should such clinical trials be undertaken by the Company as well as for commercial manufacture if any of Aequus' product candidates receive marketing approval. The Company plans to negotiate a manufacturing agreement with Supernus to produce Topiramate XR and Oxcarbazepine XR on behalf of the Company for the Canadian market if commercial approval is obtained from Health Canada.

#### **Aequus' Experienced Management and Advisory Team**

Aequus' senior executives, in their capacities with various pharmaceutical and life sciences organizations, have completed over \$1.5 billion in licensing and strategic transactions, overseen clinical trials involving thousands of patients, achieved regulatory approval for a number of drugs and devices, successfully led the launch of approved drugs in Canada and other regions, including having these new drugs added to formularies for reimbursement, and gained industry recognized expertise in multinational sales, marketing and commercial supply chain management. (See "*Executive Officers and Directors*").

In addition, Aequus has a team of clinical and scientific advisors with drug development experience and over 100 publications in scientific journals on the subject of transdermal drug applications. Aequus' initial pipeline has been strategically focused on transdermal delivery due to Aequus' belief that there are high market barriers to entry in the transdermal delivery product category.

In November of 2018, Aequus formed a Strategic Advisory Board in Ophthalmology to assist in assessing and rationalizing the many ophthalmology pipeline opportunities, both in therapeutics and medical devices, available to the Company. The advisory board will help Aequus in determining whether a product can improve patient outcomes, integrate into a clinician's workflow, and navigate the Canadian reimbursement and commercial landscape. The advisory board combines clinic expertise from ophthalmologists with deep commercial and regulatory experience within the field.

## Regulatory Environment

Aequus' product candidates and its research and development activities are subject to regulation for safety, efficacy, quality and ethics by various governmental authorities around the world, which regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing and import and export of pharmaceutical products. In Canada, these activities are primarily regulated by the *Food and Drugs Act* and the rules and regulations thereunder, which are enforced by the Therapeutic Products Directorate of Health Canada (the "TPD"). In the U.S., drugs and biological products are subject to regulation by the FDA. Drug approval laws require licensing of manufacturing facilities, carefully controlled research and testing of products, government review and approval of experimental results prior to giving approval to sell drug products. Regulators also typically require that rigorous and specific standards such as Good Manufacturing Practices, Good Laboratory Practice and Good Clinical Practices ("cGCP") are followed in the manufacture, testing and clinical development, respectively, of any drug product. The processes for obtaining regulatory approvals in Canada, the U.S. and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. For further information, see "*Risk Factors*".

The principal steps required for drug approval in both Canada and the U.S. are as follows:

### *Pre-Clinical Toxicology Studies*

Non-clinical studies are conducted *in vitro* and in animals to evaluate pharmacokinetics, metabolism and possible toxic effects to provide evidence of the safety of the drug candidate prior to its administration to humans in clinical studies and throughout development. Such studies have been completed for AQS1303.

### *Initiation of Human Testing*

The process of conducting clinical trials with a new drug cannot begin until the Company has submitted to the appropriate regulatory authorities an application to do so and the required number of days have lapsed without objection from the regulatory authority. (In certain jurisdictions, a no objection letter or approval may be required before the clinical trial can proceed.) In the U.S., this application is called an Investigational New Drug ("IND") application, and in Canada, a CTA. In July 2017, the Company received approval from Health Canada to initiate a POC study for AQS1303 and the Company reported positive results in September 2017. (see "*General Development of the Business – Three Year Development – Year Ended December 31, 2017 Developments*").

In the U.S., an IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND, unless the sponsor is relying on prior FDA findings of safety or efficacy of the drug product, in which case, some of the above information may be omitted. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Similar regulations apply in Canada and foreign jurisdictions in which Aequus may seek approval.

Two key factors influencing the rate of progression of clinical trials are the rate at which patients can be enrolled to participate in the research program and whether effective treatments are currently available for the disease that the drug is intended to treat. Patient enrollment is largely dependent upon the incidence and severity of the disease, the treatments available and the potential side effects of the drug to be tested and any restrictions for enrollment that may be imposed by regulatory agencies. For further information, see "*Risk Factors*".

## *Clinical Trials*

Clinical trials involve the administration of an investigational new drug to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices (“GCP”) requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial, and review and approval by regulatory bodies and ethics review boards or institutional review boards. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. In the U.S., a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an institutional review board (“IRB”) for each clinical trial site participating in the clinical trial must review and approve the plan for any clinical trial before it commences, and the IRB must continue to oversee the clinical trial while it is being conducted, including any changes. Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website. Similar regulations apply in Canada and foreign jurisdictions in which Aequus may seek approval. In Canada, Research Ethics Boards, instead of IRBs, are used to review and approve clinical trial plans.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into a small group of healthy human subjects or subjects with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. The number of subjects in a Phase 1 trial typically ranges from 20 to 80. Phase 2 trials are typically initiated if the Phase 1 studies do not reveal unacceptable toxicity levels. In Phase 2, the drug typically is administered through controlled studies to a limited subject population with the target disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for specific targeted diseases and to determine dosage tolerance and optimal dosage. The number of subjects in a Phase 2 study typically ranges from 100 to 300. If the Phase 2 trials present evidence of effectiveness, the clinical sponsor typically meets with FDA to try to come to an agreement on the structure of the Phase 3 studies. In Phase 3, the drug is administered to an expanded subject population, generally at geographically dispersed clinical trial sites in two adequate and well-controlled clinical trials, in order to generate enough data to statistically evaluate the efficacy and safety of the product candidate for approval, to establish the overall risk-benefit profile of the product candidate and to provide adequate information for the labeling of the product candidate. The number of subjects in a Phase 3 trial usually ranges from several hundred to about 3,000 people. In the U.S., in the case of a 505(b)(2) NDA, which is a marketing application in which sponsors may rely on information from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference, some of the above-described studies and preclinical studies may not be required or may be abbreviated. Bridging studies may be needed, however, to demonstrate the applicability of the studies that were previously conducted by other sponsors to the drug that is the subject of the marketing application.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to Current Good Manufacturing Practice (“cGMP”) requirements. Investigational drugs and active pharmaceutical ingredients imported into the U.S. or Canada are also subject to regulation by the FDA/TPD relating to their labeling and distribution.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the TPD or FDA and the IRB or REB, as applicable, and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, in the U.S. and Canada, the FDA/TPD or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB/REB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's/REB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor

regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

In most cases in the U.S., the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

### *New Drug Application*

Upon successful completion of Phase 3 clinical trials, the company sponsoring a new drug then assembles all the pre-clinical and clinical data and other testing relating to the product's pharmacology, chemistry, manufacture, and controls, and submits it to the TPD or the FDA as part of a New Drug Submission ("NDS"), in Canada, or an NDA in the U.S. The NDS or NDA is then reviewed by the applicable regulatory body for approval to market the drug. Other jurisdictions, such as Europe and Japan, have their own equivalents for these approvals.

As part of the approval process, the FDA/TPD will inspect the facility or the facilities at which the drug is manufactured. FDA/TPD will not approve the product unless compliance with cGMP—a quality system regulating manufacturing—is satisfactory and the NDA/NDS contains data that provide substantial evidence that the drug is safe and effective in the indication studied. In addition, before approving an NDA/NDS, the FDA/TPD will typically inspect one or more clinical sites to assure compliance with cGCP.

The testing and approval process for an NDA/NDS requires substantial time, effort and financial resources, and may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA/TPD may not grant approval of an NDA/NDS on a timely basis, or at all. In the U.S., the submission of most NDAs is additionally subject to a substantial application user fee and the manufacturer and/or sponsor under an approved new drug application are also subject to annual program fees. Both fees are typically increased annually. In Canada, NDSs are also subject to user fees and these fees are typically increased annually to reflect inflation.

Even if the FDA or TPD approves a product candidate, the relevant authority may limit the approved indications for use of the product candidate, require that contraindications, warnings or precautions be included in the product labeling, including a black box warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a risk evaluation and mitigation strategy ("REMS"), as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. A REMS could materially affect the potential market and profitability of the product. The FDA or TPD may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements, notification, and regulatory authority review and approval. Further, should new safety information arise, additional testing, product labeling or regulatory notification may be required.



### *Approvals in the U.S. pursuant to the Hatch-Waxman Act*

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) if the patent has not expired the date on which such patent expires and the date on which approval is sought after patent expiration; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA holder and patent owner(s) once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. If the Paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the Paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The U.S. *Drug Price Competition and Patent Term Restoration Act of 1984* (the "*Hatch-Waxman Act*") establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA,

including a 505(b)(2) NDA, may obtain five years of marketing exclusivity upon approval of a new drug containing new chemical entities (“NCEs”) that have not been previously approved by the FDA. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The *Hatch-Waxman Act* also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug’s approval. As a general matter, the three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

In Canada, an atypical antipsychotic could only be marketed if an NDS or, in certain cases, an Abbreviated New Drug Submission (“ANDS”) is filed and the TPD approves the submission and issues a notice of compliance (“NOC”). An NDS requires safety, efficacy and quality information, while an ANDS requires quality information as well as information showing bioequivalence between the drug that is the subject of the ANDS and the drug it is being compared to. An ANDS will only be sufficient to obtain an NOC in limited situations, namely if a company is seeking to market a generic version of a drug that is already marketed and certain other requirements are met.

Similar to the *Hatch-Waxman Act* in the U.S., Canada has the Patented Medicines (NOC) Regulations which requires a company that files an ANDS to address any relevant patents listed on the Patent Register prior to being able to receive a NOC from the TPD. The Canadian regime is similar to the U.S. regime, but a number of important distinctions do exist.

Like the U.S., Canada also has data protection, but again significant differences exist between the two jurisdictions. For example, Canada’s data protection applies to “innovative drugs” (i.e., a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph) and, where it exists, lasts for 8 years in most circumstances.

## [Intellectual Property, Patents, Proprietary Protection](#)

### *Intellectual Property*

Aequus believes its intellectual property is a barrier to potential competitors.

On March 1, 2016, Aequus and TRPL entered into the IP Assignment Agreement. Pursuant to the terms of the IP Assignment Agreement, Aequus owns all patents and patent applications associated with AQS1301 Aripiprazole, AQS1302 Clobazam and AQS1303 Doxylamine / Pyridoxine. The Company’s current patent portfolio includes one issued patent in eight jurisdictions and one additional published or pending patent application in North America, Europe and other jurisdictions worldwide for AQS1301 Aripiprazole, and one pending patent application in North America, Europe and other jurisdictions worldwide for AQS1303 Doxylamine / Pyridoxine. Aequus intends to file, when appropriate, additional patent applications with respect to inventions. However, because the patent positions of life sciences companies are highly uncertain and involve complex legal and factual questions, it is uncertain that any patents will be issued or that, if issued, they will be of commercial value. See “*Risk Factors – Risks Related to Intellectual Property Rights*”.

## Patent Portfolio

Aequus considers its patent portfolio to be an important contributor to its business and therefore devotes resources to maintaining and augmenting its patent portfolio. Aequus' patent strategy is to pursue the broadest possible patent protection on Aequus' proprietary formulations, products and technology in selected jurisdictions and to achieve the maximum duration of patent protection available. Where appropriate, and consistent with management's objectives, patents are pursued once concepts have been validated through appropriate laboratory work. To that end, patents will continue to be sought in relation to those components or concepts that management of the Company perceives to be important. In general, Aequus' strategic approach is to build a portfolio which provides broad protection of Aequus' technology.

## *Proprietary Protection*

In addition to Aequus' patents, the Company also relies upon trade secrets, know-how and continuing technological innovations to develop its competitive position. It is Aequus' policy to require its directors, employees, consultants, members of its scientific advisory board and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment, consulting or collaborative relationships with Aequus. In the case of employees and consultants, the agreements provide that all inventions resulting from work performed for Aequus utilizing Aequus' property or relating to Aequus' business and conceived of or completed by the individual during employment are Aequus' exclusive property.

## Employees

As of December 31, 2019, Aequus had eleven full-time employee positions and two full-time equivalent positions held by contractors.

## Facilities

The Company operates from its head office located in Vancouver, BC, Canada.

## RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the following risks in addition to the other information included in this annual information form, including our historical consolidated financial statements and related notes, before you decide to purchase our common shares. If any of the following risks actually occur, our business, financial condition and results of operations could materially suffer. As a result, the trading price of our securities, including Common Shares, could decline and you could lose part or all of your investment. The risks set out below are not the only risks we face; risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business, financial condition and results of operations. You should also refer to information set out in our consolidated financial statements and management's discussion and analysis for the year ended December 31, 2019.

### Risks Relating to Marketing Products Produced by Third Parties

*Aequus has a limited history of marketing drug products or other systems, produced by third parties. Aequus' current salesforce and marketing infrastructure may be unable to generate significant revenue to cover its commercial expenses.*

Aequus has been building a commercial platform since the Company's acquisition of TeOra in July 2015. The cost of establishing and maintaining that infrastructure may exceed the cost effectiveness of doing so. In order to market any products, Aequus must maintain, and may further expand, its sales, marketing, managerial and other non-technical

capabilities or make arrangements with third parties to perform these services. If Aequus does not have adequate sales, marketing and distribution capabilities, whether independently or with third parties, Aequus may not be able to generate sufficient product revenue and promotional service revenue to become profitable. Aequus competes with many companies that have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, Aequus may be unable to compete successfully against these more established companies. Furthermore, Aequus' relationships with its third-party suppliers are subject to various risks and uncertainties that are outside of its control, including agreements with third party suppliers not being renewed or being terminated in accordance with their terms and supply and reputational risks in the event that a third party supplier is in default under the provisions of such agreement.

*The Company is subject to risks associated with compliance with regulations related to marketing and promotional practices.*

The marketing and promotional practices of pharmaceutical companies, as well as the manner in which companies, or their internal or third-party sales forces interact with purchasers, physicians or other prescribers and patients, are subject to significant regulation. Breaches of these regulations may result in the imposition of significant civil and/or criminal penalties, injunctions, and/or limitations on marketing practices for products the Company markets or on the Company. Many companies have been the subject of claims related to these practices asserted by applicable authorities. Historically, these claims have resulted, and future claims could result, in fines and other consequences or restrictions.

Companies may not promote drugs for "off-label" uses, that is, uses that are not described in the product's labeling and that differ from those approved by applicable regulatory agencies, such as the FDA. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, management's attention could be diverted from business operations, and the Company's reputation could be adversely impacted.

*Aequus currently generates revenue from a limited number of promotional or distribution services agreements and may not be successful in obtaining rights to market additional third-party products.*

The Company has entered into promotional or distribution service agreements with Sandoz and Medicom. These agreements have to date been the Company's sole source of revenue, with the majority of which having been derived from the agreement with Sandoz. The loss of these agreements for any reason could have a material adverse effect on Aequus' business, financial condition and results of operations. There can be no assurance that Aequus will be successful in securing the rights to market third-party products or that any of those products will be successful. The Company competes with a number of other companies for third-party market rights, many of whom have greater resources and a longer track record than the Company.

The Company's revenues may experience significant volatility as a result of their dependence on a small number of third-party products.

*The Company may be adversely affected by product liability claims relating to third-party products it markets, even where the Company does not incur any liability.*

The third-party products that Aequus markets may be subject to product liability claims. Aequus may be named as a party in such claims and, even if Aequus is ultimately found not to have any liability, may incur significant legal costs in defending itself or having the Company removed as a party from such claims. In addition, negative publicity around such claims may result in decreased sales and reduced revenue for the Company. Aequus may also face reputational damage based on its association with such claims, which may impair its efforts to market not only the products subject to such claims, but other products as well.

*Aequus is reliant upon contractors and consultants for its marketing activities.*

Aequus is primarily reliant on contractors and consultants to conduct its marketing activities. As a result, Aequus may have less control over their activities or ability to supervise or enforce compliance with applicable laws and regulations and Aequus' policies. Misconduct by Aequus' marketing contractors and consultants may result in the loss of or penalties under Aequus' contracts to market third-party products or in fines or penalties for Aequus.

Aequus may also be subject to greater turnover among contractors and consultants, which may be disruptive to the Company's ability to successfully market third party products or may lead to increased costs to recruit, train and retain personnel. If and when Aequus seeks to launch market efforts for additional third-party products, such launches may be delayed, if Aequus is unable to adequately train or expand its marketing force.

In addition, the recent outbreak of the novel coronavirus (COVID-19) may cause Aequus to have inadequate access to available skilled contractors or consultants.

*Aequus' third-party products may be subject to sales quotas.*

The agreements under which Aequus has marketing rights to third-party products may impose quotas or specify minimum sales volumes in order to Aequus to retain marketing rights. If Aequus is unable to achieve the required volumes, these agreements may be terminated by its third-party collaborators or Aequus may receive lower payments (or be entitled to retain a smaller portion of revenues), either of which may have a material and adverse effect on Aequus' revenues or results of operations.

*Aequus' third-party products may be subject to regulatory approvals.*

From time to time Aequus may enter into agreements providing it with marketing rights for products which have not yet obtained all regulatory approvals. The timing and receipt of such approvals, if it all, may be outside of Aequus' control and may not occur either as a result of failure to receive regulatory approval or failure of the third-party to advance the regulatory approval process. In such cases, Aequus may never realize any revenues under such contracts or the launch of marketing efforts may be delayed.

*The market may not accept or may be slow to adopt third-party products.*

The third-party products that Aequus markets may be new to the Canadian market or marketed under brand names that are not well known or established in the Canadian market. Even if such products have been successful in other markets, there can be no assurance that such products will achieve similar levels of acceptance and market penetration in the Canadian market as elsewhere. Physicians, patients, insurance companies, applicable provincial agencies or other payors in Canada may be slow to accept new products, if at all, or may adopt such products in more limited circumstances than in other markets. As a result, Aequus may fail to achieve the expected revenues and sales for these products.

