



Up to US\$75,000,000 Common Shares

We have entered into a sales agreement with B. Riley Securities, Inc., Oppenheimer & Co. Inc., and H.C. Wainwright & Co., LLC (collectively the “Agents” and each an “Agent”), relating to the sale of our common shares, no par value per common share, offered by this prospectus supplement. In accordance with the terms of the sales agreement, we may offer and sell from time to time our common shares having an aggregate offering price of up to US\$75,000,000 through or to the Agents, each acting as sales agent or principal.

Our common shares trade on the NASDAQ Stock Market (“NASDAQ”), and on the TSX Venture Exchange (“TSXV”), under the symbol “ACST”. On November 8, 2021, the last reported sale price for our common shares on NASDAQ was US\$1.70 per common share and on the TSXV was C\$2.11 per share.

Sales of our common shares, if any, under this prospectus supplement may be made by any method deemed to be an “at the market offering” as defined in Rule 415 under the U.S. Securities Act of 1933, as amended (the “Securities Act”).

Each Agent is not required to sell any specific number of our common shares. Each Agent has agreed to use its commercially reasonable efforts to sell on our behalf all of the common shares requested to be sold by us, consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of NASDAQ, on mutually agreed terms between each Agent and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Each Agent will be entitled to compensation under the terms of the sales agreement at a commission rate equal to 3.0% of the gross proceeds from each sale of our common shares. The net proceeds from any sales under this prospectus supplement will be used as described under “Use of Proceeds.” The proceeds we receive from sales of our common shares, if any, will depend on the number of shares actually sold and the sale price of such shares.

In connection with the sale of our common shares on our behalf, the Agents will be deemed to be underwriters within the meaning of the Securities Act, and the compensation of the Agents will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to the Agents with respect to certain liabilities, including liabilities under the Securities Act.

Investing in our common shares involves a high degree of risk. Please consider carefully the [Risk Factors](#)” section beginning on page S-22 of this prospectus supplement and page 5 of the accompanying prospectus, as well as the section captioned “Item 1A – Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, which is incorporated by reference into this prospectus supplement and the accompanying prospectus.

Neither the U.S. Securities and Exchange Commission (“SEC”), nor any U.S. state securities commission or any Canadian securities regulator has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The common shares offered by this prospectus supplement have not been and will not be qualified for sale under the securities laws of any province or territory of Canada or to any resident of Canada and may not be offered or sold, directly or indirectly, in Canada or to or for the account of any resident of Canada. This prospectus supplement has not been filed in respect of, and will not qualify, any distribution of these common shares in any province or territory of Canada. No common shares will be sold on the TSXV or on other trading markets in Canada as at the market distributions.

B. Riley Securities

Oppenheimer & Co.

H.C. Wainwright & Co.

The date of this prospectus supplement is November 10, 2021.

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PROSPECTUS

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is part of a “shelf” registration statement on Form S-3 that we filed with the SEC, and is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering of common shares and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated June 29, 2020, including the documents incorporated by reference into it, provides more general information. Generally, when we refer to this “prospectus,” we are referring to both parts of this document combined.

If there is any inconsistency between the information in this prospectus supplement and the accompanying prospectus, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date and that is incorporated by reference herein, the statement in the document having the later date modifies or supersedes the earlier statement.

This prospectus supplement relates to the offering of our common shares. Before investing in our securities, please carefully read this prospectus supplement together with the documents incorporated by reference herein, as listed under “Documents Incorporated by Reference,” and the additional information described below under “Where You Can Find More Information.”

You should rely only on the information contained in or incorporated by reference into this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The distribution or possession of this prospectus supplement in or from certain jurisdictions may be restricted by law. This prospectus supplement is not an offer to sell the securities and is not soliciting an offer to buy the securities in any jurisdiction where the offer or sale is not permitted or where the person making the offer or sale is not qualified to do so or to any person to whom it is not permitted to make such offer or sale. You should assume that the information contained in this prospectus supplement is accurate only as of the date on the front cover of this prospectus supplement, or the accompanying prospectus, as applicable, and the information incorporated by reference into this prospectus supplement is accurate only as of the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since that date.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference into this prospectus supplement were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreement, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Other than in the United States, no action has been taken by us or the Agents that would permit a public offering of the securities offered by this prospectus supplement in any jurisdiction where action for that purpose is required. The common shares offered by this prospectus supplement may not be offered or sold, directly or indirectly, nor may this prospectus supplement or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus supplement comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus supplement. This prospectus supplement does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus supplement in any jurisdiction in which such an offer or a solicitation is unlawful.

Owning common shares may subject you to tax consequences in the United States. This prospectus supplement and the accompanying prospectus may not describe these tax consequences fully. You should read the tax discussion in this prospectus supplement and consult your own tax advisor with respect to your own particular circumstances.

The trademarks, trade names and service marks appearing in this prospectus supplement and the documents incorporated by reference into this prospectus supplement are the property of their respective owners. Solely for convenience, the trademarks, service marks, tradenames and copyrights referred to in this prospectus supplement may be listed without the ©, ® and TM symbols.

Unless stated otherwise or the context otherwise requires, references in this prospectus supplement and the accompanying prospectus to “Acasti,” the “Company,” “we,” “us,” or “our” refer to Acasti Pharma Inc. and its consolidated subsidiaries.

All references in this prospectus supplement to “dollars” and “US\$” refer to United States dollars and references to “CS” refer to Canadian dollars. The consolidated financial statements incorporated by reference into this prospectus supplement are presented in accordance with U.S. generally accepted accounting principles.

On August 31, 2021, an 8:1 consolidation of our common shares became effective. All references in this prospectus supplement to the number of common shares, warrants and stock options, and the price per common share, warrant and stock option have been adjusted to reflect the share consolidation on a retroactive basis.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein, contains information that may be forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements can be identified by the use of terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “intend,” “estimate,” “predict,” “potential,” “continue” or other similar expressions concerning matters that are not statements about the present or historical facts. Forward-looking statements in this prospectus supplement, the accompanying prospectus and in the documents incorporated by reference herein include, among other things, information or statements about:

- our ability to build a premier, late-stage specialty pharmaceutical company specialized in rare and orphan disease and focused on developing and commercializing products that improve clinical outcomes using novel drug delivery technologies;
- our ability to apply new proprietary formulations to existing pharmaceutical compounds to achieve enhanced efficacy, faster onset of action, reduced side effects, and more convenient drug delivery that can result in increased patient compliance;
- the potential for our drug candidates to receive orphan drug status from the U.S. Food and Drug Administration (“FDA”) or regulatory approval under the Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act;
- the future prospects of our GTX-104 drug candidate, including but not limited to GTX-104’s potential to be administered to improve the management of hypotension; GTX-104’s potential to reduce the incidence of vasospasm and lead to better outcomes; the ability of GTX-104 to achieve a pharmacokinetic (“PK”) and safety profile similar to the oral form of nimodipine; GTX-104’s potential to provide improved bioavailability and the potential for reduced use of rescue therapies, such as vasopressors; the timing of the completion of the PK bridging study, and the timing and outcome of the Phase 3 safety study for GTX-104; our ability to ultimately file a new drug application (“NDA”) for GTX-104 under Section 505 (b)(2) NDA; and the timing and ability to receive FDA approval for marketing GTX-104;
- the future prospects of our GTX-101 drug candidate, including but not limited to GTX-101’s potential to be administered to postherpetic neuralgia patients to treat pain associated with the disease; assumptions about the biphasic delivery mechanism of GTX-101, including its potential for rapid onset and continuous pain relief for up to eight hours; and the timing and outcomes of single ascending dose/multiple ascending dose and PK bridging studies, a Phase 2 and Phase 3 efficacy and safety study; the timing of an NDA filing under Section 505 (b) (2) for GTX-101; and the timing and ability to receive FDA approval for marketing GTX-101;
- the future prospects of our GTX-102 drug candidate, including but not limited to GTX-102’s potential to provide clinical benefits to decrease Ataxia Telangiectasia symptoms; GTX-102’s potential ease of drug administration; the timing and outcomes of a PK bridging study and Phase 3 efficacy and safety study for GTX-102; the timing of an NDA filing under Section 505 (b)(2) in connection with GTX-102; and the ability to receive FDA approval for marketing GTX-102;

- the quality of our clinical data, the cost and size of our development programs, expectations and forecasts related to our target markets and the size of our target markets; the cost and size of our commercial infrastructure and manufacturing needs in the United States, European Union, and the rest of the world; and our expected use of a range of third-party contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”) at diverse locations;
- expectations and forecasts related to our intellectual property portfolio, including but not limited to consequences of orphan drug status designation from the FDA for our leading pipeline products; our patent portfolio strategy; and outcomes of our patent protection filings;
- our strategy, future operations, prospects and the plans of our management with a goal to enhance shareholder value, following our recent merger with Grace Therapeutics Inc. (“Grace”);
- our intellectual property position and duration of our patent rights;
- the potential adverse effects that the COVID-19 pandemic may have on our business and operations;
- our need for additional financing, and our estimates regarding our operating runway and future financing and capital requirements;
- our expectation regarding our financial performance, including our costs and expenses, liquidity, and capital resources;
- our projected capital requirements to fund our anticipated expenses; and
- our ability to establish collaborations or obtain additional funding.

In addition, the forward-looking statements in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein are subject to a number of known and unknown risks, uncertainties and other factors, including those described in this prospectus supplement under “Risk Factors” and in the documents incorporated by reference herein, many of which are beyond our control, that could cause our actual results and developments to differ materially from those that are disclosed in or implied by the forward-looking statements, including, among others:

- We may not achieve our publicly announced milestones on time, or at all.
- A failure to successfully integrate the businesses of Acasti and Acasti Pharma U.S., Inc. (“Acasti Pharma U.S.”, which is formerly Grace) in the expected timeframe would adversely affect our future results.
- Our future results will suffer if we do not effectively manage our expanded operations.
- We have incurred and expect to continue to incur substantial expenses related to the merger and expect to continue to incur substantial expenses related to the integration of the companies.
- Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.
- We may be subject to foreign exchange rate fluctuations.
- If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.
- Lawsuits have been filed, and other lawsuits may be filed, against us and members of our board of directors challenging the Grace merger, and an adverse ruling in any such lawsuit may result in an award of damages against us.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

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- We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations and our ability to compete.
 - We may face future product liability, and if claims are brought against us, we may incur substantial liability.
 - We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.
 - Even if our drug candidates receive regulatory approval in the United States, we may never obtain regulatory approval or successfully commercialize our products outside of the United States.
 - We are subject to uncertainty relating to healthcare reform measures and reimbursement policies which, if not favorable to our drug candidates, could hinder or prevent our drug candidates' commercial success.
 - Our commercial success depends upon attaining significant market acceptance of our drug products and drug candidates, if approved, among physicians, nurses, pharmacists, patients and the medical community.
 - Guidelines and recommendations published by government agencies can reduce the use of our drug candidates and negatively impact our ability to gain market acceptance and market share.
 - If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug products, if approved we may be unable to generate any revenue.
 - If we obtain approval to commercialize any approved drug products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.
 - If we are unable to differentiate our drug products from branded reference drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve products that compete with any of our drug products, our ability to successfully commercialize our drug products would be adversely affected.
 - We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
 - We could incur substantial costs and disruption to our business and delays in the launch of our drug products if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.
 - The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our drug candidates.
 - We are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.
 - We are heavily dependent on the success of our lead drug candidates, GTX-104, GTX-102 and GTX-101.
 - If the FDA does not conclude that our drug candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our drug candidates under Section 505(b)(2) are not as we expect, the approval pathway for our drug candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.
 - Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.

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- Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our drug candidates.
 - Our drug products or drug candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following marketing approval, if any.
 - The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.
 - An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our drug candidate. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.
 - Our business is subject to extensive regulatory requirements and our drug candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.
 - Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.
 - Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors are and will continue to be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure, or sunshine laws, government price reporting and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.
 - We are required to obtain regulatory approval for each of our drug candidates in each jurisdiction in which we intend to market such drug products, and the inability to obtain such approvals would limit our ability to realize their full market potential.
 - If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.
 - Our success depends in part upon our ability to protect our intellectual property for our drug candidates, such as GTX-104, GTX-102 and GTX-101.
 - Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications often result in third-party claims of intellectual property infringement, the defense of which can be costly and time consuming, and an unfavorable outcome in any such litigation may prevent or delay our development and commercialization efforts which would harm our business.
 - If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.
 - We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

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- We may be subject to claims challenging our inventorship or ownership of our patents and other intellectual property.
 - Intellectual property rights do not necessarily address all potential threats to our competitive advantage.
 - Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect any of our other future drug products and drug candidates.
 - We may not be able to protect our intellectual property rights throughout the world.
 - We do not have internal manufacturing capabilities, and if we fail to develop and maintain supply relationships with various third-party manufacturers, we may be unable to develop or commercialize our drug candidates.
 - Our contract manufacturers may encounter manufacturing failures that could delay the clinical development or regulatory approval of our drug candidates, or their commercial production if approved.
 - We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.
 - We rely on third parties to manufacture commercial and clinical supplies of our drug candidates, and we intend to rely on third parties to manufacture commercial supplies of any approved drug products. The commercialization of any of our drug products could be stopped, delayed, or made less profitable if those third parties fail to provide us with sufficient quantities of active pharmaceutical ingredients, excipients, or drug products, or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.
 - The design, development, manufacture, supply, and distribution of our drug candidates are highly regulated and technically complex.
 - We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prevent, our ability to develop our drug candidates.
 - We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our drug candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our drug candidates and our financial condition and operating results.
 - We may be treated as a passive foreign investment corporation for U.S. federal income tax purposes.
 - We may not be able to use our net operating loss carryforwards to offset future taxable income for Canadian or U.S. federal income tax purposes.
 - We do not expect to pay any cash dividends for the foreseeable future.
 - The price of our common shares may be volatile.
 - Raising additional capital in the future may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.
 - The market price of our common shares could decline as a result of operating results falling below the expectations of investors or fluctuations in operating results each quarter.
 - An active market for our common shares may not be sustained.

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- If we fail to meet applicable listing requirements, the NASDAQ Stock Market or the TSX Venture Exchange may delist our common shares from trading, in which case the liquidity and market price of our common shares could decline.
 - We may pursue opportunities or transactions that adversely affect our business and financial condition.
 - We are a “smaller reporting company” under the U.S. Securities and Exchange Commission’s (“SEC’s”) disclosure rules and have elected to comply with the reduced disclosure requirements applicable to smaller reporting companies.
 - As a non-accelerated filer, we are not required to comply with the auditor attestation requirements of the Sarbanes-Oxley Act.
 - We are a Québec incorporated company headquartered in Canada, and U.S. investors may be unable to enforce certain judgments against us.

All of the forward-looking statements in this prospectus supplement, the accompanying prospectus and in the documents incorporated by reference are qualified by this cautionary statement. There can be no guarantee that the results or developments that we anticipate will be realized or, even if substantially realized, that they will have the consequences or effects on our business, financial condition or results of operations that we anticipate. As a result, you should not place undue reliance on the forward-looking statements. Except as required by applicable law, we do not undertake to update or amend any forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements in this prospectus supplement are made as of the date of this prospectus supplement. Forward-looking statements made in the accompanying prospectus and the documents incorporated by reference herein and therein are made as of the date of the original document and have not been updated by us except as expressly provided for in this prospectus supplement.

SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common shares. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information referred to under the heading "Risk Factors" in this prospectus supplement beginning on page S-22 and in the sections captioned "Item 1A – Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, which is incorporated by reference into this prospectus supplement, the other information incorporated by reference into this prospectus supplement and the accompanying prospectus and the information included in any free writing prospectus that we have authorized for use in connection with this offering.

Our Company

On August 27, 2021, we completed our acquisition of Grace via a merger following the approval of Acasti's shareholders and Grace's stockholders. Following completion of the merger, Grace became a wholly owned subsidiary of Acasti and was renamed Acasti Pharma U.S. Inc.

The successful completion of the merger positions Acasti to build a premier, late-stage specialty pharmaceutical company specialized in rare and orphan disease and focused on developing and commercializing products that improve clinical outcomes using novel drug delivery technologies. We seek to apply new proprietary formulations to existing pharmaceutical compounds to achieve enhanced efficacy, faster onset of action, reduced side effects, and more convenient drug delivery and increased patient compliance; all of which could result in improved patient outcomes. The active ingredients chosen by Acasti for further development may be already approved in a target indication or could be repurposed for use in new indications.

In connection with the merger, we acquired Grace's entire therapeutic pipeline addressing critical unmet medical needs for the treatment of rare and orphan diseases, consisting of three unique clinical stage and multiple pre-clinical stage assets supported by an intellectual property portfolio consisting of more than 40 granted and pending patents in various jurisdictions worldwide. These drug candidates aim to improve clinical outcomes by applying proprietary formulation and drug delivery technologies to existing pharmaceutical compounds to achieve improvements over the current standard of care, or to provide treatment for diseases with no currently approved therapy.

Rare disorders represent an attractive area for drug development, and there remains an opportunity for us to utilize already approved drugs that have established safety profiles and clinical experience to potentially address significant unmet medical needs. A key advantage of pursuing therapies for rare disorders is the potential to receive orphan drug designation ("ODD") from the FDA. ODD provides for seven years of marketing exclusivity in the United States post-launch, provided certain conditions are met. Rare diseases also allow for more manageably scaled clinical trials and provide market opportunities that may require a smaller, more targeted commercial infrastructure.

In addition, the existing safety profiles of these products combined with the prospect to utilize the Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act (the "FDCA") may provide a potentially shorter path to regulatory approval. Under Section 505(b)(2), if sufficient support of a product's safety and efficacy either through previous FDA experience or sufficiently within the scientific literature can be established, it may eliminate the need to conduct some of the early studies that new drug candidates might otherwise require.

The specific diseases targeted for drug development by Acasti are well understood although these patient populations may remain poorly served by available therapies or in some cases approved therapies do not yet exist. We aim to effectively treat debilitating symptoms that result from these underlying diseases.

Our three most advanced programs are:

- GTX-104, an IV formulation of nimodipine designed to treat Subarachnoid Hemorrhage ("SAH"), a rare brain disorder for which Acasti Pharma U.S. (formerly Grace) had completed multiple pharmacokinetic ("PK") studies. SAH is a central nervous system condition that causes acute bleeding in the brain and requires immediate medical attention to prevent long-term disability or death. GTX-104 could be administered to

improve the management of hypertension and reduce the incidence of vasospasm in SAH patients and potentially lead to better outcomes.

- GTX-102, an oral-mucosal betamethasone spray for the treatment of Ataxia Telangiectasia (“A-T”), an orphan pediatric complex genetic neurodegenerative disorder usually diagnosed in young children, for which no FDA approved treatment exists.
- GTX-101, a topical bioadhesive film-forming bupivacaine spray for Postherpetic Neuralgia (“PHN”), which is persistent and often causes debilitating pain following infection by the shingles virus. We believe that GTX-101 could be administered to patients with PHN to treat pain associated with the disease.

Our management team possesses significant experience in drug delivery research and evaluation, clinical and pharmaceutical development and manufacturing, regulatory affairs, and business development, as well as being well versed in late-stage drug development and commercialization. The Acasti team has been collectively involved in the development and approval of several successful marketed drugs including TORADOL™, NAPROSYN™, ANDROGEL™, SUBSYS™, MARINOL™ and KEPPRA XR™.

The table below summarizes planned key calendar year milestones for our three clinical drug candidates:

Product Candidate	Planned Regulatory Pathway	Target Indication	Near-Term Milestones
GTX-104	505(b)(2)	Subarachnoid Hemorrhage (SAH) – ODD status granted	<ul style="list-style-type: none"> • PK bridging study results expected 1H'22 • Start of Phase 3 safety study expected 2H'22*
GTX-102	505(b)(2)	Ataxia Telangiectasia (A-T) – ODD status granted	<ul style="list-style-type: none"> • PK bridging study results expected 2H'22 • Start of Phase 3 expected 1H'23*
GTX-101	505(b)(2)	Postherpetic Neuralgia (PHN) – ODD status granted	<ul style="list-style-type: none"> • SAD/MAD** study results expected 2H'22 • Start of Phase 2 expected 2H'22

***Potential fast-track status possible where clinical Phase 2 trials would not be required assuming PK Bridging Studies for GTX-104 and GTX-102 meet their endpoints**

**Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD)

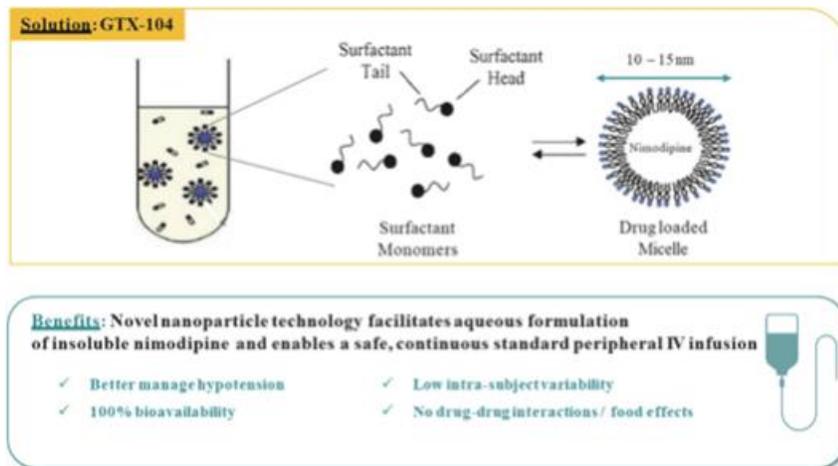
GTX-104 Overview

Nimodipine was granted FDA approval in 1988, and is the only drug approved to improve neurological outcomes in SAH. It is only available in the United States as a generic oral capsule and as a branded oral liquid solution called NYMALIZE™, which is manufactured and sold by Arbor Pharmaceuticals. Nimodipine has poor water solubility and high permeability characteristics as a result of its high lipophilicity. Additionally, orally administered nimodipine has dose-limiting side-effects such as hypotension, low bioavailability resulting from high first-pass metabolism, and a narrow administration window as food effects lower bioavailability significantly. Nimodipine capsules are also difficult to administer, particularly to unconscious patients or those with impaired swallowing. Concomitant use with CYP3A inhibitors is contraindicated (NIMODIPINE Capsule PI).

