



# Company Presentation

November 2022

# Forward-Looking Statements

Certain statements contained in this presentation or in other documents of Organovo Holdings, Inc. (the “Company” or “Organovo”) and of any of its affiliates, along with certain statements that may be made by management of the Company orally in presenting this material, are or may be considered “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995. These statements can be identified by the fact that they do not relate strictly to historic or current facts. They use words such as “estimate,” “expect,” “intend,” “believe,” “plan,” “anticipate,” “potential,” “projected” and other words and terms of similar meaning in connection with any discussion of future operating or financial performance or condition. Organovo cautions that these statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties.

Statements regarding future action, future performance and/or future results may differ from those set forth in the forward-looking statements. Market size estimates have been determined on the basis of market research and comparable product analysis, but no assurances can be given that such market size estimates will prove accurate.

# Forward-Looking Statements (con't)

Because actual results are affected by potential risks, contingencies and uncertainties, the Company cautions investors that actual results may differ materially from those expressed or implied in any forward-looking statement. The Company assumes no obligation to update forward-looking statements as circumstances change. Investors are advised to consult further disclosures that the Company makes or has made on related subjects in the Company's most recent periodic reports filed with the Securities and Exchange Commission, including Organovo's Annual Report on Form 10-K for the year ended March 31, 2022 and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, including the risk factors set forth in those filings.

In presenting this material or responding to inquiries in connection with a presentation, management may refer to results, projections or performance measures that are not prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") as reported in the Company's SEC filings. These results, projections or performance measures are non-GAAP measures and are not intended to replace or substitute for results measured under GAAP and are supplemental to GAAP reported results.



