October 11, 2016

Acasti Pharma Reports Second Quarter 2017 Financial Results

Key Developments Include New Leadership and Advancement of Drug Candidate CaPre

LAVAL, QUEBEC -- (Marketwired) -- 10/11/16 -- Acasti Pharma (NASDAQ:ACST)(TSX VENTURE:APO) today announced its operating and financial results for the second quarter of its 2017 fiscal year, which ended August 31, 2016. All amounts are in Canadian dollars.

"During our second fiscal quarter, we continued to improve our business operations while simultaneously building the value of our drug candidate CaPre® by advancing it towards late-stage development," said Jan D'Alvise, president and CEO of Acasti Pharma. "Last month we reported positive results from our bridging study and believe the data supports the 505(b)(2) regulatory pathway chosen by Acasti to gain U.S. marketing approval of CaPre for the treatment of patients with severe hypertriglyceridemia. We look forward to working with the FDA to confirm the pathway and optimize the design of our Phase 3 program, which we expect to begin before the end of next year."

Second Quarter 2017 and Year-to-Date Financial Results (1)

- ***Research and development (R&D) expenses*** were $1.6 million for the second quarter, down from $1.7 million in the second quarter of fiscal 2016. For the first six months of fiscal 2017, R&D expenses were $4.0 million, an increase from $3.6 million for the same period last year, attributed to increased expenses for the bridging study and Phase 3 study preparations.
- ***General and administrative (G&A) expenses*** were $0.9 million for the second quarter, up from $0.5 million in the second quarter of fiscal 2016. For the first six months of fiscal 2017, G&A expenses were $1.4 million, an increase from $1.1 million for the same period last year. The current year's higher G&A expenses are attributed to increases in consulting services, business development activities, and compensation.
- ***Non-IFRS operating loss*** (2) was $1.6 million for the second quarter, compared to $1.5 million in the second quarter of last year. For the first six months of fiscal 2017, the Non-IFRS operating loss was $3.9 million, an increase from $3.4 million for the same six-month period of last year.
- ***Net loss*** was $2.3 million or $0.22 loss per share for the second quarter, compared to a net loss of $1.2 million or $0.12 loss per share in the second quarter of last fiscal year. Net loss was $5.5 million or $0.51 loss per share for the first six months of fiscal 2017, compared to a net loss of $2.2 million or $0.21 loss per share for the same period of the last fiscal year. The higher net loss for the current quarter reflects the $0.4 million increased G&A expenses combined with a decrease of $0.9 million in

foreign exchange gain for the current year, offset by the $0.1 million decreased R&D expenses in the current year. The higher net loss for the current six-month period was primarily based on the increased R&D and G&A expenses, as well as a $1.6 million incremental decreased value of derivative warrant liabilities, and a $1.1 million change from a foreign exchange gain last year to a foreign exchange loss in the current year.
- ***Cash and short-term investments*** of $8.1 million as of August 31, 2016 including $1.0 million in restricted short-term investments fully released on September 20, 2016.

Cash Flows

With cash and short-term investments of $8.1 million as of August 31, 2016, 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.

Key Developments

- On September 14, 2016, Acasti announced positive data from its bioavailability study that compared CaPre (omega-3 free fatty acid/phospholipid composition) with the approved hypertriglyceridemia drug LOVAZA (omega-3-acid ethyl esters) in healthy volunteers. The study met its primary objective and demonstrated that the levels of omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), following administration of CaPre did not exceed the levels following administration of LOVAZA in subjects who were fed a high-fat meal. In addition, among subjects in the fasting state, CaPre demonstrated better bioavailability than LOVAZA, as measured by blood levels of EPA and DHA. The study results are expected to support Acasti's plan to request authorization to use the FDA's 505(b)(2) pathway, enabling the company to streamline its development program required to support a New Drug Application (NDA) by relying on the safety data of an approved drug.
- Acasti appointed Jan D'Alvise as president and chief executive officer effective June 1, 2016. D'Alvise is an accomplished executive with experience in large, public multi-national companies, as well as in private start-ups in the life sciences industry. Her track-record includes leadership roles across the enterprise life-cycle, from start-up to commercialization and growth.
- A new board of directors was elected at the Annual and Special Meeting of Shareholders in July, including D'Alvise, Jean-Marie (John) Canan, Roderick N. Carter, James S. Hamilton, and Leendert H. Staal.
- Acasti initiated the process leading to the cGMP manufacturing of CaPre for the planned Phase 3 clinical trial with qualified and experienced pharmaceutical CMO partners.
- Acasti completed primary market research with Key Opinion Leaders (KOLs) and payers to support the CaPre development and commercialization strategy.

