

July 11, 2016



## Acasti Announces First Quarter Results

LAVAL, QUÉBEC -- (Marketwired) -- 07/11/16 -- Acasti Pharma Inc. ("**Acasti**" or the "**Corporation**") (NASDAQ:ACST)(TSX VENTURE:APO), an emerging biopharmaceutical company focused on the research, development and commercialization of new krill oil-based forms of omega-3 phospholipid therapies for the treatment of severe hypertriglyceridemia, announces its operating and financial results for the first quarter of the 2017 fiscal year. All amounts are in Canadian dollars.

"Acasti has made important progress this quarter. The last subject in the Bioavailability Bridging study completed dosing on May 27, 2016. The data are being collected and analyzed, and will be reported later this year. The results of this study will inform the feasibility of the 505(b)(2) regulatory pathway", highlighted Jan D'Alvise, President & CEO. "Our focus now is to design a Phase 3 program that we expect will demonstrate the efficacy of CaPre® in patients with severe hypertriglyceridemia. In parallel, we are evaluating our strategies for commercial success in the US, which represents a significant portion of the global market for prescription omega 3's. We expect to have a clear view of our path forward by the end of this year".

### ***First Quarter Financial Results***

- Research and development (R&D) expenses were \$2,395,000 for the quarter, up from \$1,980,000 in the same quarter last year
- Non-IFRS operating loss<sup>1</sup> was \$2,286,000 for the quarter, versus \$1,946,000 in the quarter last year
- Net loss was \$3,154,000 or \$0.29 loss per share for the quarter, versus a net loss of \$966,000 or \$0.09 loss per share in the quarter last year

R&D expenses were higher for the current quarter in comparison with last year largely due to increases in research contract expenses related to the advancement of Acasti's clinical trials, and partly offset by lower regulatory expenses.

The quarter-over-quarter increase in Non-IFRS operating loss was largely due to higher R&D expenses.

### ***Cashflows***

Cash and short-term investment amounted to \$9.6 million as at May 31, 2016 of which \$2 million was considered as restricted short-term investment. If Acasti does not raise additional funds, there exists a material uncertainty that casts substantial doubt about the Corporation's ability to continue as a going concern and, therefore, realize its assets and discharge its liabilities in the normal course of business. Management has reasonable expectation that the Corporation will be able to raise additional funds.

1 See comment on Non-IFRS operating loss which follows

### **CaPre® Development Plan**

As previously announced, Acasti intends to pursue the regulatory pathway for CaPre® under section 505(b)(2)<sup>2</sup> of the Federal Food, Drug, and Cosmetic Act. In conjunction with this, Acasti has submitted an amendment to its original FDA Investigational New Drug (IND) application for its pivotal bioavailability Bridging study, comparing the pharmacokinetic profile of CaPre® to another omega-3 prescription drug as a means of establishing a scientific bridge between the two. The Bridging study will help determine the feasibility of a 505(b)(2) regulatory pathway, while also optimizing the protocol design of the Phase 3 trial. All subjects of the bridging study have been fully enrolled and Acasti is expecting results from the study before the end of the year, which is expected to confirm Acasti's chosen regulatory pathway.

The 505(b)(2) approval pathway has been used by many other pharmaceutical companies and Acasti's regulatory and clinical experts believe such a strategy is the best pathway for CaPre®. This should allow the Corporation to further optimize the advancement of CaPre®, while benefiting most importantly from the substantial clinical and nonclinical safety data already available with another FDA-approved omega-3 prescription drug. In addition, it is expected to reduce the costs and timeline to completion of the overall CaPre® development program required to support a New Drug Application (NDA) submission to the US FDA.

