

Organovo Holdings Inc.

14:25 23 May 2019

Organovo tumbles after fiscal 4Q revenue miss, extended timeline for liver tissue program

Organovo Holdings Inc (NASDAQ:ONVO) stock tumbled Thursday after the company's fiscal fourth-quarter earnings showed a decline in revenue driven by lower products and services revenue.

Investors also knocked the shares down about 11% as Organovo indicated more preclinical work had to be done before it could submit its first investigational new drug application for its 3D-bioprinted liver tissue program.

"We've determined that we need to conduct additional preclinical studies, optimize our manufacturing processes, and most importantly generate decisive scientific data regarding the prolonged functionality and therapeutic benefits of our liver tissue patch," said Organovo Holdings CEO Taylor J Crouch.

READ: Organovo expects FDA meeting in 2019 on 3D-bioprinted tissues for liver disease treatment
As a result, Crouch said preclinical development will be extended into calendar 2020.

"Consequently, we now expect to have our pre-IND meeting with the FDA in calendar 2020, rather than the latter part of this calendar year," disclosed Crouch. "This change in our timeline also pushes the start of our IND-enabling studies back, with our revised plan now supporting an IND submission and the start of first-in-human trials in calendar 2021."

The San Diego biotechnology company is pioneering the development of 3D bioprinted tissues aimed at treating a range of serious adult and pediatric liver diseases.

The company's Phase 1 trial will target patients with end-stage liver disease, and subject to favorable outcomes, Organovo will explore NovoTissues benefits in one or more metabolism disease such as Alpha-1 antitrypsin deficiency, which is an inherited disorder that may cause lung disease and liver disease. The company may also study its product as a bridge-to-transplant.

Well-funded till IND submission

As of March 31, the company had cash and cash equivalents of \$36.5 million. Organovo expects a net cash utilization rate of \$20 million to \$22 million in fiscal 2020, and believes it has sufficient funds, to meet its operating and capital requirements through its forecasted IND submission in calendar 2021.

The company posted a net loss of \$7 million, a \$0.5 million improvement over the year-ago period, as expenses declined 10% primarily due to lower employee costs.

Total revenue was \$0.7 million, a 38% decrease from the year-ago period, primarily driven by lower products and services revenue.

Price: 0.4826

Market Cap: \$62.95 m

1 Year Share Price Graph



November 2018 May 2019 November 20

Share Information

Code: ONVO

Listing: NASDAQ

52 week	High	Low
	1.175	0.2211

Sector: Health

Website: organovo.com

Company Synopsis:

Organovo design and creates functional human tissues using our proprietary three-dimensional bioprinting technology. Our goal is to build living human tissues that are proven to function like native tissues.

action@proactiveinvestors.com

Contact Uttara Choudhury at uttara@proactiveinvestors.com

Follow her on Twitter: [@UttaraProactive](https://twitter.com/UttaraProactive)

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts, journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

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

No investment advice

The Company is a publisher. You understand and agree that no content published on the Site constitutes a recommendation that any particular security, portfolio of securities, transaction, or investment strategy is suitable or advisable for any specific person. You understand that the Content on the Site is provided for information purposes only, and none of the information contained on the Site constitutes an offer, solicitation or recommendation to buy or sell a security. You understand that the Company receives either monetary or securities compensation for our services. We stand to benefit from any volume which any Content on the Site may generate.

You further understand that none of the information providers or their affiliates will advise you personally concerning the nature, potential, advisability, value, suitability or profitability of any particular security, portfolio of securities, transaction, investment, investment strategy, or other matter.

You understand that the Site may contain opinions from time to time with regard to securities mentioned in other products, including Company-related products, and that those opinions may be different from those obtained by using another product related to the Company. You understand and agree that contributors may write about securities in which they or their firms have a position, and that they may trade such securities for their own account. In cases where the position is held at the time of publication and such position is known to the Company, appropriate disclosure is made. However, you understand and agree that at the time of any transaction that you make, one or more contributors may have a position in the securities written about. You understand that price and other data is supplied by sources believed to be reliable, that the calculations herein are made using such data, and that neither such data nor such calculations are guaranteed by these sources, the Company, the information providers or any other person or entity, and may not be complete or accurate.

From time to time, reference may be made in our marketing materials to prior articles and opinions we have published. These references may be selective, may reference only a portion of an article or recommendation, and are likely not to be current. As markets change continuously, previously published information and data may not be current and should not be relied upon.

The Site does not, and is not intended to, provide investment, tax, accounting, legal or insurance advice, and is not and should not be construed as providing any of the foregoing. You should consult an attorney or other relevant professional regarding your specific legal, tax, investment or other needs as tailored to your specific situation.