*Third-parties may fail to meet their commitments with respect to their products.*

The third-parties with whom the Company enters into agreements to market products may fail to meet or may breach their contractual commitments to Aequus. This may result in disruptions of product supplies, intellectual property infringement claims, payment disputes or other costs to, or litigation involving, Aequus that may adversely impact its revenues or results of operations. Some of the third-parties that the Company enters into agreements with may be located or have the bulk of their assets in other jurisdictions, which may make it difficult or cost prohibitive for Aequus to enforce its contracts or other rights. In addition, if any of these third parties becomes insolvent or enters into bankruptcy or creditor protection, Aequus'

enforcement rights may be stayed during such proceedings or as a result of such proceedings the Company's agreement with such third-party may be terminated or restructured on terms less favourable to the Company.

#### Risks Related to Aequus' Financial Position and Need for Capital

*Aequus has never been profitable. Currently, Aequus has no internal products approved for commercial sale and has a limited history of generating revenue by promoting products of a third party. Aequus does not expect profitability in the next two years and may never become profitable.*

Aequus has not been profitable to date and may not become so. Aequus has no internal products approved for commercial sale and has a limited history of generating revenue by promoting tacrolimus IR and Vistitan and, most recently, Evolve®, all products produced by third parties. Aequus' ability to generate additional revenue and become profitable depends upon Aequus' ability to successfully gain market share with its commercial products, successfully launch and market third-party products in Canada, complete the development of AQS1303, AQS1304 or its other internal product candidates, and obtain the necessary regulatory approvals for AQS1303, AQS1304, its internal product candidates, Topiramate XR or Oxcarbazepine XR. To date, Aequus has not generated any revenue from its internal product candidates or its licensed products, Topiramate XR and Oxcarbazepine XR. Aequus may never be able to obtain regulatory approval for the marketing of Topiramate XR, Oxcarbazepine XR or its internal product candidates. Further, even if Aequus is able to gain approval for and commercialize its own product candidates, there can be no assurance that Aequus will generate significant revenues or ever achieve profitability. Aequus' ability to generate revenue depends on a number of factors, including Aequus' ability to:

- Successfully complete clinical development of, and receive regulatory approval for, Aequus' product candidates;
- Successfully marketing its third-party products;
- Set an acceptable price for Aequus' products, if approved, and obtain adequate coverage and reimbursement from third party payors;
- Obtain commercial quantities of Aequus' products, if approved, at acceptable cost levels;
- Enter into additional agreements or collaborations for the marketing of third-party products and systems in Canada; and
- Successfully market and sell Aequus' products, if approved, in Canada, the U.S. and in other foreign jurisdictions.

In addition, because of the numerous risks and uncertainties associated with product candidate development, Aequus is unable to predict the timing or amount of increased expenses, or when or if Aequus will be able to achieve or maintain profitability. In addition, Aequus' expenses could increase beyond Aequus' current expectations if Aequus is required by the TPD, FDA or other regulatory authorities to perform studies in addition to those that Aequus currently anticipates. Even if Aequus' product candidates are approved for commercial sale, Aequus anticipates incurring significant costs associated with the commercial launch of these products.

Aequus' ability to become and remain profitable depends on its ability to generate additional revenue. Even if Aequus is able to generate additional revenues from its current or future third-party products, or from the sale of Aequus' internal product candidates or from Topiramate XR or Oxcarbazepine XR, if approved, Aequus may not become profitable and may need to obtain additional funding to continue operations. If Aequus fails to become profitable or obtain additional funding, or is unable to sustain profitability on a continuing basis, then Aequus may be unable to continue its operations at planned levels and be forced to reduce operations. Even if Aequus does achieve profitability, Aequus may not be able to sustain or increase profitability on a quarterly or annual basis. Aequus' failure to become and remain profitable would decrease the value of Aequus and could impair Aequus' ability to raise capital, expand Aequus' business or continue Aequus' operations. A decline in the value of Aequus could also cause you to lose all or part of your investment.

*Aequus has incurred operating losses in each year since its inception and expects to continue to incur substantial losses for the foreseeable future.*

Aequus's operations consist of both revenue-generating operations marketing third-party products and a developmental stage life-sciences arm. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. Aequus does not have any internal products approved by regulatory authorities for marketing or commercial sale for its internal programs and Aequus continues to incur significant research, development and other expenses related to ongoing operations. As a result, Aequus is not profitable and has incurred losses in every financial reporting period since Aequus' inception on January 3, 2013. As of December 31, 2019, Aequus had an accumulated deficit since inception of \$23,564,673.

Aequus expects to continue to incur significant expenses and operating losses for the foreseeable future. Aequus anticipates these losses to increase as Aequus continues the R&D of, and seeks regulatory approvals for any of Aequus' future product candidates, and potentially begin to commercialize any products that may achieve regulatory approval. Aequus may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect Aequus' financial condition. The size of Aequus' future net losses will depend, in part, on the rate of future growth of Aequus' expenses and Aequus' ability to generate additional revenues. Aequus' prior losses and expected future losses have had and will continue to have an adverse effect on Aequus' financial condition. If any future product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, Aequus may never become profitable. Even if Aequus achieves profitability in the future, Aequus may not be able to sustain profitability in subsequent periods.

*If Aequus fails to obtain the capital necessary to fund Aequus' operations, Aequus may be unable to obtain regulatory approval of AQS1303, AQS1304, Topiramate XR, Oxcarbazepine XR or its other product candidates.*

Based on Aequus' current operating plans, Aequus believes that anticipated revenue and Aequus' cash and cash equivalents will be sufficient to meet Aequus' anticipated operating needs until the third quarter of 2020. Aequus' cash and cash equivalents were \$484,506 as of December 31, 2019. Aequus anticipates requiring additional capital to fund operating needs thereafter. Aequus may also need to raise additional funds sooner if it chooses to expand more rapidly than it presently anticipates.

*Aequus will need to obtain additional financing to fund Aequus' operations and, if unable to obtain such financing, Aequus may be unable to complete the development or commercialization of Aequus' product candidates.*

Aequus' operations have consumed substantial amounts of cash since inception. Aequus will need to obtain additional financing to fund Aequus' future operations, including completing the development and commercialization of Aequus' product candidates. Aequus will need to obtain additional financing to conduct additional trials for the approval of Aequus' product candidates if requested by regulatory authorities, and to complete the development of any additional product candidates Aequus might acquire. Moreover, Aequus' fixed expenses such as rent and other contractual commitments are substantial and are expected to increase in the future.

Aequus' future funding requirements will depend on many factors, including, but not limited to:

- Progress, timing, scope and costs of Aequus' proposed clinical trials, including the ability to timely enroll subjects in Aequus' planned and potential future clinical trials;
- Time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities;
- Aequus' ability to successfully partner and commercialize Aequus' product candidates, if approved;

- Aequus' ability to commercialize and generate revenues from third-party products in Canada that the Company has acquired or licensed;
- Amount of sales and other revenues from product candidates that Aequus may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement;
- Terms and timing of any potential future collaborations, licensing or other arrangements that Aequus may establish;
- Cash requirements of any future acquisitions or the development of other product candidates;
- The costs of operating as a public company;
- Time and cost necessary to respond to technological and market developments; and
- Costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Until Aequus can generate a sufficient amount of revenue, Aequus may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. Aequus believes that its existing cash and cash equivalents will be sufficient to fund Aequus' projected operating requirements until the third quarter of 2020. Aequus expects that these funds will not be sufficient to enable Aequus to complete all necessary development and commercial approval regulatory processes of its internal product candidates or commercially launch Topiramate XR, Oxcarbazepine XR, AQS1303, AQS1304 or Aequus' other product candidates. Accordingly, Aequus will be required to obtain further funding through other public or private offerings, debt financing, collaboration or licensing arrangements or other sources. Adequate additional funding may not be available to Aequus on acceptable terms, or at all. If Aequus is unable to raise capital when needed or on attractive terms, Aequus would be forced to delay, reduce or eliminate Aequus' R&D programs or future commercialization efforts. Aequus may seek to access the public or private capital markets whenever conditions are favorable, even if Aequus does not have an immediate need for additional capital at that time. In addition, if Aequus raises additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, Aequus may have to relinquish valuable rights to Aequus' technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to Aequus.

Aequus' forecast of the period of time through which its financial resources will be adequate to support Aequus' operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. Aequus has based this estimate on a number of assumptions that may prove to be incorrect, and changing circumstances beyond Aequus' control may cause Aequus to consume capital more rapidly than Aequus currently anticipates. Aequus' inability to obtain additional funding when required could seriously harm Aequus' business.

*Raising additional capital may cause dilution to Aequus' existing shareholders or restrict Aequus' operations.*

Aequus may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. The sale of additional equity or convertible debt securities could result in the issuance of additional shares of in the capital of Aequus and could result in dilution to Aequus' shareholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on Aequus' ability to incur additional debt, limitations on Aequus' ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact Aequus' ability to conduct Aequus' business. Aequus cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to Aequus, if at all. If Aequus is unable to raise additional capital in sufficient amounts or on terms acceptable to Aequus, Aequus will be prevented from pursuing R&D efforts. This could harm Aequus' business, operating results and financial condition and cause the price of Aequus' securities to fall, including the price of the Company's Common Shares.

*Aequus is a development stage company which may make it difficult for you to evaluate the success of Aequus' business to date and to assess Aequus' future viability.*



Aequus is a development stage company. Aequus was incorporated and commenced active operations in 2013. Aequus' operations to date have been limited to organizing and staffing the Company, business planning, raising capital, developing Aequus' product candidates and, most recently, building its commercial arm. Aequus has not yet demonstrated its ability to successfully complete clinical trials for, obtain regulatory approval of or manufacture on a commercial scale any of Aequus' product candidates, or arrange for a third party to do so on Aequus' behalf, or conduct sales and marketing activities necessary for successful product commercialization or promotion. Consequently, any predictions about Aequus' future success or viability may not be as accurate as they could be if Aequus had a longer operating history.

In addition, as a development stage company, Aequus may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Aequus will need to transition from a company with a focus on product candidate development to a company capable of supporting commercial activities. Aequus may not be successful in such a transition.

*Aequus has a history of negative operating cash flow and may continue to experience negative operating cash flow.*

Aequus had negative operating cash flow for every financial reporting period since its inception on January 3, 2013. Aequus anticipates that it will continue to have negative operating cash flow until such time, if at all, it acquires additional commercial stage products, has profitable sales of its third party commercial products, Tacrolimus IR, Vistitan<sup>TM</sup> and Evolve<sup>®</sup> or that profitable commercial production is achieved with AQS1303, AQS1304, Topiramate XR, Oxcarbazepine XR or Aequus' other internal product candidates. To the extent that Aequus has negative operating cash flow in future periods, Aequus may need to allocate a portion of its cash reserves to fund such negative cash flow. Aequus may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that additional capital or other types of financing will be available when needed or that these financings will be on terms favourable to Aequus.

#### [Risks Related to the Clinical Trial Process and Regulatory Approval for Aequus' Product Candidates](#)

*Aequus has not obtained regulatory approval for any of Aequus' internal product candidates in Canada, the U.S. or any other country.*

Aequus currently does not have any of its own product candidates that have gained regulatory approval for sale in Canada, the U.S. or any other country, and Aequus cannot guarantee that its development programs will ever obtain marketing approval. Aequus' business is substantially dependent on Aequus' ability to complete the development of, obtain regulatory approval for and successfully commercialize product candidates in a timely manner. Aequus' potential product candidates will be principally regulated in the U.S. by the FDA, in Canada by the TPD, in the European Union by the European Medicines Agency ("EMA"), and in other jurisdictions by applicable regulatory authorities.

Before obtaining regulatory approvals in Canada, the U.S. or in other countries where Aequus may market Aequus' potential product candidates for a target indication, Aequus must demonstrate in preclinical studies and well-controlled clinical trials that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In the U.S., it is necessary to submit an NDA to obtain FDA approval. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication, although Aequus may partially rely on public information or the FDA's prior approval of similar products. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. The FDA may further inspect Aequus' manufacturing facilities to ensure that the facilities can manufacture Aequus' product candidates and Aequus' products, if and when approved, in compliance with the applicable regulatory requirements, as well as inspect Aequus' clinical trial sites to ensure that Aequus' studies are properly conducted. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Upon submission of an NDA, the FDA must make an initial determination that the application is sufficiently complete to accept the submission

for filing. Aequus cannot be certain that any submissions will be accepted for filing and review by the FDA, or ultimately be approved. If the application is not accepted for review or approval, the FDA may require that Aequus conduct additional clinical or preclinical trials, or take other actions before it will reconsider Aequus' application. If the FDA requires additional studies or data, Aequus would incur increased costs and delays in the marketing approval process, which may require Aequus to expend more resources than Aequus has available. In addition, the FDA may not consider any additional information to be complete or sufficient to support approval.

Regulatory authorities outside of the U.S., such as in Canada, Europe and Japan and in emerging markets, also have requirements for approval of drugs for commercial sale with which Aequus must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of Aequus' product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country, or any regulatory approval obtained may not be as broad as what was obtained in other jurisdictions. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on Aequus' ability to obtain approval in a different jurisdiction. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. Foreign regulatory approval may include all of the risks associated with obtaining FDA approval. For all of these reasons, Aequus may not obtain foreign regulatory approvals on a timely basis, if at all.

The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of the U.S., and approval is never guaranteed. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including, to some extent, the discretion of the regulatory authorities. For example, governing legislation, approval policies, regulations, regulatory policies, or the type and amount of pre-clinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing or future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval, or that changes in the relevant markets during the development timeline may lead us to halt development.

Even if Aequus' product candidates were to successfully obtain approval from regulatory authorities, any such approval might significantly limit the approved indications for use, including more limited patient populations, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical studies, REMS or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that Aequus may make, which may impede the successful commercialization of Aequus' product candidates. Following any approval for commercial sale of Aequus' product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, will be subject to additional FDA notification (and similar requirements outside the U.S.), or review and approval. Also, regulatory approval for any of Aequus' product candidates may be withdrawn. If Aequus is unable to obtain regulatory approval for Aequus' product candidates in one or more jurisdictions, or any approval contains significant limitations, Aequus' ability to market to Aequus' full target market will be reduced and Aequus' ability to realize the full market potential of Aequus' product candidates will be harmed. Furthermore, Aequus may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue or complete the development of any of Aequus' current or future product candidates.

*As an organization, Aequus has never submitted an IND or NDA in the United States or an NDS in Canada before, and may be unable to do so for Aequus' potential products or any other future products Aequus develops.*

Aequus' internal development product candidates are currently at the pre-clinical stage, with AQS1303 having completed a non-IND POC studies and is now IND submission ready following pre-IND feedback from the FDA. Aequus' internal

product candidates still must undergo all levels of registration clinical trials. The conduct of registration clinical trials and the submission of a successful IND/NDA in the United States or CTA/NDS in Canada is a complicated process. As an organization, Aequus has not conducted a registration clinical trial before and has limited experience in preparing, submitting and prosecuting regulatory filings. Aequus also has had limited interactions with the TPD, FDA and similar regulatory agencies in other jurisdictions and has not discussed Aequus' current clinical trial designs or implementation with the TPD, FDA or similar regulatory agencies. Consequently, even if Aequus' initial clinical trials are successful, Aequus may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA/NDS submission and approval of Aequus' proposed products or any other future product candidate Aequus may develop. Aequus may require more time and incur greater costs than Aequus' competitors and may not succeed in obtaining regulatory approvals of products that Aequus develops. Failure to commence or complete, or delays in, Aequus' planned clinical trials, would prevent Aequus from or delay Aequus in commercializing Aequus' proposed products or any other future product candidate Aequus develops.

*Failure can occur at any stage of clinical development. If the clinical trials for AQS1303, AQS1304 or any of Aequus' potential future product candidates are unsuccessful, Aequus could be required to abandon development of such product.*

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more clinical trials can occur at any stage of testing for a variety of reasons. The outcome of preclinical testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in or adherence to trial protocols, differences in size and type of the subject populations and the rates of dropout among clinical trial subjects. Aequus' future clinical trial results therefore may not demonstrate safety and efficacy sufficient to obtain regulatory approval for its product candidates. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trials Aequus may undertake may not be successful.

Flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. The Company has never conducted a clinical trial before and may be unable to design and execute clinical trials to support regulatory approval of its product candidates. In addition, clinical trials often reveal that it is not practical or feasible to continue development efforts for a product candidate.

Aequus may voluntarily suspend or terminate its proposed clinical trials if at any time it believes that they present an unacceptable risk to subjects. Furthermore, regulatory agencies, IRBs or similar research ethics boards, or data safety monitoring boards may at any time order the temporary or permanent discontinuation of Aequus' proposed clinical trials or request that Aequus cease using certain investigators in the clinical trials if such regulatory agencies or boards believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to subjects.

If the results of the proposed clinical trials for Aequus' current product candidates or clinical trials for any future product candidates do not achieve the primary efficacy endpoints or demonstrate unexpected safety issues, the prospects for approval of Aequus' product candidates will be materially adversely affected. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to achieve similar results in later clinical trials, including longer-term trials, or have failed to obtain regulatory approval of their product candidates. Many compounds that initially showed promise in clinical trials or earlier preclinical studies have later been found to cause undesirable or unexpected adverse effects that have prevented further development of the compound. Aequus' planned clinical trials for its product candidates may not produce the results that Aequus expects, or the TPD, FDA or similar regulatory agencies in other jurisdictions may interpret the data differently than Aequus does.