**Custom Disease Models Using 3D Bioprinting**

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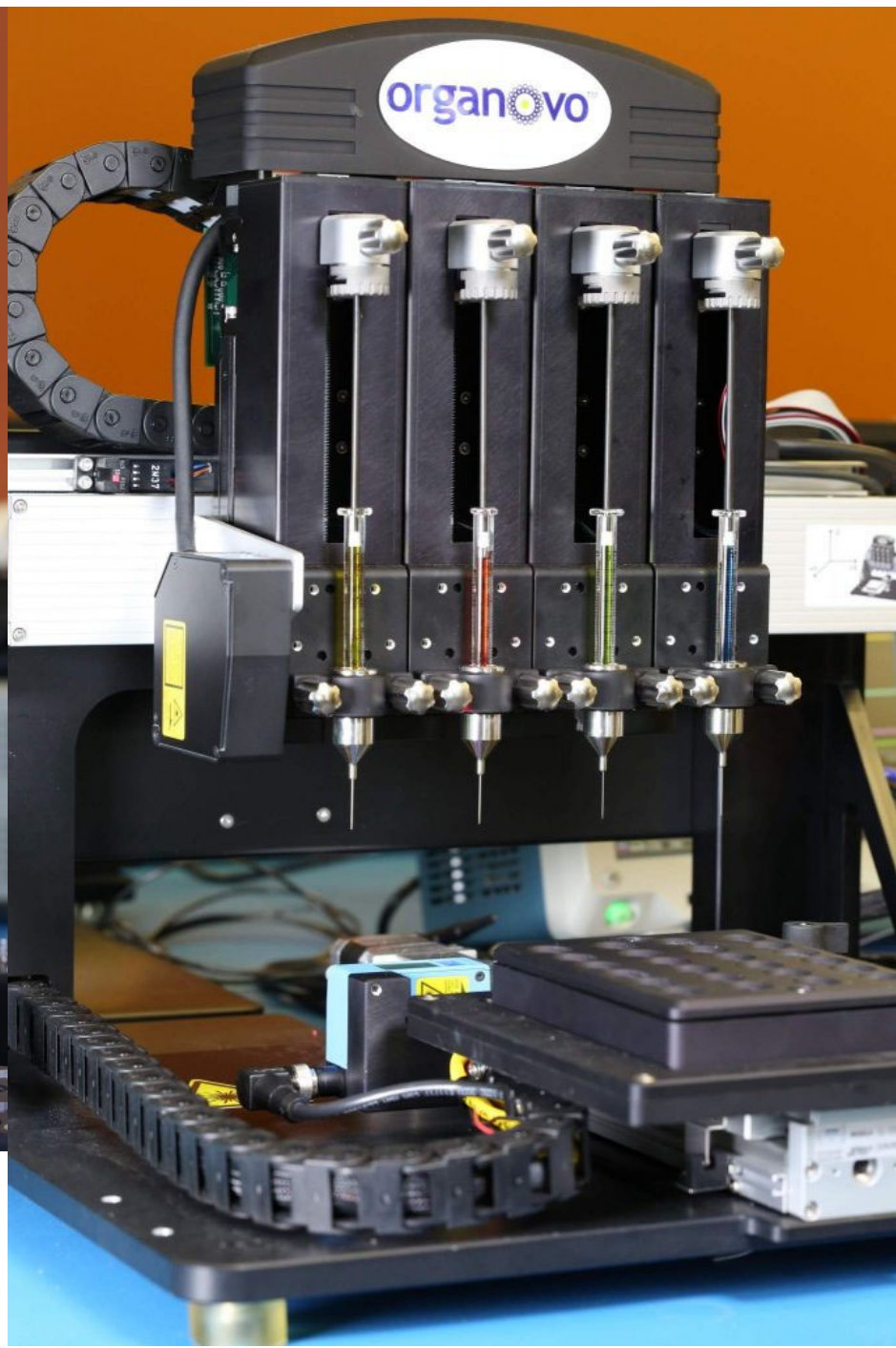
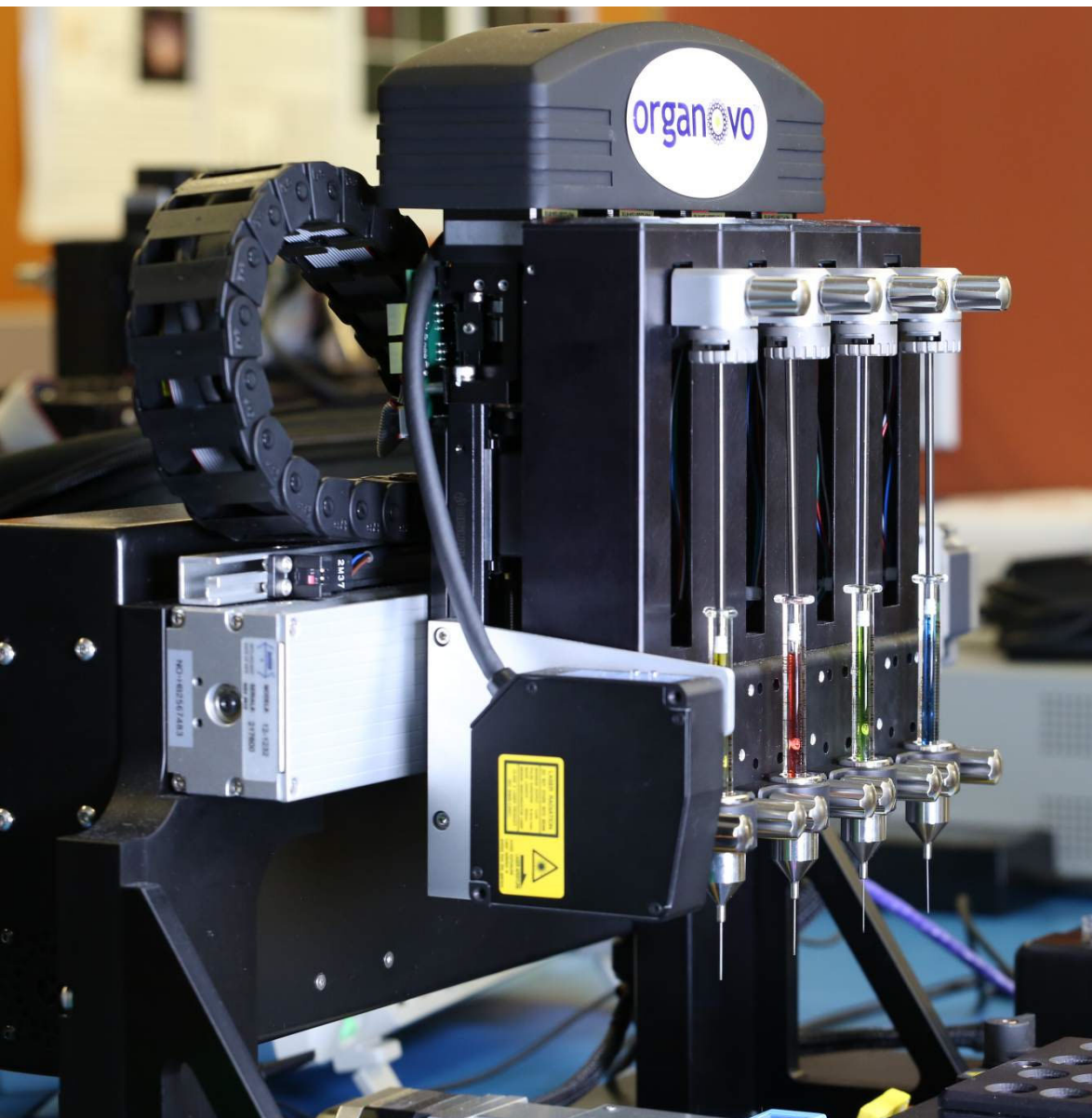
**First Opportunity: Inflammatory Bowel Disease**

