

Organovo Holdings Inc.

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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: 0.4367

Market Cap: \$56.96 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.

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