In addition to the circumstances noted above, Aequus may experience numerous unforeseen events that could cause its proposed clinical trials to be delayed, suspended or terminated, or which could delay or prevent Aequus' ability to receive regulatory approval for or commercialize any of its product candidates, including:

- Clinical trials of Aequus' product candidates may produce negative or inconclusive results, and Aequus may decide, or regulators may require Aequus, to conduct additional clinical trials or implement a clinical hold;
- The number of subjects required for clinical trials of Aequus' product candidates may be larger than Aequus currently anticipates, enrollment in these clinical trials may be slower than it anticipates or participants may drop out of these clinical trials at a higher rate than it anticipates;
- Aequus' third party CRO, or study sites may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to Aequus in a timely manner, or at all;
- Regulators or IRBs (or similar research ethics boards) may not authorize Aequus or Aequus' investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or amend a trial protocol;
- Aequus may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and Aequus' CRO;
- Aequus may have delays in adding new investigators or clinical trial sites, or it may experience a withdrawal of clinical trial sites;
- Aequus may elect or be required to suspend or terminate clinical trials of its product candidates based on a finding that the subjects are being exposed to health risks or due to other reasons;
- The cost of clinical trials for Aequus' product candidates may be greater than it anticipates;
- The supply or quality of Aequus' product candidates or other materials necessary to conduct clinical trials of Aequus' product candidates may be insufficient or inadequate;
- There may be changes in government regulations or administrative actions;
- Aequus' product candidates may have undesirable adverse effects or other unexpected characteristics;
- Aequus may not be able to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- Aequus may not be able to demonstrate that a product candidate provides an advantage over current standards of care or future competitive therapies in development; and
- There may be changes in the approval policies or regulations that render Aequus' data insufficient for approval.

If Aequus elects or is required to suspend or terminate a clinical trial for any of its product candidates, or its product candidate development is otherwise delayed, Aequus' development costs may increase, its commercial prospects will be adversely impacted, any periods during which it may have the exclusive right to commercialize its product candidates may be shortened and Aequus' ability to generate product revenues may be delayed or eliminated.

Aequus expects to conduct additional clinical trials in the future for AQS1303, AQS1304 and its other product candidates. Subject enrollment, which is a significant factor in the timing of clinical trials, is affected by a variety of factors, including the following:

- Size and nature of the subject population;
- Proximity of subjects to clinical sites and the number of sites;
- Effectiveness of publicity created by clinical trial sites regarding the trial;
- Eligibility and exclusion criteria for the trial;
- Design of the clinical trial, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- Competing clinical trials;
- Clinician and subject perceptions as to the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for the indications Aequus is investigating;

- Subjects' ability to comply with the specific instructions related to the trial protocol, proper documentation and use of the drug product;
- Inability to obtain or maintain subject informed consents; and
- Risk that enrolled subjects will drop out before completion.

Furthermore, Aequus currently expects to rely on a CRO and clinical trial sites to ensure the proper and timely conduct of its clinical trials, and while Aequus may have agreements governing their committed activities, Aequus has limited influence over their actual performance. Additionally, the CRO and clinical trial sites may have business, regulatory, personnel or other issues that keep Aequus from satisfactorily completing Aequus' clinical trials. Any delays or unanticipated problems during clinical trials, such as additional monitoring of clinical trial sites, slower than anticipated enrollment in Aequus' clinical trials or subjects dropping out of or being excluded from participation in its clinical trials at a higher rate than Aequus anticipates, could increase Aequus' costs, slow down its product development and approval process and harm its business.

*Aequus may in the future conduct clinical trials for its internal product candidates in sites outside the U.S. and the FDA may not accept data from trials conducted in such locations.*

Aequus may in the future choose to conduct one or more of Aequus' clinical trials outside the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to certain conditions imposed by the FDA. This same comment applies to other jurisdictions. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the U.S. must be representative of the population for whom Aequus intends to label the product in the U.S. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the U.S. If the FDA chooses to not accept Aequus' data collected outside the U.S., it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt Aequus' development of its proposed products or any future product candidates.

*Aequus may be required to conduct clinical trials for Topiramate XR and Oxcarbazepine XR since Health Canada may not accept the same data packages previously submitted to FDA for commercialization in the U.S.*

Aequus may be required to conduct one or more of clinical studies in Canada for Topiramate XR or Oxcarbazepine XR. Although the FDA has approved these products for marketing in the U.S., Health Canada may have different regulatory requirements for Canadian approval. For example, the studied population must adequately represent the Canadian population, and the data must be applicable to the Canadian population and Canadian medical practice in ways that Health Canada deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of Canada must be representative of the population for whom Aequus intends to label the product in Canada. There can be no assurance Health Canada will fully accept data used for U.S. approval purposes. If Health Canada chooses to not fully accept this data, it may result in the need for additional studies or data in Canada, which would be costly and time-consuming and delay or permanently halt Aequus' commercialization of these products.

*Regulatory approval may be substantially delayed or may not be obtained for one or all of Aequus' product candidates if regulatory authorities require additional time or studies to assess the safety and efficacy of its product candidates.*

Aequus may be unable to initiate or complete development of its product candidates on Aequus' currently expected timeline, or at all. The timing for the completion of the studies for Aequus' product candidates will require funding beyond the Company's existing cash and cash equivalents. In addition, if regulatory authorities require additional time or studies

to assess the safety or efficacy of a product candidate, Aequus may not have or be able to obtain adequate funding to complete the necessary steps for approval for Topiramate XR, Oxcarbazepine XR or its internal product candidates. Additional delays may result if the FDA or other regulatory authority recommends non-approval or restrictions on approval. Studies required to demonstrate the safety and efficacy of Aequus' product candidates are time consuming, expensive and together take several years or more to complete. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Aequus has not obtained regulatory approval for any product candidate and it is possible that none of its existing product candidates or any product candidates it may seek to develop in the future will ever obtain regulatory approval. Delays in regulatory approvals or rejections of applications for regulatory approval in Canada, the United States, Europe, Japan or other markets may result from a number of factors, many of which are outside of Aequus' control, including:

- Aequus' inability to obtain sufficient funds required for a clinical trial;
- Regulatory requests for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;
- Regulatory questions regarding interpretations of data and results and the emergence of new information regarding Aequus' product candidates or other products;
- Clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- Failure to reach agreement with the TPD, FDA or other similar regulatory agencies regarding the scope or design of Aequus' clinical trials;
- Aequus' inability to enroll or retain a sufficient number of subjects who meet the inclusion and exclusion criteria in its clinical trials;
- Aequus' inability to conduct its clinical trials in accordance with regulatory requirements or its future clinical trial protocols;
- Unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding safety or efficacy of Aequus' product candidates during clinical trials;
- Failure to meet the level of statistical significance required for approval;
- Any determination that a clinical trial presents unacceptable health risks to subjects;
- Lack of adequate funding to commence or complete Aequus' clinical trials due to unforeseen costs or other business decisions;
- Aequus' inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- Aequus' inability to identify and maintain a sufficient number of sites, many of which may already be engaged in other clinical trial programs, including other clinical trials for the same indications targeted by its product candidates;
- Aequus' inability to obtain approval from IRBs or similar research ethics boards to conduct clinical trials at their respective sites;
- Aequus' inability to timely obtain from Aequus' third party manufacturer sufficient quantities or quality of the product candidate or other materials required for a clinical trial;
- Aequus may be unable to obtain approval for the manufacturing processes or facilities of the third-party manufacturer with whom Aequus contract for clinical and commercial supplies;
- Aequus may have insufficient funds to pay the significant user fees required by the TPD, FDA or regulatory authorities in other jurisdictions upon the filing of an NDA/NDS or analogous applications; and
- Aequus may have difficulty in maintaining contact with subjects in any future clinical trial, resulting in incomplete data.

The lengthy and unpredictable approval process, as well as the unpredictability of future clinical trial results, may result in Aequus' failure to obtain regulatory approval to market any of its product candidates, which would significantly harm Aequus' business, results of operations and prospects.

*Aequus' product candidates may have undesirable adverse effects, which may delay or prevent regulatory approval or, if approval is received, require Aequus' products, if any, to be taken off the market, require them to include safety warnings or otherwise limit their sales.*

Unforeseen adverse effects from any of Aequus' product candidates could arise either during clinical development or, if approved, after the approved product has been marketed.

Any undesirable adverse effects that may be caused by Aequus' product candidates could interrupt, delay or halt clinical trials and could result in more restrictive labeling or the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent Aequus from commercializing its product candidates and generating revenues from their sale. Adverse effects could also impact subject recruitment or the ability or willingness of enrolled subjects to complete the trial, or result in product liability claims. Any of these occurrences may harm Aequus' business, financial condition and prospects significantly. Certain types of unexpected adverse events for atypical antipsychotic class drugs may also impact the perception of Aequus' product and may result in additional regulatory obligations and/or labeling changes.

In addition, if any of Aequus' product candidates receive regulatory approval and Aequus or others later identify undesirable adverse effects caused by the product, Aequus could face one or more of the following consequences:

- Aequus may suspend marketing of, withdraw or recall the product;
- Regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication, or other labeling changes;
- Regulatory authorities may withdraw their approval of the product;
- Regulatory authorities may seize the product or seek an injunction against its manufacture or distribution;
- The TPD, FDA or other regulatory authorities may issue safety alerts, 'Dear Healthcare Provider' letters, press releases or other communications containing warnings about the product;
- The FDA may require the establishment or modification of a REMS or a comparable regulatory authority in Canada or other jurisdictions may require the establishment or modification of a similar strategy that may, for instance, require Aequus to issue a medication guide outlining the risks of such adverse effects for distribution to patients, or restrict distribution of the product, if and when approved, and impose burdensome implementation requirements on Aequus;
- Aequus may be required to conduct additional trials;
- Aequus may be required to change the way that the product is administered, conduct additional clinical trials or recall the product;
- Aequus may be subject to litigation or product liability claims, fines, injunctions or criminal penalties;
- Regulatory authorities may impose additional restrictions on marketing and distribution of the product; and
- Aequus' reputation may suffer.

Any of these events could prevent Aequus from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent Aequus from generating significant revenues from its sale.

*Aequus' development and commercialization strategy for AQS1303 and AQS1304 depends, in part, upon the FDA's prior findings regarding the safety and efficacy of aripiprazole based on data not developed by Aequus, but upon which the FDA may rely in reviewing Aequus' NDA.*

The U.S. Hatch-Waxman Act added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA, for the purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous

findings of safety and efficacy for an approved product. The FDA may also require companies to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions. Aequus anticipates submitting an NDA for AQS1303 and AQS1304 under Section 505(b)(2) and as such the NDA will rely in the case of AQS1303, in part, on the FDA's previous findings of safety and efficacy for aripiprazole and Diclegic®. Even though Aequus may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for AQS1303 and AQS1304, the FDA may require Aequus to perform additional clinical trials or measurements to support approval. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that Aequus may submit. Such a result could require Aequus to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of Aequus' product candidates, including AQS1303 and AQS1304.

#### Risks Relating to the Commercialization of Aequus' Product Candidates

*The successful commercialization of Aequus' product candidates is substantially dependent on forming a third-party partnership.*

Even if Aequus is able to obtain regulatory approvals for Aequus' product candidates, the success of those products is dependent upon achieving and maintaining market acceptance. New product candidates that appear promising in development may fail to reach the market or may have only limited or no commercial success. Levels of market acceptance for Aequus' products could be impacted by several factors, many of which are not within Aequus' control, including but not limited to:

- Efficacy, safety and other potential advantages of Aequus' product candidates in relation to alternative treatments;
- Relative convenience and ease of administration of Aequus' product candidates;
- Availability of adequate coverage or reimbursement of Aequus' product candidates by third parties, such as insurance companies and other payors, and by government healthcare programs, including, in the U.S., Medicare, Medicaid and state health insurance exchanges and comparable government health-care programs in other jurisdictions;
- Prevalence and severity of adverse events associated with Aequus' product candidates;
- Cost of Aequus' product candidates in relation to alternative treatments, including generic products;
- Extent and strength of Aequus' third-party manufacturer and supplier support;
- Extent and strength of Aequus' marketing and distribution support;
- Limitations or warnings contained in Aequus' potential product's labeling as approved or required by the TPD, FDA or other regulatory agencies; and
- Distribution and use restrictions imposed by the TPD, FDA or other regulatory agencies or to which Aequus agree as part of a mandatory REMS or voluntary risk management plan.

*It will be difficult for Aequus to profitably sell AQS1303, AQS1304, Topiramate XR or Oxcarbazepine XR, if such products are approved, as well as tacrolimus IR, Vistitan™, Evolve® or any other product that Aequus obtains marketing approval for in the future, if coverage and reimbursement for such product is limited.*

Market acceptance and sales of tacrolimus IR, Vistitan™, Evolve® or future market acceptance and sales of AQS1303, AQS1304, Topiramate XR or Oxcarbazepine XR, if such products are approved, or any other product that Aequus obtains marketing approval for in the future, will depend on coverage and reimbursement policies and may be affected by future



healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for approved medications or medical devices. A primary trend in the U.S. and Canadian healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Some payors also require manufacturers to enter into agreements with them in order for drugs to be reimbursed by the payor, and the agreements may contain cost sharing or other onerous provisions. Also, current conditions and rules relating to the listing submissions to public and private formulary listings may change or become more onerous in the future. If Aequus fails to achieve the listing of our products, it will affect the physicians' decisions regarding the use of our products. Aequus cannot be sure that coverage or reimbursement will be available for AQS1303, AQS1304, Topiramate XR or Oxcarbazepine XR, if such products are approved, as well as Tacrolimus IR, Vistitan™, Evolve® or any other product that Aequus obtains marketing approval for in the future and, if coverage is available, Aequus cannot be sure of the level of reimbursement. Reimbursement may impact the demand for, or the price of, AQS1303, AQS1304, Topiramate XR or Oxcarbazepine XR, if such products are approved, as well as Tacrolimus IR, Vistitan™, Evolve® and any other products that Aequus obtains marketing approval for and commercialize. Numerous generic products may be available at lower prices than branded therapy products, such as AQS1303, AQS1304, Topiramate XR and Oxcarbazepine XR, which may also reduce the likelihood and level of reimbursement for such products. If coverage and reimbursement are not available or are available only at limited levels, Aequus may not be able to successfully commercialize AQS1303, AQS1304, Topiramate XR or Oxcarbazepine XR, if such products are approved, as well as tacrolimus IR, Vistitan™, Evolve® or any other product for which Aequus obtains marketing approval.

*Aequus may be unable to enter into agreements with third parties to market and sell AQS1303 or AQS1304, if approved, for commercialization outside of Canada.*

Aequus is seeking to engage a third-party partner to commercialize AQS1303, AQS1304 and any other internal product candidate outside of Canada. If Aequus is successful in entering into a commercialization agreement for rights outside of Canada, Aequus may have limited or no control over sales, marketing and distribution activities of these third parties. Aequus' future revenues may depend on the success of the efforts of these third parties. To the extent that Aequus relies on, or partners with, third parties to commercialize AQS1303 or AQS1304, if approved, or any other product candidate for which Aequus obtains marketing approval in the future, Aequus may receive less revenue than if Aequus commercialized these products itself. In addition, Aequus would have less control over the sales efforts of any other third parties involved in Aequus' commercialization efforts. In the event that Aequus is unable to partner with a third-party marketing and sales organization, Aequus' ability to generate product revenues may be limited in the U.S. or other jurisdictions in which its product candidates may be approved for sale, if any.

*A variety of risks associated with potential international business relationships could materially adversely affect Aequus' business.*

Aequus may enter into agreements with third parties for the development and commercialization of AQS1303, AQS1304 and possibly other product candidates in international markets. If Aequus does so, Aequus would be subject to additional risks related to entering into international business relationships, including:

- Differing regulatory requirements in foreign countries including, among others, requirements relating to drug approvals, pricing, reimbursement and sales and marketing practices;
- Potentially reduced protection for intellectual property rights;
- The potential for so-called parallel importing, which is when a local seller, faced with higher local prices, opts to import goods from a foreign market with lower prices, rather than buying them locally;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- Economic weakness, including inflation, or political instability in foreign economies and markets;
- Compliance with tax, employment, immigration and labor laws for employees traveling and working abroad;

- Foreign taxes;
- Foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other risks incident to doing business in another country;
- Workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- Business interruptions resulting from geo-political actions, including war and terrorism, natural disasters, including earthquakes, volcanoes, typhoons, floods, tsunamis, hurricanes and fires, or global health pandemics, including as a result of the COVID-19 outbreak.

These and other risks may materially adversely affect Aequus' ability to develop and commercialize products in international markets and may harm Aequus' business.

*Even if Aequus receives regulatory approval for any of its product candidates, Aequus still may not be able to successfully commercialize it and the revenue that Aequus generate from its sales, if any, may be limited.*

The commercial success of any product candidate in any indication for which Aequus obtains marketing approval from the TPD, FDA or other regulatory authorities will depend upon the antipsychotic market landscape as well as acceptance and uptake of each such product candidate by physicians, patients and third-party payors.

Risks related to the antipsychotic market landscape include:

- The prescription antipsychotic market could experience a decrease in growth or negative growth if fewer patients choose to use pharmaceutical intervention;
- The perceived safety of antipsychotics could be negatively affected by media reports of adverse effects and advertisements for class action lawsuits due to adverse effects;
- Price pressures from third-party payors, including managed care organizations and government-sponsored health systems, could limit Aequus' revenue;
- The proportion of the antipsychotic market comprised of generic products could continue to increase, making introduction of a branded transdermal antipsychotic difficult and expensive;
- Competition in the antipsychotic market could increase, with the introduction of new antipsychotics, including the potential of a new generic or branded alternative;
- Competition from generic antipsychotic products could increase as additional generic antipsychotics receive TPD or FDA approval, or approval from similar regulatory authorities in other jurisdictions;
- The U.S. *Patient Protection and Affordable Care Act*, as amended by the *Healthcare and Education Reconciliation Act of 2010* or, collectively, the *Affordable Care Act* ("ACA"), and its effect on pharmaceutical coverage, reimbursement and pricing could limit Aequus' revenue; and
- Access to the prescriber universe could be limited, decreasing Aequus' ability to promote its product candidates efficiently.