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**Goal of Multiple INDs by End of 2025**

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Replacing animal models with 3D  
bioprinted human disease models



# Drug Discovery in 3D



# Animal Testing – The Problem

- 92% of drugs fail during clinical trials
- 50% of those failures are due to human-animal gap
- Treatments show potential cure in rodents but fail in human clinical trials
- “We test them [drugs] on animals, and it’s not reliable... Ultimately, the ability to develop and test medicines will be you on a chip” — Francis Collins, NIH Director, at TEDMED, discussing the challenges with animal models and the new developments in 3D tissue models

Arrowsmith, J., Miller, P. *Nat Rev Drug Discov* **12**, 569 (2013).

# Moving Past the Animal Testing Paradigm

- Our 3D Bioprinted tissues offer a **fully human** system that shows better biology
- Strategy – Organovo is advancing novel drugs discovered with 3D tissues
- Biotech therapeutics company – We will advance drugs to clinical trials, building investor value by:
  - Advancing drugs to IND and clinical trials
  - Developing pharma partnerships



# 3D Tissues Allow for Better Biology

- Minimizes plastic interaction
- More relevant cell-cell interaction
- Four or more cell types



- Cells in full contact with plastic
- One or two cell types



# After Initial Target Discovery, Our Drug Development Parallels Normal Steps of Pharma Drug Development

The Benefits of 3D Human Tissues Apply Across the Range of Drug Development Steps