Future Corporate Milestones

- Complete the protocol and planning of the CaPre Phase 3 clinical trial in patients with severe hypertriglyceridemia in the first half of calendar year 2017, including an End-of-Phase 2 meeting with the FDA.
- Complete the scale-up of the manufacturing process of CaPre under cGMP conditions

in the first half of calendar year 2017, and complete the production of the clinical trial product for the initiation of the Phase 3 clinical trial.
- Initiate the Phase 3 clinical study for CaPre in patients with severe hypertriglyceridemia during the second half of calendar year 2017.

About CaPre

CaPre is a novel composition of omega-3s (delivered both as free fatty acids and bound to phospholipids) sourced from krill oil. Acasti has successfully completed Phase 2 clinical trials for the treatment of hypertriglyceridemia, a very common metabolic condition in which blood levels of triglycerides, a type of lipid, are significantly elevated, posing a risk to cardiovascular health. Acasti plans to conduct a pivotal Phase 3 trial in patients with severe hypertriglyceridemia to support a New Drug Application filing for CaPre. Severe hypertriglyceridemia affects about 3 to 4 million adults in the U.S.[(3)] and is associated with an increased risk of coronary artery disease and pancreatitis and is often caused or exacerbated by uncontrolled diabetes mellitus, obesity and sedentary habits. CaPre is intended to be taken orally once per day in capsule form.

About Acasti Pharma

Acasti Pharma is a biopharmaceutical innovator advancing a potentially best-in-class cardiovascular drug, CaPre, for the treatment of hypertriglyceridemia, a chronic condition affecting an estimated one-third of the U.S. population[(4)]. The company's strategy is to initially develop and commercialize CaPre for the 3 to 4 million patients in the U.S. with severe hypertriglyceridemia. Since its founding in 2008, Acasti Pharma has focused on addressing a critical market need for an effective, safe and well-absorbing omega-3 therapeutic that can address patients' complete lipid profile, making a positive impact on the major lipids associated with cardiovascular disease risk. For more information, visit www.acastipharma.com.

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, and other non-monetary expenses), to assess its operating performance. These Non-IFRS financial measures are directly derived from the Corporation's financial statements and are presented in a consistent manner. The Corporation 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 Corporation to plan and forecast for future periods as well as to make operational and strategic decisions. The Corporation believes that providing this information to investors, in addition to IFRS measures, allows them to see the Corporation'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 in its operating performance,

and because the Corporation believes it provides meaningful information on the Corporation financial condition and operating results. Acasti's method for calculating Non-IFRS operating loss may differ from that used by other corporations.

Acasti calculates its Non-IFRS operating loss measurement by adding to net loss, finance costs, depreciation and amortization and by subtracting finance income. Other items that do not impact core operating performance of the Corporation are excluded from the calculation as they may vary significantly from one period to another. Finance income/costs include foreign exchange gain (loss) and change in fair value of derivative warrant liabilities. 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 non-recurring.

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, on EDGAR at www.sec.gov/edgar.shtml and on the investor section of Acasti's website at www.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.

RECONCILIATION OF NET LOSS TO NON-IFRS OPERATING LOSS

(Expressed in millions of dollars)

	Three-month periods ended		Six-month periods ended	
	August 31, 2016	August 31, 2015	August 31, 2016	August 31, 2015
	$	$	$	$
Net loss	(2.3)	(1.2)	(5.5)	(2.2)
Add (deduct):				
Finance costs	-	-	0.3	0.1
Finance income	-	(0.9)	(0.1)	(0.9)
Change in fair value of derivative warrant liabilities	(0.1)	-	(0.1)	(1.7)
Depreciation and amortization	0.6	0.6	1.2	1.2
Stock-based compensation	0.2	-	0.3	0.1
Non-IFRS operating loss	(1.6)	(1.5)	(3.9)	(3.4)

(1) The quarterly unaudited financial statements with footnotes and the MD&A are available on SEDAR at www.sedar.com, on EDGAR at www.sec.gov/edgar.shtml and on the investor section of Acasti's website at www.acastipharma.com.

(2) See comment on Non-IFRS financial measures and the summary table, both of which follow.

(3) Source: Am J Med. 2014, 127, 36-44

(4) Source: Datamonitor and Archives of Internal Medicine, 2009; 169(6):572-578

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