NIMOTOP™ is an injectable form of nimodipine that is manufactured by Bayer Healthcare. It is approved in Europe and other regulated markets (but not in the United States), but it has limited utility for SAH patients because of its high organic solvent content, namely 23.7% ethanol and 17% polyethylene glycol 400 (NIMOTOP SmPC).

GTX-104 is a clinical stage, novel formulation of nimodipine for IV infusion in SAH patients. It uses surfactant micelles as the drug carrier to solubilize nimodipine. This unique nimodipine injectable formulation is composed of a nimodipine base, an effective amount of polysorbate 80, a non-ionic hydrophilic surfactant, and a pharmaceutically acceptable carrier for injection. GTX-104 is an aqueous solution substantially free of organic

solvents, such that the nimodipine is contained in a concentrated injection solution, suspension, emulsion or complex as a micelle, a colloidal particle or an inclusion complex, and the formulation is stable and clear.



GTX-104 could provide a more convenient dosing schedule as it may be administered every twelve hours in patients with SAH as compared to generic nimodipine capsules or NYMALIZE™, which must be administered every four hours. In addition, since GTX-104 is peripherally infused, the dosing regimen is continuous during the period of therapy as compared to six times per day for both NYMALIZE™ oral solution and nimodipine oral capsules. Therefore, GTX-104 could be considered as a major contribution to patient care by potentially reducing the dosing frequency to twice daily. In addition, GTX-104 has the potential to provide improved bioavailability, and lower intra-subject variability. Because of its IV formulation, we also expect it to reduce drug-drug interactions or food effects.

Despite the positive impact it has on recovery, physicians often must discontinue their patients on oral nimodipine, primarily as a result of hypotensive episodes that cannot be controlled by titrating the oral form of drug. Such discontinuation could potentially be avoided by administering GTX-104, which because of its IV administration, may obviate the complexity that results from the need for careful attention to the timing of nimodipine administration at least once before or two hours after a meal. Administration of GTX-104 via a peripheral vein is often much more comfortable for the patients compared to administration by central venous access, which can often be a difficult and invasive procedure. Also, unconscious patients will likely receive more consistent concentrations of nimodipine when delivered by the IV route as compared to oral gavage or a nasogastric tube. More consistent dosing is expected to result in a reduction of vasospasm and a better, more consistent management of hypotension. As summarized in the table below, we anticipate reduced use of rescue therapies, such as vasopressors, and expensive hospital resources, such as the angiography suite, by more effectively managing blood pressure with GTX-104. Reduced incidences of vasospasm could result in shorter length of stay and better outcomes.

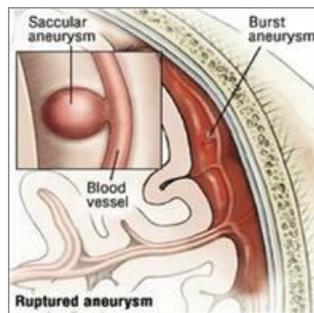


Note: (1) Nimodipine administration in SAH patients is a key Joint Commission (JCI) quality measure for hospitals with stroke certification. Sources: Nimodipine capsule packaging insert; Patcher Spagitt market research report; Suppa V. (2007)

About Subarachnoid Hemorrhage (SAH)

SAH is bleeding over the surface of the brain in the subarachnoid space between the brain and the skull, which contains blood vessels that supply the brain. A primary cause of such bleeding is rupture of an aneurysm. The result is a relatively uncommon type of stroke that accounts for about 5% of all strokes and has an incidence of six per 100,000 person years (Beckske, 2018).

In contrast to common types of stroke in elderly individuals, an SAH often occurs at a relatively young age, with approximately half the affected patients younger than 60 years old (Beckske, 2018). Particularly devastating for patients younger than 45, around 10% to 15% of aneurysmal SAH (“aSAH”) patients die before reaching the hospital (Rinkel, 2016), and those who survive the initial hours post hemorrhage are admitted or transferred to tertiary care centers with high risk of complications, including rebleeding and delayed cerebral ischemia (“DCI”). Systemic manifestations affecting cardiovascular, pulmonary, and renal function are common and often complicate management of DCI. Approximately 70% of aSAH patients experience death or a permanent dependence on family members, and half die within one month after the hemorrhage. Of those who survive the initial month, half remain permanently dependent on a caregiver to maintain daily living (Beckske, 2018).



Treatment offerings currently include sustained hypervolemia, hemodilution, and/or induced hypertension (Triple-H therapy), calcium antagonists and angioplasty. Because vasospasm may result from an increase of calcium in the vascular smooth-muscle cell, a medical rationale has emerged for the use of calcium antagonists. The addition of calcium antagonists like nimodipine to the treatment arsenal for the prevention of cerebral vasospasm after aSAH is based on the notion that these drugs can counteract the influx of calcium into the vascular smooth-muscle cell (Rinkel, 2002).

The incidence of SAH in the United States is approximately 10 in every 100,000 persons per year (Beckske, 2016; NINDS, 2016; Ingall, 1989; Schievink, 1995; Schievink, 1997; Zacharia, 2010), based on multiple analyses of the

population of Rochester, Minnesota. Ingall (1989) studied the incidence of SAH in this population over the 40-year period from 1945 through 1984. At that time, the population of Rochester lent itself well to epidemiological studies because medical care was provided primarily by the Mayo Clinic. Over this period the average annual incidence rate of aSAH remained constant at approximately 11 per 100,000 population. More recently, the American Heart Association/American Stroke Association Guidelines for the Management of Aneurysmal Subarachnoid Hemorrhage (Connolly, 2012) refer to the 2003 Nationwide Inpatient Sample as providing an annual estimate of 14.5 discharges for aSAH per 100,000 adults, although, because death resulting from aSAH often occurs before hospital admission (in an estimated 12% to 15% of cases), the true incidence may be higher. According to the U.S. Census Bureau, Population Estimates for 2015, the U.S. population was estimated at 321,418,820. Therefore, approximately 53,596 individuals experience aSAH each year. The total addressable market for SAH is approximately \$300 million in the U.S., and an estimated 50,000 patients in the European Union based on annual inpatient admissions and the average length-of-stay.

GTX-104—R&D History and Clinical Studies to Date

During 2017 and 2018, Acasti Pharma U.S. (formerly Grace) evaluated GTX-104 in a four-part, single center, randomized, safety and dose-escalation and crossover study in over 80 healthy male and female subjects designed to assess the PK, bioavailability (“BA”), and the safety of GTX-104 administered via IV infusion compared to nimodipine oral capsules.

Details of the four-part PK study follow below:

Part One:

Primary objective:	Evaluate the preliminary cardiovascular safety and tolerability of incremental doses of IV GTX-104 in healthy male and female subjects
Method:	Evaluate incremental dose-escalation of GTX-104 administered at dose levels of 0.3 mg/h to 1.22 mg/h over 16 hours, with dose-escalation occurring every 4 hours (0.3, 0.6, 0.9, and 1.22 mg/h)
Adverse Events:	Arthralgia, constipation, flatulence, headache, infusion site irritation, peripheral edema, and vomiting—all adverse events (“AEs”) were rated as mild in severity

Part Two:

Primary Objective:	Evaluate the PK and BA of GTX-104 administered via IV infusion compared to the reference product of oral nimodipine capsules and to select the dose of IV GTX-104 with an exposure profile most closely matching that of oral nimodipine capsules
Method:	Two-period, crossover BA study. Pilot study that evaluated GTX-104 administered open-label as 1.22 mg/h continuous IV infusion for 16 hours compared to oral nimodipine (60 mg every 4 hours for 12 hours) in 12 subjects
Adverse Events:	No serious adverse events (“SAEs”) in any subjects. 20.0% of subjects reported non-serious AEs following administration of GTX-104 compared to 50.0% of subjects reporting AEs following administration of oral nimodipine

Part Three:

Primary Objective:	Determine the comparative bioavailability of IV GTX-104 versus oral nimodipine capsules and to evaluate the safety and tolerability of IV GTX 104 compared to oral nimodipine capsules in healthy male and female subjects
Method:	BA study, with GTX-104 administered as 1.1 mg/h continuous IV infusion for 28 hours compared to oral nimodipine capsules administered every four hours for 24 hours at a dose level of 60 mg in approximately 32 subjects

Adverse Events:

No SAEs; 20.0% of the subjects reported non-serious AEs following administration of GTX-104 whereas 8 (50.0%) subjects reported AEs following administration of oral nimodipine. Fourteen (34.1%) subjects reported AEs following administration of GTX-104 whereas 18 (43.9%) subjects reported AEs following administration of oral nimodipine

Part Four:

Primary Objective:

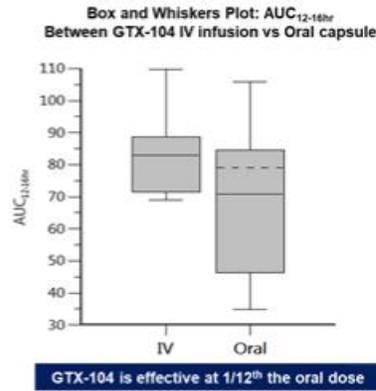
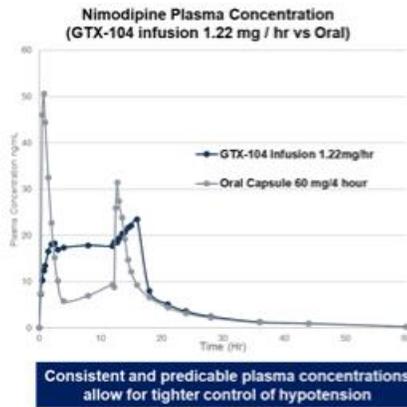
Determine the comparative BA of IV GTX-104 versus oral nimodipine capsules and to evaluate the safety and tolerability of IV GTX 104 compared to oral nimodipine capsules in healthy male and female subjects

Method:

BA study: extension study with the same study design as Part Three, where only GTX-104 was administered open-label as a continuous IV infusion of 1.4 mg/h for 36 hours with oral nimodipine administered for 20 hours (approximately 24 subjects)

Adverse Events:

No SAEs; 10 (41.7%) subjects reported AEs following administration of GTX-104 whereas eight (36.4%) subjects reported AEs following administration of oral nimodipine



GTX-104 Near Term Milestones—Conduct PK Bridging and Phase 3 Safety Studies

In September 2021, we initiated our planned PK bridging study to evaluate the relative bioavailability of GTX-104 compared to currently marketed oral nimodipine capsules in 50 healthy subjects. The PK study is the next required step in our proposed 505(b)2 regulatory pathway for GTX-104.

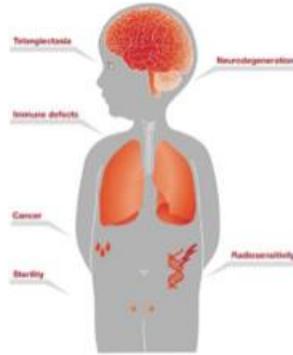
Results from this study are expected in the first half of calendar 2022, and after review with the FDA, will help determine the final design of our planned Phase 3 safety study of GTX-104 in SAH patients. If the PK study and related FDA review progress as planned, we expect to begin the Phase 3 safety study during the second half of 2022. If the safety study also meets its primary end points, we expect to submit the data in a Section 505(b)(2) NDA filing with the goal to obtain FDA approval.

GTX-102 Overview

GTX-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve neurological symptoms of Ataxia Telangiectasia (“A-T”) for which there are no FDA approved therapies. GTX-102 is a stable, concentrated oral spray formulation comprised of the glucocorticoid betamethasone and other excipients, that can be sprayed conveniently over the tongue of the A-T patient.

About Ataxia Telangiectasia

A-T is a rare genetic progressive autosomal recessive neurodegenerative disorder that affects children, with the hallmark symptoms of cerebellar ataxia and other motor dysfunction, and dilated blood vessels (telangiectasia) that occur in the sclera of the eyes. A-T is caused by mutations in the ataxia telangiectasia gene, which is responsible for modulating cellular response to stress, including breaks in the double strands of DNA.



Children with A-T begin to experience balance and coordination problems when they begin to walk (toddler age), and ultimately become wheelchair-bound in their second decade of life. In pre-adolescence (between ages 5 and 8), patients experience oculomotor apraxia, dysarthria, and dysphagia. They also often develop compromised immune systems and are at increased risk of developing respiratory tract infections and cancer (typically lymphomas and leukemia) (U.S. National Cancer Institute A-T, 2015).

A-T is diagnosed through a combination of clinical assessment (especially neurologic and oculomotor deficits), laboratory analysis, and genetic testing. There is no known treatment to slow disease progression, and treatments that are used are strictly aimed at controlling the symptoms (e.g., physical, occupational or speech therapy for neurologic issues), or conditions secondary to the disease (e.g., antibiotics for lung infections, chemotherapy for cancer, etc.) (U.S. National Cancer Institute A-T, 2015). There are no FDA-approved therapeutic options currently available. Patients typically die by age 25 from complications of lung disease or cancer. According to a third-party report commissioned by Acsti Pharma US, A-T affects approximately 4,300 patients per year in the United States and has a potential total addressable market of \$150 million, based on the number of treatable patients in the United States.

The U.S. National Institutes of Health (NIH) Genetics Home Reference, the U.S. National Organization for Rare Disorders (NORD), the U.S. National Cancer Institute, and the United States National Ataxia Foundation, all estimate the incidence of A-T worldwide to be between 1:40,000 and 1:100,000 live births. It has been reported in all races throughout the world and is represented equally in males and females (Lavin, 2007; Sedgwick and Boder, 1972).

For the purposes of estimating prevalence, the maximum survival age observed by Crawford et al., 40 years, has been used. Assuming a maximum survival of 40 years, the total number of A-T cases has been calculated from 1975 to 2015. The highest incidence rate reported in the United States of 1:40,000 has been used to obtain an estimate of A-T prevalence today. Between 1975 and 2015, the highest number of births in one year was 4,316,233 in 2007 (Martin, 2010; Martin, 2015) and so for the purposes of this prevalence calculation, this has been taken as the number of births per year.

Total A-T cases/year = 25 A-T births/million live births x 4.32 million live births/year = 108 A-T cases/year. Assuming that all 108 people possibly born with A-T are still alive today, the total number of individuals with A-T today in the United States, at the very outside estimate = 108 births/year x 40 years = 4320 cases. With a current U.S. population of 321,251,852 (United States Census Bureau) the highest estimated prevalence of A-T is 4320:321,251,852 or 1:74,364.

GTX-102—R&D and Clinical Studies to Date

In a multicenter, double-blind, randomized, placebo-controlled crossover trial conducted in Italy, Zannolli et. al. studied the effect of an oral liquid solution of betamethasone on the reduction of ataxia symptoms in 13 children (between ages 2 to 8 years) with A-T. Patients were randomly assigned to first receive either betamethasone or placebo at a dose of 0.1 mg/kg/day for 30 days: at full dose for the first 10 days, at a tapered dose on days 11–20 (i.e., for 4 days, 0.075 mg/kg/day; for 4 days, 0.050 mg/kg/day; and for 2 days, 0.025 mg/kg/day); and at full dose for the last 10 days (the full dose was tapered in the middle of the treatment phase to reduce risk from potential functional suppression of the hypothalamus-hypophysis-adrenal axis). Each phase of the trial was followed by a washout period of 30 days. The primary outcome measure was the reduction in ataxia symptoms as assessed by the International Cooperative Ataxia Rating Scale (“ICARS”).

In the trial, oral liquid betamethasone reduced the ICARS total score by a median of 13 points in the intent-to-treat (“ITT”) population and 16 points in the per-protocol (“PP”) population (the median percent decreases of ataxia symptoms of 28% and 31%, respectively). In the ITT population, significant differences were observed in the posture and gait disturbance (p = 0.02), kinetic function (p = 0.02), and speech disorders ICARS subscales (p = 0.02), but not in the oculomotor disorders subscale (p > 0.05). Similar results were found in the PP population. Adverse events in the trial were minimal, with no compulsory withdrawals and only minor side effects that did not require medical intervention. Small increases in body weight were observed in 12 patients on betamethasone and in 4 patients on placebo. Moon face was present in 8 patients on betamethasone. Clinical study results in A-T patients administered oral betamethasone indicated that betamethasone significantly reduced ICARS total score relative to placebo (P = 0.01). The median ICARS change score (change in score with betamethasone minus change in score with placebo) was -13 points (95% confidence interval for the difference in medians was -19 to -5.5 points).

Clinical Study Results in A-T Patients Administered Oral Betamethasone							
ICARS	Placebo		Betamethasone		Efficacy		P values
	Day -1	Day 31	Day -1	Day 31	Db	95% CI for the median	
Total score	46(14-69)	41.5(26-68)	50(20-68)	33(19-55)	-13 (-28 to 14)	-19 to -5.5	.01
I. Posture and gait disturbance	13.5(3-30)	14.5(7-30)	18 (7-29)	9(4-26)	-5 (-15 to 5)	-9.5 to -1.5	.02
II. Kinetic function	22 (6-32)	20.5 (13-31)	23 (10-33)	18 (8-28)	-8 (-15 to 10)	-10 to -0.5	.02
III. Speech disorder	3 (1-5)	2.5 (2-5)	3 (2-5)	2 (1-5)	-1 (-3 to 1)	-2.5 to -0.5	.02
IV. Oculomotor disorders	3 (2-5)	3.5 (1-5)	3 (1-5)	3 (1-5)	0 (-2 to 2)	-2 to 1	.43

- a Data are medians (ranges). Thirteen ITT A-T patients are included.
- b Median differences between the change in the ICARS score related to BETA treatment (d BETA) and the change related to placebo treatment (d placebo).
- c P values calculated using the Wilcoxon rank sum test.

Betamethasone significantly reduced ICARS total score relative to placebo (P = .01). The median ICARS change score (change in score with Betamethasone minus change in score with placebo) was -13 points (95% CI for the difference in medians was -19 to -5.5 points).

Based on the Zannolli data, we believe GTX-102 concentrated oral spray has the potential to provide clinical benefits in decreasing A-T symptoms, including assessments of posture and gait disturbance and kinetic, speech and oculomotor functions. In addition, GTX-102 may ease drug administration for patients experiencing A-T given its application of 1-3x 140µL of concentrated betamethasone liquid spray onto the tongue using a more convenient metered dose spray, as these A-T patients typically have difficulty swallowing (lefton-greif 2000).

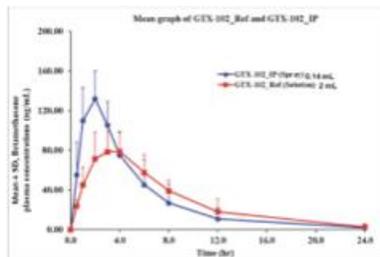
GTX-102 PK Data to Date

GTX-102 administered as a concentrated oral spray achieves similar blood levels at only 1/70th the volume of an oral solution of betamethasone. This is important for A-T patients who have difficulties swallowing large volumes of liquids.

Group/Formulation	Group 1, GTX-102_IP	Group 2, GTX-102_Ref
Lot Number	GTX-102-009	GTX-102-009
Pk	0.352 mg/ml, Oral	0.25 mg/ml, Oral
Parameters/Case/No.	Range	Median
C _{max} (ng/mL)	158.11 - 213.22 (25)	82.83 - 23.55 (25)
T _{max} (h) PK	2.0 (1.0 - 3.0)	3.0 (2.0 - 4.0)
AUC ₀₋₂₄ (ng*hr/mL)	891.16 - 314.19 (37)	738.29 - 193.91 (37)
AUC _{0-∞} (ng*hr/mL)	886.02 - 338.77 (36)	728.40 - 217.88 (36)
K _{el} (1/hr)	0.18 - 0.94 (23)	0.18 - 0.96 (29)
t _{1/2} (hr)	3.81 - 0.80 (23)	3.89 - 1.21 (31)
CL/F (mL/hr)	8.19 - 1.80 (28)	8.11 - 1.87 (37)
V _{d/F} (L)	2.08 - 0.75 (37)	2.00 - 0.82 (36)
Relative Bioavailability (% P)	193.79 - 23.7 (23)	-

Note: Values are mean ± SD (n/N) (N denotes total number tested); SD=Standard deviation; PK=Pharmacokinetic; CL=Clearance of solution.

Mean plasma pharmacokinetic parameters of Betamethasone following reference (oral solution) and GTX-102 (oral spray) administered orally in rabbits show similar characteristics.



GTX-102 Near-Term Milestones: Conduct PK Bridging and Confirmatory Phase 3 Clinical Trials

Acasti Pharma US has licensed the data from the multicenter, double-blinded, randomized, placebo-controlled crossover trial from Azienda Ospedaliera Universitaria Senese, Siena, Italy, where Dr. Zannolli et. al. studied the effect of oral liquid solution of betamethasone to reduce ataxia symptoms in patients with A-T. Note that this oral liquid solution is not approved in the United States, and therefore is not available for clinical use. Betamethasone is only available in the United States as an injectable or as a topical cream. However, this license gives Acasti Pharma US the right to reference the study’s data in its NDA filing. On November 12, 2015, Acasti Pharma US submitted the data from the Zannolli study to the FDA’s Division of Neurology at a pre-Investigational New Drug (“IND”) meeting and received guidance from the agency on the regulatory requirements to seek approval.