The degree of acceptance and uptake of any of its internal development programs, if approved, by physicians, patients and third-party payors will depend upon a number of factors, including:

- The level of effectiveness demonstrated in Aequus' clinical trials;
- The incidence and severity of adverse effects associated with such program;
- Limitations on use or warnings contained in approved labeling;
- Acceptability to patients of the appearance and feel of the product;
- Willingness of patients to use a transdermal patch as their form of medical therapy;
- The cost to the patient, as compared to other medications in that class;

- Aequus' ability to obtain and maintain sufficient third-party coverage or reimbursement from private health insurers, government healthcare programs (including Medicare, Medicaid and 340B Clinics) and other third-party payors; and
- The effectiveness of Aequus' or any future collaborators' sales and marketing strategies.

In addition, even if Aequus obtains regulatory approval for any of its internal development programs, the timing of an approval may reduce Aequus' ability to commercialize such programs successfully. For example, if the approval process takes too long, Aequus may miss market opportunities and give other companies the ability to develop competing products. Any regulatory approval Aequus ultimately obtains may be limited or subject to restrictions or post-approval commitments that render its product candidates not commercially viable. For example, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, including REMS, or may approve our product candidates with a label that contains fewer, or more limited, indications than requested, warnings, precautions or contraindications, including black box warnings, and the label may not include the claims necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If any of our product candidates are approved, but does not achieve an adequate level of acceptance by physicians, third-party payors and patients, Aequus may not generate sufficient revenue and Aequus may not be able to achieve or sustain profitability. The efforts of Aequus' future commercial partners, if any, to educate physicians, patients and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. Even if Aequus is able to demonstrate and maintain a competitive advantage over Aequus' competitors and become profitable, if the market for antipsychotics fails to achieve expected future growth or decreases, Aequus may not generate sufficient revenue or sustain profitability.

*Currently enacted and future legislation may increase the difficulty and cost for Aequus to obtain marketing approval of and to commercialize our product candidates and may affect the prices Aequus may obtain.*

In the U.S. and some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect Aequus' ability to profitably sell our product candidates. For example, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Aequus does not know whether additional legislative changes will be enacted, whether the TPD or FDA's regulations, guidance or interpretations will change, or what the impact of such changes on the potential marketing approval of our product candidates, if any, may be. In addition, in the U.S., increased scrutiny by U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject Aequus to more stringent product labeling and post-marketing testing and other requirements. There may also be regulatory changes in Canada or other jurisdictions in the future that may adversely affect Aequus' development of its product candidates and its proposed operations should such product candidates be approved.

*Third party coverage and reimbursement and healthcare cost containment initiatives and treatment guidelines may constrain Aequus' future revenues.*

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. Aequus' ability to successfully market any of our product candidates, if approved, will depend in part on the level of coverage and reimbursement that government authorities, private health insurers and other organizations provide for our product candidates and antipsychotics in general. Countries in which any of our product candidates are sold through reimbursement schemes under national or provincial health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the U.S., government-funded and private medical care plans can exert significant indirect pressure on prices. Aequus may not be able to sell any of our product candidates profitably if adequate

prices are not approved or coverage and reimbursement are unavailable or limited in scope. Increasingly, third-party payors attempt to contain healthcare costs in ways that are likely to impact Aequus' development of products including:

- Failing to approve or challenging the prices charged for healthcare products;
- Introducing reimportation schemes from lower-priced jurisdictions;
- Limiting both coverage and the amount of reimbursement for new therapeutic products, especially with respect to line extensions of existing drugs that are more expensive;
- Denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental, not medically necessary or investigational by third-party payors;
- Requiring a patient to receive prior authorization or requiring the product to be on an approved list or formulary; and
- Refusing to provide coverage when an approved product is used for off-label indications.

### Risks Related to Manufacturing and Aequus' Reliance on Third Parties

*Aequus has no manufacturing capacity and relies on its key strategic collaborators to manufacture their clinical and commercial supply of finished goods.*

Aequus relies on Sandoz for the manufacturing and supply of tacrolimus IR and Vistitan™ and on Medicom to manufacture and supply Evolve®. Aequus plans to negotiate a manufacturing agreement with a third party to produce Topiramate XR and Oxcarbazepine XR on behalf of the Company for the Canadian market if commercial approval is obtained from Health Canada.

Aequus does not own or operate, and has no plans to establish, any manufacturing facilities for Aequus' commercial products or product candidates. Aequus lacks the resources and capabilities to manufacture tacrolimus IR, Vistitan™, Topiramate XR, Oxcarbazepine XR, Evolve®, AQS1303, AQS1304 or any of Aequus' product candidates on a clinical or commercial scale. The facilities used by any third party manufacturer must be approved by the FDA pursuant to inspections that will be conducted after submission of an NDA to the FDA, and similar regulatory inspections and approvals will be required where Aequus' products or product candidates will be sold outside the U.S. Aequus does not control the manufacturing process of, and is completely dependent on, Aequus' contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of Aequus' products and Aequus' product candidates, if and when approved. If contract manufacturers that Aequus may use cannot successfully manufacture material that conforms to Aequus' specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, Aequus has no control over the ability of Aequus' contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the TPD, FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of Aequus' products or product candidates or if it withdraws any such approval in the future, Aequus may need to find alternative manufacturing facilities, which would significantly impact Aequus' ability to develop, obtain regulatory approval for or market Aequus' products or product candidates, if approved. Moreover, if Aequus' contract manufacturer cannot successfully manufacture materials that conform to Aequus' specifications and the strict regulatory requirements of the TPD, FDA or others, Aequus may be subject to other regulatory enforcement action such as Warning Letters, Untitled Letters, recalls, product seizures, fines, imprisonment, consent decrees, refusal to permit import or export of the product and injunction against manufacture or distribution.

The machinery to produce the commercial supply of our commercial products and product candidates must be qualified and validated, which is time consuming and expensive, and this machinery is located within one manufacturing site and is customized to the particular manufacturing specifications of each product or product candidate. If Sandoz, Medicom or any other manufacturer is unable to qualify and validate this equipment in a timely manner, Aequus' ability to supply or launch and commercialize, as applicable, tacrolimus IR, Vistitan™, Evolve® or any of its product candidates, will be compromised. If this customized equipment malfunctions at any time during the production process, the time it may take

the manufacturer to secure replacement parts, to undertake repairs and to revalidate the equipment and process could limit Aequus' ability to meet the commercial demand for its products or product candidates. This may increase the risk that the third party manufacturer may not manufacture the product or product candidate in accordance with the applicable regulatory requirements, that Aequus may not have sufficient quantities of that product or that Aequus may not have such quantities at an acceptable cost, any of which could delay, prevent, or impair the sale or commercialization of any of our commercial products or product candidates, if approved, and the development of Aequus' other product candidates. Although Aequus does not expect to begin any clinical trials unless Aequus believes it has a sufficient supply of a product or product candidate to complete the clinical trial, any significant delay in the supply of a product or product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third party manufacturer could considerably delay completion of Aequus' clinical trials, product testing and potential regulatory approval of Aequus' products and product candidates.

Reliance on a third-party manufacturer subjects Aequus to risks that would not affect Aequus if Aequus manufactured the commercial product or product candidates itself, including:

- Reliance on the third party for regulatory compliance and quality assurance;
- Reduced control over the manufacturing process for Aequus' products and product candidates;
- The possible breach of the manufacturing agreements by the third party because of factors beyond Aequus' control;
- The possibility of termination or nonrenewal of the agreements by the third party because of Aequus' breach of the manufacturing agreement or based on their own business priorities; and
- The disruption and costs associated with changing suppliers.

Aequus' commercial products and product candidates may compete with other products and product candidates for access to manufacturing resources and facilities. There are a limited number of manufacturers that operate under cGMP requirements and that are both capable of manufacturing for Aequus and willing to do so. If Aequus' existing third-party manufacturer, or the third parties that Aequus may engage in the future to manufacture a product for commercial sale or for Aequus' clinical trials, should cease to continue to manufacture Aequus' products or product candidates for any reason, Aequus likely would experience delays in obtaining sufficient quantities of Aequus' products or product candidates for Aequus to meet commercial demand or to advance Aequus' clinical trials while Aequus identifies and qualifies replacement suppliers. If for any reason Aequus is unable to obtain adequate supplies of Aequus' products or product candidates or the drug substances used to manufacture them, it will be more difficult for Aequus to develop Aequus' products and product candidates and compete effectively.

Aequus' third-party manufacturers are subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to Aequus' commercial products and product candidates, and subject to ongoing inspections by the regulatory agencies. In addition to the above-described regulatory actions, failures by Aequus' third-party manufacturer to comply with applicable regulations may result in long delays and interruptions to Aequus' manufacturing capacity while Aequus seek to secure another third-party manufacturer that meets all regulatory requirements.

*Aequus expects to rely on third parties to conduct aspects of Aequus' clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with applicable regulatory requirements, Aequus may be delayed in obtaining or ultimately not be able to obtain marketing approval for Aequus' product candidates.*

Aequus anticipates engaging a CRO for most aspects of Aequus' clinical trials, including trial conduct, data management, statistical analysis and electronic compilation of Aequus' NDA/NDS. Aequus may enter into agreements with CROs to obtain additional resources and expertise in an attempt to accelerate Aequus' progress on new or ongoing clinical and preclinical programs. Typically entering into relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, typically there is a transition period between engagement of a CRO and the time the CRO commences work. As a result, delays may occur, which may materially impact Aequus' ability to meet Aequus' desired

clinical development timelines and ultimately have a material adverse impact on Aequus' operating results, financial condition or future prospects.

As CROs are not Aequus' employees, Aequus cannot control whether or not they devote sufficient time and resources to Aequus' clinical trials for which they are engaged to perform, and whether they comply with the applicable regulatory requirements, known as cGCPs which are regulations and guidelines enforced by the TPD, FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for all of Aequus' product candidates, which include requirements related to the conduct of the study, subject informed consent, and IRB or similar research ethics board's approval. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. Although Aequus may rely on third parties for the execution of Aequus' trials, Aequus is nevertheless responsible for ensuring that each of Aequus' studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and Aequus' reliance on CROs does not relieve Aequus of Aequus' regulatory responsibilities. If Aequus or any of Aequus' CROs fail to comply with applicable cGCPs, the clinical data generated in Aequus' clinical trials may be deemed unreliable and the TPD, FDA, EMA or comparable foreign regulatory authorities may require Aequus to perform additional clinical trials before approving Aequus' marketing applications. Aequus cannot assure you that, upon inspection by a given regulatory authority, such regulatory authority will determine that any of Aequus' clinical trials comply with cGCP regulations. In addition, Aequus' clinical trials must be conducted with product candidate materials produced under cGMP regulations. Aequus' failure to comply with these regulations may require Aequus to discontinue or repeat clinical trials, which would delay the regulatory approval process. If the CROs Aequus engage do not successfully carry out their contractual duties or obligations, conduct the clinical trials in accordance with all regulatory requirements, or meet expected deadlines, or if they need to be replaced, or the quality or accuracy of the data they provide is compromised due to the failure to adhere to regulatory requirements or for other reasons, then Aequus' development programs may be extended, delayed or terminated, or Aequus may not be able to obtain marketing approval for or successfully commercialize Aequus' product candidates. Failure to comply with clinical trial regulatory requirements may further subject Aequus to regulatory action, including Warning Letters, Untitled Letters, adverse inspectional findings, clinical holds, fines and monetary penalties, imprisonment, injunction against manufacture or distribution and debarment. As a result, Aequus' financial results and the commercial prospects for Aequus' product candidates would be harmed and Aequus' costs would increase.

*Any collaboration arrangements that Aequus may enter into in the future may not be successful, which could adversely affect Aequus' ability to develop and commercialize Aequus' product candidates.*

Aequus may seek partnerships, collaborations and other strategic transactions to maximize the commercial potential its product candidates and Aequus' proprietary technologies in Canada, the U.S. and other territories throughout the world. Aequus may enter into such arrangements on a selective basis depending on the merits of retaining commercialization rights for itself as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for each of Aequus' product candidates and technologies, both in the U.S. and internationally. Aequus faces competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. Aequus may not be successful in Aequus' efforts to establish and implement collaborations or other alternative arrangements should Aequus choose to enter into such arrangements. The terms of any collaborations or other arrangements that Aequus may establish may not be favorable to Aequus.

Any future collaborations that Aequus enters into may not be successful. The success of Aequus' collaboration arrangements will depend heavily on the efforts and activities of Aequus' collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters could lead to delays in the development process or commercialization of Aequus' product candidates and, in some

cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect Aequus financially and could harm Aequus' business reputation.

*Aequus currently holds, and in the future will hold, finished goods in inventory and such inventory has a shelf life and is subject to spoilage and/or damage.*

The Company currently holds, and will in the future hold, finished goods in inventory and such inventory has a shelf life and is subject to spoilage and/or damage. The Company's inventory may reach its expiration or may be subject to spoilage or other loss or damage, and, as such, may not be sold. Although management regularly reviews the amount of inventory on hand and its remaining shelf life, and estimates the time required to sell such inventory, write-downs of inventory may still be required. Any such write-down of inventory could have a material adverse effect on Aequus' business, financial condition and results of operations.

#### **Risks Related to Regulatory Matters Following Approval**

*Even if Aequus obtains marketing approval for AQS1303, AQS1304, Topiramate XR, Oxcarbazepine XR or any other product candidate, Aequus will be subject to ongoing obligations and extensive regulatory review, which may result in significant additional expense. Additionally, AQS1303, AQS1304, Topiramate XR, Oxcarbazepine XR or another product candidate could be subject to labeling and other restrictions, including withdrawal from the market, and Aequus may be subject to penalties if Aequus fails to comply with regulatory requirements or if Aequus experiences unanticipated problems with AQS1303, AQS1304, Topiramate XR, Oxcarbazepine XR or any other of its product candidates.*

Even if Aequus obtains regulatory approval of AQS1303, AQS1304, Topiramate XR, Oxcarbazepine XR or another product candidate, the TPD, FDA or other regulatory authority may still impose significant restrictions on its indicated uses, including more limited patient populations, require that precautions, contraindications, or warnings be included on the product labeling, including black box warnings, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Claims that Aequus may make may also be restricted through Aequus' approved labeling. In addition, any products for which Aequus receives regulatory approval or otherwise markets will be subject to ongoing regulatory requirements relating to the manufacturing, labeling, packaging, storage, distribution, import, export, safety surveillance, advertising, marketing promotion, recordkeeping, reporting of adverse events and other post-market information, and further development. These requirements include registration with the TPD, FDA or other regulatory authorities, listing of Aequus' drug products, payment of annual fees, as well as continued compliance with cGCPs for any clinical trials that Aequus conducts post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. In the U.S., should the inspectional findings not be resolved to the FDA's satisfaction or should the finding rise to a sufficient level, the FDA may issue a Warning Letter or Untitled Letter, or take other regulatory action such as a product seizure, withdrawal of product approval, request for a recall, refusal to allow the import or export of the product, fines, injunction against manufacture or distribution, consent decrees or imprisonment. Similar inspections may also occur in other jurisdictions.

In the U.S., the FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the information that patients must be provided, distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting

treatment to patients who meet certain safe-use criteria or requiring treated patients to enroll in a registry, dispensing only under certain circumstances and special monitoring.

With respect to sales and marketing activities by Aequus or any future collaborative partner, advertising and promotional materials must comply with the FDA's rules in addition to other applicable federal and local laws in the U.S. and similar legal requirements in other countries. In the U.S., the distribution of product samples to physicians must comply with the requirements of the U.S. *Prescription Drug Marketing Act*. Application holders must notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. Aequus may also be subject, directly or indirectly through Aequus' customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. *False Claims Act* and similar state laws, which impact, among other things, Aequus' proposed sales, marketing and scientific/educational grant programs. If Aequus participates in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, Aequus will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if QS1303, AQS1304 or another internal product candidate is approved in the U.S., Aequus' product labeling, advertising and promotional materials would be subject to regulatory requirements and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, a practice known as off-label promotion. If Aequus receives marketing approval for AQS1303, AQS1304 or another product candidate, physicians may nevertheless prescribe AQS1303, AQS1304 or other product candidates to their patients in a manner that is inconsistent with the approved label. If Aequus is found to have promoted such off-label uses, Aequus may become subject to significant liability and government fines. In the U.S., the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have promoted off-label uses may be subject to significant sanctions. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

In the U.S., engaging in the impermissible promotion of Aequus' products, following approval, for off-label uses can also subject Aequus to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which Aequus promotes or distributes drug products through, for example, corporate integrity agreements, and debarment, suspension or exclusion from participation in federal and state healthcare programs. These false claims statutes include the U.S. federal civil *False Claims Act*, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. Since 2004, these *False Claims Act* lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines that have been as much as \$3.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If Aequus does not lawfully promote Aequus' approved products, if any, Aequus may become subject to such litigation and, if Aequus does not successfully defend against such actions, those actions may have a material adverse effect on Aequus' business, financial condition, results of operations and prospects.



If Aequus or a regulatory agency discover previously unknown problems with a product candidate, once approved, such as adverse events of unanticipated severity or frequency lack of efficacy, data integrity issues with regulatory filings, problems with the facility where the product is manufactured or Aequus or Aequus' manufacturers fail to comply with applicable regulatory requirements, Aequus may be subject to reporting obligations as well as the following administrative or judicial sanctions in the U.S. or elsewhere:

- Costly and repeated regulatory inspections;
- Restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- Issuance of Warning Letters, Cyber Letters or Untitled Letters;
- Mandate modification to promotional materials or require Aequus to provide corrective information to healthcare providers;
- Require Aequus to enter into a consent decree, which can include imposition of various fines, reimbursement for inspection costs, required due dates for specific actions and penalties for noncompliance;
- Clinical holds;
- Injunctions or the imposition of civil or criminal penalties, imprisonment or monetary fines;
- Suspension or withdrawal of regulatory approval;
- Suspension of any ongoing clinical trials;
- Refusal to approve pending applications or supplements to approved applications filed by Aequus, or suspension or revocation of product license approvals;
- Debarment;
- Suspension or imposition of restrictions on operations, including costly new manufacturing requirements;
- Product seizure or detention or refusal to permit the import or export of product; or
- Restrictions on prices charged going forward.