### **About Acasti Pharma Inc .**

Acasti is an emerging biopharmaceutical company focused on the research and development of a prescription drug candidate, CaPre®, for the treatment of severe hypertriglyceridemia, a condition characterized by abnormally high levels of triglycerides in the bloodstream. CaPre® is a krill oil-derived mixture of polyunsaturated fatty acids (PUFAs), primarily composed of omega-3 fatty acids, principally eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) present as a combination of phospholipid esters and free fatty acids. Krill is a major source of phospholipids and omega-3 fatty acids well known to be beneficial for human health.

### **505(b)(2) Regulatory Pathway**

*The 505(b)(2) regulatory pathway is defined in The Federal Food Drug and Cosmetics Act as a New Drug Application (NDA) containing investigations of safety and effectiveness that are being relied upon for approval and were not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. These applications differ from the typical NDA (described under Section 505(b)(1) of the Act), in that they allow a sponsor to rely, at least in part, on the FDA's findings of safety and/or effectiveness for a previously approved drug.*

### **Caution Regarding Non-IFRS Financial Measures**

*The Corporation uses adjusted financial measures, including Non-IFRS operating loss (Loss from operating activities before interest, taxes, depreciation and amortization), to assess its operating performance. These non-IFRS financial measures are directly derived from the*

*Company's financial statements and are presented in a consistent manner. The Company uses these measures for the purposes of evaluating its historical and prospective financial performance, as well as its performance relative to competitors. These measures also help the Company to plan and forecast for future periods as well as to make operational and strategic decisions. The Company believes that providing this information to investors, in addition to IFRS measures, allows them to see the Company's results through the eyes of management, and to better understand its historical and future financial performance.*

*Securities regulations require that companies caution readers that earnings and other measures adjusted to a basis other than IFRS do not have standardized meanings and are unlikely to be comparable to similar measures used by other companies. Accordingly, they should not be considered in isolation. The Corporation uses Non-IFRS operating loss to measure its performance from one period to the next without the variation caused by certain adjustments that could potentially distort the analysis of trends its operating performance, and because the Corporation believes it provides meaningful information on the Corporation's financial condition and operating results. Acasti's method for calculating Non-IFRS operating loss may differ from that used by other corporations.*

<sup>2</sup> See note on "505(b)(2) Regulatory Pathway"

*Acasti obtains its Non-IFRS operating loss measurement by adding to net loss, finance costs, depreciation and amortization, impairment loss and income taxes and by subtracting finance income. Finance income/costs include foreign exchange gain (loss) and change in fair value of derivatives. Acasti also excludes the effects of certain non-monetary transactions recorded, such as stock-based compensation, from its Non-IFRS operating loss calculation. The Corporation believes it is useful to exclude this item as it is a non-cash expense. Excluding this item does not imply it is necessarily nonrecurring.*

### **Forward Looking Statements**

*Statements in this press release that are not statements of historical or current fact constitute "forward-looking statements" within the meaning of the U.S. securities laws and Canadian securities laws. Such forward-looking statements involve known and unknown risks, uncertainties, and other unknown factors that could cause the actual results of Acasti to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labeled with the terms "believes," "belief," "expects," "intends," "anticipates," "will," or "plans" to be uncertain and forward-looking. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release.*

*The forward-looking statements contained in this news release are expressly qualified in their entirety by this cautionary statement and the "Cautionary Note Regarding Forward-Looking Information" section contained in Acasti's latest Annual Information Form, which also forms part of Acasti's latest annual report on Form 20-F, and which is available on SEDAR at [www.sedar.com](http://www.sedar.com), on EDGAR at [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml) and on the investor section of Acasti's website at [acastipharma.com](http://acastipharma.com) (the "AIF"). All forward-looking statements in this press release are made as of the date of this press release. Acasti does not undertake to update any such forward-looking statements whether as a result of new*

*information, future events or otherwise, except as required by law. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in Acasti's public securities filings with the Securities and Exchange Commission and the Canadian securities commissions. Additional information about these assumptions and risks and uncertainties is contained in the AIF under "Risk Factors".*

*Neither NASDAQ, the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.*

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