Target  
Selection

Lead  
Discovery

Medicinal  
Chemistry

In Vitro  
Studies

In Vivo  
Studies

Clinical  
Trials



Increasing Value for Investors

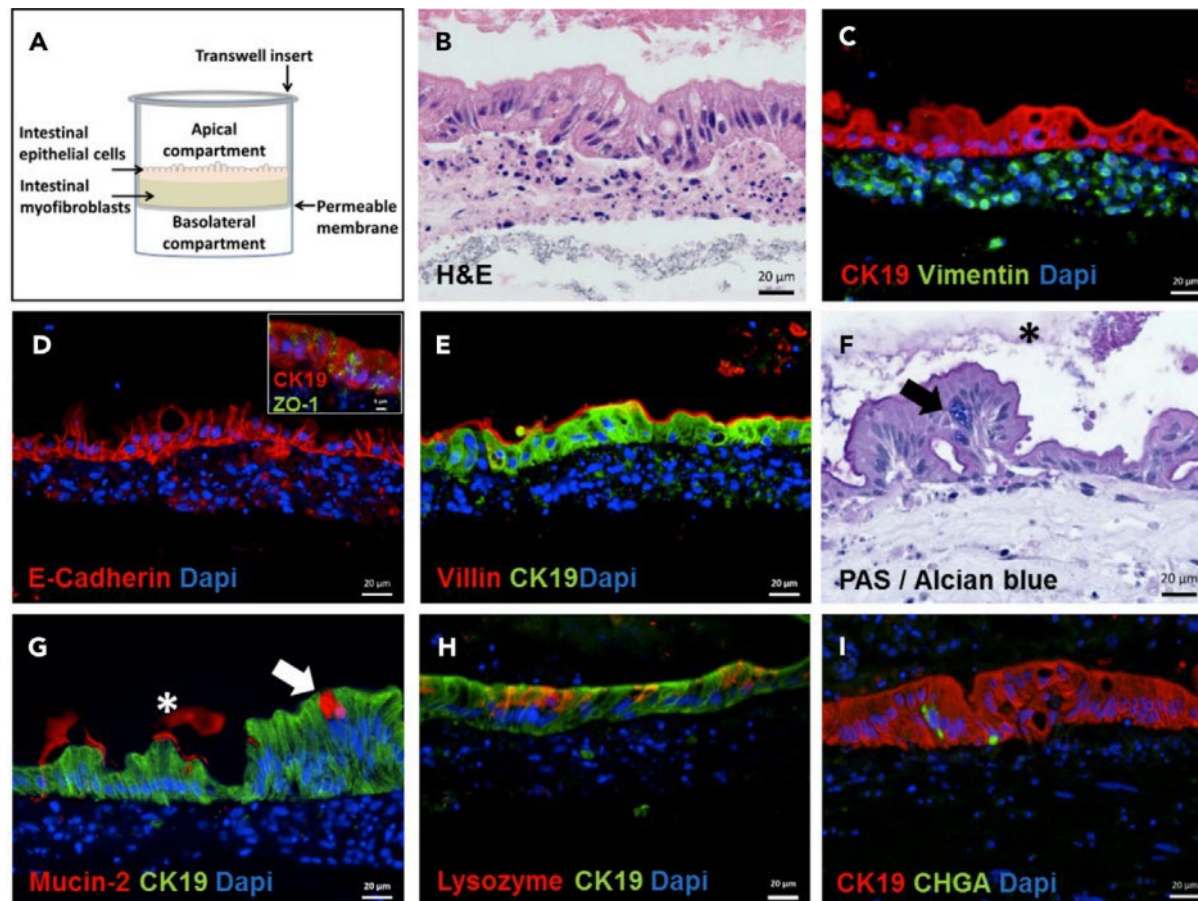


## Areas of Opportunity in 3D



# First Opportunity: Crohn's and Ulcerative Colitis Using 3D Models – Inflammatory Bowel Disease (IBD)

Organovo can create accurate 3D tissue models for IBD



# IBD Market is Attractive Commercially

- 15.5B market globally by 2026<sup>1</sup>
- Projected 6% CAGR<sup>2</sup>
- Treatments offer value for patients but considered to be strong opportunity for improvement
- Main treatments today: TNF inhibitors, aminosalicyclates, integrin antagonists, and corticosteroids

<sup>1</sup>Grandviewresearch market analysis report on Inflammatory Bowel Disease Treatment By Type (Ulcerative Colitis, Crohn's Disease), By Route of Administration, By Distribution Channel, And Segment Forecasts, 2019 - 2026

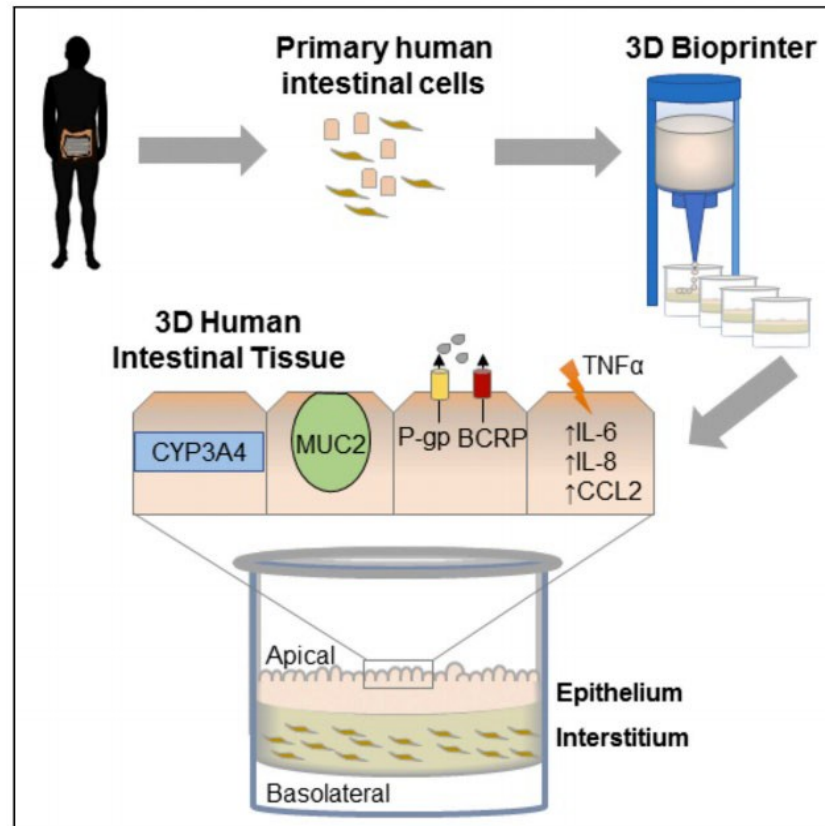
<sup>2</sup>Transparency Market Research report on the IBD (ulcerative colitis and Crohn's disease) treatment market for the forecast period of 2019–2027.