The occurrence of any event or penalty described above may inhibit Aequus' ability to commercialize its product candidates, if approved, and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase Aequus' product liability exposure.

Moreover, the TPD or FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion of Aequus' product candidates in Canada or the U.S. If Aequus is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Aequus is not able to maintain regulatory compliance, Aequus may lose any marketing approval that Aequus may have obtained, which would adversely affect Aequus' business, prospects and ability to achieve or sustain profitability.

*Even if a product candidate receives marketing approval by the FDA in the U.S., Aequus may never receive marketing approval for or commercialize such product candidate outside the U.S.*

In order to market any product candidate outside the U.S., Aequus must obtain separate marketing approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of Aequus' product candidates. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks associated with obtaining FDA approval in the U.S., as well as other risks. For example, legislation analogous to Section 505(b)(2) of the FDCA in the U.S., which relates to the ability of an NDA applicant to use published data not developed by such applicant, may not exist in other countries. In territories where data is not freely available, Aequus may not have the ability to commercialize Aequus' products, when and if approved, without negotiating rights from third parties to refer to their clinical data in Aequus' regulatory applications, which could require the expenditure of significant additional funds. Further, Aequus may be unable to obtain rights to the

necessary clinical data and may be required to develop Aequus' own proprietary safety and efficacy dossiers. In addition, in many countries outside the U.S., it is required that a product receive pricing and reimbursement approval before the product can be commercialized. This can result in substantial delays in such countries. Further, the product labeling requirements outside the U.S. may be different and inconsistent with the U.S. labeling and to the detriment of the product, and therefore negatively affect the ability to market in countries outside the U.S.

Marketing approval in one country does not ensure marketing approval in another, or any regulatory approval obtained may not be as broad as what was obtained in other jurisdictions, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. In addition, Aequus may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if Aequus fails to comply with applicable foreign regulatory requirements. If Aequus fails to comply with regulatory requirements in international markets or to obtain and maintain required approvals, Aequus' ability to market to Aequus' full target market will be reduced and Aequus' ability to realize the full market potential of Aequus' product candidates will be harmed.

*Aequus will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect Aequus' business.*

Any name Aequus intends to use in the U.S. for AQS1303, AQS1304 or Aequus' other product candidates, will require approval from the FDA regardless of whether Aequus has secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of Aequus' proposed product names, Aequus may be required to adopt alternative names for Aequus' product candidates. If Aequus adopts alternative names, Aequus would lose the benefit of Aequus' existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Aequus may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit Aequus' ability to commercialize Aequus' product candidates. Further, if the regulator does not approve the trademark in one jurisdiction, then Aequus may be required to obtain different trademarks in many jurisdictions. Similar comments apply to other jurisdictions.

*Aequus' relationships with physicians, customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose Aequus to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.*

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any product candidates that Aequus may commercialize. Aequus' arrangements with third-party payors, including government healthcare programs, and customers will expose Aequus to broadly-applicable U.S. and foreign fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which Aequus markets, sells and distributes any of its product candidates, if approved, and any other product candidates Aequus may commercialize. Restrictions under applicable U.S. federal and state healthcare laws and regulations include the following:

- The U.S. federal *Anti-Kickback Statute* prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- The U.S. *False Claims Act*, including civil whistleblower or qui tam actions, imposes criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- The U.S. federal *Health Insurance Portability and Accountability Act of 1996* ("HIPAA"), created federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the U.S. *Health Information Technology for Economic and Clinical Health Act*, and its implementing regulations, impose obligations on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates that create receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- The federal physician payment transparency requirements under the ACA and applicable regulations require manufacturers of drugs, devices, biologics and medical supplies to report certain information to the Department of Health and Human Services including information related to payments and other transfers of value made to physicians and teaching hospitals and the ownership and investment interests held by physicians and their immediate family members; and
- Analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

The risk of Aequus being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the relevant government or regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes; such that a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the ACA provided that the U.S. government may assert that a claim including items or services resulting from a violation of the U.S. federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

Efforts to ensure that Aequus' business arrangements with third parties will comply with applicable healthcare laws and regulations are costly. It is possible that governmental authorities will conclude that Aequus' business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Aequus' operations are found to be in violation of any of these laws or any other governmental regulations that may apply to Aequus, Aequus may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of Aequus' operations. If any of the physicians or other providers or entities with whom Aequus expects to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Similar comments apply to analogous healthcare laws and regulations in other jurisdictions.

## Risks Related to Intellectual Property Rights

*Aequus may not be able to protect Aequus' proprietary technology in the marketplace.*

Aequus depends on its ability to protect Aequus' proprietary technology. Aequus relies on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with executives, consultants and third parties, all of which offer only limited protection. Aequus' success depends in large part on Aequus' ability and any future licensee's ability to maintain Aequus' patents and to obtain additional patent protection in Canada, the U.S. and other countries with respect to Aequus' proprietary technology and products. Aequus believes it will be able to obtain, through prosecution of Aequus' pending patent applications, additional patent protection for Aequus' proprietary technology. If Aequus is compelled to spend significant time and money protecting or enforcing Aequus' patents, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, Aequus' business and financial prospects may be harmed. If Aequus is unable to effectively protect the intellectual property that Aequus owns, other companies may be able to offer for sale the same or similar products containing the generically available active pharmaceutical ingredients in Aequus' product candidates, which could materially adversely affect Aequus' competitive business position and harm Aequus' business prospects. Aequus' patents may be challenged, narrowed, invalidated or circumvented, which could limit Aequus' ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that Aequus may have for Aequus' product candidates. Even if Aequus' patents are unchallenged, they may not adequately protect Aequus' intellectual property, provide exclusivity for Aequus' product candidates or prevent others from designing around Aequus' claims. Any of these outcomes could impair Aequus' ability to prevent competition from third parties, which may have an adverse impact on Aequus' business.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in Canada, the U.S. and many jurisdictions outside of Canada and the U.S. is not consistent. For example, in many jurisdictions the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in Canada, the U.S. and other countries may diminish the value of Aequus' intellectual property or create uncertainty. In addition, publication of information related to Aequus' current product candidates and potential products may prevent Aequus from obtaining or enforcing patents relating to these product candidates and potential products, including without limitation transdermal delivery systems and methods of using such transdermal delivery systems. Aequus' product candidates contain generically available active pharmaceutical ingredients. As a result, composition-of-matter patents directed to the active pharmaceutical ingredients in Aequus' product candidates, which are generally believed to offer the strongest form of patent protection, are not available for Aequus' product candidates.

Patents that Aequus owns or may license in the future do not necessarily ensure the protection of Aequus' intellectual property for a number of reasons, including without limitation, the following:

- The active pharmaceutical ingredients in Aequus' product candidates are generic and therefore Aequus' patents do not include claims directed solely to the active pharmaceutical ingredients;
- Aequus' patents may not be broad or strong enough to prevent competition from other products that are identical or similar to Aequus' product candidates using the same active pharmaceutical ingredients;
- There can be no assurance that the term of a patent protection will be long enough for Aequus' company to realize sufficient economic value under the patents following commercialization of Aequus' product candidates;
- Aequus does not expect, upon approval of Aequus' NDA, to receive patent term restoration under the U.S. *Hatch-Waxman Act* for any patents that have been submitted to the FDA for listing in the Orange Book;
- Aequus' issued patents and pending patent applications that may issue as patents in the future may not prevent entry into the Canada or U.S. markets or other markets of generic versions of Aequus' AQS1303, AQS1304 and other product candidates;

- Aequus does not at this time own or control issued foreign patents in all markets that would prevent generic entry into some markets for Aequus' product candidates;
- Aequus may be required to disclaim part of the term of one or more patents;
- There may be prior art of which Aequus is not aware that may affect the validity or enforceability of a patent claim;
- There may be prior art of which Aequus is aware, which Aequus does not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- There may be other patents issued to others that will affect Aequus' freedom to operate;
- If Aequus' patents are challenged, a patent office or a court could determine that they are invalid or unenforceable;
- There might be changes in the law that governs patentability, validity and infringement of Aequus' patents that adversely affects the scope or enforceability of Aequus' patent rights;
- A court could determine that a competitor's technology or product that is the same as or similar to Aequus' product candidates does not infringe Aequus' patents; and
- Aequus' patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

If Aequus encounters delays in its development or clinical trials, the period of time during which Aequus could market Aequus' product candidates under patent protection would be reduced.

Aequus' competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Aequus' competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA or other regulatory authorities in which Aequus' competitors claim that Aequus' patents are invalid, unenforceable or not infringed. Alternatively, Aequus' competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with Aequus' product candidates. In these circumstances, Aequus may need to defend or assert Aequus' patents, by means including filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or government agency with jurisdiction may find Aequus' patents invalid, unenforceable or not infringed. Aequus may also fail to identify patentable aspects of Aequus' R&D before it is too late to obtain patent protection. Even if Aequus has valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve Aequus' business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In that regard, third parties may challenge Aequus' patents in the courts or patent offices in Canada, the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit Aequus' ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of Aequus' technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire or be held invalid or unenforceable before Aequus' company can realize sufficient economic value following commercialization of Aequus' product candidates.

*Aequus' intellectual property portfolio is currently comprised of pending patent applications. If Aequus' pending patent applications fail to issue or fail to issue with a scope that is meaningful to Aequus' product candidates, Aequus' business will be adversely affected.*

There can be no assurance that our pending patent applications will result in issued patents in Canada, the U.S. or foreign jurisdictions in which such applications are pending. Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity or enforceability, or that Aequus will obtain sufficient claim scope or term in those patents to prevent a third party from competing successfully with Aequus' product candidates.

*Aequus may not be able to enforce Aequus' intellectual property rights throughout the world.*

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of Canada and the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. To the extent that Aequus has obtained or is able to obtain patents or other intellectual property rights in any foreign jurisdictions, it may be difficult for Aequus to stop the infringement of Aequus' patents or the misappropriation of other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the availability of certain types of patent rights and enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce Aequus' patent rights in foreign jurisdictions could result in substantial costs and divert Aequus efforts and attention from other aspects of Aequus' business. Accordingly, Aequus' efforts to protect Aequus' intellectual property rights in such countries may be inadequate.

*Patent reform legislation in the U.S. could increase the uncertainties and costs surrounding the prosecution of Aequus' patent applications and the enforcement or defense of Aequus' issued patents, if any.*

On September 16, 2011, the *Leahy-Smith America Invents Act* (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the U.S. transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, re-examination, inter-partes review or interference proceedings challenging Aequus' patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, Aequus' patent rights, which could adversely affect Aequus' competitive position.

The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. However, the full impact of the Leahy-Smith Act and the courts' review of any appeals to related proceedings, is in its early stages. Accordingly, the full impact that the Leahy-Smith Act will have on the operation of Aequus' business is not clear. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of Aequus' patent applications and the enforcement or defense of Aequus' issued patents, as well as Aequus' ability to bring about timely favorable resolution of any disputes involving Aequus' patents and the patents of others.

*Obtaining and maintaining Aequus' patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and Aequus' patent protection could be reduced or eliminated for noncompliance with these requirements.*

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in unenforceability, invalidity, abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in unenforceability, invalidity, abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment

of fees and failure to properly legalize and submit formal documents. If Aequus or any future licensors fail to maintain the patents and patent applications covering Aequus' product candidates, Aequus' competitive position would be adversely affected.

*Aequus may infringe the intellectual property rights of others, which may prevent or delay Aequus' product development efforts and stop Aequus from commercializing or increase the costs of commercializing Aequus' products, when and if approved.*

Aequus' commercial success depends significantly on Aequus' ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which Aequus is not aware that Aequus' current or future product candidates infringe. There also could be patents that Aequus believes Aequus does not infringe, but that Aequus may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. There may be currently pending applications of which Aequus is unaware that may later result in issued patents that Aequus' current or future product candidates infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that Aequus' current or future product candidates infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover Aequus' product candidates.

Third parties may assert that Aequus is employing their proprietary technology without authorization and may sue Aequus for patent or other intellectual property infringement or misappropriation. These lawsuits are costly and could adversely affect Aequus' results of operations and divert the attention of managerial and scientific personnel. If Aequus is sued for patent infringement, Aequus would need to demonstrate that Aequus' product candidates or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and Aequus may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if Aequus is successful in these proceedings, Aequus may incur substantial costs and the time and attention of Aequus' management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on Aequus. In addition, Aequus may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover Aequus' product candidates or their use, the holders of any of these patents may be able to block Aequus' ability to commercialize Aequus' product candidates unless Aequus acquires or obtains a license under the applicable patents or until the patents expire. Aequus may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of Aequus' product candidates or lead to prohibition of the manufacture or sale of product candidates by Aequus. Even if Aequus is able to obtain a license, it may be non-exclusive, thereby giving Aequus' competitors access to the same technologies licensed to Aequus. Aequus could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, Aequus could be found liable for monetary damages, including treble damages and attorneys' fees if Aequus is found to have willfully infringed a patent. A finding of infringement could prevent Aequus from commercializing Aequus' product candidates or force Aequus to cease some of Aequus' business operations, which could materially harm Aequus' business. Any claims by third parties that Aequus has misappropriated their confidential information, know-how or trade secrets could have a similar negative impact on Aequus' business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on Aequus' ability to raise the funds necessary to continue Aequus' operations.

*Aequus may be subject to claims that Aequus or Aequus' consultants or contractors have misappropriated the intellectual property, including know-how or trade secrets, of a third party, or that claim ownership of what Aequus regards as Aequus' own intellectual property.*

Many of Aequus' consultants and contractors were previously employed at or engaged by biotechnology companies or other pharmaceutical companies, including Aequus' competitors or potential competitors. Some of these consultants and contractors, including each member of Aequus' senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Aequus may be subject to claims that Aequus or its consultants and contractors have used or disclosed the intellectual property and other proprietary information or know-how or trade secrets of others in their work for Aequus. Litigation may be necessary to defend against these claims. Aequus is not aware of any threatened or pending claims related to these matters or concerning agreements with Aequus' senior management, or other of Aequus' employees, consultants and contractors, but litigation may be necessary in the future to defend against such claims. If Aequus fails in defending any such claims, in addition to paying monetary damages, Aequus may lose valuable intellectual property rights, or personnel or access to consultants and contractors. Even if Aequus is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while Aequus typically requires Aequus' consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to Aequus, Aequus may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that Aequus regards as Aequus' own, which may result in claims by or against Aequus related to the ownership of such intellectual property. If Aequus fails in prosecuting or defending any such claims, in addition to paying monetary damages, Aequus may lose valuable intellectual property rights. Even if Aequus is successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to Aequus' management and scientific personnel.

*Aequus may be unable to adequately prevent disclosure of trade secrets and other proprietary information.*

Aequus relies on trade secrets to protect Aequus' proprietary technological advances and know-how, especially where Aequus does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Aequus relies in part on confidentiality agreements with Aequus' consultants, contractors, outside scientific collaborators, sponsored researchers and other advisors, including the third parties Aequus relies on to manufacture Aequus' product candidates, to protect Aequus' trade secrets and other proprietary information. However, any party with whom Aequus has executed such an agreement may breach that agreement and disclose Aequus' proprietary information, including Aequus' trade secrets. Accordingly, these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of Aequus' proprietary rights. In addition, others may independently discover Aequus' trade secrets and proprietary information. Further, the FDA, as part of its Transparency Initiative, a proposal to increase disclosure and make data more accessible to the public, is currently considering whether to make additional information publicly available on a routine basis, including information that Aequus may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Failure to obtain or maintain trade secret protection could enable competitors to use Aequus' proprietary information to develop products that compete with Aequus' products or cause additional, material adverse effects upon Aequus' competitive business position and financial results.

*Any lawsuits relating to infringement of intellectual property rights brought by or against Aequus will be costly and time consuming and may adversely impact the price of Aequus' Common Shares.*

Aequus may be required to initiate litigation to enforce or defend Aequus' intellectual property rights. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings could substantially increase Aequus'



operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In infringement litigation, any award of monetary damages Aequus receives may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Aequus' confidential information and trade secrets could be compromised by disclosure during litigation. Moreover, there can be no assurance that Aequus will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims Aequus asserts against a perceived infringer could provoke these parties to assert counterclaims against Aequus alleging that Aequus has infringed their patents. Some of Aequus' competitors may be able to sustain the costs of such litigation or proceedings more effectively than Aequus can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on Aequus' ability to compete in the marketplace.

In addition, Aequus' patents and patent applications could face other challenges, such as interference proceedings, opposition proceedings, reissue, inter partes review, re-examination proceedings, third-party submissions of prior art, and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope or preventing the issuance of, any of Aequus' patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert Aequus' management and scientific personnel's time and attention.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of Aequus' Common Shares.

*Intellectual property disputes could cause Aequus to spend substantial resources and distract Aequus' personnel from their normal responsibilities.*

Even if resolved in Aequus' favor, litigation or other legal proceedings relating to intellectual property claims may cause Aequus to incur significant expenses and could distract Aequus' technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of Aequus' Common Shares. Such litigation or proceedings could substantially increase Aequus' operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Aequus may not have sufficient financial or other resources to adequately conduct such litigation or proceedings.