Based on such FDA guidance, we plan to conduct a PK bridging study of our proprietary concentrated oral spray as compared to the oral liquid solution of betamethasone used in the Zannolli study. We believe this study may result in a better, more convenient use experience as patients with A-T often have trouble swallowing. Additionally, based on the FDA’s subsequent guidance and assuming the PK bridging study meets its primary endpoint, we plan to conduct a confirmatory Phase 3 safety and efficacy trial in A-T patients. If both studies meet their primary endpoints, an NDA filing under Section 505(b)(2) would follow.

GTX-101 Overview

GTX-101 is a topical bio-adhesive film-forming bupivacaine spray designed to ease the symptoms of patients suffering with postherpetic neuralgia (“PHN”). GTX-101’s metered-dose of bupivacaine spray forms a thin bioadhesive topical film on the surface of the patient’s skin, which enables a touch-free, non-greasy application. It also comes in convenient, portable 30 ml plastic bottles. Unlike oral gabapentin and lidocaine patches, we believe that the biphasic delivery mechanism of GTX-101 has the potential for rapid onset and continuous pain relief for up to eight hours. No skin sensitivity was reported in a Phase 1 study.



About Postherpetic Neuralgia (PHN)

PHN is neuropathic pain due to damage caused by the varicella zoster virus (“VZV”). Infection with VZV causes two distinct clinical conditions. Primary VZV infection causes varicella (i.e., chickenpox), a contagious rash illness that typically occurs among young children. Secondary VZV can reactivate clinically, decades after initial infection, to cause herpes zoster (“HZ”), otherwise known as shingles. Acute HZ arises when dormant virus particles, persisting within an affected sensory ganglion from the earlier, primary infection with VZV become reactivated when cellular immunity to varicella decreases. Viral particles replicate and may spread to the dorsal root, into the dorsal horn of the spinal cord, and through peripheral sensory nerve fibers down to the level of the skin. Viral particles also may circulate in the blood. This reactivation is accompanied by inflammation of the skin, immune response, hemorrhage, and destruction of peripheral and central neurons and their fibers. Following such neural degeneration, distinct types of pathophysiological mechanisms involving both the central and peripheral nervous systems may give rise to the severe nerve pain associated with PHN.

While the rash associated with HZ typically heals within two to four weeks, the pain may persist for months or even years, and this PHN manifestation is the most common and debilitating complication of HZ. There is currently no consensus definition for PHN, but it has been suggested by the Centers for Disease Control and Prevention (“CDC”) that PHN is best defined as pain lasting at least three months after resolution of the rash. PHN persisting beyond three months may occur in 10% to 20% of HZ patients aged over fifty years (CDC Morbidity and Mortality Weekly Report, 2008).

PHN is associated with significant loss of function and reduced quality of life, particularly in the elderly. It has a detrimental effect on all aspects of patients’ quality of life. The nature of PHN pain varies from mild to excruciating in severity, constant, intermittent, or triggered by trivial stimuli. Approximately half of patients with PHN describe their pain as “horrible” or “excruciating,” ranging in duration from a few minutes to constant on a daily or almost daily basis (Katz, 2004). The pain can disrupt sleep, mood, work, and activities of daily living, adversely impacting the quality of life and leading to social withdrawal and depression. PHN is the number-one cause of intractable, debilitating pain in the elderly, and has been cited as the leading cause of suicide in chronic pain patients over the age of 70 (Hess, 1990).

Current treatment of PHN most often consists of oral gabapentin and lidocaine patches, and refractory cases may be prescribed opioids to address persistent pain. Gabapentin and opioid abuse have continued to proliferate, and lidocaine patches are suboptimal for many reasons. According to a third-party report commissioned by Acasti Pharma US, approximately 40% of patients using lidocaine patches experience insufficient pain relief. Lidocaine patches are difficult to use, fall off, and look unsightly with possible skin sensitivity and irritation. Additionally, an optimal analgesic effect could take up to two weeks to be achieved. PHN affects approximately 150,000 patients per year in the United States. According to a third-party report commissioned by Acasti Pharma US, the total addressable market for GTX-101 is \$1.6 billion, consisting of \$400 million for PHN pain and \$1.2 billion for non-PHN pain.

Treatment of PHN most often consists of gabapentin and lidocaine patches

First Line	Second Line	Third Line
Generic gabapentin	Branded Anticonvulsants	Opioids
Topical anesthetic 5% Lidocaine patch, ZT Lido 1.8%		Intervention

~150,000 patients per year in the U.S. are affected by PHN. Total addressable market in the U.S. for GTX-101 is estimated to be ~\$400M for PHN pain alone, with significant market potential in Europe and Asia.

While the PHN will resolve within 1 to 2 months in many cases, and within the year in the majority of cases, it may persist in some patients for an extended period of time (more than 1 year), adding to the prevalence. On average, 4.6% of patients with PHN still experience pain at 1 year following development of the HZ rash, with 9% being the most reported. In a very small number of patients (2%), PHN remains persistent for over 5 years. Assuming in the worst case that 2% of PHN patients will experience pain for up to 10 years, an extra 2500 patients per year for 10 years could be added to the prevalence of 125,000 a year, adding 25,000 patients to any given year.

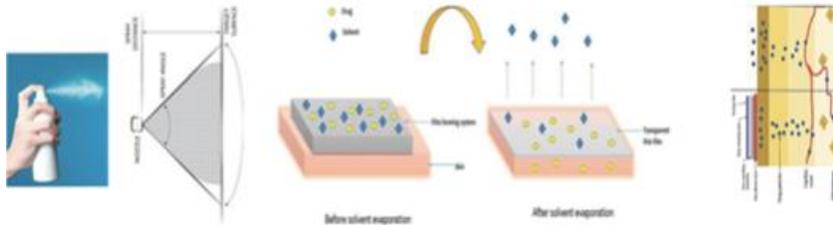
The CDC estimates that there are 1 million cases of HZ a year in the United States. The definition of PHN used in the pivotal study for the approved HZ vaccine was, “pain persisting or appearing more than 90 days after the onset of rash (Oxman, 2005).” Using this definition, and the numbers provided by the CDC, PHN would occur in approximately 125,000-150,000 new cases per year.

GTX-101 R&D History and Clinical Studies Completed to Date

To date, Acasti Pharma US has conducted three Phase I studies in healthy volunteers to assess the PK, safety and tolerability of GTX-101 and to determine the plasma levels of bupivacaine HCl administered as a single dose in various concentrations, namely 30 mg (three sprays), 50 mg (five sprays), 70 mg (seven sprays) or 100 mg (ten sprays).

The initial study was conducted to determine the PK levels of GTX-101 following a single dose of either 30 mg, 50 mg or 70 mg, and to compare the plasma levels to those produced by a single 30 mg dose of injectable bupivacaine (SENSORCAINE™). In this study, the plasma levels of bupivacaine were below the limit of quantitation (limit of quantitation (“LOQ”) was 1.00 ng/mL) for almost all subjects administered GTX-101, and at almost all time points. Mean Cmax and AUC0-T for injectable bupivacaine were 129.3 ng/mL and 517.7 ng/mL, respectively. Bupivacaine was not detected due to assay sensitivity limited to 1ng/ml.

Mechanism of GTX-101 Bioadhesive Film Formation

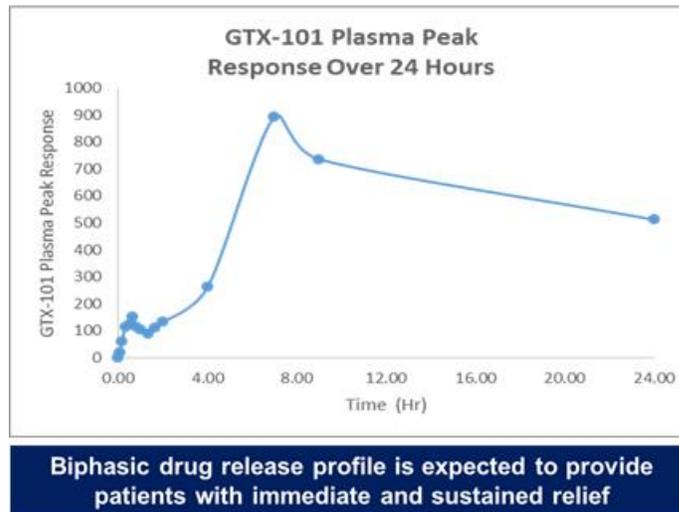


The second study investigated the PK, safety, and tolerability of a single 100 mg dose (ten sprays) of GTX-101. The mean bupivacaine C_{max} in this study was 1.249 ng/mL for the first set of samples and 1.067 ng/mL for the second set of samples; the two mean values differing from each other by less than 20%. The LOQ of the bioanalytical method used for this study was 5 pg/mL. This study confirmed the C_{max} values as being similar from two sets of samples collected from the same patients at the same time points.

In the third study, the PK, safety, and tolerability of a single 100 mg dose (ten sprays) of GTX-101 were again investigated. This study was a single-center, non-randomized, single dose, open-label, 1-period, 1-treatment design in 10 healthy male and female subjects. The PK results show the maximum observed plasma concentration of bupivacaine was reached within 20 to 48 hours for all subjects. The maximum concentration reached was 19.59 ng/mL. This study confirmed that bupivacaine delivered as a spray (GTX-101) is well absorbed through the skin, as demonstrated in the graph below.

In all three studies, the administration of GTX-101 to healthy volunteers was safe and well tolerated. In addition, no evidence of skin irritation was observed at the application site following the spray administrations.

Phase 1 Single Dose PK Data in Humans



GTX-101 Near-Term Milestones: Conduct Dose Ranging Phase 1 Clinical Trials of GTX-101

We believe that the PHN pain market will continue to grow, and non-opioid products like GTX-101 that can relieve PHN pain more quickly and in a sustained manner by means of a more efficient delivery system, will be an attractive therapy option for patients and physicians. GTX-101 is administered by spraying a proprietary bupivacaine formulation over the affected area, which we believe has the potential to provide several advantages over currently marketed products such as the lidocaine patch, including faster onset of action, sustained pain relief, possibly lower dosing requirements and improved dosing convenience, all which could lead to increased patient compliance. The data from the single dose Phase 1 clinical trial for topical bupivacaine spray along with regulatory guidance from the FDA's Division of Anesthesiology received at a pre-IND meeting on April 18, 2018, has informed the design of the preclinical toxicology, clinical and regulatory pathway to approval.

Overall Commercialization Strategy

We plan to retain our worldwide commercialization rights for some of our key drug candidates, while for other drug candidates we might consider collaboration opportunities to maximize market penetration and returns. If we receive regulatory approval, we expect to build a small and focused commercial organization in the United States to market

and sell GTX-104 and GTX-102. We believe the patient populations and medical specialists for these indications are sufficiently concentrated to allow us to cost-effectively promote these products following approval for commercial sale. Given that GTX-101 will be targeted to a larger primary care and pain specialist market, if GTX-101 receives regulatory approval, it is likely we will seek commercial partnerships to fully exploit the market potential of this drug product.

As product candidates advance through the pipeline, our commercial plans may change. Clinical data, the size of the development programs, the size of the target market, the size of a commercial infrastructure and manufacturing needs may all have influence on U.S., European Union, and rest-of-world strategies.

Manufacturing and Supply

We currently do not own any manufacturing facilities. The manufacture of our pipeline of drug candidates is highly reliant on complex techniques and personnel aseptic techniques, which present significant challenges and require specialized expertise. Further, these processes undergo a high level of scrutiny by regulatory agencies. Consequently, we utilize a network of third-party contract manufacturers (each, a “CMO”) for manufacturing of our drug candidates. All CMOs are monitored and evaluated by us to assess compliance with regulatory requirements.

We work with and regularly inspect our manufacturers to review the manufacturing process for our drug candidates and to provide input on quality issues. We have addressed the risk of supply chain disruptions through risk management strategies designed to mitigate the effects of any disruptions. While this strategy creates additional effort and requires maintaining dialogue and traveling to and overseeing production at multiple facilities, we believe our manufacturing risks are better managed by utilizing a range of specialized third-party manufacturers at diverse locations.

Intellectual Property Portfolio

We have a strong and multi-layered intellectual property protection strategy, which we believe will create barriers to entry and solidify our position in the market. All leading pipeline products have received orphan status designation from the FDA, which could result in 7 years of marketing exclusivity in the United States and 10 years in Europe provided they receive the final marketing authorizations from the applicable government agencies, and they can meet the conditions for receiving such marketing exclusivity. In addition, we protect our drug candidates through a well-defined patent filing strategy. Our patent estate includes more than 40 granted and pending patents in various global jurisdictions, including four U.S. issued patents and 7 filed U.S. patent applications. We believe that our intellectual property portfolio, consisting primarily of composition and method-of-use patents, will protect the market value of our products by extending exclusivity beyond what is granted through the orphan designation. We intend to continue to build our patent portfolio by filing for patent protection on new developments with respect to our product candidates. We expect that these patents will, if and when issued, allow us to list our own patents in the Orange Book: Approved Drug Products with Therapeutic Equivalence issued by the FDA, to which potential competitors will be required to certify upon submission of their applications referencing our drug products, if approved.

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to the development of our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets relating to manufacturing know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position. We may also rely on regulatory protections afforded through orphan drug status, data exclusivity, market exclusivity, and patent term extensions, where available.

We are actively seeking U.S. and international patent protection for a variety of technologies and intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets and that may be used to identify and develop novel pharmaceutical products. We seek these protections, in part, through confidentiality and proprietary information agreements.

Individual patents extend for varying periods depending on the date of filing or the date of issuance, and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA

regulatory review period. However, as to the FDA component, the restoration period cannot be longer than 5 years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. The actual protection afforded by a patent may vary on a product-by-product basis from country to country and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Acasti Pharma US has several issued U.S. patents and patent applications as well as patents and patent applications in other jurisdictions. Four patents for GTX-104 have been granted in the United States. One patent for GTX-101 has been granted in Europe, China, Hong Kong, Mexico and South Africa. One patent for GTX-102 has been granted in Japan.

Regulation

We are subject to extensive regulation by the various national health regulatory authorities such as the FDA, Health Canada, European Medicines Agency and other national, state and provincial regulatory agencies. Failure to comply with the regulations of these governmental agencies may result in suspension of regulatory approval and potential civil and criminal actions against us in addition to other potential sanctions. The regulatory environment, particularly enforcement positions, statutes, and legal interpretations applicable to the pharmaceutical industry are constantly in flux and not always clear. Significant changes in this environment could have a material adverse effect on our financial condition and results of operations.

U.S. Food and Drug Administration

The research, development, and marketing authorization of drugs and other pharmaceutical products in the United States is subject to the FDCA, which authorizes the FDA to require extensive non-clinical and clinical testing before a new drug or biologic is deemed safe and effective and receives marketing authorization. Following pre-clinical laboratory and animal testing that show that investigational use in humans is reasonably safe, a drug can be studied in clinical trials in humans under an IND in accordance with the regulations at 21 CFR 312. Clinical trial programs must establish efficacy, determine an appropriate dose and dosing regimen, and define the conditions for safe use. Clinical development is a high-risk process that requires stepwise clinical studies in which the candidate product must successfully meet predetermined endpoints. The results of the preclinical and clinical testing of a product are then submitted to the FDA in the form of a NDA or a Biologics License Application (“BLA”). In response to an NDA or BLA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval.

The receipt of regulatory approval often takes several years, involves the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, potential safety signals observed in preclinical or clinical tests, and the risks and benefits of the product as demonstrated in clinical trials. The FDA has substantial discretion in the product approval process, and it is impossible to predict with any certainty whether and when the FDA will grant marketing approval. The agency may on occasion require the sponsor of an NDA or BLA to conduct additional clinical studies or to provide other scientific or technical information about the product, and these additional requirements may lead to unanticipated delay or expense.

Hatch-Waxman Act

Section 505 of the FDCA describes three types of NDAs that may be submitted to request marketing authorization for a new drug. A 505(b)(1) NDA is an application that contains full reports of investigations of safety and effectiveness. The Hatch-Waxman Act created two additional marketing pathways under Sections 505(j) and 505(b)(2) of the FDCA. Section 505(j) establishes an abbreviated approval process for generic versions of approved drug products through the submission of an Abbreviated New Drug Application (an “ANDA”). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. ANDA applicants in most cases must be required to conduct bioequivalence testing to confirm chemical and therapeutic equivalence to the branded reference drug. Generic versions of drugs can often be substituted by pharmacists under prescriptions written for the branded reference drug. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant. This

alternate regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicants. Upon submission of an ANDA or a 505(b)(2) NDA with respect to each patent listed in FDA's so-called Orange Book for the branded reference drug, 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) the date on which such patent expires; 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. This last certification is known as a paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or 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 date of 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 such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the thirty-month stay. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. 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 may obtain five years of exclusivity upon approval of a new drug containing a new chemical entity ("NCE"), that has not been previously approved by the FDA. 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) NDA for drugs that include the innovation that required the new clinical data.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the U.S. per year, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the U.S. for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in shortening the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product based on greater efficacy or safety, or providing a major contribution to patient care, or if we, with orphan product exclusivity, are not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

United States Marketing Exclusivity

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain follow-on drug approval applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve an ANDA, or a 505(b)(2) NDA submitted by another company for review for another version of such drug where the

applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement, a so-called Paragraph IV certification described above. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving AND As for the original non-modified version of the drug. 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 studies necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds an additional six months of exclusivity to the end of listed patents and marketing exclusivity for the sponsor's drug products containing the active moiety (for example, seven-year orphan product exclusivity is extended to seven and a half years, while 5-year NCE exclusivity is extended to five and a half years). This six-month exclusivity may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Third-Party Payor Coverage and Reimbursement

The commercial success of our product portfolio, should the products be approved by the FDA, will in part depend upon the availability of coverage and adequate reimbursement from third-party payors at the federal, state and private levels. Patients who are prescribed treatments for their conditions by medical providers generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our product portfolio will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our product portfolio will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or are reimbursed by government health administration authorities, such as Medicare and Medicaid, private health coverage insurers and other third-party payors.

Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and coverage and reimbursement for therapeutic products can differ significantly from payor to payor. As a result, the coverage determination process will require scientific and clinical support to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained. The cost of pharmaceuticals and medical devices continues to generate substantial governmental and third-party payor scrutiny. It is to be expected that the pharmaceutical industry will continue to experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Operations could be adversely affected by current and future third-party payor policies as well as healthcare legislative reforms. Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements could have a material adverse effect on the ability to obtain adequate pricing for our product portfolio and to operate profitably. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Healthcare Reform

In the U.S. and foreign jurisdictions, the legislative landscapes continue to evolve. There have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. There have been and continue to be several initiatives at the U.S. federal and state levels that seek to reduce healthcare costs. In 2010, the Patient Protection and Affordable Care Act ("ACA") and the Health Care Education and Reconciliation Act of 2010 were passed, which include measures that have the potential to significantly change health care financing by both governmental and private insurers. Among the provisions of the ACA of importance to the pharmaceutical and biotechnology industry are:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extension products;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (which, as a result of the Bipartisan Budget Act of 2018 (BBA), the discount was increased from 50% to 70% beginning in 2019);
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under and other potential modifications to the Public Health Service pharmaceutical pricing program, known as 340B;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- price transparency initiatives that may make prices negotiated with managed care companies public;
- new requirements under the federal Physician Payment Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members; and
- a new requirement to annually report certain drug samples that manufacturers and distributors provide to licensed practitioners, or to pharmacies of hospitals or other healthcare entities, effective April 1, 2012.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws (collectively with the ACA, the Health Care Education and Reconciliation Act of 2010 and other Federal laws referred to herein as the "Health Reform Laws") may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers and accordingly, our financial operations. It is expected that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product portfolio or additional pricing pressures. As an example, U.S. Congress is considering legislation as part

of President Biden's Build Back Better program to lower prescription drug prices by allowing the Medicare program to negotiate drug prices.

The Health Reform Laws also are the subject of ongoing litigation. A collection of 20 state governors and state attorneys general (subsequently two states have dropped out) filed a lawsuit against the federal government in the Northern District of Texas seeking to enjoin the entire ACA following the elimination of the individual mandate penalty in 2019. In an opinion issued in June 2021, the United States Supreme Court held that plaintiffs did have standing to raise the constitutional challenges they asserted and remanded the case with instructions to dismiss.

Federal and state governments will likely continue to review and assess alternative healthcare delivery systems and payment methodologies, and public debate regarding these issues will continue in the future. Changes in the law or new interpretations of existing laws can have a substantial effect on permissible activities, the relative costs associated with doing business in the healthcare industry, and the amount of reimbursement available from government and other third-party payors. If the Health Reform Laws are repealed or modified, or if implementation of certain aspects of the Health Reform Laws continues to be delayed, such repeal, modification, or delay may have a material and adverse impact on our business, financial condition, results of operations, cash flow, capital resources and liquidity.

Foreign Regulation

To market any product outside of the United States, it is necessary to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of its products. Regardless of FDA approval for a product, the necessary approvals by comparable foreign regulatory authorities are required before commencing clinical trials or marketing any product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States may apply similarly in the context of foreign countries, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, the FDA and other government agencies have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any of which could have a material adverse effect.

Should operations be found to be in violation of any of such laws or any other applicable governmental regulations, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and achieve financial results.

Recent Developments

Management and Operations

Post-merger, Acasti continues to be led by Jan D'Alvise as President and CEO, and we continue to maintain our corporate headquarters in Laval, Quebec, Canada and a quality laboratory in Sherbrooke, Quebec, Canada. We will also maintain the Acasti Pharma U.S. research and development laboratory and commercial presence in North Brunswick, New Jersey.

About the Merger

In connection with our acquisition of Grace, Grace merged with Acasti Pharma US, a new wholly owned subsidiary of Acasti. Grace was the surviving company in the merger, was renamed Acasti Pharma US Inc., and is now a wholly

owned subsidiary of Acasti. Grace stockholders received newly issued Acasti common shares pursuant to an equity exchange ratio formula set forth in the merger agreement.