## 3D Toolkit



Organovo uses multiple 3D technologies to maximize fidelity with human disease to identify and drug validated targets



By careful selection of cells, handling during processing, conditions during culture, we believe the disease can be reproduced “in a dish”

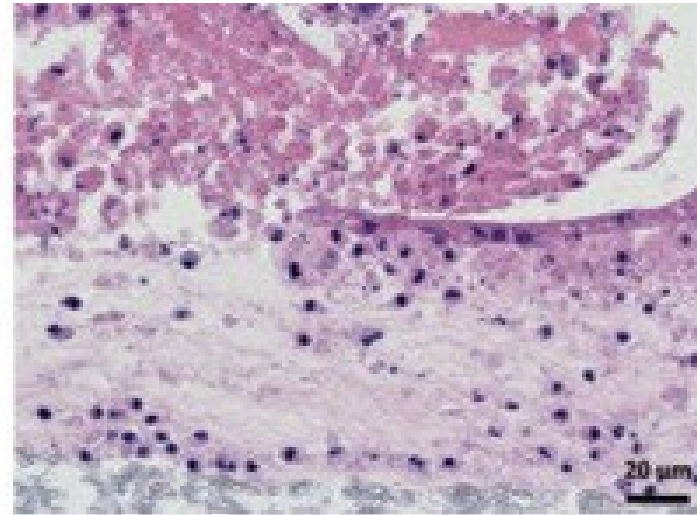


# Organovo's 3D Tissues Model IBD

# Organovo's intestinal modeling efforts already have demonstrated solid results



Bioprinted control intestine



Bioprinted diseased model

## **“Bioprinted 3D Primary Human Intestinal Tissues Model Aspects of Native Physiology and ADME/ Tox Functions”**

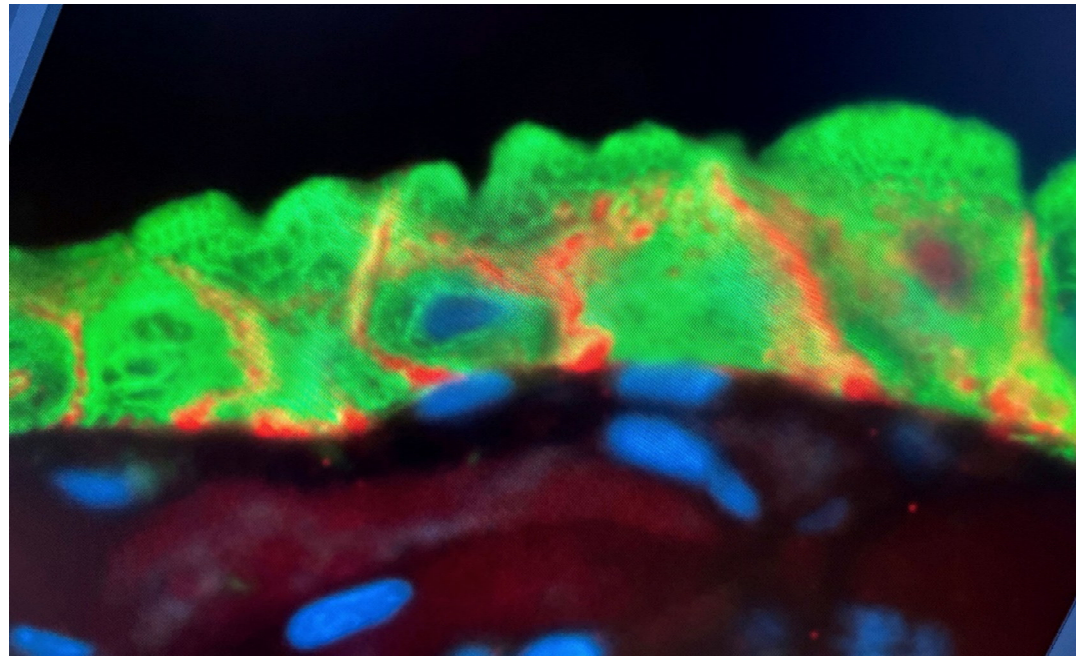
Lauran R. Madden, Theresa V. Nguyen, Salvador Garcia-Mojica, ..., Sharon C. Presnell, Deborah G. Nguyen, Kelsey N. Retting