#### **Risks Related to the Development, Licensing and Acquisition of Additional Product Candidates**

*If Aequus fails to develop and commercialize Aequus' current pipeline of additional product candidates, Aequus' prospects for future growth and Aequus' ability to reach or sustain profitability may be limited.*

A key element of Aequus' strategy is to develop, obtain regulatory approval for and commercialize Aequus' current portfolio of product candidates. Aequus may not be successful in Aequus' efforts to develop Aequus' portfolio of product candidates, and any product candidates Aequus does develop may not produce commercially viable products that safely and effectively treat their indicated conditions. To date, Aequus' efforts have yielded five additional product candidates, AQS1301, AQS1303, AQS1304, Topiramate XR and Oxcarbazepine XR, which are all focused on treating diseases of the CNS.

Aequus' development programs may initially show promise in identifying potential product leads, yet fail to produce product candidates for clinical development. In addition, identifying new treatment needs and product candidates requires substantial technical, financial and human resources on Aequus' part. If Aequus is unable to obtain development partners or additional development program funding, or to continue to devote substantial technical and human resources to such programs, Aequus may have to delay or abandon these programs. Any product candidate that Aequus successfully identifies may require substantial additional development efforts prior to commercial sale, including preclinical studies, extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are susceptible to the risks of failure that are inherent in pharmaceutical product development.

*Aequus may be unable to license or acquire suitable additional product candidates or technologies from third parties for a number of reasons.*

The licensing and acquisition of pharmaceutical products is competitive. A number of more established companies are also pursuing strategies to license or acquire products. These established companies may have a competitive advantage over Aequus due to their size, cash resources or greater clinical development and commercialization capabilities. In addition, Aequus expects competition in acquiring product candidates to increase, which may lead to fewer suitable acquisition opportunities for Aequus as well as higher acquisition prices.

Other factors that may prevent Aequus from licensing or otherwise acquiring suitable product candidates include the following:

- Aequus may be unable to license or acquire the relevant technology on terms that would allow Aequus to make an appropriate return on Aequus' investment in such product;
- Companies that perceive Aequus to be their competitor may be unwilling to assign or license their product rights to Aequus;
- Aequus may be unable to identify suitable products or product candidates within Aequus' areas of expertise; or
- Aequus may not have sufficient funds to acquire, develop or commercialize additional product candidates or technologies.

*Changes in laws, regulations, guidelines and similar issues relating to marijuana may impact the business, results of operations and financial condition of the Company.*

The Company's operations are subject to a variety laws, regulations and guidelines including relating to the manufacture, management, transportation, storage, and disposal of medical marijuana as well as laws and regulations relating to health and safety, the conduct of operations and the protection of the environment. Approval policies, laws, regulations and guidelines may change during the course of a product candidate's clinical development and may vary among jurisdictions. Any delays in obtaining, or failure to obtain regulatory approvals, including at the pre-clinical, clinical or marketing stage, would significantly delay the development of markets and products and could have a material adverse effect on the business, results of operations and financial condition of the Company.

*The Company may be subject to unfavourable publicity or consumer perception in connection with AQS1304, its cannabinoid transdermal patch.*

The Company believes the medical marijuana industry is highly dependent upon consumer perception regarding the safety, efficacy and quality of the medical marijuana products. Consumer perception of AQS1304 can be significantly influenced by scientific research or findings, regulatory investigations, litigation, media attention and other publicity regarding the use of medical marijuana products. There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention or other research findings or publicity will be favourable to the medical marijuana market or any particular product, or consistent with earlier publicity. Future research reports, findings, regulatory proceedings, litigation,

media attention or other publicity that are perceived as less favourable than, or that question, earlier research reports, findings or publicity could have a material adverse effect on the demand for AQS1304 and the business, results of operations, financial condition and cash flows of the Company. Aequus' dependence upon consumer perceptions means that adverse scientific research reports, findings, regulatory proceedings, litigation, media attention or other publicity, whether or not accurate or with merit, could have a material adverse effect on the Company, the demand for AQS1304, and the business, results of operations, financial condition and cash flows of the Company. Further, adverse publicity reports or other media attention regarding the safety, efficacy and quality of medical marijuana in general, or AQS1304 specifically, or associating the use of medical marijuana with illness or other negative effects or events, could have such a material adverse effect. Such adverse publicity reports or other media attention could arise even if the adverse effects associated with such products resulted from consumers' failure to consume such products appropriately or as directed.

*The full effect of the legalization of adult-use cannabis in Canada on the medical cannabis industry is unknown, and may have a significant negative effect upon our medical cannabis program if individuals decide to purchase products available in the proposed adult-use market instead of medical cannabis products.*

The *Cannabis Act* was enacted as federal legislation in Canada in 2018 and allows individuals over the age of 18 to legally purchase, process and cultivate limited amounts of cannabis for adult use in Canada. As a result, individuals who currently utilize the medical cannabis market for their supply of cannabis and cannabis-based products may instead turn to the adult-use cannabis market for their supply of cannabis and cannabis-based products. This decision may be influenced by a number of factors, including price of medical cannabis products in relation to similar adult-use cannabis products, the amount of active ingredients in medical cannabis products in relation to similar adult-use cannabis products, the types of cannabis products available to adult users and limitations on access to adult-use cannabis products imposed by the regulations under the *Cannabis Act* and the legislation governing distribution of cannabis that has been enacted by the individual provinces and territories of Canada. We are unable to predict how each of those factors will evolve or their relative impacts on the medical cannabis market.

The *Cannabis Act* and the legal adult-use market in Canada may reduce the potential market for any products developed through our medical cannabis program, including AQS1304.

*Assuming we are successful commercializing AQS1304 the future success of AQS1304 may be dependent on additional states legalizing medical marijuana.*

Assuming we are successful in commercializing AQS1304, the future success of AQS1304 may depend on the continued development of the medical marijuana market, and on our ability to penetrate that market. According to the Marijuana Policy Project, a pro-legalization group, medical marijuana is legal in 33 states and Washington, D.C., Puerto Rico and Guam. However, continued development of the medical marijuana market in the United States is dependent upon continued legislative authorization of marijuana at the state level for medical purposes and, in certain states, based on the specifics of the legislation passed in that state. Numerous factors impact the legislative process. Any one of these factors could slow or halt the progress and adoption of marijuana for medical purposes, which would limit the market for AQS1304 and negatively impact our business and revenues.

*Marijuana remains illegal under United States federal law.*

As described above, while 33 states and Washington, D.C. have laws and/or regulations that recognize, in one form or another, legitimate medical and consumer uses for marijuana, marijuana use remains prohibited under United States federal law and the risk of strict enforcement of the Controlled Substance Act (the "CSA") in light of Congressional activity, judicial holdings and stated federal policy remains uncertain. Because we do not currently cultivate, produce, sell or distribute any marijuana, we believe that we have no risk that we will be deemed to facilitate the selling or distribution of marijuana in violation of United States federal law. Strict enforcement of United States federal law regarding marijuana

could discourage the activities of some of our potential customers, which could result in our inability to proceed with our business plan.

*We may have difficulty accessing the service of U.S. banks.*

If we are successful in commercializing AQS1304, there is a compelling argument that U.S. banks would not be able to accept for deposit funds from the drug trade and therefore would not be able to do business with the Company.

The United States federal government regulates drugs through the Controlled Substances Act (the “CSA”), which currently classifies marijuana as a Schedule I drug. A Schedule I drug means the Drug Enforcement Agency has not approved marijuana as a safe and effective drug for any indication. Due to the CSA categorization of cannabis as a Schedule I drug, U.S. federal law makes it illegal for financial institutions that depend on the Federal Reserve’s money transfer system to take any proceeds from cannabis sales or cannabis-related activities. Banks and other financial institutions could be prosecuted and possibly convicted of money laundering for providing services to cannabis businesses under the United States Currency and Foreign Transactions Report Act of 1970 (the “Bank Secrecy Act”). Under U.S. federal law, banks or other financial institutions that provide a marijuana business with a checking account, debit or credit card, small business loan, or any other service could be found guilty of money laundering or conspiracy.

While there has been no change in U.S. federal banking laws to account for the trend towards legalizing medical and recreational cannabis by U.S. states, the Department of the Treasury Financial Crimes Enforcement Network (“FinCEN”) has issued guidance advising prosecutors of money laundering and other financial crimes not to focus their enforcement efforts on banks and other financial institutions that serve cannabis-related businesses, so long as that business is legal in their state and none of the federal enforcement priorities are being violated (such as keeping cannabis away from children and out of the hands of organized crime). The FinCEN guidance also clarifies how financial institutions can provide services to cannabis-related business consistent with their Bank Secrecy Act obligations, including through customer due diligence, but makes it clear that they are doing so at their own risk. Due to the fear by financial institutions of being implicated in or prosecuted for money laundering, banks and other financial institutions in the U.S. are generally unwilling to risk a potential violation of federal law without guaranteed immunity from prosecution and most refuse to provide any kind of services to cannabis or cannabis-related businesses.

#### **Risks Related to Aequus’ Business Operations and Industry**

*Aequus’s business activities may be adversely impacted by the recent outbreak of the novel coronavirus (COVID-19).*

The recent outbreak of the coronavirus, also known as COVID-19, has spread across the globe and is impacting worldwide economic activity. Conditions surrounding the coronavirus continue to rapidly evolve and government authorities have implemented emergency measures to mitigate the spread of the virus. The outbreak and the related mitigation measures may have an adverse impact on global economic conditions as well as on Aequus’ business activities. The extent to which the coronavirus may impact Aequus’ business activities will depend on future developments, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, business disruptions, and the effectiveness of actions taken in Canada and other countries to contain and treat the disease. These events are highly uncertain and as such, Aequus cannot determine their financial impact at this time.

*If Aequus is not successful in attracting and retaining highly qualified personnel, Aequus may not be able to successfully implement Aequus’ business strategy.*

Aequus’ ability to compete in the highly competitive pharmaceuticals industry depends in large part upon Aequus’ ability to attract and retain highly qualified managerial, scientific and medical personnel. Aequus is highly dependent on Aequus’ management, scientific and medical personnel, as well as its subcontracted salesforce. In order to induce valuable

executives and consultants to remain with Aequus, Aequus has provided these executives and consultants with stock options that vest over time. The value to executives and consultants of stock options that vest over time is significantly affected by movements in Aequus' stock price that Aequus cannot control and may at any time be insufficient to counteract more lucrative offers from other companies.

Aequus' management team has expertise in many different aspects of drug development and commercialization. Competition for skilled personnel in Aequus' market is intense and competition for experienced personnel may limit Aequus' ability to hire and retain highly qualified personnel on acceptable terms. Despite Aequus' efforts to retain valuable executives and consultants, members of Aequus' management, scientific and medical teams may terminate their employment with Aequus on short notice. The loss of the services of any of Aequus' executive officers or other key individuals could potentially harm Aequus' business, operating results or financial condition. Aequus does not currently carry "key person" insurance on the lives of members of executive management. Aequus' success also depends on Aequus' ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Other pharmaceutical companies with which Aequus competes for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than Aequus does. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than those that Aequus has to offer. If Aequus is unable to continue to attract and retain high-quality personnel, the rate of and success with which Aequus can develop and commercialize product candidates would be limited.

*If product liability lawsuits are brought against Aequus, Aequus may incur substantial liabilities and may be required to limit commercialization of any of its internal development programs, if approved.*

Aequus faces a potential risk of product liability as a result of the clinical testing of its product candidates and will face an even greater risk if Aequus commercializes any of them, if approved. For example, Aequus may be sued if any product candidate Aequus develops allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If Aequus cannot successfully defend itself against product liability claims, Aequus may incur substantial liabilities or be required to limit commercialization of the product candidate subject to such claims. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- Decreased demand for AQS1303, AQS1304 and any other product candidates that Aequus may develop;
- Injury to Aequus' reputation;
- Withdrawal of clinical trial participants;
- Costs to defend any related litigation;
- A diversion of management's time and Aequus' resources;
- Substantial monetary awards to trial participants or patients;
- Product recalls, withdrawals or labeling, marketing or promotional restrictions;
- Loss of revenue;
- The inability to commercialize AQS1303, AQS1304 or any other of Aequus' internal product candidates, if approved;
- A decline in Aequus' stock price; and
- Exposure to adverse publicity.

Aequus' inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates Aequus develops. Aequus

does not currently maintain product liability insurance given its current level of product development. Although Aequus does maintain other forms of insurance, any claim that may be brought against Aequus could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by Aequus' insurance or that is in excess of the limits of Aequus' insurance coverage. Aequus' insurance policies also have various exclusions, and Aequus may be subject to a product liability claim for which Aequus has no coverage. Aequus may have to pay any amounts awarded by a court or negotiated in a settlement that exceed Aequus' coverage limitations or that are not covered by Aequus' insurance, and Aequus may not have, or be able to obtain, sufficient capital to pay such amounts.

*Aequus may acquire businesses or products, or form strategic alliances in the future, and Aequus may not realize the benefits of such acquisitions or alliances.*

Aequus may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that Aequus believes will complement or augment Aequus' existing business. If Aequus acquires businesses with promising markets or technologies, Aequus may not be able to realize the benefit of acquiring such businesses if Aequus is unable to successfully integrate them with Aequus' existing operations and company culture. Aequus may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent Aequus from realizing their expected benefits or enhancing Aequus' business. Aequus cannot assure you that, following any such acquisition, Aequus will achieve the expected synergies to justify the transaction.

*Aequus' business is affected by macroeconomic conditions.*

Various macroeconomic factors could adversely affect Aequus' business and the results of Aequus' operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates, and overall economic conditions and uncertainties, including those resulting from political instability and the current and future conditions in the global financial markets. For instance, if inflation or other factors were to significantly increase Aequus' business costs, it may not be feasible to pass through price increases to patients. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of Aequus' investments and Aequus' ability to liquidate Aequus' investments in order to fund Aequus' operations, if necessary.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payors and distributors to purchase, pay for and effectively distribute Aequus' products if and when approved. Similarly, these macroeconomic factors could affect the ability of Aequus' current or potential future contract manufacturers, sole-source or single-source suppliers, or licensees to remain in business or otherwise manufacture or supply Aequus' product candidates. Failure by any of them to remain in business could affect Aequus' ability to manufacture product candidates.

*Aequus incurs significant increased costs as a result of operating as a public company, and Aequus' management is required to devote substantial time to compliance initiatives.*

As a public company, Aequus incurs significant legal, accounting and other expenses that Aequus did not incur as a private company. Legal, accounting and other expenses associated with public company reporting requirements have increased significantly in the past few years. Aequus anticipates that costs may continue to increase with corporate governance related requirements, including, without limitation, requirements under National Instrument 52-109 - *Certification of Disclosure in Issuers' Annual and Interim Filings* ("NI 52-109"), National Instrument 52-110 - *Audit Committees* ("NI 52-110") and National Instrument 58-101 - *Disclosure of Corporate Governance Practices*.

Aequus' management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased Aequus' legal and financial compliance costs and made some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for Aequus to obtain director and officer liability insurance.

Aequus' testing, or the subsequent testing by Aequus' independent registered public accounting firm, may reveal deficiencies in Aequus' internal control over financial reporting that are deemed to be material weaknesses. Aequus will incur substantial accounting expense and expend significant management efforts to comply with internal control over financial reporting requirements. Aequus currently does not have an internal audit group, and Aequus hires additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if Aequus is not able to comply with these requirements in a timely manner or if Aequus or Aequus' independent registered public accounting firm identifies deficiencies in Aequus' internal control over financial reporting that are deemed to be material weaknesses, the market price of Aequus' Common Shares could decline, and Aequus could be subject to sanctions or investigations by applicable securities regulatory authorities, which would require additional financial and management resources.

*Business interruptions could delay Aequus in the process of developing its product candidates and could disrupt Aequus' sales.*

Aequus' headquarters is located in Vancouver, British Columbia, Canada; Sandoz manufacturing occurs in Fort Worth, Texas and Medicom is located in the United Kingdom. Aequus is vulnerable to natural disasters, such as severe storms and other events that could disrupt Aequus, Medicom or Sandoz's operations. Aequus does not carry insurance for natural disasters and Aequus may not carry sufficient business interruption insurance to compensate Aequus for losses that may occur. Any losses or damages Aequus incurs could have a material adverse effect on Aequus' business operations.

*Aequus' business and operations would suffer in the event of system failures.*

Despite the implementation of security measures, Aequus' internal computer systems, and those of Aequus' CROs and other third parties on which Aequus relies, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in Aequus' operations, it could result in a material disruption of Aequus' drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in Aequus' regulatory approval efforts and significantly increase Aequus' costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to Aequus' data or applications, or inappropriate disclosure of confidential or proprietary information, Aequus could incur liability and the further development of Aequus' product candidates could be delayed.

*Aequus' employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm Aequus' business.*

Aequus is exposed to the risk that employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in fraudulent or other illegal activity, fraud or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to Aequus that violates: (i) the law and regulations of the FDA and non-U.S. regulators, including those laws that require the reporting of true, complete and accurate information to the FDA and non-U.S. regulators, (ii) healthcare fraud and abuse laws and regulations in the U.S. and abroad and (iii) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct in violation of these laws may also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to Aequus' reputation. It is not always possible to identify and deter misconduct by Aequus' executives, consultants and other third parties, and any precautions Aequus takes to detect and prevent this activity may

not be effective in controlling unknown or unmanaged risks or losses or in protecting Aequus from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against Aequus, and Aequus is not successful in defending itself or asserting Aequus' rights, those actions could have a significant impact on Aequus' business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of Aequus' operations, any of which could adversely affect Aequus' ability to operate Aequus' business and Aequus' results of operations.

*The directors and officers of Aequus may be subject to conflicts of interest.*

Some of the directors and officers are engaged and will continue to be engaged in the search for additional business opportunities on behalf of other corporations, and situations may arise where these directors and officers will be in direct competition with Aequus. Some of the directors and officers of Aequus are or may become directors or officers of the other companies engaged in other business ventures whose operations may, from time to time, be in direct competition with Aequus' operations. Conflicts, if any, will be dealt with in accordance with the relevant provisions of the BCBCA.