The merger closed on August 27, 2021, following approval by Acasti shareholders at our annual and special meeting of shareholders, which took place on August 26, 2021.

Nasdaq Update

On May 11, 2021, we received written notice from the NASDAQ Listing Qualifications Department notifying us that based upon non-compliance with the \$1.00 minimum bid price requirement set forth in NASDAQ Listing Rule 5550(a) as of May 10, 2021, our common shares were subject to delisting unless we timely requested a hearing before the NASDAQ Hearings Panel. We requested a hearing, which stayed any further action by NASDAQ pending the conclusion of the hearing process.

At the hearing on June 17, 2021, we presented a detailed plan of compliance for the NASDAQ Hearing Panel's consideration, which included our commitment to implement a share consolidation if needed in connection with the merger with Grace to regain compliance with NASDAQ minimum bid price rule.

On July 12, 2021 the NASDAQ Hearings Panel issued its decision, which extended the time for us to regain compliance with Listing Rule 5550(a), subject to the following: 1) that we hold a shareholders meeting on or before August 26, 2021 to obtain approval for a share consolidation at a ratio allowing for long term compliance with Listing Rule 5550(a) and 2) on or before September 10, 2021, that we will have regained compliance with Listing Rule 5550(a).

On August 27, 2021, we announced that, in connection with the merger and in furtherance to the advisory resolution passed by Acasti shareholders at the shareholders meeting on August 26, 2021, approving a share consolidation, a share consolidation of our common shares at an 8-1 ratio had been implemented to regain compliance with NASDAQ's Listing Rule 5550(a). The share consolidation became effective on August 31, 2021.

On September 22, 2021, Acasti announced the confirmation by NASDAQ that we had regained compliance with NASDAQ's Listing Rule 5550(a).

Newly Elected Directors

As contemplated by the merger agreement, at the Acasti shareholders meeting on August 26, 2021, Vimal Kavuru and William Haseltine were elected as new directors (as well as our incumbent directors). Following the shareholders meeting, there remains one seat on our board of directors that was to be filled by a candidate recommended by the former Grace stockholders.

GHR Committee Composition and New Executive Titles

George Kottayil has been named Chief Operating Officer, U.S. of Acasti. Mr. Kottayil was a co-founder and previously served as Chief Executive Officer of Grace prior to its acquisition by Acasti. Pierre Lemieux continues as Chief Operating Officer, Canada, and Chief Scientific Officer of Acasti.

Mr. Vimal Kavuru, director, has replaced John Canan as a member of the Governance & Human Resources Committee of the Board. Mr. Canan will continue to serve as Chair of the Audit Committee of the Board.

COVID-19 Update

To date, the ongoing COVID-19 pandemic has not caused significant disruptions to our business operations and research and development activities.

The extent to which the COVID-19 pandemic impacts our business and prospects and the timing and completion of future clinical trials for our new drug candidates will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 pandemic and the actions to contain the COVID-19 pandemic or treat its impact, among others.

Corporate Information

We were incorporated on February 1, 2002 under Part 1A of the Companies Act (Québec) under the name “9113-0310 Québec Inc”. On August 7, 2008, pursuant to a Certificate of Amendment, we changed our name to “Acasti Pharma Inc.” and on February 14, 2011, the Business Corporations Act (Québec) came into effect and replaced the Companies Act (Québec). We are now governed by the Business Corporations Act (Québec), or the QBCA.

Our principal executive offices are located at 3009 boul. De la Concorde E., Suite 102, Laval, Québec, Canada H7E 2B5. Our telephone number is (450) 686-4555. Our corporate website is <http://www.acastipharma.com>. Information appearing on our website is not incorporated by reference into this prospectus supplement.

THE OFFERING

The following summary contains basic information about our common shares and the offering and is not intended to be complete. It does not contain all of the information that may be important to you. For a more complete understanding of our common shares, you should read the section entitled "Description of Share Capital" in this prospectus supplement.

Common shares offered by us	Common shares having an aggregate offering price of up to US\$75,000,000.
Manner of offering	<p>"At the market offering" that may be made from time to time through or to the Agents, as sales agents or principals. See "Plan of Distribution."</p> <p>The common shares offered hereby have not been and will not be qualified for sale under the securities laws of any province or territory of Canada or to any resident of Canada and will not be offered or sold, directly or indirectly, in Canada or to or for the account of any resident of Canada. No common shares will be sold on the TSXV or on other trading markets in Canada as at the market distributions.</p>
Common shares to be sold in this offering	Up to 44,117,647 shares, assuming a sales price of US\$1.70 per share, which was the closing price of our common shares on NASDAQ on November 8, 2021. The actual number of shares issued will vary depending on the sales price under this offering. As of November 8, 2021, there were 44,288,183 common shares outstanding.
Use of proceeds	We intend to use the net proceeds from this offering for working capital and general corporate purposes, which includes the planning and conduct of clinical trials, the manufacturing of clinical and commercial products, regulatory activities, market development and commercialization activities, and business and corporate development. See "Use of Proceeds."
Risk factors	You should read the description of risks described in "Risk Factors" beginning on page S-22 of this prospectus supplement and those otherwise incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of material risks that prospective purchasers of our common shares should consider.
NASDAQ and TSXV ticker symbol	ACST

The number of common shares to be outstanding immediately after the completion of the offering is based on 44,288,183 common shares outstanding on November 8, 2021, and excludes the following:

- 903,876 common shares issuable upon the exercise of options issued to our directors, officers and employees, at a weighted-average exercise price of C\$8.32 per common share;
- 215,491 common shares issuable upon the exercise of warrants at an exercise price of C\$17.20 per common share;
- 32,390 common shares issuable upon the exercise of underwriter warrants at an exercise price of US\$10.10 per common share;
- 884,120 common shares issuable upon the exercise of warrants at an exercise price of US\$10.08 per common share; and
- 824,218 common shares issuable upon the exercise of warrants at an exercise price of C\$10.48 per common share.

RISK FACTORS

Investing in our common shares involves risk. Before making any investment decision, you should carefully read the risk factors set forth below, under the caption “Risk Factors” in the accompanying prospectus, under the caption “Item 1A – Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and other documents that are incorporated by reference into this prospectus supplement and the accompanying prospectus. It is not possible to predict or identify all such risks. Consequently, we could also be affected by additional factors that are not presently known to us or that we currently consider to be immaterial to us.

The risks we have identified and the risks that remain unknown could materially affect our business, results of operation or financial condition and affect the value of our common shares. You could lose all or part of your investment.

Sales of a substantial number of our common shares, or the perception that such sales might occur, could adversely affect the trading price of our common shares.

We may issue up to US\$75,000,000 of common shares from time to time in this offering. Sales of a substantial number of our common shares, or the perception that such sales might occur, could adversely affect the trading price of our common shares. We cannot predict the effect, if any, that market sales of those common shares or the availability of those common shares for sale will have on the market price of our common shares. In addition, the market price of our common shares could fall as a result of resales of any of these common shares due to an increased number of shares available for sale in the market.

You may experience immediate dilution in the book value per share of the common shares you purchase.

Because the price per share of our common shares being offered may be substantially higher than the book value per share of our common shares, you may experience substantial dilution in the net tangible book value of the common shares you purchase in this offering. Assuming that an aggregate of 44,117,647 common shares are sold at a price of US\$1.70 per share pursuant to this prospectus supplement, which was the last reported sale price of our common shares on NASDAQ on November 8, 2021, and based on the net tangible book value of the common shares of US\$1.13 per share as of September 30, 2021, if you purchase common shares in this offering, you will experience dilution of US\$0.31 per share in the as-adjusted net tangible book value of the common shares.

It is not possible to predict the actual number of shares we will sell under the sales agreement, or the gross proceeds resulting from those sales.

Subject to certain limitations in the sales agreement and compliance with applicable law, we have the discretion to deliver a placement notice to the Agents at any time throughout the term of the sales agreement. The number of shares that are sold through the Agents after delivering a placement notice will fluctuate based on a number of factors, including the market price of our common shares during the sales period, the limits we set with the Agents in any applicable placement notice, and the demand for our common shares during the sales period. Because the price per share of each share sold will fluctuate during the sales period, it is not currently possible to predict the number of shares that will be sold or the gross proceeds to be raised in connection with those sales.

Our common shares offered hereby may be sold in “at the market offerings,” and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares in this offering at different times will likely pay different prices, and so may experience different levels of dilution and different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold in this offering. In addition, there is no minimum or maximum sales price for shares to be sold in this offering. Investors may experience a decline in the value of the shares they purchase in this offering as a result of sales made at prices lower than the prices they paid.

We may be classified as a PFIC for U.S. federal income tax purposes.

We have not yet determined whether we will be a “passive foreign investment company,” (“PFIC”), for our current taxable year and subsequent years, but we believe that we may not be classified as a PFIC for our current taxable year and subsequent years. However, the determination of PFIC status of a non-U.S. corporation is fundamentally factual in nature, depends on the application of complex U.S. federal income tax rules (which are subject to differing

interpretations), generally cannot be determined until the close of the taxable year in question, and is determined annually. Accordingly, there can be no assurance that we are not a PFIC in our current taxable year or will not become a PFIC in subsequent years. If we are a PFIC for any year during a U.S. Holder's holding period of the common shares acquired pursuant to this prospectus supplement, then such U.S. taxpayer generally will be required to treat any gain realized upon a disposition of such common shares or any so-called "excess distribution" received on such common shares, as ordinary income (with a portion subject to tax at the highest rate in effect), and to pay an interest charge on a portion of such gain or excess distribution. In certain circumstances, the sum of the tax and the interest charge may exceed the total amount of proceeds realized on the disposition, or the amount of excess distribution received, by the U.S. Holder. Subject to certain limitations, a timely and effective QEF Election (as defined below) under Section 1295 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), or a Mark-to-Market Election (as defined below) under Section 1296 of the Code may be made with respect to the common shares. A U.S. Holder who makes a timely and effective QEF Election generally must report on a current basis its share of our net capital gain and ordinary earnings for any year in which we are a PFIC, whether or not we distribute any amounts to our shareholders. A U.S. Holder who makes the Mark-to-Market Election generally must include as ordinary income each year the excess of the fair market value of their common shares over the holder's basis therein. This paragraph is qualified in its entirety by the discussion below under the heading "Certain U.S. Federal Income Tax Considerations—U.S. Federal Income Tax Considerations of the Acquisition, Ownership, and Disposition of Common Shares—Passive Foreign Investment Company Rules". The PFIC rules are complex and each potential investor who is a U.S. Holder should consult its own tax advisor regarding the U.S. federal, state and local, and non-U.S. tax consequences of the acquisition, ownership, and disposition of common shares acquired pursuant to this prospectus supplement, the U.S. federal tax consequences of the PFIC rules, and the availability of any election to the holder to mitigate adverse U.S. federal income tax consequences of holding shares in a PFIC.

We have broad discretion to determine how to use the proceeds raised in this offering, and we may not use the proceeds effectively.

We intend to use the net proceeds from this offering for working capital and general corporate purposes, which includes the planning and conduct of clinical trials, the manufacturing of clinical and commercial products, regulatory activities, market development and commercialization activities, and business and corporate development. Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways with which you may not agree or that do not yield a favorable return. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity as part of your investment decision to assess whether the proceeds are being used appropriately. Our needs may change as the business and the industry that we address evolves. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

USE OF PROCEEDS

The amount of net proceeds from this offering will depend upon the number of common shares sold and the market price at which they are sold after deduction of commissions or discounts and offering expenses payable by us. There can be no assurance that we will be able to sell any shares under or fully utilize the sales agreement with the Agents.

We currently anticipate using the net proceeds from the sale of our common shares offered by this prospectus supplement, if any, for working capital and general corporate purposes, which includes the planning and conduct of clinical trials, the manufacturing of clinical and commercial products, regulatory activities, market development and commercialization activities, and business and corporate development. We have not allocated any portion of the net proceeds for any particular use as of the date of this prospectus supplement. The net proceeds may be invested temporarily until they are used for their stated purpose.

The occurrence of unforeseen events or changed business conditions, however, could result in the application of the net proceeds from this offering in a manner other than as described in this prospectus supplement. As a result, our management will retain broad discretion over the use of the net proceeds from any sale of our common shares offered hereby.

DESCRIPTION OF SHARE CAPITAL

Overview

Our authorized capital consists of an unlimited number of no par value common shares and an unlimited number of no par value Class B, Class C, Class D and Class E preferred shares (collectively, the preferred shares), issuable in one or more series. As of September 30, 2021, there were:

- a total of 44,288,183 common shares issued and outstanding and no preferred shares issued and outstanding;
- options to purchase 903,876 common shares issued and outstanding, at a weighted average exercise price of C\$8.32 per common share;
- warrants issued in connection with our February 2017 public offering in Canada to purchase up to 215,491 common shares at an exercise price of C\$17.20 per common share;
- broker warrants issued in connection with our December 2017 public offering in the United States to purchase up to 32,390 common shares at an exercise price of US\$10.10 per common share;
- warrants issued in connection with our December 2017 public offering in the United States to purchase up to 884,120 common shares at an exercise price of US\$10.08 per common share; and
- warrants issued in connection with our May 2018 public offering in Canada to purchase up to 824,218 common shares at an exercise price of C\$10.48 per common share.

Under our ATM sales agreement with B. Riley Securities, Inc, Oppenheimer & Co. Inc., and H.C. Wainwright & Co., LLC, our common shares may be sold from time to time for aggregate gross proceeds of up to US\$75 million, with sales only being made on NASDAQ. The common shares will be distributed at market prices prevailing at the time of the sale and, as a result, prices may vary between purchasers and during the period of distribution.

The following is a brief description of the rights, privileges, conditions and restrictions attaching to the common shares and preferred shares.

Common Shares

Voting Rights

Each common share entitles its holder to receive notice of, and to attend and vote at, all annual or special meetings of our shareholders. Each common share entitles its holder to one vote at any meeting of our shareholders, other than meetings at which only the holders of a particular class or series of shares are entitled to vote due to statutory provisions or the specific attributes of that class or series.

Dividends

Subject to the prior rights of the holders of preferred shares ranking before the common shares as to dividends, the holders of common shares are entitled to receive dividends as declared by the board of directors out of funds that are available for the payment of dividends.

Winding-up and Dissolution

In the event of our voluntary or involuntary winding-up or dissolution, or any other distribution of our assets among our shareholders for the purposes of winding up our affairs, the holders of common shares will be entitled to receive, after payment by us to the holders of preferred shares ranking prior to common shares regarding the distribution of our assets in the case of winding-up or dissolution, share for share, the remainder of our property, with neither preference nor distinction. The order of priority applicable to all classes of our shares with respect to the redemption, liquidation, dissolution or distribution of property is as follows: first, the Class E non-voting shares; second, the Class D non-voting shares; third, the Class B multiple voting shares and Class C non-voting shares, *pari passu*; and fourth, the common shares. Notwithstanding the order of priority, shareholders of a class of shares may renounce the order of priority by unanimous approval by all shareholders of that class of shares.

Dividend Policy

We do not anticipate paying any cash dividends on our common shares in the foreseeable future. We presently intend to retain future earnings to finance the development and growth of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors the board of directors deems relevant. In addition, the terms of any future debt or credit facility may preclude us from paying dividends. Any remittances of dividends to United States residents and to other non-Canadian residents are, however, subject to withholding tax.

Preferred Shares**Class B Multiple Voting Shares**

Each Class B multiple voting share entitles the holder thereof to 10 votes per share at all of our shareholder meetings.

Dividends. Holders of Class B multiple voting shares are entitled to receive, as and when such dividends are declared, an annual non-cumulative dividend of 5% on the amount paid for the shares, payable at the time and in the manner which the board of directors may determine and subject to the order of priority.

Participation. Subject to the provisions of subsection 5.2.2 of our articles of incorporation, or Articles, holders of Class B multiple voting shares do not have the right to participate in our profits or surplus assets.

Conversion. Holders of Class B multiple voting shares have the right, at their entire discretion, to convert part or all of the Class B multiple voting shares they hold into common shares on the basis of 1 common share for each Class B multiple voting share converted.

Redemption. Subject to the provisions of the QBCA and the order of priority, holders of Class B multiple voting shares have the right to demand from us, upon 30 days' written notice, that we redeem the Class B multiple voting shares at a price equivalent to the amount paid for such shares plus the redemption premium, as defined in subsection 5.2.4.1 of the Articles, and any and all declared but yet unpaid dividends on same.

Liquidation. In the event of our dissolution or liquidation or any other distribution of our property, the Class B voting shareholders will have the right to be reimbursed for the amount paid for their Class B multiple voting shares plus the redemption premium, as defined in subsection 5.2.4.1 of our Articles, as well as the amount of any and all declared but yet unpaid dividends on their shares, subject to the order of priority.

Class C Non-Voting Shares

Subject to the provisions of the QBCA, holders of Class C non-voting shares are neither entitled to vote at any meeting of our shareholders, receive a notice of any such meeting, nor attend any such meeting.

Dividends. Holders of Class C non-voting shares are entitled to receive, as and when such dividends are declared, an annual non-cumulative dividend of 5% on the amount paid for the shares, plus a redemption premium as defined in subsection 5.3.6.1 of our Articles, payable at the time and in the manner which the board of directors may determine and subject to the order of priority.

Participation. Subject to the provisions of subsection 5.3.2 of our Articles, holders of Class C non-voting shares do not have the right to participate in our profits or surplus assets.

Conversion. Holders of Class C non-voting shares have the right, at their entire discretion, to convert part or all of the Class C non-voting shares they hold into common shares on the basis of 1 common share for each Class C non-voting share converted.

Forced Conversion. All of our Class C non-voting shares will automatically be converted into common shares upon the request of an unrelated third-party investor investing more than C\$500,000, or any other amount to be determined by the board of directors and requesting as a condition to the investment that the Class C non-voting shares be converted into common shares on the basis of 1 common share for each Class C non-voting share converted.

Redemption. Subject to the provisions of the QBCA and the order of priority, holders of Class C non-voting shares have the right to demand, upon 30 days' written notice, that we redeem their Class C non-voting shares at a price equivalent to the amount paid for the shares plus the redemption premium, as defined in subsection 5.3.6.1 of our Articles, and any and all declared but yet unpaid dividends on the shares.

Liquidation. In the event of our dissolution or liquidation or any other distribution of our property, Class C non-voting shareholders will have the right to be reimbursed for the amount paid for their Class C non-voting shares plus the redemption premium, as defined in subsection 5.3.6.1 of our Articles, as well as the amount of any and all declared but yet unpaid dividends on their shares, subject to the order of priority.

Class D Non-Voting Shares

Subject to the provisions of the QBCA, holders of Class D non-voting shares are neither entitled to vote at any meeting of the shareholders, receive a notice of any such meeting, nor attend any such meeting.

Dividends. Holders of Class D non-voting shares are entitled to receive, as and when such dividends are declared, a monthly non-cumulative dividend of 0.5% to 2% on the amount paid for the shares, plus a redemption premium as defined in subsection 5.4.6.1 of our Articles, payable at the time and in the manner which the board of directors may determine and subject to the order of priority.

Participation. Subject to the provisions of subsection 5.4.2 of our Articles, holders of Class D non-voting shares do not have the right to participate in our profits or surplus assets.

Conversion. Holders of Class D non-voting shares have the right, at their discretion, to convert part or all of their Class D non-voting shares into common shares on the basis of a number of common shares equal to the number of Class D non-voting shares converted multiplied by a conversion ratio, calculated as follows:

Conversion Ratio =
$$\frac{\text{The product obtained by multiplying a factor to be agreed at the time of the issuance of the Class D non-voting shares by the average amount paid per share for the Class D non-voting shares plus the redemption premium per share, as defined in subsection 5.4.6.1 of our Articles as well as the amount of any and all declared but yet paid dividends on the shares}}{\text{Fair market value of the common shares at the date of any conversion of Class D non-voting shares into common shares}}$$

Forced Conversion. All of our Class D non-voting shares automatically convert into common shares upon the request of an unrelated third party investor, investing more than C\$500,000, or any other amount to be determined by the board of directors, and requesting as a condition to the investment that the Class D non-voting shares be converted into common shares on the basis of a number of common shares equal to the number of Class D non-voting shares converted multiplied by the conversion ratio, calculated as follows:

Conversion Ratio =
$$\frac{\text{The product obtained by multiplying a factor to be agreed at the time of the issuance of the Class D non-voting shares by the average amount paid per share for the Class D non-voting shares plus the redemption premium per share, as defined in subsection 5.4.6.1 of our Articles as well as the amount of any and all declared but yet paid dividends on the shares}}{\text{Fair market value of the common shares at the date of any conversion of Class D non-voting shares into common shares}}$$

Redemption. Subject to the provisions of the QBCA and the order of priority, holders of Class D non-voting shares have the right to demand, upon 30 days' written notice, that we redeem their Class D non-voting shares at a price equivalent to the amount paid for the shares plus the redemption premium, as defined in subsection 5.4.6.1 of our Articles, and any and all declared but yet unpaid dividends on the shares.

Liquidation. In the event of our dissolution or liquidation or any other distribution of our property, the Class D non-voting shareholders will have the right to be reimbursed for the amount paid for their Class D non-voting shares plus

the redemption premium, as defined in subsection 5.4.6.1 of our Articles as well as the amount of any and all declared but yet unpaid dividends on their shares, subject to the order of priority.

Class E Non-Voting Shares

Subject to the provisions of the QBCA, holders of Class E non-voting shares are neither entitled to vote at any meeting of the shareholders, receive a notice of any such meeting, nor attend any such meeting.

Dividends. Holders of Class E non-voting shares are entitled to receive, as and when such dividends are declared, a monthly non-cumulative dividend of 0.5% to 2% on the amount paid for the shares, payable at the time and in the manner which the board of directors may determine and subject to the order of priority.

Participation. Subject to the provisions of subsection 5.5.2 of our Articles, holders of Class E non-voting shares do not have the right to participate in our profits.