*iScience* 2, 156–167, April 27, 2018

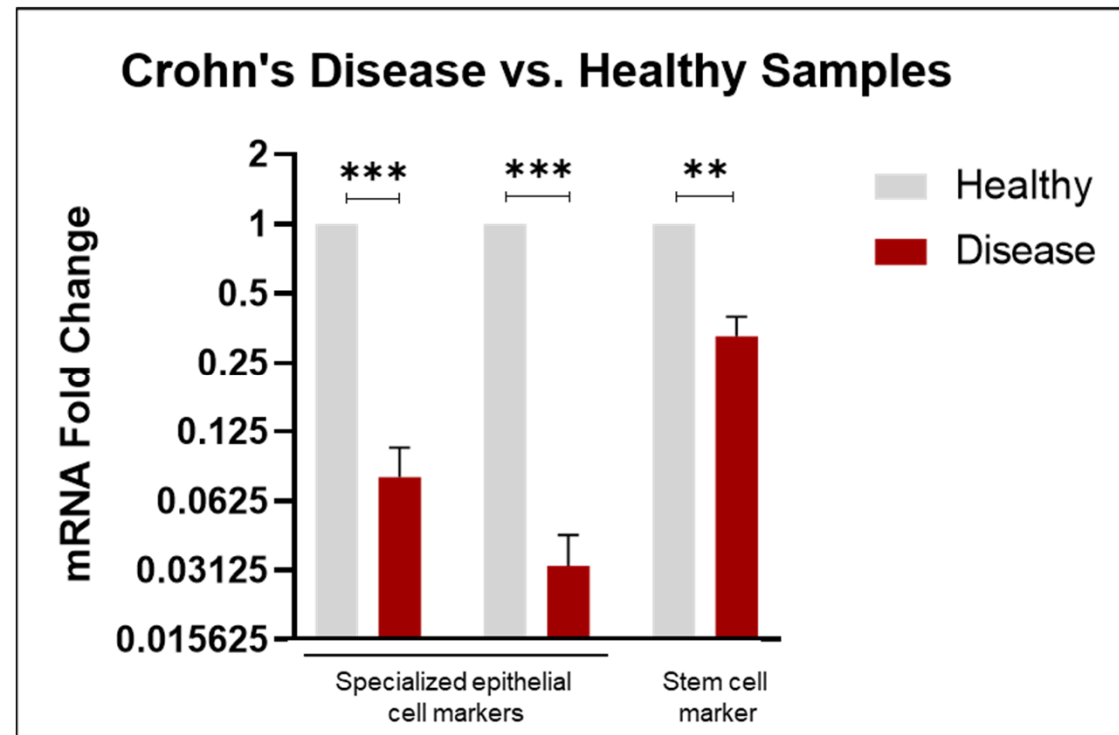


# Epithelial layer forming in 3D cultures of diseased and healthy intestinal cell donors

- Polarized epithelium
- Tight junctions
- Specialized epithelial cell types
- Expresses functional, inducible CYP450 enzymes
- Physiological barrier function
- Functional P-gp and BCRP transporters.