#### **Risks Related to Ownership of Aequus' Common Shares**

*Future sales or the issuances of Aequus' securities may cause the market price of Aequus' equity securities to decline.*

The market price of our equity securities could decline as a result of issuances of securities by us or sales by our existing shareholders of Common Shares in the market, or the perception that these sales could occur, during the currency of this annual information form. Sales of Common Shares by shareholders may make it more difficult for us to sell equity securities at a time and price that we deem appropriate. Sales or issuances of substantial numbers of Common Shares, or the perception that such sales could occur, may adversely affect prevailing market prices of the Common Shares. With any additional sale or issuance of Common Shares, investors will suffer dilution to their voting power and the Company may experience dilution in its earnings per share.

*Aequus expects that Aequus' share price may fluctuate significantly.*

The market price of securities of many companies, particularly development stage pharmaceutical companies, experience wide fluctuations in price that are not necessarily related to the operating performance, underlying asset values or prospects of such companies.

The market price of Aequus' Common Shares could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond Aequus' control, including:

- Adverse results in Aequus' planned clinical trials for its internal programs;
- Aequus' failure to commercialize its internal programs, if approved, or develop and commercialize additional product candidates;
- Aequus' ability to successfully market and sell third-party products in Canada;
- Unanticipated efficacy, safety or tolerability concerns related to the use of AQS1303 or AQS1304;
- Regulatory actions with respect to AQS1303 or AQS1304;
- Inability to obtain adequate product supply of AQS1303 or AQS1304 or inability to do so at acceptable prices;
- Failure to obtain Health Canada approval for the commercialization of Topiramate XR and Oxcarbazepine XR in Canada;
- Adverse results or delays in Aequus' clinical trials for Aequus' other product candidates;
- Changes in laws or regulations applicable to AQS1303, AQS1304 or any future product candidates, including but not limited to clinical trial requirements for approvals;



- Aequus' inability to effectively promote and market Tacrolimus IR, Vistitan or Evolve® in Canada;
- Actual or anticipated fluctuations in Aequus' financial condition and operating results;
- Actual or anticipated changes in Aequus' growth rate relative to Aequus' competitors;
- Competition from existing products or new products that may emerge;
- Announcements by Aequus, Aequus' collaborators or Aequus' competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- Failure to meet or exceed financial estimates and projections of the investment community or that Aequus provides to the public;
- Issuance of new or updated research or reports by securities analysts;
- Fluctuations in the valuation of companies perceived by investors to be comparable to Aequus;
- Share price and volume fluctuations attributable to inconsistent trading volume levels of Aequus' shares;
- Additions or departures of key management or scientific personnel;
- Disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for Aequus' technologies;
- Announcement or expectation of additional debt or equity financing efforts;
- Sales of Aequus' Common Shares by Aequus, Aequus' insiders or Aequus' other shareholders; and
- General economic and market conditions.

These and other market and industry factors may cause the market price and demand for Aequus' Common Shares to fluctuate substantially, regardless of Aequus' actual operating performance, which may limit or prevent investors from readily selling their Common Shares and may otherwise negatively affect the liquidity of Aequus' Common Shares. In addition, the stock market in general, and the TSX-V and the share prices of pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of shares has been volatile, holders of those shares have instituted securities class action litigation against the company that issued the shares. If any of Aequus' shareholders brought a lawsuit against Aequus, Aequus could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of Aequus' management.

*Aequus may be subject to securities litigation, which is expensive and could divert management attention.*

The market price of Aequus' Common Shares may be volatile, and in the past companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. Aequus may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact Aequus' business. Any adverse determination in litigation could also subject Aequus to significant liabilities.

*Aequus' existing principal shareholders, executive officers and directors own a significant percentage of Aequus' Common Shares and will be able to exert a significant control over matters submitted to Aequus' shareholders for approval.*

Aequus' executive officers and directors together beneficially owned approximately 9% of Aequus' outstanding Common Shares as of the date of this annual information form. This significant concentration of share ownership may adversely affect the trading price for Aequus' Common Shares because investors often perceive disadvantages in owning shares in companies with controlling shareholders. As a result, these shareholders, if they acted together, could significantly influence all matters requiring approval by Aequus' shareholders, including the election of directors and the approval of mergers or other business combination transactions. These shareholders may be able to determine all matters requiring shareholder approval. The interests of these shareholders may not always coincide with Aequus' interests or the interests of other shareholders. This may also prevent or discourage unsolicited acquisition proposals or offers for Aequus' Common Shares that other shareholders may feel are in their best interest and Aequus' large shareholders may act in a manner that

advances their best interests and not necessarily those of other shareholders, including seeking a premium value for their Common Shares, and might affect the prevailing market price for Aequus' Common Shares.

*Future sales of shares of Aequus' Common Shares by its existing shareholders could cause Aequus' share price to decline.*

Subject to compliance with applicable securities laws, Aequus' officers, directors and significant shareholders may sell some or all of their Common Shares in the future. No prediction can be made as to the effect, if any, such future sales of Common Shares will have on the market price of the Common Shares prevailing from time to time. However, the future sale of a substantial number of Common Shares by Aequus' officers, directors and significant shareholders or the perception that such sales could occur, could adversely affect prevailing market prices for the Common Shares.

*As a venture issuer, Aequus is not required to make representations relating to the establishment and maintenance of disclosure controls and procedures and internal control over financial reporting.*

In contrast to the certificate required for non-venture issues under NI 52-109, the certifying officers of Aequus, as a venture issuer, are not required to make representations relating to the establishment and maintenance of disclosure controls and procedures ("DC&P") and internal control over financial reporting ("ICFR"), as defined in NI 52-109. In particular, the certifying officers of Aequus are not required to make any representations that they have:

- designed, or caused to be designed, DC&P to provide reasonable assurance that information required to be disclosed by Aequus in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and
- designed, or caused to be designed, ICFR to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the Aequus' GAAP.

Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost-effective basis DC&P and ICFR may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

*Aequus has never paid dividends on Aequus' Common Shares and Aequus does not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in Aequus' Common Shares will likely depend on whether the price of Aequus' Common Shares increases.*

Aequus has not paid dividends on Aequus' Common Shares to date and Aequus currently intends to retain Aequus' future earnings, if any, to fund the development and growth of Aequus' business. As a result, capital appreciation, if any, of Aequus' Common Shares will be your sole source of gain for the foreseeable future. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in Aequus' Common Shares if the price of Aequus' Common Shares increases.

*If equity research analysts do not publish research or reports about Aequus' business or if they issue unfavorable commentary or downgrade Aequus' Common Shares, the price of Aequus' Common Shares could decline.*

The trading market for Aequus' Common Shares will rely in part on the research and reports that equity research analysts publish about Aequus and Aequus' business. Aequus does not control these analysts. The price of Aequus' Common Shares could decline if one or more equity analysts downgrade Aequus' Common Shares or if analysts issue other unfavorable commentary or cease publishing reports about Aequus or Aequus' business.

*Anti-takeover provisions could discourage a third party from making a takeover offer that could be beneficial to Aequus' shareholders.*

Some of the provisions in Aequus' Articles could delay or prevent a third party from acquiring Aequus or replacing members of Aequus' board of directors (the "Board"), even if the acquisition or the replacements would be beneficial to Aequus' shareholders. Such provisions include that Aequus' Board can, without shareholder approval, issue Class A Preferred Shares having any terms, conditions, rights and preferences that the Board determines.

These provisions could also reduce the price that certain investors might be willing to pay for Aequus' securities and result in the market price for Aequus' securities, including the market price for Aequus' Common Shares, being lower than it would be without these provisions.

## **DIVIDEND POLICY**

The Company has not, since its inception, declared or paid any dividends on its Common Shares. The declaration of dividends on our Common Shares is within the discretion of the Board and will depend on the assessment of, among other factors, capital requirements, earnings, and the operating and financial condition of the Company. At the present time, Aequus' anticipated capital requirements are such that Aequus follows a policy of retaining all available funds and any future earnings in order to finance Aequus' technology advancement, business development and corporate growth. Aequus does not intend to declare or pay cash dividends on its Common Shares within the foreseeable future. See "*Risk Factors – Risks Related to Ownership of Aequus' Common Shares – Aequus has never paid dividends on Aequus' Common Shares and Aequus does not anticipate paying any dividends in the foreseeable future*".

## **CAPITAL STRUCTURE**

As of the date of this annual information form, the authorized capital of the Company consisted of an unlimited number of Common Shares without par value and an unlimited number of Class A Preferred shares (the "Class A Preferred Shares") without par value. The Company had 80,437,970 Common Shares and no Class A Preferred Shares issued and outstanding, as of the date of this annual information form.

### **Common Shares**

Each Common Share entitles the holder thereof to one vote at any meeting of our shareholders. The holders of Common Shares are entitled to receive if, as and when declared by the Board, dividends in such amounts as shall be determined by the Board. After the holders of Class A Preferred Shares have first received from the property and assets of the Company the amount they are entitled to, the holders of Common Shares have the right to receive the Company's remaining property and assets in the event of a liquidation, dissolution or winding-up, whether voluntary or involuntary.

### **Class A Preferred Shares**

Each Class A Preferred Share entitles the holder thereof to one vote at any meeting of Aequus shareholders. The Class A Preferred Shares are entitled to priority over the Common Shares with respect to the distribution of assets of the Company in the event of any liquidation, dissolution or winding up of the Company's affairs, whether voluntary or involuntary.

## **MARKET FOR SECURITIES**

The Company's Common Shares trade on the TSX-V under the symbol "AQS" and on the OTCQB® Venture Marketplace in the United States under the symbol "AQSZF".

The following table sets forth, for the periods indicated, the reported high and low prices (in Canadian dollars) and volume traded on the TSX-V.

Month	Monthly High Price (\$)	Monthly Low Price (\$)	Monthly Volume
January 2019	0.19	0.145	3,489,772
February 2019	0.245	0.17	4,386,288
March 2019	0.245	0.19	3,137,071
April 2019	0.215	0.17	2,947,517
May 2019	0.19	0.13	2,024,286
June 2019	0.015	0.01	143,000
July 2019	0.025	0.015	146,000
August 2019	0.18	0.14	1,006,666
September 2019	0.175	0.135	1,633,836
October 2019	0.145	0.12	1,678,521
November 2019	0.18	0.13	1,159,233
December 2019	0.155	0.12	2,581,047

### PRIOR SALES

This table sets out particulars of the Common Shares and securities exercisable for or exchangeable into Common Shares issued during the year ended December 31, 2019.

Date of Issuance/Grant	Type of Security	Number of Securities Issued	Issue/Exercise Price
May 2, 2019	Convertible Debenture Units <sup>(1)</sup>	2,384	\$1000
May 2, 2019	Brokers' Warrants <sup>(2)</sup>	1,173,842	\$0.22
May 30, 2019	Common Shares <sup>(3)</sup>	1,000	\$0.22
February 1, 2019	Stock Options	700,000	\$0.18

Notes:

- (1) Issued in connection with the May 2019 offering of Convertible Debenture Units. Each Convertible Debenture Unit was comprised of one 9.5% unsecured Convertible Debenture in the amount of \$1,000 and 2,380 warrants. Each Convertible Debenture is convertible at the option of the holder into common shares at \$0.21, with interest payable semi-annually in arrears on June 30 and December 31 of each year, maturing May 2, 2022. The Company issued 5,588,240 warrants pursuant to the May 2019 offering. Each warrant entitles the holder to purchase one common share at \$0.22 per share until May 2, 2022.
- (2) Issued in connection with the May 2019 offering of the Convertible Debenture Units. Each warrant entitles the holder to purchase one common share at \$0.22 per share until May 2, 2022.
- (3) During the year ended December 31, 2019, 1,000 share purchase warrants were exercised at \$0.22 and the Company issued 1,000 Common Shares for proceeds of \$220.

### ESCROWED SECURITIES

There were no securities of the Company held in escrow or which were subject to contractual restrictions on transfer as of December 31, 2019, to the knowledge of the Company.

## EXECUTIVE OFFICERS AND DIRECTORS

The following sets forth the names and province or state and country of residence of our directors and executive officers, the offices held by them in the Corporation and their principal occupations during the last five years as at December 31, 2019. The term of each director expires on the date of our next annual meeting. Subsequent to December 31, 2019, Stuart Fowler was appointed to the board of directors, Damien King resigned as a director of the Company and Ian Ball, the Company's former Chief Commercial Officer, transitioned to a full-time role with the Company's partner, Medicom.

Name, Province of Residence and Position with Aequus	Director Since	Position and Principal Occupation in the Past Five Years <sup>(1)</sup>
Douglas Glen Janzen British Columbia, Canada Director, President, Chairman and Chief Executive Officer	January 3, 2013	Director and President, Aequus Pharmaceuticals Inc. (January 3, 2013 – Present); Chief Executive Officer and Chairman, Aequus Pharmaceuticals Inc. (December 10, 2014 – Present); President, Northview Venture Inc. (November 1, 2012 – Present), Managing Director, Northview Venture and Associates General Partnership (April 1, 2014 – Present); Chief Executive Officer, President and Director, Cardiome Pharma Corp. (2003-2012)
Anne Michelle Stevens <sup>(2)</sup> British Columbia, Canada Director, Chief Operating Officer, and Corporate Secretary	December 10, 2014	Corporate Secretary, Aequus Pharmaceuticals Inc. (December 10, 2014 – Present); Chief Operating Officer, Aequus Pharmaceuticals Inc. (July 13, 2015 – Present); Director, Aequus Pharmaceuticals Inc. (October 20, 2014 – Present); Vice President, Corporate Development, Aequus Pharmaceuticals Inc. (October 20, 2014 – July 13, 2015); Commercial Lead, New Project Development, Aequus Pharmaceuticals Inc. (January 1, 2013 – December 10, 2014); President, Crecera Consulting Inc. (August 1, 2012-Present); Senior Partner, Northview Venture and Associates General Partnership (April 1, 2014 – Present); Corporate and External Affairs Analyst, Cardiome Pharma Corp. (2010-2012)
Ann Fehr British Columbia, Canada Chief Financial Officer	N/A	Chief Financial Officer, Aequus Pharmaceuticals Inc. (July 22, 2016 – Present) Professional accountant and consultant at Fehr & Associates (December 5, 2010 – present).
Dr. Don McAfee Point Roberts, Washington, USA Chief Scientific Officer	N/A	Chief Scientific Officer, Aequus Pharmaceuticals Inc. (October 20, 2014 – Present); Independent Scientific Consultant (2012 – Present); Chief Scientific Officer, Cardiome Pharma Corp. (2004 – 2012)
Stuart Fowler Ontario, Canada Strategic Commercial Advisor & Director	February 19, 2020	General Manager, Alcon Canada Inc. (October 2016 – January 2020); President and General Manager, Canada at Allergan plc (August 2010 – November 2015)

Name, Province of Residence and Position with Aequus	Director Since	Position and Principal Occupation in the Past Five Years <sup>(1)</sup>
Rodoula Plakogiannis NY, USA Director	October 20, 2014	Associated Professor of Pharmacy Practice, Long Island University (2002 – Present); Director, Transdermal Pharma Research Laboratories LLC (2013 – Present)
Chris Clark <sup>(2)(3)</sup> British Columbia, Canada Director	December 18, 2014	Chief Financial Officer, Neovasc Inc. (April 2007 – Present)
Jason Flowerday <sup>(2)</sup> Ontario, Canada Director	January 29, 2014	Chief Executive Officer, mdBriefCase Group, Inc (September 2018 – Present); Chief Executive Officer and Director, 3D Signatures Inc. (September 2016 – September 2018); Independent consultant (February 2016 – September 2016); Chief Executive Officer, Pro Bono Bio Inc. (February 2015 – February 2016); Vice President Commercial Operations, Knight Therapeutics Inc. (September 2014 – February 2015); Owner and Chief Commercial Officer, Orphan Canada (January 2010 – August 2014); Owner and Vice President, RxMedia Healthcare Communications (September 2006 – March 2014)

Notes:

- (1) All of the directors' appointments expire at the next annual meeting of the shareholders of the Company.  
(2) Member of the Audit Committee.  
(3) Chair of the Audit Committee.

## Biographies

The information provided below has been provided to us by the individuals themselves and has not been independently verified by us.

### *Douglas Glen Janzen, President, Chief Executive Officer and Chairman of the Board*

Mr. Janzen has over 20 years of experience in life sciences with leadership experience in corporate finance, business development and management. Mr. Janzen is currently Co-Founder and Managing Director of NorthView Ventures and Associates General Partnership; President, Chairman and CEO of Aequus Pharmaceuticals Inc.; and serves on the Boards of Aequus Pharmaceuticals Inc., Lexington Biosciences Inc., Perimeter Medical Imaging Inc. (Chairman), Renaissance Biosciences Corp. and Synaptive Technologies, Inc. Mr. Janzen is responsible for the management of the Company, developing objectives, strategy and standards of performance, securing and leading a team of professionals and directing them to deliver the required performance. As the Chairman of the Board, Mr. Janzen is responsible for the management of the Board to ensure the Company has appropriate objectives and an effective strategy, and that it is operating in accordance with a high standard of corporate governance. Mr. Janzen is past Chair of LifeSciences BC, previously served as a Director of Biotech Canada and iCo Therapeutics Inc., and is a past winner of Business in Vancouver's "Top 40 Under 40 Award".