Conversion. Holders of Class E non-voting shares have the right, at their discretion, to convert part or all of their Class E non-voting shares into common shares on the basis of a number of common shares equal to the number of Class E non-voting shares converted multiplied by the conversion ratio, calculated as follows:

$$\text{Conversion Ratio} = \frac{\text{The product obtained by multiplying a factor to be agreed at the time of the issuance of the Class E non-voting shares by the average amount paid per share for the Class E non-voting shares plus the amount of any and all declared but yet paid dividends on the shares}}{\text{Fair market value of the common shares at the date of any conversion of Class E non-voting shares into common shares}}$$

Redemption. Subject to the provisions of the QBCA and the order of priority, we have the right, upon 30 days' written notice, to redeem the Class E non-voting shares at a price equivalent to the amount paid for the shares and any and all declared but yet unpaid dividends on the shares.

Liquidation. In the event of our dissolution or liquidation or any other distribution of our property, the Class E non-voting shareholders will have the right to be reimbursed for the amount paid for their Class E non-voting shares as well as the amount of any and all declared but yet unpaid dividends on the shares, subject to the order of priority.

DILUTION

If you invest in our common shares, your interest will be diluted immediately to the extent of the difference between the public offering price per common share and the adjusted net tangible book value per common share after this offering.

The net tangible book value of our common shares as of September 30, 2021 was approximately US\$50.1 million, or approximately US\$1.13 per common share. Net tangible book value per common share represents the amount of our total assets, excluding intangible assets, less total liabilities, excluding derivative warrant liabilities, divided by the total number of our common shares outstanding. Dilution per common share to new investors represents the difference between the amount per share paid by purchasers for each common share in this offering and the net tangible book value per common share immediately following the completion of this offering.

After giving effect to the sale of our common shares pursuant to this prospectus supplement in the aggregate amount of US\$75,000,000 at an assumed price of US\$1.70 per common share, which was the last reported sale price of our common shares on NASDAQ on November 8, 2021, and after deducting commissions (estimated at 3.0% of the gross proceeds from each sale of our common shares) and estimated offering expenses payable by us (estimated at US\$140,000), our as-adjusted net tangible book value as of September 30, 2021 would have been approximately US\$122.7 million, or approximately US\$1.39 per common share. This represents an immediate increase in net tangible book value of approximately US\$0.26 per common share to our existing shareholders and an immediate dilution in as-adjusted net tangible book value of approximately US\$0.31 per common share to purchasers of our common shares in this offering, as illustrated by the following table:

Assumed price per common share	US\$1.70
Net tangible book value per share as of September 30, 2021	US\$1.13
Increase per common share attributable to this offering	US\$0.26
As-adjusted net tangible book value per share after giving effect to this offering	US\$1.39
Dilution per common share to new investors	US\$0.31

Our common shares sold in this offering, if any, will be sold from time to time at various prices. The as adjusted information is illustrative only and will adjust based on the actual price to the public, the actual number of shares sold and other terms of the offering determined at the time our common shares are sold pursuant to this prospectus supplement and the accompanying prospectus.

Except as otherwise indicated herein, the foregoing discussion and table are calculated based on 44,288,183 common shares that were outstanding on September 30, 2021 and exclude the following:

- 903,876 common shares issuable upon the exercise of options issued to our directors, officers and employees, at a weighted-average exercise price of C\$8.32 per common share;
- 215,491 common shares issuable upon the exercise of warrants at an exercise price of C\$17.20 per common share;
- 32,390 common shares issuable upon the exercise of underwriter warrants at an exercise price of US\$10.10 per common share;
- 884,120 common shares issuable upon the exercise of warrants at an exercise price of US\$10.08 per common share; and
- 824,218 common shares issuable upon the exercise of warrants at an exercise price of C\$10.48 per common share.

To the extent that any options or warrants are exercised, new options are issued under our equity incentive plans or we otherwise issue additional common shares in the future, there will be further dilution to new investors.

PLAN OF DISTRIBUTION

We entered into a sales agreement with B. Riley Securities, Inc., Oppenheimer & Co. Inc., and H.C. Wainwright & Co., LLC, as Agents, on June 29, 2020 under which we may offer and sell our common shares having an aggregate offering price of up to US\$75,000,000 from time to time through or to the Agents, as sales agents or principals. Sales of our common shares, if any, under this prospectus supplement may be made in transactions that are deemed to be “at the market offerings” as defined in Rule 415 under the Securities Act.

Each time we wish to issue and sell our common shares under the sales agreement, we will notify an Agent of the number or dollar value of shares to be issued, the dates on which such sales are anticipated to be made, any minimum price below which sales may not be made and other sales parameters as we deem appropriate. Once we have so instructed the Agent, unless the Agent declines to accept the terms of the notice, the Agent has agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such shares up to the amount specified on such terms. The obligations of the Agents under the sales agreement to sell our common shares are subject to a number of conditions that we must meet.

We will pay each Agent, as applicable, commissions for its services in acting as agent in the sale of our common shares at a commission rate equal to 3.0% of the gross proceeds from each sale of our common shares.

We have also agreed to reimburse the Agents for reasonable out-of-pocket expenses, including attorney’s fees, in an amount not to exceed US\$50,000. We estimate that the total expenses for the offering, excluding compensation payable to the Agents under the sales agreement, will be approximately US\$140,000.

Settlement for sales of our common shares will occur on the second business day following the date on which any sales are made, or on some other date that is agreed upon by us and the Agents in connection with a particular transaction, in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

In connection with the sale of our common shares on our behalf, the Agents will be deemed to be underwriters within the meaning of the Securities Act, and the compensation of the Agents will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to the Agents against certain civil liabilities, including liabilities under the Securities Act.

The offering pursuant to the sales agreement will terminate upon the earlier of (1) the issuance and sale of all of our common shares subject to the sales agreement; and (2) the termination of the sales agreement as permitted therein.

Each Agent and its affiliates may in the future provide various investment banking and other financial services for us and our affiliates, for which services it may in the future receive customary fees. In connection with our acquisition of Grace, which was completed on August 27, 2021, Oppenheimer & Co. Inc. acted as our financial advisor, for which we paid Oppenheimer & Co. Inc US\$1.2 million in advisory fees.

To the extent required by Regulation M, the Agents will not engage in any market making activities involving our common shares while the offering is ongoing under this prospectus supplement. This summary of the material provisions of the sales agreement does not purport to be a complete statement of its terms and conditions. A copy of the sales agreement is filed as an exhibit to the registration statement of which this prospectus supplement and the accompanying prospectus form a part.

Notwithstanding the foregoing, the common shares offered by this prospectus supplement and the accompanying prospectus have not been and will not be qualified for sale under the securities laws of any province or territory of Canada or to any resident of Canada and may not be offered or sold, directly or indirectly, in Canada or to or for the account of any resident of Canada. This prospectus supplement and the accompanying prospectus have not been filed in respect of, and will not qualify, any distribution of these securities in any province or territory of Canada. No common shares will be sold on the TSXV or on other trading markets in Canada as at the market distributions.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of certain U.S. federal income tax considerations arising from and relating to the acquisition, ownership, and disposition of our common shares by a U.S. Holder (as defined below) who acquires such common shares pursuant to this prospectus supplement. This discussion does not address the tax consequences to a subsequent purchaser of our common shares. This summary provides only general information and does not purport to be a complete analysis or listing of all potential U.S. federal income tax consequences that may apply to a U.S. Holder as a result of the acquisition, ownership, and disposition of our common shares. In addition, this summary does not take into account the individual facts and circumstances of any particular U.S. Holder that may affect the U.S. federal income tax consequences applicable to that U.S. Holder. Accordingly, this summary is not intended to be, and should not be construed as, legal or U.S. federal income tax advice with respect to any U.S. Holder. Each U.S. Holder should consult its own tax advisor regarding the U.S. federal, state and local, and non-U.S. tax consequences arising from or relating to the acquisition, ownership, and disposition of our common shares.

No legal opinion from U.S. legal counsel or ruling from the Internal Revenue Service (“IRS”), has been requested, or will be obtained, regarding the U.S. federal income tax consequences to U.S. Holders of the acquisition, ownership, and disposition of our common shares. This summary is not binding on the IRS, and the IRS is not precluded from taking a position that is different from, and contrary to, the positions taken in this summary. In addition, because the authorities on which this summary is based are subject to various interpretations, the IRS and the U.S. courts could disagree with one or more of the positions taken in this summary.

Scope of this Disclosure

Authorities

This summary is based on the Code, U.S. Treasury Regulations promulgated thereunder (whether final, temporary or proposed), published IRS rulings, judicial decisions, published administrative positions of the IRS, and the Convention between Canada and the United States of America with Respect to Taxes on Income and on Capital, signed September 26, 1980, as amended (the Canada-U.S. Tax Treaty), in each case, as in effect as of the date of this prospectus supplement. Any of the authorities on which this summary is based could be changed in a material and adverse manner at any time, and any such change could be applied on a retroactive basis. Unless otherwise discussed, this summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation.

U.S. Holders

For purposes of this summary, a “U.S. Holder” is a beneficial owner of common shares that, for U.S. federal income tax purposes, is (a) an individual who is a citizen or resident of the United States, (b) a corporation, or other entity classified as a corporation for U.S. federal income tax purposes, that is created or organized in or under the laws of the United States, any state in the United States or the District of Columbia, (c) an estate if the income of such estate is subject to U.S. federal income tax regardless of the source of such income, or (d) a trust if (i) such trust has validly elected to be treated as a U.S. person for U.S. federal income tax purposes or (ii) a U.S. court is able to exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of such trust.

U.S. Holders Subject to Special U.S. Federal Income Tax Rules Not Addressed

This summary does not address the U.S. federal income tax consequences applicable to U.S. Holders that are subject to special provisions under the Code, including, but not limited to, the following U.S. Holders: (a) U.S. Holders that are tax-exempt organizations, qualified retirement plans, individual retirement accounts, or other tax deferred accounts; (b) U.S. Holders that are financial institutions, insurance companies, real estate investment trusts, or regulated investment companies; (c) U.S. Holders that are dealers in securities or currencies or U.S. Holders that are traders in securities that elect to apply a mark-to-market accounting method; (d) U.S. Holders that have a “functional currency” other than the U.S. dollar; (e) U.S. Holders subject to the alternative minimum tax provisions of the Code; (f) U.S. Holders that own common shares as part of a straddle, hedging transaction, conversion transaction, integrated transaction, constructive sale, or other arrangement involving more than one position; (g) U.S. Holders that acquired common shares through the exercise of employee stock options or otherwise as compensation for services; (h) U.S. Holders that hold common shares other than as a capital asset within the meaning of Section 1221 of the Code; (i) U.S. Holders that beneficially own (directly, indirectly or by attribution) 10% or more of our equity securities (by vote

or value); and (j) U.S. expatriates. U.S. Holders that are subject to special provisions under the Code, including U.S. Holders described above, should consult their own tax advisor regarding the U.S. federal, U.S. federal alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences arising from and relating to the acquisition, ownership, and disposition of the common shares.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax consequences to that partnership and the partners of that partnership generally will depend on the activities of the partnership and the status of the partners. Partners of entities that are classified as partnerships for U.S. federal income tax purposes should consult their own tax advisors regarding the U.S. federal income tax consequences arising from and relating to the acquisition, ownership and disposition of the common shares.

Tax Consequences Other than U.S. Federal Income Tax Consequences Not Addressed

This summary does not address the U.S. estate and gift, alternative minimum, state, local or non-U.S. tax consequences to U.S. Holders of the acquisition, ownership, and disposition of our common shares. Each U.S. Holder should consult its own tax advisor regarding the U.S. estate and gift, alternative minimum, state, local and non-U.S. tax consequences arising from and relating to the acquisition, ownership, and disposition of our common shares.

U.S. Federal Income Tax Considerations of the Acquisition, Ownership, and Disposition of Common Shares

Distributions on Common Shares

Subject to the discussion under “—*Passive Foreign Investment Company Rules*” below, a U.S. Holder that receives a distribution, including a constructive distribution or a taxable stock distribution, with respect to the common shares generally will be required to include the amount of that distribution in gross income as a dividend (without reduction for any Canadian income tax withheld from such distribution) to the extent of our current or accumulated “earnings and profits” (as computed for U.S. federal income tax purposes). To the extent that a distribution exceeds our current and accumulated “earnings and profits”, the excess amount will be treated (a) first, as a tax-free return of capital to the extent of a U.S. Holder’s adjusted tax basis in the common shares with respect to which the distribution is made (resulting in a corresponding reduction in the tax basis of those common shares) and, (b) thereafter, as gain from the sale or exchange of those common shares (see the more detailed discussion at “—*Disposition of Common Shares*” below). We do not intend to calculate our current or accumulated earnings and profits for U.S. federal income tax purposes and, therefore, will not be able to provide U.S. Holders with that information. U.S. Holders should therefore assume that any distribution by us with respect to our common shares will constitute a dividend. However, U.S. Holders should consult their own tax advisors regarding whether distributions from us should be treated as dividends for U.S. federal income tax purposes. Dividends paid on our common shares generally will not be eligible for the “dividends received deduction” allowed to corporations under the Code with respect to dividends received from U.S. corporations.

A dividend paid by us generally will be taxed at the preferential tax rates applicable to long-term capital gains if, among other requirements, (a) we are a “qualified foreign corporation” (as defined below), (b) the U.S. Holder receiving the dividend is an individual, estate, or trust, and (c) the dividend is paid on common shares that have been held by the U.S. Holder for at least 61 days during the 121-day period beginning 60 days before the “ex-dividend date” (i.e., the first date that a purchaser of the common shares will not be entitled to receive the dividend).

For purposes of the rules described in the preceding paragraph, we generally will be a “qualified foreign corporation” (“QFC”), if (a) we are eligible for the benefits of the Canada-U.S. Tax Treaty, or (b) our common shares are readily tradable on an established securities market in the United States, within the meaning provided in the Code. However, even if we satisfy one or more of the requirements, we will not be treated as a QFC if we are classified as a PFIC (as discussed below) for the taxable year during which we pay the applicable dividend or for the preceding taxable year. The dividend rules are complex, and each U.S. Holder should consult its own tax advisor regarding the application of those rules to them in their particular circumstances. Even if we satisfy one or more of the requirements, as noted below, there can be no assurance that we will not be a PFIC in the current taxable year, or become a PFIC in the future. Thus, there can be no assurance that we will qualify as a QFC.

Disposition of Common Shares

Subject to the discussion under “—*Passive Foreign Investment Company Rules*” below, a U.S. Holder will recognize gain or loss on the sale or other taxable disposition of common shares (that is treated as a sale or exchange for U.S. federal income tax purposes) equal to the difference, if any, between (a) the U.S. dollar value of the amount realized on the date of the sale or disposition and (b) the U.S. Holder’s adjusted tax basis (determined in U.S. dollars) in the common shares sold or otherwise disposed of. Any such gain or loss generally will be capital gain or loss, which will be long-term capital gain or loss if the common shares are held for more than one year. A U.S. Holder’s initial tax basis in the common shares generally will equal the U.S. dollar cost of such common shares. Each U.S. Holder should consult its own tax advisor as to the tax treatment of dispositions of common shares in exchange for Canadian dollars.

Preferential tax rates apply to long-term capital gains of a U.S. Holder that is an individual, estate, or trust. There are currently no preferential tax rates for long-term capital gains of a U.S. Holder that is a corporation. Deductions for capital losses are subject to complex limitations.

Passive Foreign Investment Company Rules

If we are or become a PFIC, the preceding sections of this summary may not describe the U.S. federal income tax consequences to U.S. Holders of the acquisition, ownership, and disposition of our common shares.

Passive Foreign Investment Company Status

Special, generally unfavorable, rules apply to the ownership and disposition of the stock of a PFIC. For U.S. federal income tax purposes, a non-U.S. corporation is classified as a PFIC if:

- at least 75% of its gross income for the taxable year is “passive” income (referred to as the “income test”); or
- at least 50% of the average value of its assets held during the taxable year is attributable to assets that produce passive income or are held for the production of passive income (referred to as the “asset test”).

Passive income generally includes the following types of income:

- dividends, royalties, rents, annuities, interest, and income equivalent to interest; and
- net gains from the sale or exchange of property that gives rise to dividends, interest, royalties, rents, or annuities and certain gains from the commodities transactions.

In determining whether we are a PFIC, we will be required to take into account a pro rata portion of the income and assets of each corporation in which we own, directly or indirectly, at least 25% by value.

As described above, PFIC status of a non-U.S. corporation depends on the relative values of certain categories of assets and the relative amount of certain kinds of income for a taxable year. Therefore, our status as a PFIC for any given taxable year depends upon the financial results for such year and upon relative valuations, which are subject to change and beyond our ability to predict or control. We have not yet determined whether we will be a PFIC for the current taxable year or the likelihood that we will be a PFIC in future taxable years, but we believe that we may not be classified as a PFIC for the current taxable year or future taxable years. However, PFIC status is fundamentally factual in nature, depends on the application of complex U.S. federal income tax rules (which are subject to differing interpretations), generally cannot be determined until the close of the taxable year in question and is determined annually. Accordingly, there can be no assurance that we will not be a PFIC in our current taxable year or will not become a PFIC in subsequent years. The PFIC rules are complex, and each U.S. Holder should consult its tax advisor regarding the application of the PFIC rules to us.

Default PFIC Rules Under Section 1291 of the Code

Generally, if we are or have been treated as a PFIC for any taxable year during a U.S. Holder’s holding period of common shares, subject to the special rules described below applicable to a U.S. Holder who makes a Mark-to-Market Election or a QEF Election (each as defined below), any “excess distribution” with respect to the common shares would be allocated ratably over the U.S. Holder’s holding period. The amounts allocated to the taxable year of the

excess distribution and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations in that taxable year, as appropriate, and an interest charge would be imposed on the amount allocated to that taxable year. Distributions made in respect of common shares during a taxable year will be excess distributions to the extent they exceed 125% of the average of the annual distributions on common shares received by the U.S. Holder during the preceding three taxable years or the U.S. Holder's holding period, whichever is shorter. In addition, dividends generally will not be qualified dividend income if we are a PFIC in the taxable year of payment or the preceding year.

Generally, if we are treated as a PFIC for any taxable year during which a U.S. Holder owns common shares, any gain on the disposition of the common shares would be treated as an excess distribution and would be allocated ratably over the U.S. Holder's holding period and subject to taxation in the same manner as described in the preceding paragraph, and would not be eligible for the preferential long-term capital gains rate.

Certain elections (including the Mark-to-Market Election and the QEF Election, as defined and discussed below) may sometimes be used to mitigate the adverse impact of the PFIC rules on U.S. Holders, but these elections may not be available or may accelerate the recognition of taxable income and have other adverse results.

Each current or prospective U.S. Holder should consult its own tax advisor regarding potential status of us as a PFIC, the possible effect of the PFIC rules to such holder in their particular circumstances, information reporting required if we were treated as a PFIC and the availability of any election that may be available to the holder to mitigate adverse U.S. federal income tax consequences of holding shares in a PFIC.

QEF Election

A U.S. Holder of common shares in a PFIC generally would not be subject to the PFIC rules discussed above if the U.S. Holder had made a timely and effective election (a "QEF Election") to treat us as a "qualified electing fund" (a "QEF"). Instead, such U.S. Holder would be subject to U.S. federal income tax on its pro rata share of our (i) net capital gain, which would be taxed as long-term capital gain to such U.S. Holder, and (ii) ordinary earnings, which would be taxed as ordinary income to such U.S. Holder, in each case regardless of whether such amounts are actually distributed to such U.S. Holder. However, a U.S. Holder that makes a QEF Election may, subject to certain limitations, elect to defer payment of current U.S. federal income tax on such amounts, subject to an interest charge. If such U.S. Holder is not a corporation, any such interest paid will be treated as "personal interest," which is not deductible.

A U.S. Holder that makes a timely and effective QEF Election generally (a) may receive tax-free distribution from us to the extent that such distribution represents our "earnings and profits" that were previously included in income by such U.S. Holder because of such QEF Election and (b) will adjust such U.S. Holder's tax basis in the common shares to reflect the amount included in income or allowed as a tax-free distribution because of such QEF Election. In addition, for U.S. federal income tax purposes, a U.S. Holder that makes a timely QEF Election generally will recognize capital gain or loss on the sale or other taxable disposition of the common shares.

A QEF Election will be treated as "timely" if such QEF Election is made for the first taxable year in the U.S. Holder's holding period for the common shares in which we are a PFIC. A U.S. Holder may make a timely QEF Election by filing the appropriate QEF Election documents at the time such U.S. Holder files a U.S. federal income tax return for such first year. If a U.S. Holder makes a QEF Election after the first taxable year in the U.S. Holder's holding period for the common shares in which we are a PFIC, then, in addition to filing the QEF Election documents, a U.S. Holder may elect to recognize gain (which will be taxed under the rules discussed under "*Default PFIC Rules Under Section 1291 of the Code*") as if the common shares were sold on the qualification date. The "qualification date" is the first day of the first taxable year in which we are a QEF with respect to such U.S. Holder. The election to recognize such gain can only be made if such U.S. Holder's holding period for the common shares includes the qualification date. By electing to recognize such gain, such U.S. Holder will be deemed to have made a timely QEF Election. In addition, under very limited circumstances, it is possible that a U.S. Holder might make a retroactive QEF Election if such U.S. Holder failed to file the QEF Election documents in a timely manner. If a U.S. Holder fails to make a QEF Election for the first taxable year in the U.S. Holder's holding period for the common shares in which we are a PFIC and does not elect to recognize gain as if the common shares were sold on the qualification date, such holder will not be treated as having made a "timely" QEF Election and will continue to be subject to the special adverse taxation rules discussed above under "*Default PFIC Rules Under Section 1291 of the Code*".

