Acasti Pharma Inc

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Acasti Pharma making 'steady progress' on CaPre trials, says CEO

Acasti Pharma Inc (NASDAQ:ACST) (CVE:ACST) CEO Jan D'Alvise said that the company was making "steady progress" with the audit of its TRILOGY 1 study data of its lead drug, CaPre.

The Laval, Quebec-based company reported preliminary topline results earlier this week for the primary endpoint from its Phase 3 TRILOGY 1 trial for CaPre, an omega-3 phospholipid to treat severe hypertriglyceridemia.

Acasti reported a 30.5% median reduction in triglyceride (TG) levels among all patients receiving CaPre, compared to a 27.5% median reduction in triglyceride levels among patients receiving placebo at 12 weeks.

READ: Acasti Pharma updates on TRILOGY 1 and TRILOGY 2 Phase 3 trials of lead heart drug CaPre

Despite monitoring activities conducted throughout the TRILOGY 1 trial to ensure adherence to the protocol and identify protocol violations, Acasti said it subsequently identified some unexpected and inconsistent findings that it believes may have negatively contributed to the overall topline results.

These findings are now being further explored via a comprehensive and rigorous review of data and patient medical records by an independent team of auditors, the firm said in a statement.

"This data has been very informative, and provided we have the FDA's support, any learnings we can take from this investigation that may allow us to adjust the Statistical Analysis Plan (SAP) for TRILOGY 2, gives us a better chance of accurately reflecting the clinical value that we see in CaPre," D'Alvise told shareholders on Friday.

"As previously noted, we have confirmed that there is established precedent for the FDA accepting post-hoc analyses of study results, assuming the analyses are transparent, well justified and well supported. We are moving as quickly as possible now to complete this work and secure a meeting with the FDA."

DEEP DIVE: Acasti Pharma edging closer to commercializing CaPre as it eyes topline clinical data for Christmas

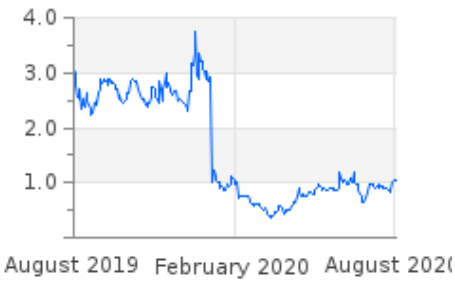
Acasti said it plans to keep TRILOGY 2 blinded until it meets with the FDA. The firm anticipates the unblinding of the topline results for TRILOGY 2 sometime in calendar Q3 of 2020, to allow time for the FDA meeting, it told shareholders.

Accordingly, key secondary and exploratory endpoints from both TRILOGY 1 and TRILOGY 2 studies, would now be expected after the unblinding of TRILOGY 2 results, D'Alvise said. "We are moving as quickly as possible and will provide material updates when available."

The firm also reported its fiscal 3Q 2020 results showed a cash balance of C$25.7 million, which is expected to fund ongoing study investigations.

Price:	1.05
Market Cap:	$97.11 m

1 Year Share Price Graph



Share Information

Code:		ACST
Listing:		TSX-V
52 week	**High**	**Low**
	4.05	**0.35**
Sector:		**Pharma & Biotech**
Website:		**www.acastipharma.com**

Company Synopsis:

Acasti is a biopharmaceutical innovator focused on the research, development and commercialization of prescription drugs using omega-3 fatty acids derived from krill oil. Omega-3 fatty acids have extensive clinical evidence of safety and efficacy in lowering triglycerides in patients with hypertriglyceridemia.

action@proactiveinvestors.com

Net loss for the period was C$15.7 million or C$0.18 per share, compared to a net loss of C$4.6 million or C$0.07 per share for the quarter ended December 31, 2018. According to Acasti, the higher net loss was primarily due to the non-cash financial loss of C$7.9 million for the three months ended December 31, 2019, due mostly to the change in the fair value of the warrant derivative liability, partially offset by a decrease in the number of warrants.

Contact Angela at angela@proactiveinvestors.com

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Contact us +44 (0)207 989 0813 action@proactiveinvestors.com

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