

January 12, 2016



## Acasti Announces Third Quarter Results

- *Important progress made with FDA on CaPre® development pathway*
- *Amended IND application to commence bioavailability bridging study submitted*
- *Entered into licensing agreement with Neptune to market Onemia®*

LAVAL, Québec, Jan. 12, 2016 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("**Acasti**" or the "**Corporation**") (NASDAQ:ACST) (TSX-V: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 hypertriglyceridemia, announces its financial and operating results for the third quarter ended November 30, 2015. All amounts in Canadian dollars.

On December 16, 2015 Acasti announced that it had made important progress in its correspondence with the US Food and Drug Administration (FDA) regarding next steps in the development plans for CaPre®. "Based on this, we recently submitted an amendment to our original Investigational New Drug (IND) application to commence a bioavailability bridging study," highlighted Pierre Lemieux, PhD, Acasti's Chief Operating Officer. "At the same time, we will continue to work closely with the FDA to ensure the Corporation is aligned with their views on the development pathway for CaPre®, while also endeavoring to advance our future clinical trials as quickly as possible."

### Third Quarter Financial Results

- Research and development (R&D) expenses were \$1,412,000 for the quarter, versus \$1,749,000 in the prior year
- Adjusted EBITDA<sup>1</sup> was negative \$(1,988,000) for the quarter, versus negative \$(2,099,000) in the prior year
- Net loss was \$2,191,000 for the quarter, versus net earnings of \$3,012,000 in the prior year.

Adjusted EBITDA improved slightly over the prior year, largely due to lower R&D expenses.

The \$3.0 million of net earnings recorded in the prior year is largely due to the variation in the fair value of Acasti's derivative warrant liability arising from its 2013 public offering. The derivative warrant liabilities are required to be measured at fair value at each reporting date with changes in fair value recognized in earnings.

For the quarter ended November 30, 2015, Acasti had cash and cash equivalents of \$14.1 million.

### Year-to-Date Financial Results

- Research and development expenses were \$3,874,000 for the nine-month period, compared to \$4,771,000 in the prior year
- Adjusted EBITDA was negative \$(5,418,000) for the current year-to-date, versus negative \$(6,244,000) in the prior year
- Net loss was \$4,398,000, versus net earnings of \$656,000 in the prior year.

The nine-month year-over-year variances are mainly attributable to the same factors highlighted above for third quarter financial results.

### **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 recently submitted an amendment to its original FDA Investigational New Drug (IND) application to commence a pivotal bioavailability bridging study, comparing CaPre® to an 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 a Phase 3 trial.

The 505(b)(2) approval pathway has been used by many other companies and Acasti's regulatory and clinical experts believe such a strategy is best for CaPre®. This should allow the Corporation to further optimize the advancement of CaPre®, while benefiting most importantly from the substantial clinical and nonclinical data already available with another FDA-approved omega-3 prescription drug. In addition, it should reduce the expected expenses and streamline the overall CaPre® development program required to support a New Drug Application (NDA) submission. The 505(b)(2) application also enables regulatory submission of a New Chemical Entity (NCE) approval when some part of the data application is derived from studies not conducted by the applicant.

### **Subsequent Event and Restricted Cash**

As part of an acquisition announced on January 7, 2016 by Acasti's parent company, Neptune Technologies & Bioresources Inc. ("Neptune"), the Corporation has pledged an amount of \$2 million dollars in favour of the lender financing the said transaction. Consequently, the corresponding amount shall be considered as restricted cash until release by the lender or reduced by Neptune.

Also, as previously disclosed, Acasti has decided to find strategic alternatives for Onemia® and focus its energy and resources on the development of CaPre®.

Consequently, in connection with the aforesaid transaction, the Corporation entered into a non-exclusive licensing agreement with Neptune in which Neptune will engage on a best commercial efforts basis to market Onemia®. Acasti will receive a royalty of 17.5% on net sales of Onemia®. Given Neptune's sales and marketing leadership in the krill oil space, Acasti believes that Neptune represents the best partner for Onemia®.

### **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 Adjusted EBITDA (Earnings 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 Adjusted EBITDA 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 adjusted EBITDA may differ from that used by other corporations.*

*Acasti obtains its Adjusted EBITDA measurement by adding to net loss, finance costs, depreciation and amortization 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 Adjusted EBITDA 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.*

### **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 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. Because krill feed on phytoplankton, it is a major source of phospholipids and omega-3 fatty acids well known to be beneficial for human health.*

### **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.*

<sup>1</sup> See "Caution Regarding Non-IFRS Financial Measures" which follows.

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

Acasti Contact:  
John Ripplinger  
Investor Relations  
+1.450.687.2262  
[j.ripplinger@acastipharma.com](mailto:j.ripplinger@acastipharma.com)  
[acastipharma.com](http://acastipharma.com)



Source: Acasti Pharma Inc.