*Anne Michelle Stevens, BSc, MHA, Chief Operating Officer, Corporate Secretary, and Director*

Ms. Stevens has extensive experience in the Pharmaceutical, Biotech, and Medical Device industry. Ms. Stevens is the Co-Founder and Senior Partner of Northview, an entity which invests in and provides strategic advisory services to a number of life sciences companies. Ms. Stevens will be responsible for overseeing business development, new products and pipeline management, corporate communications and matters related to human resources and facilities for the Company. Previously, Ms. Stevens served as the VP of Corporate Development for Aequus and as Corporate and External Affairs Analyst for Cardiome Pharma Corp., where she was responsible for strategic planning and value analysis of internal R&D. Ms. Stevens' earlier experience includes five years with Bayer HealthCare, where she was responsible for the commercial success and business development of a portfolio of products within several key therapeutic areas. Ms. Stevens holds a Bachelor of Science degree and Master of Health Administration degree from University of British Columbia and is a past winner of Business in Vancouver's "Top 40 Under 40 Award".

*Ann Fehr, CPA, CGA, Chief Financial Officer*

Ms. Fehr is the Principal at Fehr & Associates, and has held a number of senior level positions over the last 24 years, including having served as CFO of companies listed on the TSX. During the course of her management and consulting career, Ms. Fehr has worked with a number of companies through significant change and corporate milestones such as public listing applications, mergers and acquisitions, as well as strategic planning and execution. Ms. Fehr is also an active volunteer in the community. Since 2013, she has been a director and former Treasurer of the Boys and Girls Clubs of South Coast BC as well as a director for The20 Ideas Education Society.

*Dr. Don McAfee, PhD, Acting Chief Scientific Officer*

Dr. McAfee earned his Ph.D. degree in Physiology from the University of Oregon School of Medicine. His academic and faculty appointments include Yale University School of Medicine; University of Miami School of Medicine; and Chairman Neurosciences, Beckman Research Institute, City of Hope Medical Center. Dr. McAfee has been an Honorary Professor in the Department of Anesthesiology, Pharmacology, and Therapeutics at the University of British Columbia since 2012. He has authored more than 100 papers in neuro and cardiovascular science. His industry positions include VP Research, Whitby Research and Development; Founder, CEO and Chief Technology Officer of Discovery Therapeutics; and Chief Scientific Officer of Cardiome Pharma Corp. Dr. McAfee is responsible for participating in Aequus' research and development, and with the assessment and review of business and scientific matters. Dr. McAfee led the preclinical development and initial clinical development of eight NCEs, three of which completed clinical development and two are now marketed. One of these products is Neupro, a transdermal patch for the treatment of Parkinson's disease and Restless Legs Syndrome, now marketed worldwide. Dr. McAfee intends to devote approximately 40% of his time to the affairs of the Company.

*Stuart Fowler, Strategic Commercial Advisor & Director*

Mr. Fowler has an impressive background of operational and leadership experience in ophthalmology, with two of the largest ophthalmology companies in Canada and globally. Having been with Allergan Canada for over 23 years, Stu held numerous roles with increased responsibility in sales, marketing and management. His last role at Allergan was Vice President, Regional President and General Manager, Canada. Stu most recently held the lead role as President and General Manager at Alcon Canada, the country's leading ophthalmic med-device organization. Throughout his career Stu has pushed the envelope for pharmaceutical and med-device sales and marketing initiatives. He was one of the early pioneers utilizing direct-to-consumer advertising in pharma, with campaigns that have received international recognition and garnered numerous awards; as such, Stu and his team were inducted into the Healthcare Marketing Hall of Fame in 2007. He has also developed innovated approaches to sales force effectiveness and customer interface, building physician competency to thrive in a fee-for-service, competitive aesthetic medicine

environment. Stu and his teams have also worked tirelessly to improve patient access to medications through ground-breaking, fully integrated market access and reimbursement programs across numerous therapeutic categories.

*Rodoula Plakogiannis, PharmD, BCPS, CLS, FNLA, Director*

Dr. Plakogiannis has been an Associate Professor of Pharmacy Practice at the Arnold & Marie Schwartz College of Pharmacy since 2002, and Adjunct Associate Professor at NYU Langone Health since 2011. She received both her Bachelor of Science in Pharmacy and traditional Doctor of Pharmacy degrees from the Arnold & Marie Schwartz College of Pharmacy & Health Sciences. Dr. Plakogiannis completed an ASHP-accredited specialized pharmacy residency in primary care at the Bay Pines Veterans Medical Center in Tampa, FL. She is a Board Certified Pharmacotherapy Specialist, a Diplomate and Fellow of the Accreditation Council for Clinical Lipidology, and a Board Certified Clinical Lipid Specialist. She serves as one of the Board of Directors for the National Lipid Association and on the Accreditation Council for Clinical Lipidology's Board of Governors. She also serves as the Adverse Drug Reactions Section Editor for the Journal of Pharmacy Practice. Dr. Plakogiannis has presented on a national level in addition to local seminars.

*Christopher Clark, CA, BA (Honours), Director*

Mr. Clark has over 20 years finance and accounting experience in public practice and in public and private companies, most recently focused in the medical device sector. Previous experience includes financial leadership roles with large automotive and telecom firms in which he developed deep expertise in the development and management of sophisticated financial systems. A highly sought after consultant for biotechnology start-ups, Mr. Clark accepted the role of Chief Financial Officer at Neovasc Inc. ("Neovasc"), a medical device company that develops, manufactures, and markets products for the cardiovascular marketplace, and was instrumental in the initial and ongoing development of Neovasc as a publicly traded company. He received his designation as a Chartered Accountant from the Institute of Chartered Accountants of England and Wales and articulated with KPMG before moving to Canada from England in 1998. He has an honors degree in Economics from Swansea University and a post graduate diploma from Keble College, Oxford.

*Jason Flowerday, MBA, BSc (Honours), Director*

Mr. Flowerday is a highly respected business leader with two decades of executive life sciences management and startup experience. For over a decade, Mr. Flowerday was groomed at Bayer and JnJ before he expanded his successful career into leading specialty pharmaceutical, biotech and device companies in their pursuit of growth and capital. He has consistently developed his entrepreneurial drive and governance expertise, and has been a passionate leader and champion for change. Mr. Flowerday currently serves as Chief Executive Officer of mdBriefCase Group, Inc., a leading provider of online continuing professional development for physicians, pharmacists, nurses, and other allied healthcare professionals in Canada, Australia, the Middle East, Africa, and around the world. Mr. Flowerday was previously the Chief Executive Officer and Director of 3D Signatures Inc, a personalized medicine company with proprietary software in the area of cancer diagnostics and the Chief Executive Officer of Pro Bono Bio Inc. He served as Vice President Commercial Operations of Knight Therapeutics Inc. ("Knight") following the successful sale of his company, Orphan Canada, to Knight in 2014. In his role as founder and Chief Commercial Officer of Orphan Canada, Mr. Flowerday funded and led the company through in-licensing and commercializing of its lead products which dealt with genetic and rare diseases. Prior to founding Orphan Canada, Mr. Flowerday established RxMedia Healthcare Communications, leading the Company through a period of



sustained growth and expansion. Mr. Flowerday holds a Bachelor of Science (Honours) from the University of Toronto and a Master of Business Administration from Queen's University.

#### Share Ownership by Directors and Executive Officers

As of April 28, 2020, as a group, the Company's directors and executive officers beneficially owned, directly or indirectly, or exercised control over 7,283,425 Common Shares, representing approximately 9% of the issued and outstanding Common Shares.

#### **CORPORATE CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES AND SANCTIONS**

Except as disclosed below, no director or executive officer of Aequus is, as at the date of this annual information form, or was within 10 years before the date of this annual information form, a director, chief executive officer or chief financial officer of any company (including Aequus), that 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 in effect for a period of more than 30 consecutive days:

- (a) that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer; or
- (b) that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

With respect to Ann Fehr, CFO: On September 27, 2010, Global Uranium Corporation became subject to a cease trade order as a result of failure to file a compliant NI 43-101 technical report. SRK Consulting (Canada) Inc. then prepared a compliant NI 43-101 Technical Report which was then filed on SEDAR and the Cease Trade Order was subsequently revoked. The cease trade order was lifted in all jurisdictions on June 6, 2011. Ms. Fehr was Chief Financial Officer at the relevant time.

No director or executive officer of Aequus, or a shareholder holding a sufficient number of securities of the Company to affect materially the control of Aequus:

- (a) is, as at the date of this annual information form, or has been within the 10 years before the date of this annual information form, a director or executive officer of any company (including Aequus) 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
- (b) has, within the 10 years before the date of this annual information form, 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 director, executive officer or shareholder.

No director or executive officer of Aequus, or a shareholder holding a sufficient number of securities of Aequus to affect materially the control of Aequus, has been subject to (a) 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 (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

### **CONFLICTS OF INTEREST**

Other than as disclosed herein, none of our directors, officers or principal shareholders and no associates or affiliates of any of them, have or have had any material interest in any transaction which materially affects us. There are potential conflicts of interest to which our directors and officers will be subject in connection with our operations. In particular, certain of our directors are involved in managerial and/or director positions with other companies whose operations may, from time to time, be in direct competition with our operations or with entities which may, from time to time, provide financing to, or make equity investments in, our competitors. See *“Risk Factors – Risks Related to Aequus’ Business Operations and Industry – The directors and officers of Aequus may be subject to conflicts of interest”*.

Conflicts, if any, will be subject to the procedures and remedies available under the BCBCA. The BCBCA generally provides that in the event that a director has an interest in a contract or proposed contract or agreement, the director shall disclose his interest in such contract or agreement and shall refrain from voting on any matter in respect of such contract or agreement unless otherwise provided by the BCBCA.

### **LEGAL PROCEEDINGS AND REGULATORY ACTIONS**

There are no outstanding material legal proceedings or regulatory actions to which we are a party, nor, to our knowledge, are any material legal proceedings or regulatory actions contemplated.

### **INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Other than as described elsewhere in this annual information form, none of our directors, executive officers or shareholders, owning or exercising control or direction over more 10% of the Common Shares, or any associate or affiliate of the foregoing, has had any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year prior to the date of this annual information form that has materially affected us or is reasonably expected to materially affect the Company.

### **MATERIAL CONTRACTS**

Except for contracts entered into in the ordinary course of business, as of date of this annual information form, the only material contracts which the Company has entered into are set out below:

1. Debenture Indenture
2. Warrant Indenture
3. Agency Agreement; and
4. Supernus Agreement.

### **AUDITOR, TRANSFER AGENT, WARRANT AGENT AND REGISTRAR**

The auditor of the Company is Dale Matheson Carr-Hilton LaBonte LLP at its offices located at #1500-1140 W Pender Street, Vancouver, British Columbia, V6E 2R9. Dale Matheson Carr-Hilton LaBonte LLP is independent within the meaning of the Rules of Professional Conduct of the Chartered Professional Accountants of British Columbia.

As of the date of this annual information form, the registrar and transfer agent of the Company is Computershare Investor Services Inc. at its offices in Vancouver, British Columbia.

## INTEREST OF EXPERTS

The Company's auditor, Dale Matheson Carr-Hilton LaBonte LLP, has audited the Company's financial statements as at December 31, 2019 and 2018. Dale Matheson Carr-Hilton LaBonte LLP has confirmed that they are independent from the Company in accordance with the Chartered Professional Accountants Rules of Professional Conduct in British Columbia, Canada.

## AUDIT COMMITTEE

The Company has formed an Audit Committee (the "Audit Committee"). The Audit Committee is comprised of Chris Clark (Chair of the Audit Committee), Jason Flowerday and Stuart Fowler, all of whom are financially literate as such term is defined in NI 52-110. Mr. Flowerday and Mr. Fowler are considered independent pursuant to NI 52-110. Mr. Clark is not considered independent. A description of the education and experience of each Audit Committee member that is relevant to the performance of his responsibilities as an Audit Committee member may be found above under the heading "*Executive Officers and Directors – Biographies*".

The Audit Committee is responsible for reviewing the Company's financial reporting procedures, internal controls and the performance of the financial management and external auditors of the Company. The Audit Committee will also review the annual audited financial statements and make recommendations to the Board. The Company is relying on the exemption set out in section 6.1 of NI 52-110. A copy of the Audit Committee's charter is set out below.

### Audit Committee Charter

#### I. Purpose

The main objective of the Audit Committee is to act as a liaison between the Board and the Company's independent auditors and to assist the Board in fulfilling its oversight responsibilities with respect to the financial statements and other financial information provided by the Company to its shareholders and others.

#### II. Organization

The Audit Committee shall consist of three or more Directors and shall satisfy the laws governing the Company and the independence, financial literacy, expertise and experience requirements under applicable securities law, stock exchange requests and any other regulatory requirements applicable to the Audit Committee of the Company.

The members of the Audit Committee and the Chair of the Audit Committee shall be appointed by the Board. A majority of the members of the Audit Committee shall constitute a quorum. A majority of the members of the Audit Committee shall be empowered to act on behalf of the Audit Committee. Matters decided by the Audit Committee shall be decided by majority votes.

Any member of the Audit Committee may be removed or replaced at any time by the Board and shall cease to be a member of the Audit Committee as soon as such member ceases to be a Director.

The Audit Committee may form and delegate authority to subcommittees when appropriate.

#### III. Meetings

The Audit Committee shall meet as frequently as circumstances require.

The Audit Committee may invite, from time to time, such persons as it may see fit to attend its meetings and to take part in discussion and consideration of the affairs of the Audit Committee.

The Company's accounting and financial officer(s) and independent auditors shall attend any meeting when requested to do so by the Chair of the Audit Committee.

#### IV. Responsibilities

1. The Audit Committee shall recommend to the Board:
  - (a) the external auditor to be nominated for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company; and
  - (b) the compensation of the external auditor.
2. The Audit Committee shall be directly responsible for overseeing the work of the external auditor engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company, including the resolution of disagreements between management and the external auditor regarding financial reporting.
3. The Audit Committee must pre-approve all non-audit services to be provided to the Company or its subsidiary entities by the Company's external auditor.
4. The Audit Committee must review the Company's financial statements, MD&A and annual and interim earnings press releases before the Company publicly discloses this information.
5. The Audit Committee must be satisfied that adequate procedures are in place for the review of the Company's public disclosure of financial information extracted or derived from the Company's financial statements, other than the public disclosure referred to in subsection (4), and must periodically assess the adequacy of those procedures.
6. The Audit Committee must establish procedures for:
  - (a) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters; and
  - (b) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.
7. An audit committee must review and approve the Company's hiring policies regarding partners, employees and former partners and employees of the present and former external auditor of the issuer.

#### V. Authority

The Audit Committee shall have the following authority:

- (a) to approve interim financial statements,
- (b) to engage independent counsel and other advisors as it determines necessary to carry out its duties,
- (c) to set and pay the compensation for any advisors employed by the Audit Committee, and
- (d) to communicate directly with the external auditors.

## Relevant Education and Experience

See heading “*Executive Officers and Directors – Biographies*” above for a description of the education and experience of each of the members of the Audit Committee that is relevant to their performance as an audit committee member, in particular, any education or experience that would provide the member with:

- (a) an understanding of the accounting principles used by the issuer to prepare its financial statements, and the ability to assess the general application of those principles in connection with estimates, accruals and reserves;
- (b) experience preparing, auditing, analysing and evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the issuer’s financial statements, or experience actively supervising individuals engaged in such activities; and
- (c) an understanding of internal controls and procedures for financial reporting.

### *Audit Committee Oversight*

Since the commencement of the Company’s most recently completed financial year, there has not been a recommendation of the Audit Committee to nominate or compensate an external auditor which was not adopted by the Company’s Board.

## Reliance on Certain Exemptions

Since the effective date of NI 52-110, the Company has not relied on the exemptions contained in section 2.4 or Part 8 of NI 52-110. Section 2.4 provides an exemption from the requirements that the Audit Committee must pre-approve all non-audit services to be provided by the auditor, where the total amount of fees related to the non-audit services are not expected to exceed 5% of the total fees payable to the auditor in the fiscal year in which the non-audit services were provided. Section 8 permits a company to apply to a securities regulatory authority for an exemption from the requirements of NI 52-110, in whole or in part.

### *Pre-Approval Policies and Procedures*

The Audit Committee has authority and responsibility for pre-approval of all non-audit services to be provided to the Company or its subsidiary entities by the external auditors or the external auditors of the Company’s subsidiary entities, unless such pre-approval is otherwise appropriately delegated or if appropriate specific policies and procedures for the engagement of non-audit services have been adopted by the Audit Committee.

## Exemption

The Company is relying upon the exemption in section 6.1 of NI 52-110 in respect of its reporting obligations under NI 52-110 for the year ended December 31, 2018.

### *External Auditor Service Fees by Category*

In connection with the Company’s last fiscal year end, the Company expensed audit fees as set out in the table below. In the table, “audit fees” are fees billed by the Company’s external auditor for services provided in auditing the Company’s annual financial statements. “Audit-related fees” are fees not included in audit fees that are billed by the auditor for assurance and related services that are reasonably related to the performance of the auditor’s review of the Company’s financial statements. “Tax fees” are fees billed by the auditor for professional services rendered for tax compliance, tax advice and tax planning. “All other fees” are fees billed by the auditor for products and services not included in the foregoing categories. All amounts in the table are expressed in Canadian dollars.

Financial Year Ending	Audit Fees	Audit Related Fees	Tax Fees	All Other Fees
December 31, 2018	\$23,540	\$13,120	\$Nil	\$Nil
December 31, 2019	\$17,000	\$16,000	\$Nil	\$Nil

#### ADDITIONAL INFORMATION

Additional information relating to us may be found on SEDAR at [www.sedar.com](http://www.sedar.com).

Additional information, including directors' and officers' remuneration and indebtedness, the Company's principal shareholders, and securities authorized for issuance under equity compensation plans, if applicable, is contained in the Company's most recently filed management information circular available on SEDAR at [www.sedar.com](http://www.sedar.com).

Additional financial information is provided in our consolidated financial statements and management's discussion and analysis for the financial year ended December 31, 2019.