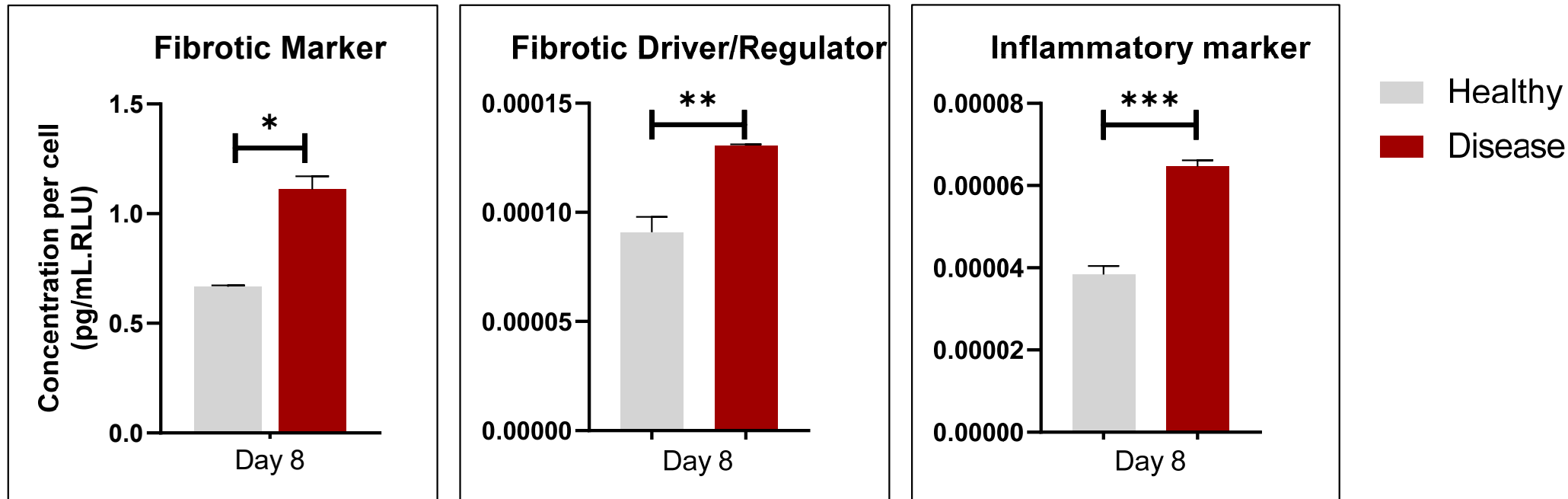


# Epithelial gene expression profiles in disease and healthy 3D models closely mimic the subjects profiles



- Markers of epithelial cell damage in Crohn's disease are lower in our model
- This matches what happens in the diseased human intestine

# 3D models built from IBD patients secrete a higher level of fibrotic and inflammatory markers than healthy samples



- Markers of fibrosis and inflammation are higher in our model
- This matches what happens in the diseased human intestine





# Value Proposition

# Moving drugs towards the clinic is a major valuation driver

- Disease Model Building in Inflammatory Bowel Disease, Crohn's Disease (CD) and Ulcerative Colitis (UC)
  - 2022 ([first CD model advanced May 2022](#))
- Target Validation and Selection
  - 2022
- Screening and Lead Compound Selection
  - 2023
- Investigative New Drug (IND) Enabling Studies
  - 2024
- IND Filings with FDA
  - 2024-2025
- Clinical trials (Crohn's Disease and/or Ulcerative Colitis)
  - 2025



Increasing Value for Investors

# We have opportunities for pharma partnerships as added valuation catalyst

- Disease Model Building
  - 2022
- Target Validation and Selection
  - 2022

## We Expect to be able to do Pharma Partnerships on Targets

- Pharma partner pays up front and milestones
- Pharma partner owns molecule, pays royalty to us
- Pharma partner does chemistry to select drug
- Organovo supports all chemistry and development with 3D models

# Significant Potential Impact of 3D Human Disease Models Overall

- Clinical trial overall failure rate is >92%
- Many of the failures are due to use of animals in testing not
- Largest cause of failure in Phase 2-3 is Efficacy issues
- Our approach addresses those issues, promises potential for greater chance of clinical trial success

Causes of Phase 2/3 failure



Arrowsmith, J., Miller, P. *Nat Rev Drug Discov* **12**, 569 (2013).



# Stock and Financial Information

## Stock & Financial Information

### Share & Stock Price Summary

Ticker	Nasdaq: ONVO
Shares Outstanding	8.71 M
Avg Daily Volume	85,245
52-Week Range	\$1.50 - \$6.11
Year End	March 31st

### Financial Summary

Cash (as of 9/30/22)	\$13.3 M
ST Investments (as of 9/30/22)	\$9.9 M
Cash Burn (6 mos. ended 9/30/22)	\$4.6 M
Debt	None

# Thank You!

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