A QEF Election will apply to the taxable year for which such QEF Election is made and to all subsequent taxable years, unless such QEF Election is invalidated or terminated or the IRS consents to revocation of such QEF Election. If a U.S. Holder makes a QEF Election and, in a subsequent taxable year, we cease to be a PFIC, the QEF Election will remain in effect (although it will not be applicable) during those taxable years in which we are not a PFIC. Accordingly, if we become a PFIC in another subsequent taxable year, the QEF Election will be effective and the U.S. Holder will be subject to the rules described above during any such subsequent taxable year in which we qualify as a PFIC.

A U.S. Holder cannot make and maintain a valid QEF Election unless we provide certain U.S. tax information necessary to make such an election. On an annual basis, we intend to use commercially reasonable efforts to make available to U.S. Holders that acquire common shares pursuant to this prospectus supplement, upon their written request (a) timely information as to our status as a PFIC, and (b) for each year in which we are a PFIC, information and documentation that a U.S. Holder making a QEF Election with respect to us is required to obtain for U.S. federal income tax purposes. Each U.S. Holder should consult its own tax advisor regarding the availability of, and procedure for making, a QEF Election with respect to us.

Mark-to-Market Election

A U.S. Holder of common shares in a PFIC would not be subject to the PFIC rules discussed above under “*Default PFIC Rules Under Section 1291 of the Code*” if the U.S. Holder had made a timely and effective election to mark the PFIC common shares to market (“Mark-to-Market Election”).

A U.S. Holder may make a Mark-to-Market Election with respect to the common shares only if such shares are marketable stock. Such shares generally will be “marketable stock” if they are regularly traded on a “qualified exchange,” which is defined as (a) a national securities exchange that is registered with the Securities and Exchange Commission, (b) the national market system established pursuant to section 11A of the Exchange Act or (c) a non-U.S. securities exchange that is regulated or supervised by a governmental authority of the country in which the market is located, provided that (i) such non-U.S. exchange has trading volume, listing, financial disclosure, surveillance, and other requirements, and the laws of the country in which such non-U.S. exchange is located, together with the rules of such non-U.S. exchange, ensure that such requirements are actually enforced and (ii) the rules of such non-U.S. exchange ensure active trading of listed stocks. Our common shares will generally be treated as “regularly traded” in any calendar year in which more than a *de minimis* quantity of common shares is traded on a qualified exchange for at least 15 days during each calendar quarter. Each U.S. Holder should consult its own tax advisor with respect to the availability of a Mark-to-Market Election with respect to the common shares.

In general, a U.S. Holder that makes a timely Mark-to-Market Election with respect to the common shares will include in ordinary income, for each taxable year in which we are a PFIC, an amount equal to the excess, if any, of (a) the fair market value of the common shares as of the close of such taxable year over (b) such U.S. Holder’s tax basis in such shares. A U.S. Holder that makes a Mark-to-Market Election will be allowed a deduction in an amount equal to the lesser of (a) the excess, if any, of (i) such U.S. Holder’s adjusted tax basis in the common shares over (ii) the fair market value of such shares as of the close of such taxable year or (b) the excess, if any, of (i) the amount included in ordinary income because of such Mark-to-Market Election for prior taxable years over (ii) the amount allowed as a deduction because of such Mark-to-Market Election for prior taxable years. If a U.S. Holder makes a Mark-to-Market Election after the first taxable year in which we are a PFIC and such U.S. Holder has not made a timely QEF Election with respect to us, the PFIC rules described above under “*Default PFIC Rules Under Section 1291 of the Code*” will apply to certain dispositions of, and distributions on, the common shares, and the U.S. Holder’s mark-to-market income for the year of the election. If we were to cease being a PFIC, a U.S. Holder that marked its common shares to market should not include mark-to-market gain or loss with respect to its common shares for any taxable year that we were not a PFIC.

A U.S. Holder that makes a Mark-to-Market Election generally will also adjust such U.S. Holder’s tax basis in his common shares to reflect the amount included in gross income or allowed as a deduction because of such Mark-to-Market Election. In addition, upon a sale or other taxable disposition of the common shares subject to a Mark-to-Market Election, any gain or loss on such disposition will be ordinary income or loss (to the extent that such loss does not exceed the excess, if any, of (a) the amount included in ordinary income because of such Mark-to-Market Election for prior taxable years over (b) the amount allowed as a deduction because of such Mark-to-Market Election for prior taxable years). A Mark-to-Market Election applies to the taxable year in which such Mark-to-Market Election is made and to each subsequent taxable year, unless the common shares cease to be “marketable stock” or the IRS

consents to revocation of such election. Each U.S. Holder should consult its own tax advisor regarding the availability of, and procedure for making, a Mark-to-Market Election with respect to the common shares.

Reporting

If we were to be treated as a PFIC in any taxable year, a U.S. Holder will generally be required to file an annual report with the IRS containing such information as the U.S. Treasury Department may require.

Each U.S. Holder should consult its own tax advisor regarding our potential status as a PFIC, the possible effect of the PFIC rules to such holder and information reporting required if we were a PFIC, as well as the availability and effect of any election that may be available to the holder to mitigate adverse U.S. federal income tax consequences of holding shares in a PFIC.

Receipt of Foreign Currency

The amount of a distribution paid in Canadian dollars or Canadian dollar proceeds received on the sale or other taxable disposition of common shares will generally be equal to the U.S. dollar value of the currency on the date of receipt. If any Canadian dollars received with respect to the common shares are later converted into U.S. dollars, U.S. Holders may realize foreign currency gain or loss on the conversion. Any gain or loss generally will be treated as ordinary income or loss and generally will be from sources within the United States for U.S. foreign tax credit purposes. Each U.S. Holder should consult its own tax advisor concerning the possibility of foreign currency gain or loss if any such currency is not converted into U.S. dollars on the date of receipt.

Foreign Tax Credit

Subject to certain limitations, a U.S. Holder who pays (whether directly or through withholding) Canadian or other non-U.S. income tax with respect to the common shares may be entitled, at the election of the U.S. Holder, to receive either a deduction or a credit for Canadian or other non-U.S. income tax paid. Dividends paid on common shares generally will constitute income from sources outside the United States. Any gain from the sale or other taxable disposition of the common shares by a U.S. Holder generally will constitute U.S. source income. The foreign tax credit rules (including the limitations with respect thereto) are complex, and each U.S. Holder should consult its own tax advisor regarding the foreign tax credit rules, having regard to such holder's particular circumstances.

Information Reporting; Backup Withholding

Generally, information reporting and backup withholding may apply to distributions on, and the payment of proceeds from the sale or other taxable disposition of, the common shares unless (i) the U.S. Holder is a corporation or other exempt entity, or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number, certifies that the U.S. Holder is not subject to backup withholding and otherwise complies with the applicable requirements of the backup withholding rules. The IRS may impose a penalty upon any taxpayer that fails to provide a correct taxpayer identification number.

Backup withholding is not an additional tax. Any amount withheld generally will be creditable against a U.S. Holder's U.S. federal income tax liability or refundable to the extent that it exceeds such liability provided the required information is provided to the IRS in a timely manner.

In addition, certain categories of U.S. Holders must file information returns with respect to their investment in a non-U.S. corporation. For example, certain U.S. Holders must file IRS Form 8938 with respect to certain "specified foreign financial assets" (such as the common shares) with an aggregate value in excess of US\$50,000 (and, in some circumstances, a higher threshold). Failure to do so could result in substantial penalties and in the extension of the statute of limitations with respect to such holder's U.S. federal income tax returns. Each U.S. Holder should consult its own tax advisor regarding application of the information reporting and backup withholding rules to it in connection with an investment in our common shares.

Medicare Contribution Tax

U.S. Holders that are individuals, estates or certain trusts generally will be subject to a 3.8% Medicare contribution tax on, among other things, dividends on, and capital gains from the sale or other taxable disposition of, common

shares, subject to certain limitations and exceptions. Each U.S. Holder should consult its own tax advisor regarding possible application of this additional tax to income earned in connection with an investment in our common shares.

CERTAIN CANADIAN FEDERAL INCOME TAX CONSIDERATIONS

The following is, as of the date hereof, a summary of the principal Canadian federal income tax considerations generally applicable under the *Income Tax Act* (Canada) and the regulations promulgated thereunder (collectively the “Tax Act”), to a purchaser who acquires, as beneficial owner, common shares pursuant to this prospectus supplement, and who, for purposes of the Tax Act and at all relevant times, (i) is not, and is not deemed to be, resident in Canada, (ii) holds the common shares as capital property, (iii) deals at arm’s length with, and is not affiliated with, Acasti, B. Riley Securities, Inc., Oppenheimer & Co. Inc., or H.C. Wainwright & Co., LLC, and (iv) does not use or hold and will not be deemed to use or hold, the common shares in, or in the course of, a business carried on in Canada (a “Non-Resident Holder”). A common share will generally be capital property to a Non-Resident Holder, provided the Non-Resident Holder does not acquire or hold such common share in the course of carrying on a business or as part of an adventure in the nature of trade. Special rules, which are not discussed in this summary, may apply to a Non-Resident Holder that carries on an insurance business in Canada and elsewhere. Such Non-Resident Holders should consult their own tax advisors.

This summary is based upon the provisions of the Tax Act in force as of the date hereof, all specific proposals to amend the Tax Act that have been publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof (the “Proposed Amendments”), the Canada-United States Tax Convention (1980), as amended (the “Canada-U.S. Tax Treaty”), and an understanding of the current administrative policies and assessing practices of the Canada Revenue Agency (the “CRA”), published in writing by it prior to the date hereof. This summary assumes the Proposed Amendments will be enacted in the form proposed. However, no assurance can be given that the Proposed Amendments will be enacted in their current form, or at all. This summary is not exhaustive of all possible Canadian federal income tax considerations and, except for the Proposed Amendments, does not take into account or anticipate any changes in the law or any changes in the CRA’s administrative policies or assessing practices, whether by legislative, governmental or judicial action or decision, nor does it take into account any provincial, territorial or foreign tax considerations, which may differ significantly from those discussed herein.

This summary is of a general nature only and is not intended to be, nor should it be construed to be, legal or tax advice to any prospective purchaser or holder of the common shares, and no representations with respect to the income tax consequences to any prospective purchaser or holder are made. Consequently, prospective Non-Resident Holders should consult their own tax advisors with respect to their particular circumstances.

Currency Conversion

Generally, for purposes of the Tax Act, all amounts relating to the acquisition, holding or disposition of the common shares must be converted into Canadian dollars based on the exchange rates as determined in accordance with the Tax Act. The amounts subject to withholding tax and any capital gains or capital losses realized by a Non-Resident Holder may be affected by fluctuations in the Canadian-U.S. dollar exchange rate.

Dispositions

A Non-Resident Holder will not be subject to tax under the Tax Act on a capital gain realized on a disposition or deemed disposition of a common share, unless the common share constitutes “taxable Canadian property” (as defined in the Tax Act) of the Non-Resident Holder at the time of disposition and the Non-Resident Holder is not entitled to relief under an applicable income tax treaty or convention.

Provided the common shares are listed on a “designated stock exchange”, as defined in the Tax Act (which currently includes the TSXV and NASDAQ) at the time of disposition, the common shares will generally not constitute taxable Canadian property of a Non-Resident Holder at that time, unless at any time during the 60-month period immediately preceding such time the following two conditions are satisfied concurrently: (i) (a) the Non-Resident Holder; (b) persons with whom the Non-Resident Holder did not deal at arm’s length (within the meaning of the Tax Act); (c) partnerships in which the Non-Resident Holder or a person described in (b) holds a membership interest directly or indirectly through one or more partnerships; or (d) any combination of the persons and partnerships described in (a) through (c), owned 25% or more of the issued shares of any class or series of the capital stock of the Company; and (ii) more than 50% of the fair market value of the common shares was derived directly or indirectly from one or any combination of: real or immovable property situated in Canada, “Canadian resource properties”, “timber resource properties” (each as defined in the Tax Act), or options in respect of, or interests in, or for civil law rights in, any such property. Notwithstanding the foregoing, in certain circumstances set out in the Tax Act, a common share could be

deemed to be taxable Canadian property. Even if the common shares are taxable Canadian property to a Non-Resident Holder, such Non-Resident Holder may be exempt from tax under the Tax Act on the disposition of such common shares by virtue of an applicable income tax treaty or convention. A Non-Resident Holder contemplating a disposition of common shares that may constitute taxable Canadian property should consult a tax advisor prior to such disposition.

Dividends

Dividends paid or credited on the common shares or deemed to be paid or credited on the common shares to a Non-Resident Holder will be subject to Canadian withholding tax under the Tax Act at a rate of 25% on the gross amount of the dividend, although such rate may be reduced under the provisions of an applicable income tax treaty or convention between Canada and the Non-Resident Holder's country of residence. For example, where dividends on the common shares are considered to be paid to or derived by a Non-Resident Holder that is the beneficial owner of the dividends and is a U.S. resident for the purposes of, and is fully entitled to the benefits of, the Canada-U.S. Tax Treaty, the applicable rate of Canadian withholding tax is generally reduced to 15%. Not all persons who are U.S. residents will qualify for the benefits of the Canada-U.S. Tax Treaty. Non-Resident Holders are advised to consult their own tax advisors in this regard.

LEGAL MATTERS

Certain legal matters related to our common shares offered by this prospectus supplement and the accompanying prospectus will be passed upon on for us by Osler, Hoskin & Harcourt LLP, Montreal, Quebec, Canada and certain legal matters under U.S. law will be passed upon for us by Osler, Hoskin & Harcourt LLP, New York, New York. The Agents are being represented in connection with this offering by Duane Morris LLP, New York, New York.

ENFORCEMENT OF CIVIL LIABILITIES

We are incorporated under the laws of the Province of Québec. Some of our assets are located outside the United States. In addition, several of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of such persons' assets may be located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon us or such persons or to enforce against them or against us judgments obtained in U.S. courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof. In addition, investors should not assume that the courts of Canada (i) would enforce judgments of U.S. courts obtained in actions against us or our officers or directors or experts predicated upon the civil liability provisions of the U.S. federal securities laws or other laws of the United States or (ii) would enforce, in original actions, liabilities against us or such directors, officers or experts predicated upon the U.S. federal securities laws or any securities or other laws of any state or jurisdiction of the United States.

We have also been advised by Osler, Hoskin & Harcourt LLP that there is doubt whether an action could be brought in Canada in the first instance on the basis of liability predicated solely upon U.S. federal securities laws.

We have appointed C T Corporation System as our agent to receive service of process with respect to any action brought against us in the United States.

EXPERTS

The consolidated financial statements of Acasti Pharma Inc. as of March 31, 2021 and 2020 and for the years then ended included in our Annual Report on Form 10-K for the year ended March 31, 2021, have been incorporated by reference herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The balance sheets of Grace Therapeutics, Inc. (“Grace”) as of December 31, 2020 and 2019, and the related statements of operations, changes in stockholders’ deficit, and cash flows for each of the years then ended have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference, which report includes an explanatory paragraph about the existence of substantial doubt concerning Grace’s ability to continue as a going concern. Such financial statements have been incorporated by reference herein in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

DOCUMENTS INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” into this prospectus supplement the documents we file with or furnish to the SEC, which means that we can disclose important information to you by referring you to these documents. The information that we incorporate by reference into this prospectus supplement forms a part of this prospectus supplement. We incorporate by reference into this prospectus supplement the documents listed below:

- our Annual Report on [Form 10-K](#) for the fiscal year ended March 31, 2021, filed with the SEC on June 22, 2021;
- the description of our common shares set forth in our registration statement on [Form F-1](#) (File No. 333-220755) filed with the SEC on September 29, 2017 and declared effective on [December 19, 2017](#) and our [Form 8-A](#) filed with the SEC on January 4, 2013, including any amendment or report filed for the purpose of updating that description;
- our Quarterly Reports on Form 10-Q filed with the SEC on [August 12, 2021](#) and [November 10, 2021](#); and
- our Current Reports on Form 8-K filed with the SEC on [July 21, 2021](#), [August 27, 2021](#) and [September 9, 2021](#) and our Current Report on Form 8-K/A filed with the SEC on [November 5, 2021](#).

All documents filed with the SEC by us (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of this prospectus supplement and prior to the termination of the offering of the common shares hereunder shall be deemed to be incorporated herein by reference and to be a part hereof from the date of filing of such documents with the SEC.

Any statement contained in a document incorporated by reference into this prospectus supplement shall be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement, in one of those other documents or in any other later filed document that is also incorporated by reference into this prospectus supplement modifies or supersedes that statement. Any such statement so modified shall not be deemed, except as so modified, to constitute a part of this prospectus supplement. Any such statement so superseded shall be deemed not to constitute a part of this prospectus supplement.

Any person receiving a copy of the prospectus supplement, including any beneficial owner, may obtain without charge, upon written or oral request, a copy of any of the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, except for the exhibits to those documents unless the exhibits are specifically incorporated by reference into those documents. Requests should be directed to our principal executive offices, at 3009 boul. De la Concorde E., Suite 102, Laval, Québec, Canada H7E 2B5, attention: chief financial officer (telephone: (450) 686-4555).

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3, of which this prospectus supplement and the accompanying prospectus form a part. This prospectus supplement and the accompanying prospectus do not contain all the information set out in the registration statement. For further information about us and the common shares, please refer to the registration statement, including the exhibits to the registration statement. The exhibits to the registration statement provide more details of the matters discussed in this prospectus supplement and the accompanying prospectus.

We are required to file with the securities commission or authority in each of the provinces and territories of Canada annual and quarterly reports, material change reports and other information. In addition, we are subject to the informational requirements of the Exchange Act, and, in accordance with the Exchange Act, we also file reports with the SEC.

You may read any document we file with or furnish to the securities commissions and authorities of the provinces and territories of Canada through SEDAR at <https://www.sedar.com>. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, where our SEC filings are also available. The address of the SEC's website is <http://www.sec.gov>. We maintain a corporate website at www.acastipharma.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus supplement.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 29, 2020.

PROSPECTUS



**US\$200,000,000
Common Shares
Warrants
Units**

**7,072,962 Common Shares
Issuable Upon Exercise of Warrants**

**297,430 Common Shares
Issuable Upon Exercise of Broker Warrants**

Acasti Pharma Inc. may offer and sell from time to time up to an aggregate of US\$200,000,000 of common shares (issued separately or upon exercise of warrants), warrants and units comprising any combination of common shares and warrants. The specific terms of any securities offered will be described in supplements to this prospectus. You should read this prospectus and any applicable prospectus supplement carefully before you purchase our securities. This prospectus may not be used to offer securities unless accompanied by a prospectus supplement.

We may offer and sell these securities to or through one or more underwriters, dealers and agents, or directly to purchasers, on a continuous or delayed basis. The prospectus supplement for each offering of securities will describe in detail the plan of distribution. If underwriters, dealers and agents are used to sell these securities, we will name them and describe their compensation in a prospectus supplement.

In addition, this prospectus also covers (i) the offering of up to 7,072,962 common shares issuable upon exercise of warrants to purchase 7,072,962 common shares issued pursuant to a prospectus dated December 21, 2017, or the December 2017 Warrants, and (ii) the resale of up to 297,430 common shares issuable upon exercise of warrants to purchase 297,430 common shares issued to certain selling shareholders as compensation for their service as underwriters for our public offering of common shares and warrants in December 2017, or the Broker Warrants. The December 2017 Warrants, which have an exercise price of US\$1.26 per share, are currently exercisable and may be exercised at any time on or before December 27, 2022. The Broker Warrants, which have an exercise price of US\$1.2625 per share, are currently exercisable and may be exercised at any time on or before December 19, 2022. We have agreed to register for resale the common shares underlying the Broker Warrants under the Securities Act of 1933, as amended, or Securities Act. We will not receive any proceeds from the resale of the common shares by any selling shareholder. Any proceeds received by us from the exercise of the warrants will be used for general corporate purposes. The selling shareholders may offer our common shares from time to time in a number of different methods and at varying prices. For more information on possible methods of offer and sale by the selling shareholders, refer to the section of this prospectus entitled "Plan of Distribution."

Our outstanding common shares are listed for trading on the NASDAQ Stock Market, or NASDAQ, and the TSX Venture Exchange, or TSXV, under the symbol “ACST”. On June 26, 2020, the closing price of our common shares on NASDAQ was US\$0.551 per share and on the TSXV was C\$0.76 per share.

There is currently no established trading market through which the securities, other than the common shares, may be sold and purchasers may not be able to resell the securities purchased under this prospectus. This may affect the pricing of the securities in the secondary market, the transparency and availability of trading prices, the liquidity of the securities and the extent of issuer regulation.

Investing in our securities involves risks. Prior to purchasing our securities, you should carefully consider the risk factors that will be described in any applicable prospectus supplement and the risk factors described in our filings with the Securities and Exchange Commission, or the SEC, as explained under the heading “Risk Factors” on page 5 of this prospectus.

Neither the SEC, nor any securities commission of any state of the United States or any Canadian securities regulator has approved or disapproved the securities offered hereby or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offence.

The date of this prospectus is _____, 2020.

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ABOUT THIS PROSPECTUS

This prospectus is a part of a registration statement that we have filed with the SEC utilizing a “shelf” registration process. Under this shelf registration process, we may offer our common shares or warrants to purchase our common shares, either individually or as units, in one or more offerings up to a total dollar amount of initial aggregate offering price of US\$200,000,000. In addition, this prospectus covers (i) the offering of up to 7,072,962 common shares issuable upon exercise of the December 2017 Warrants and (ii) the resale of up to 297,430 common shares issuable upon exercise of the Broker Warrants held by certain selling shareholders. This prospectus provides you with a general description of the securities that we and the selling shareholders may offer. Each time we sell securities under this process, we will provide a prospectus supplement that will contain specific information about the terms of that offering, including a description of any risks relating to the offering if those terms and risks are not described in this prospectus. A prospectus supplement may also add, update, or change information contained in this prospectus. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement, you should rely on the information in the prospectus supplement.

Before investing in our securities, please carefully read both this prospectus and any prospectus supplement together with the documents incorporated by reference into this prospectus, as listed under “Documents Incorporated by Reference,” and the additional information described below under “Where You Can Find More Information.”

We may sell securities to or through underwriters or dealers, and we may also sell securities directly to other purchasers or through agents. To the extent not described in this prospectus, the names of any underwriters, dealers, or agents employed by us in the sale of the securities covered by this prospectus, the principal amounts or number of shares or other securities, if any, to be purchased by such underwriters or dealers, and the compensation of such underwriters, dealers, or agents will be described in a prospectus supplement.

Owning securities may subject you to tax consequences in the United States. This prospectus or any applicable prospectus supplement may not describe these tax consequences fully. You should read the tax discussion in any prospectus supplement with respect to a particular offering and consult your own tax advisor with respect to your own particular circumstances.

You should rely only on the information contained in or incorporated by reference into this prospectus or a prospectus supplement. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The distribution or possession of this prospectus in or from certain jurisdictions may be restricted by law. This prospectus is not an offer to sell the securities and is not soliciting an offer to buy the securities in any jurisdiction where the offer or sale is not permitted or where the person making the offer or sale is not qualified to do so or to any person to whom it is not permitted to make such offer or sale. You should assume that the information contained in this prospectus and in any applicable prospectus supplement is accurate only as of the date on the front cover of this prospectus or prospectus supplement, as applicable, and the information incorporated by reference into this prospectus or any prospectus supplement is accurate only as of the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus and the documents incorporated by reference into this prospectus contain company names, product names, trade names, trademarks and service marks of Acasti and other organizations, all of which are the property of their respective owners. We own or have rights to trademarks, service marks or trade names that we use in connection with the operation of our business. In addition, our name, logo and website names and addresses are our service marks or trademarks. CaPre® is our registered trademark. The other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks, service marks, tradenames and copyrights referred to in this prospectus are listed without the ©, ® and TM symbols, but we will assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and tradenames.

In this prospectus, unless the context otherwise requires, references to “Acasti,” the “company,” “we,” “us” or “our” refer to Acasti Pharma Inc.

The consolidated financial statements incorporated by reference into this prospectus are presented in accordance with U.S. generally accepted accounting principles.

All references in this prospectus to “dollars” and “US\$” refer to United States dollars and references to “C\$” refer to Canadian dollars. Potential purchasers should be aware that foreign exchange rate fluctuations are likely to occur from time to time and that we do not make any representation with respect to future currency values. Investors should consult their own advisors with respect to the potential risk of currency fluctuations.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3, of which this prospectus forms a part. This prospectus does not contain all the information set out in the registration statement. For further information about us and the securities, please refer to the registration statement, including the exhibits to the registration statement. The exhibits to the registration statement provide more details of the matters discussed in this prospectus.

We are required to file with the securities commission or authority in each of the provinces and territories of Canada annual and quarterly reports, material change reports and other information. In addition, we are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and, in accordance with the Exchange Act, we also file reports with the SEC.

You may read any document we file with or furnish to the securities commissions and authorities of the provinces and territories of Canada through SEDAR at <https://www.sedar.com>. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, where our SEC filings are also available. The address of the SEC's website is <http://www.sec.gov>. We maintain a corporate website at www.acastipharma.com. *Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus.*

DOCUMENTS INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” into this prospectus the documents we file with, or furnish to, them, which means that we can disclose important information to you by referring you to these documents. The information that we incorporate by reference into this prospectus forms a part of this prospectus, and information that we file later with the SEC automatically updates and supersedes any information in this prospectus. We incorporate by reference into this prospectus the documents listed below:

- our Annual Report on [Form 10-K](#) for the fiscal year ended March 31, 2020, filed with the SEC on June 29, 2020;
- the description of our common shares set forth in our registration statement on [Form F-1](#) (File No. 333-220755) filed with the SEC on September 29, 2017 and declared effective on [December 19, 2017](#) and our [Form 8-A](#) filed with the SEC on January 4, 2013, including any amendment or report filed for the purpose of updating that description; and
- our Current Reports on Form 8-K filed with the SEC on [April 20, 2020](#) (only with respect to Item 8.01) and [June 19, 2020](#).

All documents filed with the SEC by us (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of this prospectus and prior to the termination of the offering of the securities offered by this prospectus are incorporated by reference into this prospectus and form part of this prospectus from the date of filing those documents with the SEC.

Any statement contained in a document incorporated by reference into this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, in one of those other documents or in any other later filed document that is also incorporated by reference into this prospectus modifies or supersedes that statement. Any such statement so modified shall not be deemed, except as so modified, to constitute a part of this prospectus. Any such statement so superseded shall be deemed not to constitute a part of this prospectus.

Any person receiving a copy of this prospectus, including any beneficial owner, may obtain without charge, upon written or oral request, a copy of any of the documents incorporated by reference into this prospectus, except for the exhibits to those documents unless the exhibits are specifically incorporated by reference into those documents. Requests should be directed to our principal executive offices, at 545 Promenade du Centropolis, Suite 100, Laval, Québec, Canada H7T 0A3, attention: chief financial officer (telephone: (450) 686-4555).

SUMMARY

This summary does not contain all of the information about our company that may be important to you and your investment decision. You should carefully read the entire prospectus and the applicable prospectus supplement, including the section entitled "Risk Factors" as well as the risk factors described in the documents incorporated by reference into this prospectus and the applicable prospectus supplement, before making an investment decision.

Our Company

We are a biopharmaceutical innovator focused on the research, development and commercialization of prescription drugs using omega-3 fatty acids, or OM3, delivered both as free fatty acids and bound-to-phospholipid esters derived from krill oil. OM3 fatty acids have extensive clinical evidence of safety and efficacy in lowering triglycerides, or TGs, in patients with hypertriglyceridemia, or HTG. Our lead product candidate is CaPre, an OM3 phospholipid therapeutic, which we are developing initially for the treatment of severe HTG, or sHTG, a condition characterized by very high or severe levels of TGs in the bloodstream (≥ 500 mg/dL). In accordance with a study published in 2009 in the Archives of Internal Medicine by Ford et al., it is estimated that three to four million people in the United States have sHTG. In primary qualitative market research studies commissioned by Acasti in August 2016 and November 2017 by DP Analytics, a division of Destum Partners, and in April 2019 by a well-respected third party provider, key opinion leaders, high volume prescribers and pharmacy benefit managers who were interviewed indicated a significant unmet medical need exists for an effective, safe and well-absorbing OM3 therapeutic that can also demonstrate a positive impact on the major blood lipids associated with cardiovascular disease risk. We believe that CaPre may address this unmet medical need, if our TRILOGY Phase 3 clinical program is successful in reproducing what we observed in our Phase 2 clinical data.

We also believe the potential exists to expand CaPre's initial indication to the roughly 44.4 million patients in the United States with elevated TGs in the mild to moderate range (e.g., blood levels between 200—499 mg/dL), although at least one additional clinical trial would likely be required to support the U.S. Food and Drug Administration, or FDA, approval of a supplemental new drug application, or NDA, to expand CaPre's indication to this segment. Data from our Phase 2 studies indicated that CaPre may have a positive effect on diabetes and other inflammatory and cardiometabolic diseases; consequently, we may also seek to identify new potential indications for CaPre that may be appropriate for future studies and pipeline expansion. In addition, we may also seek to in-license other cardiometabolic or other primary care-focused drug candidates for drug development and commercialization.

In four clinical trials conducted to date, we saw the following consistent results with CaPre, and we are seeking to demonstrate similar safety and efficacy in our TRILOGY Phase 3 program:

- significant reduction of TGs and non-high density lipoprotein cholesterol (non-HDL-C) levels in the blood of patients with mild to sHTG;
- no deleterious effect on low-density lipoprotein cholesterol (LDL-C), or "bad" cholesterol, with the potential to reduce LDL-C;
- potential to increase high-density lipoprotein cholesterol (HDL-C), or "good" cholesterol;
- potential to benefit diabetes patients by decreasing hemoglobin A1c (HbA1c), a marker of glucose control;
- good bioavailability (absorption by the body), even under fasting conditions;
- no significant food effect when taken with either low-fat or high-fat meals; and
- an overall safety profile similar to that demonstrated by currently marketed OM3s.

We believe that if we are able to reproduce these results in our TRILOGY Phase 3 program, that this could potentially set CaPre apart from current FDA-approved fish oil-derived OM3 treatment options, and it could give us a significant clinical and marketing advantage.

Corporate Information

We were incorporated on February 1, 2002 under Part 1A of the Companies Act (Québec) under the name “9113-0310 Québec Inc”. On August 7, 2008, pursuant to a Certificate of Amendment, we changed our name to “Acasti Pharma Inc.” and on February 14, 2011, the *Business Corporations Act* (Québec) came into effect and replaced the Companies Act (Québec). We are now governed by the *Business Corporations Act* (Québec), or the QBCA.

Our principal executive offices are located at 545 Promenade du Centropolis, Suite 100, Laval, Québec, Canada H7T 0A3. Our telephone number is (450) 686-4555. Our corporate website is <http://www.acastipharma.com>. Information appearing on our website is not incorporated by reference into this prospectus.

RISK FACTORS

An investment in our securities involves a high degree of risk and should be considered speculative. An investment in our securities should only be undertaken by those persons who can afford the total loss of their investment. You should carefully consider the risks and uncertainties described under “Item 1A.—Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020, which section is incorporated by reference herein, and the other information contained in this prospectus, as updated by our subsequent filings under the Exchange Act and the risk factors and other information contained in any applicable prospectus supplement, before purchasing any of our securities. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of these risks actually occur, our business, financial condition, prospects, results of operations or cash flow could be materially and adversely affected and you could lose all or a part of the value of your investment.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents incorporated by reference herein, contains information that may be forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements can be identified by the use of terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “intend,” “estimate,” “predict,” “potential,” “continue” or other similar expressions concerning matters that are not statements about the present or historical facts. Forward-looking statements in this prospectus and in the documents incorporated by reference herein include, among other things, information or statements about:

- our ability to conduct all required clinical and nonclinical trials for our drug candidate, CaPre, including the timing and results of those trials;
- the outcome of our ongoing dialogue with the FDA regarding the unusually large placebo effect observed in the TG topline results of our TRILOGY 1 Phase 3 clinical trial and the implications for our TRILOGY 2 Phase 3 clinical trial and its outcome;
- our ability to file an NDA based on the results of our TRILOGY Phase 3 program;
- whether the FDA may require additional clinical development work or study to support an NDA filing for CaPre;
- our strategy, future operations, prospects and the plans of our management;
- the regulatory plan, timeline, costs and results of our clinical and nonclinical trials for CaPre;
- the timing and outcome of our meetings and discussions with the FDA;
- our planned regulatory filings for CaPre, and their timing;
- our expectation that our Bridging Study (as defined below) results will support our plan to get authorization from the FDA to use the 505(b)(2) pathway with new chemical entity status towards an NDA approval in the United States;
- the potential benefits and risks of CaPre as compared to other products in the pharmaceutical, medical food, natural health and dietary supplement products markets;
- our estimates of the size and growth rate of the potential market for CaPre, unmet medical needs in that market, the potential for future market expansion, the rate and degree of market acceptance of CaPre if it reaches commercialization, and our ability to serve that market;
- our anticipated marketing advantages and product differentiation of CaPre and its potential to become abest-in-class OM3 compound for the treatment of sHTG;
- the potential to expand CaPre’s indication for the treatment of high TGs(200-499 mg/dL), assuming at least one additional study;
- the degree to which physicians would switch their patients to a product with CaPre’s target product profile based on the outcome of our TRILOGY Phase 3 trials;
- our strategy and ability to develop, commercialize and distribute CaPre in the United States and elsewhere;
- our ability to strengthen our patent portfolio and other means of protecting our intellectual property rights, including our ability to obtain additional patent protection for CaPre;
- the availability and consistency of our raw materials, including raw krill oil, or RKO, from existing and future alternative suppliers;

- our expectation that following expiration of our license agreement with Neptune Wellness Solutions Inc., we will not require any licenses from third parties to support the commercialization of CaPre;
- our expectation to be able to rely on third parties to manufacture CaPre whose manufacturing processes and facilities are in compliance with current good manufacturing practices, or cGMP;
- the potential for CaPre in other cardiometabolic medicine indications;
- our intention and ability to build a U.S. commercial organization, and to successfully launch CaPre and compete in the U.S. market;
- our intention and ability to complete development and/or distribution partnerships to support the commercialization of CaPre outside of the United States, and to pursue strategic opportunities to provide supplemental capital and market access;
- the potential adverse effects that the recent COVID-19 pandemic may have on our business and operations;
- our need for additional financing, and our estimates regarding our future financing and capital requirements;
- our expectation regarding our financial performance, including our revenues, cost-of-goods, profitability, research and development, costs and expenses, gross margins, liquidity, capital resources, and capital expenditures; and
- our projected capital requirements to fund our anticipated expenses, including our research and development, marketing and sales, general and administrative expenses, and capital equipment expenditures.

All forward-looking statements reflect our belief and assumptions based on information available at the time the assumption was made. The forward-looking statements in this prospectus are subject to a number of known and unknown risks, uncertainties and other factors, including those described in this prospectus under "Risk Factors" and in the documents incorporated by reference herein, many of which are beyond our control, that could cause our actual results and developments to differ materially from those that are disclosed in or implied by the forward-looking statements, including, among others:

- risks related to timing and possible difficulties, delays or failures in our ongoing TRILOGY Phase 3 program for CaPre;
- nonclinical and clinical trials may be more costly or take longer to complete than anticipated and may never be completed, or they may generate results that warrant future clinical trials, additional clinical development and/or delay commercialization of CaPre;
- our TRILOGY Phase 3 trials may not achieve all or any of its primary and secondary endpoints;
- assuming our TRILOGY 2 trial meets its primary endpoint, the results of pooling that data with our TRILOGY 1 trial results may not achieve statistical significance or may not be supported by the FDA;
- based on the final TRILOGY 1 and TRILOGY 2 clinical trial data, the FDA may require that we conduct additional clinical work or studies to support an NDA for CaPre;

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- our anticipated studies and submissions to the FDA may not occur as currently anticipated, or at all;
 - the FDA could reject our 505(b)(2) regulatory pathway and/or our NDA;
 - while the REDUCE-IT results (a cardiovascular outcome study conducted by Amarin Corporation plc, or Amarin, with their OM3 drug VASCEPA) were positive, on January 13, 2020, AstraZeneca plc announced that its cardiovascular Phase 3 STRENGTH trial for its OM3 drug EPANOVA had been discontinued due to its low likelihood of demonstrating a benefit to patients with mixed dyslipidemia. The potential impacts of the discontinuance of the STRENGTH trial on our business and the OM3 drug market in general are not yet known;
 - if Amarin loses its appeal of the U.S. District Court for the District of Nevada's March 30, 2020 decision invalidating its patent on the basis of obviousness, then additional generic versions of VASCEPA could potentially enter the market within the next year and this could result in downward pressure on pricing for CaPre;
 - we may encounter difficulties, delays or failures in obtaining regulatory approvals for the initiation of clinical trials or to market CaPre, or the FDA may refuse to approve CaPre or place restrictions on our ability to commercialize and promote CaPre;
 - the FDA may require, or for competitive reasons we may need to, conduct additional future clinical trials for CaPre, the occurrence and success of which cannot be assured;
 - CaPre may have unknown side effects, or may not prove to be as safe and effective or as potent as we currently believe;
 - CaPre could be subject to extensive post-market obligations and continued regulatory review, which may result in significant additional expense and affect sales, marketing and profitability;
 - we may fail to achieve our publicly announced milestones on time;
 - we may encounter difficulties in completing or funding additional development or commercialization of CaPre;
 - third parties we are relying upon to conduct our TRILOGY Phase 3 program and support the data analysis and filing of an NDA for CaPre may not effectively fulfill their obligations to us, including complying with FDA requirements;
 - there may be difficulties, delays, or failures in obtaining health care reimbursements for CaPre;
 - recently enacted and future laws may increase the difficulty and cost for us to obtain marketing approval and commercialization of CaPre, and may affect the prices we can charge;
 - new laws, regulatory requirements, and the continuing efforts of governmental and third-party payors to contain or reduce the costs of healthcare through various means could adversely affect our business;
 - the market opportunity for, and demand and market acceptance of, CaPre may not be as strong as we anticipate;
 - third parties that we will rely upon to manufacture, supply and distribute CaPre may not effectively fulfill their obligations to us, including complying with FDA requirements;
 - there may not be an adequate supply of raw materials, including RKO, in sufficient quantities and quality to produce CaPre under cGMP standards and that meet our target specifications;

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- we may not be able to meet applicable regulatory standards for the manufacture of CaPre or scale-up our manufacturing successfully;
 - as a development stage company, we currently have limited sales, marketing and distribution personnel and resources;
 - our patent applications may not result in issued patents, our issued patents may be circumvented or challenged and ultimately struck down, and we may not be able to successfully protect our trade secrets or other confidential proprietary information;
 - we may not be able to build name recognition in our markets of interest if we do not protect our trademark for CaPre or any new trademark that is developed for CaPre;
 - we may face claims of infringement of third party intellectual property and other proprietary rights;
 - we may face product liability claims and product recalls;
 - we may face intense competition from other companies in the pharmaceutical, medical food and natural health product industries;
 - we have a history of negative operating cash flow, and may never become profitable or be able to sustain profitability;
 - we have significant additional future capital needs, and may not be able to raise additional financing required to fund further research and development, clinical studies, obtain regulatory approvals, build a commercial organization in the United States, and meet ongoing capital requirements to continue our current operations on commercially acceptable terms or at all;
 - we face additional costs related to the change in our status from a foreign private issuer to a U.S. domestic issuer;
 - we may not be able to successfully compete in the U.S. market with competitors who are larger and have more resources than we do;
 - we may acquire businesses or products or form strategic partnerships in the future that may not be successful;
 - we may be unable to secure development and/or distribution partnerships to support the development and commercialization of CaPre, provide development capital, or provide market access in any key market;
 - we rely on the retention of key management and skilled scientific, manufacturing, regulatory and commercial personnel; and
 - general changes in economic and capital market conditions could adversely affect us.

All of the forward-looking statements in this prospectus and in the documents incorporated by reference are qualified by this cautionary statement. There can be no guarantee that the results or developments that we anticipate will be realized or, even if substantially realized, that they will have the consequences or effects on our business, financial condition or results of operations that we anticipate. As a result, you should not place undue reliance on the forward-looking statements. Except as required by applicable law, we do not undertake to update or amend any forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are made as of the date of this prospectus. Forward-looking statements made in a document incorporated by reference into this prospectus are made as of the date of the original document and have not been updated by us except as expressly provided for in this prospectus.

USE OF PROCEEDS

Unless otherwise indicated in a prospectus supplement, the net proceeds that we receive from the sale of the securities offered by this prospectus will be used by us for working capital and general corporate purposes, which includes filing and continued regulatory support for our NDA submission, market development and commercialization of CaPre and expansion of business development activities. We have not allocated any portion of the net proceeds for any particular use as of the date of this prospectus. The net proceeds may be invested temporarily until they are used for their stated purpose. Specific information concerning the use of proceeds from the sale of any securities will be included in the prospectus supplement relating to such securities.

If all of the December 2017 Warrants and the Broker Warrants are exercised in full and the exercise price therefor is paid in cash, we will receive approximately US\$9.3 million in proceeds. However, the timing of the exercise and the extent to which any of the December 2017 Warrants or the Broker Warrants are exercised are beyond our control and depend on a number of factors, including the market price of our common shares. There can be no assurance that any of the December 2017 Warrants or the Broker Warrants will be exercised, and it is possible that all of the warrants may expire and may never be exercised. Any proceeds received by us from the exercise of the warrants will be used for general corporate purposes. We will not receive any proceeds from the resale by the selling shareholder of common shares underlying the Broker Warrants.

SELLING SHAREHOLDERS

In December 2017, we issued the Broker Warrants in a private placement to the selling shareholders as compensation for their service as underwriters for our public offering of common shares and warrants. The Broker Warrants, which have an exercise price of US\$1.2625 per share, are currently exercisable and may be exercised at any time on or before December 19, 2022. We have agreed to register for resale the common shares underlying the Broker Warrants under the Securities Act.

When we refer to the selling shareholders in this prospectus, we mean those persons listed in the table below, as well as the permitted transferees, pledgees, donees, assignees, successors and others who later come to hold any of the selling shareholders' interests other than through a public sale.

The selling shareholders may from time to time offer and sell pursuant to this prospectus any or all of the common shares set forth in the following table upon exercise of the Broker Warrants. There is no requirement for the selling shareholders to sell common shares they receive upon the exercise of Broker Warrants, and we do not know when, or if, or in what amount the selling shareholders may resell the common shares pursuant to this prospectus.

The table below has been prepared based on the information furnished to us by the selling shareholders as of June 26, 2020. The selling shareholders identified below may have sold, transferred or otherwise disposed of some or all of their Broker Warrants or underlying common shares since the date on which the information in the following table is presented in transactions exempt from or not subject to the registration requirements of the Securities Act. Information concerning the selling shareholders may change from time to time and, if necessary, we will supplement this prospectus accordingly. We are unable to confirm whether the selling shareholders will in fact sell any or all of their common shares. To our knowledge and except as noted below, none of the selling shareholders has, or within the past three years has had, any material relationships with us or any of our affiliates, other than acting as underwriters in connection with our public offering of common shares and warrants in December 2017.

Beneficial ownership of shares and percentage ownership are determined in accordance with the SEC's rules. In calculating the number of common shares beneficially owned by an individual or entity and the percentage ownership of that individual or entity, common shares underlying options or warrants that are either currently exercisable or exercisable within 60 days from the date of this prospectus are deemed outstanding.

Selling Shareholders	Beneficial Ownership Prior to this Offering		Shares to be Sold in this Offering	Beneficial Ownership After this Offering	
	Shares	Percentage		Shares	Percentage
The Benchmark Company, LLC 150 East 58th Street, 17th Floor New York, New York 10155	235,930(1)	*	235,930(1)	-	-%
Leede Jones Gable Inc. Suite 1000, 100 Yonge Street Toronto, Ontario, Canada M5C 1T4	60,250(1)	*	60,250(1)	-	-%
Caldwell Securities Ltd. 150 King Street W. Toronto, Ontario, Canada M5H 1J9	1,250(1)	*	1,250(1)	-	-%

(1) Consists exclusively of the common shares underlying the Broker Warrants.

(*) Less than 1%.

DESCRIPTION OF SHARE CAPITAL

Overview

Our authorized capital consists of an unlimited number of no par value common shares and an unlimited number of no par value Class B, Class C, Class D and Class E preferred shares (collectively, the preferred shares), issuable in one or more series. As of March 31, 2020, there were:

- a total of 90,209,449 common shares issued and outstanding and no preferred shares issued and outstanding;
- 9,936,486 options to purchase common shares issued and outstanding, at a weighted average exercise price of C\$1.00 per common share;
- warrants issued in connection with our February 2017 public offering in Canada to purchase up to 1,723,934 common shares at an exercise price of C\$2.15 per common share;
- broker warrants issued in connection with our December 2017 public offering in the United States to purchase up to 259,121 common shares at an exercise price of US\$1.2625 per common share;
- warrants issued in connection with our December 2017 public offering in the United States to purchase up to 7,072,962 common shares at an exercise price of US\$1.26 per common share;
- warrants issued in connection with our May 2018 public offering in Canada to purchase up to 6,593,750 common shares at an exercise price of C\$1.31 per common share; and
- broker warrants issued in connection with our May 2018 public offering in Canada to purchase up to 222,976 common shares at an exercise price of C\$1.05 per common share.

In February 2019, we entered into an “at-the-market”, or ATM, sales agreement with B. Riley FBR, Inc., pursuant to which our common shares may be sold from time to time for aggregate gross proceeds of up to US\$30 million, with sales only being made on NASDAQ. On June 29, 2020 we entered into an amended and restated the ATM sales agreement with B. Riley FBR, Inc., Oppenheimer & Co. Inc., and H.C. Wainwright & Co., LLC, pursuant to which our common shares may be sold from time to time for aggregate gross proceeds of up to US\$75 million, with sales only being made on NASDAQ. The common shares will be distributed at market prices prevailing at the time of the sale and, as a result, prices may vary between purchasers and during the period of distribution.

Subsequent to March 31, 2020 and through the date of this prospectus, we issued and sold 2,278,936 common shares under our ATM program resulting in net cash proceeds of approximately US\$1.8 million.

The following is a brief description of the rights, privileges, conditions and restrictions attaching to the common shares and preferred shares.

Common Shares

Voting Rights

Each common share entitles its holder to receive notice of, and to attend and vote at, all annual or special meetings of our shareholders. Each common share entitles its holder to one vote at any meeting of our shareholders, other than meetings at which only the holders of a particular class or series of shares are entitled to vote due to statutory provisions or the specific attributes of that class or series.

Dividends

Subject to the prior rights of the holders of preferred shares ranking before the common shares as to dividends, the holders of common shares are entitled to receive dividends as declared by the board of directors out of funds that are available for the payment of dividends.

Winding-up and Dissolution

In the event of our voluntary or involuntary winding-up or dissolution, or any other distribution of our assets among our shareholders for the purposes of winding up our affairs, the holders of common shares will be entitled to receive, after payment by us to the holders of preferred shares ranking prior to common shares regarding the distribution of our assets in the case of winding-up or dissolution, share for share, the remainder of our property, with neither preference nor distinction. The order of priority applicable to all classes of our shares with respect to the redemption, liquidation, dissolution or distribution of property is as follows: first, the Class E non-voting shares; second, the Class D non-voting shares; third, the Class B multiple voting shares and Class C non-voting shares, *pari passu*; and fourth, the common shares. Notwithstanding the order of priority, shareholders of a class of shares may renounce the order of priority by unanimous approval by all shareholders of that class of shares.

Dividend Policy

We do not anticipate paying any cash dividends on our common shares in the foreseeable future. We presently intend to retain future earnings to finance the development and growth of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors the board of directors deems relevant. In addition, the terms of any future debt or credit facility may preclude us from paying dividends. Any remittances of dividends to United States residents and to other non-Canadian residents are, however, subject to withholding tax.

Preferred Shares

Class B Multiple Voting Shares

Each Class B multiple voting share entitles the holder thereof to 10 votes per share at all of our shareholder meetings.

Dividends. Holders of Class B multiple voting shares are entitled to receive, as and when such dividends are declared, an annual non-cumulative dividend of 5% on the amount paid for the shares, payable at the time and in the manner which the board of directors may determine and subject to the order of priority.

Participation. Subject to the provisions of subsection 5.2.2 of our articles of incorporation, or Articles, holders of Class B multiple voting shares do not have the right to participate in our profits or surplus assets.

Conversion. Holders of Class B multiple voting shares have the right, at their entire discretion, to convert part or all of the Class B multiple voting shares they hold into common shares on the basis of 1 common share for each Class B multiple voting share converted.

Redemption. Subject to the provisions of the QBCA and the order of priority, holders of Class B multiple voting shares have the right to demand from us, upon 30 days' written notice, that we redeem the Class B multiple voting shares at a price equivalent to the amount paid for such shares plus the redemption premium, as defined in subsection 5.2.4.1 of the Articles, and any and all declared but yet unpaid dividends on same.

Liquidation. In the event of our dissolution or liquidation or any other distribution of our property, the Class B voting shareholders will have the right to be reimbursed for the amount paid for their Class B multiple voting shares plus the redemption premium, as defined in subsection 5.2.4.1 of our Articles, as well as the amount of any and all declared but yet unpaid dividends on their shares, subject to the order of priority.

Class C Non-Voting Shares

Subject to the provisions of the QBCA, holders of Class C non-voting shares are neither entitled to vote at any meeting of our shareholders, receive a notice of any such meeting, nor attend any such meeting.

Dividends. Holders of Class C non-voting shares are entitled to receive, as and when such dividends are declared, an annual non-cumulative dividend of 5% on the amount paid for the shares, plus a redemption premium as defined in subsection 5.3.6.1 of our Articles, payable at the time and in the manner which the board of directors may determine and subject to the order of priority.

Participation. Subject to the provisions of subsection 5.3.2 of our Articles, holders of Class C non-voting shares do not have the right to participate in our profits or surplus assets.

Conversion. Holders of Class C non-voting shares have the right, at their entire discretion, to convert part or all of the Class C non-voting shares they hold into common shares on the basis of 1 common share for each Class C non-voting share converted.

Forced Conversion. All of our Class C non-voting shares will automatically be converted into common shares upon the request of an unrelated third-party investor investing more than C\$500,000, or any other amount to be determined by the board of directors and requesting as a condition to the investment that the Class C non-voting shares be converted into common shares on the basis of 1 common share for each Class C non-voting share converted.

Redemption. Subject to the provisions of the QBCA and the order of priority, holders of Class C non-voting shares have the right to demand, upon 30 days' written notice, that we redeem their Class C non-voting shares at a price equivalent to the amount paid for the shares plus the redemption premium, as defined in subsection 5.3.6.1 of our Articles, and any and all declared but yet unpaid dividends on the shares.

Liquidation. In the event of our dissolution or liquidation or any other distribution of our property, Class C non-voting shareholders will have the right to be reimbursed for the amount paid for their Class C non-voting shares plus the redemption premium, as defined in subsection 5.3.6.1 of our Articles, as well as the amount of any and all declared but yet unpaid dividends on their shares, subject to the order of priority.

Class D Non-Voting Shares

Subject to the provisions of the QBCA, holders of Class D non-voting shares are neither entitled to vote at any meeting of the shareholders, receive a notice of any such meeting, nor attend any such meeting.

Dividends. Holders of Class D non-voting shares are entitled to receive, as and when such dividends are declared, a monthly non-cumulative dividend of 0.5% to 2% on the amount paid for the shares, plus a redemption premium as defined in subsection 5.4.6.1 of our Articles, payable at the time and in the manner which the board of directors may determine and subject to the order of priority.

Participation. Subject to the provisions of subsection 5.4.2 of our Articles, holders of Class D non-voting shares do not have the right to participate in our profits or surplus assets.

Conversion. Holders of Class D non-voting shares have the right, at their discretion, to convert part or all of their Class D non-voting shares into common shares on the basis of a number of common shares equal to the number of Class D non-voting shares converted multiplied by a conversion ratio, calculated as follows:

$$\text{Conversion Ratio} = \frac{\text{The product obtained by multiplying a factor to be agreed at the time of the issuance of the Class D non-voting shares by the average amount paid per share for the Class D non-voting shares plus the redemption premium per share, as defined in subsection 5.4.6.1 of our Articles as well as the amount of any and all declared but yet paid dividends on the shares}}{\text{Fair market value of the common shares at the date of any conversion of Class D non-voting shares into common shares}}$$

Forced Conversion. All of our Class D non-voting shares automatically convert into common shares upon the request of an unrelated third party investor, investing more than C\$500,000, or any other amount to be determined by the board of directors, and requesting as a condition to the investment that the Class D non-voting shares be converted into common shares on the basis of a number of common shares equal to the number of Class D non-voting shares converted multiplied by the conversion ratio, calculated as follows:

Conversion Ratio =
$$\frac{\text{The product obtained by multiplying a factor to be agreed at the time of the issuance of the Class D non-voting shares by the average amount paid per share for the Class D non-voting shares plus the redemption premium per share, as defined in subsection 5.4.6.1 of our Articles as well as the amount of any and all declared but yet paid dividends on the shares}}{\text{Fair market value of the common shares at the date of any conversion of Class D non-voting shares into common shares}}$$

Redemption. Subject to the provisions of the QBCA and the order of priority, holders of Class D non-voting shares have the right to demand, upon 30 days' written notice, that we redeem their Class D non-voting shares at a price equivalent to the amount paid for the shares plus the redemption premium, as defined in subsection 5.4.6.1 of our Articles, and any and all declared but yet unpaid dividends on the shares.

Liquidation. In the event of our dissolution or liquidation or any other distribution of our property, the Class D non-voting shareholders will have the right to be reimbursed for the amount paid for their Class D non-voting shares plus the redemption premium, as defined in subsection 5.4.6.1 of our Articles as well as the amount of any and all declared but yet unpaid dividends on their shares, subject to the order of priority.

Class E Non-Voting Shares

Subject to the provisions of the QBCA, holders of Class E non-voting shares are neither entitled to vote at any meeting of the shareholders, receive a notice of any such meeting, nor attend any such meeting.

Dividends. Holders of Class E non-voting shares are entitled to receive, as and when such dividends are declared, a monthly non-cumulative dividend of 0.5% to 2% on the amount paid for the shares, payable at the time and in the manner which the board of directors may determine and subject to the order of priority.

Participation. Subject to the provisions of subsection 5.5.2 of our Articles, holders of Class E non-voting shares do not have the right to participate in our profits.

Conversion. Holders of Class E non-voting shares have the right, at their discretion, to convert part or all of their Class E non-voting shares into common shares on the basis of a number of common shares equal to the number of Class E non-voting shares converted multiplied by the conversion ratio, calculated as follows:

Conversion Ratio =
$$\frac{\text{The product obtained by multiplying a factor to be agreed at the time of the issuance of the Class E non-voting shares by the average amount paid per share for the Class E non-voting shares plus the amount of any and all declared but yet paid dividends on the shares}}{\text{Fair market value of the common shares at the date of any conversion of Class E non-voting shares into common shares}}$$

Redemption. Subject to the provisions of the QBCA and the order of priority, we have the right, upon 30 days' written notice, to redeem the Class E non-voting shares at a price equivalent to the amount paid for the shares and any and all declared but yet unpaid dividends on the shares.

Liquidation. In the event of our dissolution or liquidation or any other distribution of our property, the Class E non-voting shareholders will have the right to be reimbursed for the amount paid for their Class E non-voting shares as well as the amount of any and all declared but yet unpaid dividends on the shares, subject to the order of priority.

DESCRIPTION OF WARRANTS

We may issue warrants for the purchase of common shares. Warrants may be offered separately or together with other securities offered by this prospectus, as the case may be. Unless the applicable prospectus supplement otherwise indicates, each series of warrants will be issued under a separate warrant agreement to be entered into between us and one or more banks or trust companies acting as warrant agent. The applicable prospectus supplement will include details of the warrant agreements covering the warrants being offered. The warrant agent will act solely as our agent and will not assume a relationship of agency with any holders of warrant certificates or beneficial owners of warrants.

The following sets forth certain general terms and provisions of the warrants offered under this prospectus. The specific terms of the warrants, and the extent to which the general terms described in this section apply to those warrants, will be set forth in the applicable prospectus supplement. The terms of any warrants offered under a prospectus supplement may differ from the terms described below.

The particular terms of each issue of warrants will be described in the related prospectus supplement. This description will include some or all of the following:

- the designation and aggregate number of warrants;
- the price at which the warrants will be offered;
- the currency or currencies in which the warrants will be offered;
- the designation and terms of our common shares purchasable upon exercise of the warrants;
- the date on which the right to exercise the warrants will commence and the date on which the right will expire;
- the number of common shares that may be purchased upon exercise of each warrant and the price at which and currency or currencies in which our common shares may be purchased upon exercise of each warrant;
- the designation and terms of any securities with which the warrants will be offered, if any, and the number of the warrants that will be offered with each security;
- the date or dates, if any, on or after which the warrants and the related securities will be transferable separately;
- if applicable, whether the warrants will be subject to redemption or call and, if so, the terms of such redemption or call provisions;
- material United States and Canadian tax consequences of owning the warrants; and
- any other material terms or conditions of the warrants.

Each warrant will entitle the holder to purchase common shares, as specified in the applicable prospectus supplement at the exercise price that we describe therein. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

DESCRIPTION OF UNITS

We may issue units comprised of one or more of the other securities that may be offered under this prospectus, in any combination. The following information, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of any such units that we may offer under this prospectus. While the information below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the general terms described below.

We will file the form of unit agreement, if any, between us and a unit agent that describes the terms and conditions of the series of units we are offering, and any supplemental agreements, concurrently with the filing of the applicable prospectus supplement under which such series of units are offered. This summary is subject to, and qualified in its entirety by reference to, all the provisions of the unit agreement, if any, and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the particular series of units that we sell under this prospectus, as well as the complete unit agreement, if any, and any supplemental agreements that contain the terms of the units.

We may issue units comprising one or more of common shares and warrants in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit may be issued, if any, may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. We will describe in the applicable prospectus supplement the terms of the series of units.

The provisions described in this section, as well as those described under “Description of Share Capital” and “Description of Warrants” will apply to each unit and to any common share or warrant included in each unit, respectively.

We may issue units in such amounts and in numerous distinct series as we determine.

PLAN OF DISTRIBUTION

Our Plan of Distribution

We may sell the securities offered by this prospectus to or through underwriters or dealers, and also may sell those securities to one or more other purchasers directly or through agents, including sales pursuant to ordinary brokerage transactions and transactions in which a broker-dealer solicits purchasers, or if indicated in a prospectus supplement, pursuant to delayed delivery contracts, by remarketing firms or by other means. Underwriters may sell securities to or through dealers. Each prospectus supplement will set forth the terms of the offering, including the name or names of any underwriters, dealers or agents and any fees or compensation payable to them in connection with the offering and sale of a particular series or issue of securities, the public offering price or prices of the securities and the proceeds from the sale of the securities.

The securities may be sold, from time to time in one or more transactions at a fixed price or prices which may be changed or at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices, including sales made directly on NASDAQ or other existing trading markets for the securities. The prices at which the securities may be offered may vary as between purchasers and during the period of distribution. If, in connection with the offering of securities at a fixed price or prices, the underwriters have made a bona fide effort to sell all of the securities at the initial offering price fixed in the applicable prospectus supplement, the public offering price may be decreased and thereafter further changed, from time to time, to an amount not greater than the initial public offering price fixed in such prospectus supplement, in which case the compensation realized by the underwriters will be decreased by the amount that the aggregate price paid by purchasers for the securities is less than the gross proceeds paid by the underwriters to us.

Underwriters, dealers and agents who participate in the distribution of the securities may be entitled under agreements to be entered into with us to indemnification by us against certain liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which such underwriters, dealers or agents may be required to make in respect thereof. Such underwriters, dealers and agents may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

In connection with any offering of securities, the underwriters may over-allot or effect transactions which stabilize or maintain the market price of the securities offered at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. Any underwriters, dealers or agents to or through which securities other than our common shares are sold by us for public offering and sale may make a market in such securities, but such underwriters, dealers or agents will not be obligated to do so and may discontinue any such market making at any time and without notice. No assurance can be given that a market for trading in securities of any series or issue will develop or as to the liquidity of any such market, whether or not such securities are listed on a securities exchange.

The place, time of delivery, and other terms of the offered securities will be described in the applicable prospectus supplement.

Selling Shareholders' Plan of Distribution

Each selling shareholder of the common shares and any of its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of its common shares included in the registration statement of which this prospectus is a part on NASDAQ or any other stock exchange, market or trading facility on which the common shares are traded or in private transactions. These sales may be at fixed or negotiated prices.

A selling shareholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchases;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;

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- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
 - an exchange distribution in accordance with the rules of the applicable exchange;
 - privately negotiated transactions;
 - in transactions through broker-dealers that agree with the selling shareholders to sell a specified number of such securities at a stipulated price per security;
 - through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
 - a combination of any such methods of sale; or
 - any other method permitted pursuant to applicable law.

The selling shareholders may also sell our common shares under Rule 144 under the Securities Act or any other exemption from registration, if available, rather than under this prospectus.

Broker-dealers engaged by the selling shareholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling shareholders (or, if any broker-dealer acts as agent for the purchaser of our common shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121.

In connection with the sale of the common shares or interests therein, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common shares in the course of hedging the positions they assume. The selling shareholders may also sell common shares short and deliver these common shares to close out their short positions, or loan or pledge the common shares to broker-dealers that in turn may sell these common shares. The selling shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institutions of common shares offered by this prospectus, which common shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling shareholders and any broker-dealers or agents that are involved in selling the common shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the common shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay certain fees and expenses incurred by us incident to the registration of the common shares. We have agreed to indemnify the selling shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. The common shares offered hereby will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the common shares offered hereby may not simultaneously engage in market making activities with respect to the common shares for the applicable restricted period, as defined by Regulation M, prior to the commencement of the distribution. In addition, the selling shareholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common shares by the selling shareholders or any other person. We will make copies of this prospectus available to the selling shareholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

December 2017 Warranholders' Plan of Distribution

This prospectus covers the offering of common shares issuable upon exercise of the December 2017 Warrants directly to the holders of the December 2017 Warrants and such holders may purchase such common shares directly from us by exercising their December 2017 Warrants in accordance with their terms.

CERTAIN INCOME TAX CONSIDERATIONS

The applicable prospectus supplement may describe certain United States federal income tax consequences of the acquisition, ownership and disposition of securities offered by this prospectus by an initial investor who is subject to United States federal income taxation.

The applicable prospectus supplement may also describe certain Canadian federal income tax consequences to investors described therein of acquiring securities offered by this prospectus.

ENFORCEMENT OF CIVIL LIABILITIES

We are incorporated under the laws of the Province of Quebec. Substantially all of our assets are located outside the United States. In addition, several of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of such persons' assets may be located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon us or such persons or to enforce against them or against us judgments obtained in United States courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof. In addition, investors should not assume that the courts of Canada (i) would enforce judgments of U.S. courts obtained in actions against us or our officers or directors or experts predicated upon the civil liability provisions of the U.S. federal securities laws or other laws of the United States or (ii) would enforce, in original actions, liabilities against us or such directors, officers or experts predicated upon the U.S. federal securities laws or any securities or other laws of any state or jurisdiction of the United States.

We have also been advised by Osler, Hoskin & Harcourt LLP that there is doubt whether an action could be brought in Canada in the first instance on the basis of liability predicated solely upon U.S. federal securities laws.

We have appointed C T Corporation System as our agent to receive service of process with respect to any action brought against us in the United States.

EXPERTS

The consolidated financial statements of Acasti Pharma Inc. as of March 31, 2020 and 2019 and for each of the years in the two year period ended March 31, 2020 have been incorporated by reference herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The audit report covering the March 31, 2020 consolidated financial statements contains an explanatory paragraph that states that Acasti Pharma Inc. has incurred operating losses and negative cash flows from operations since its inception, and additional funds will be needed in the future that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The audit report covering the March 31, 2020 consolidated financial statements also refers to a change in accounting framework as Acasti Pharma Inc. has retrospectively adopted U.S. generally accepted accounting principles and has changed its reporting currency from Canadian dollars to U.S. dollars.

LEGAL MATTERS

Unless otherwise specified in a prospectus supplement relating to any offering of securities under this prospectus, certain matters under Canadian law relating to the offering of the securities under this prospectus will be passed upon for us by Osler, Hoskin & Harcourt LLP, Montreal, Quebec, Canada; and certain legal matters under U.S. law will be passed upon for us by Osler, Hoskin & Harcourt LLP, New York, New York. In addition, certain legal matters in connection with any offering of securities under this prospectus will be passed upon for any underwriters, dealers or agents by counsel to be designated at the time of the offering by such underwriters, dealers or agents with respect to matters of Canadian and U.S. law.



Up to US\$75,000,000 Common Shares

PROSPECTUS SUPPLEMENT

B. Riley Securities

Oppenheimer & Co.

H.C. Wainwright & Co.

November 10, 2021
