



Company Presentation

December 2023

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.

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, 2023 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.



**Advancing FXR Agonist for Inflammatory Bowel
Disease (IBD)**

Ulcerative Colitis Phase 2a POC complete 1H2025

Pipeline Summary

- Organovo has an FDA clinical trial authorization for a Phase 2 trial in ulcerative colitis for its lead therapeutic molecule FXR314.
- Organovo is also advancing FXR314 for the treatment of other Inflammatory Bowel Diseases including Crohn's Disease as well as diseases of the Liver including NASH and Primary Biliary Cholangitis.
- Organovo is planning to begin medicinal chemistry in 2023 to create a novel drug for another, as yet undisclosed, target. The target was validated in our 3d tissue models of Crohn's disease. We expect the drug created to have an IND by the end of 2025.

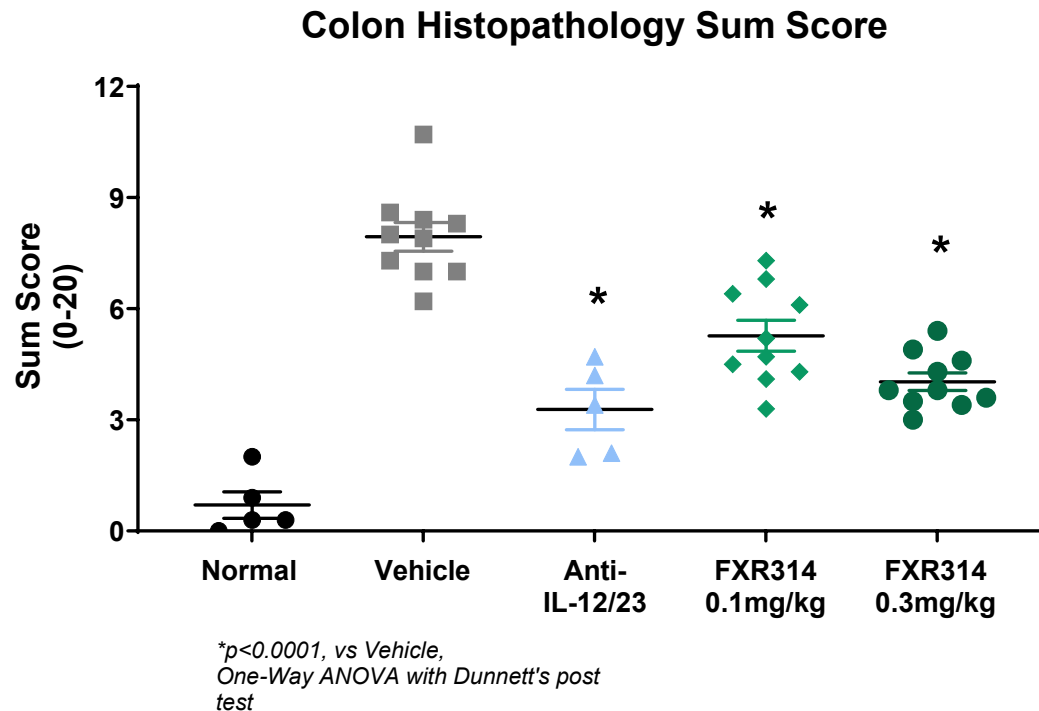


Summary of Investment Thesis

- Lead asset with strong target and drug preclinical support
- Strong differentiation within IBD, where unmet need persists
 - New mechanism, complementary to approved therapies
 - Oral once daily with high potency
- Ulcerative colitis Phase 2a POC result expected 1H2025
- FXR314 effective in 3d human models, showing improvement of intestinal epithelium in cells of UC
- Higher chance of success in Ph2 due to 3d human model results

FXR314 Improves Colitis Similarly to Approved Ulcerative Colitis Therapies

- FXR314 dose-dependently improves measures of ulcerative colitis in an adoptive T-Cell transfer model
- Effects are similar to current approved drug treatments



FXR314 Has Excellent Tolerability Profile within FXR Agonists

	FXR314 3 mg	FXR314 6 mg	FXR125 50 mg	FXR125 80 mg	Ocaliva 25 mg	EDP- 305 2.5 mg	Cilofexor 100 mg	Tropifexor 0.2 mg
Overall pruritus rate	5%	5%	16%	40%	51% (72 wk)	47%	≥14% (24 wk)	53%
Pruritus-related treatment discontinuation	0%	0%	0%	10%	9% (72 wk)	21%	2% (24 wk)	6%
Potency EC50 (nM)	2-5		16		99	8	43	0.2

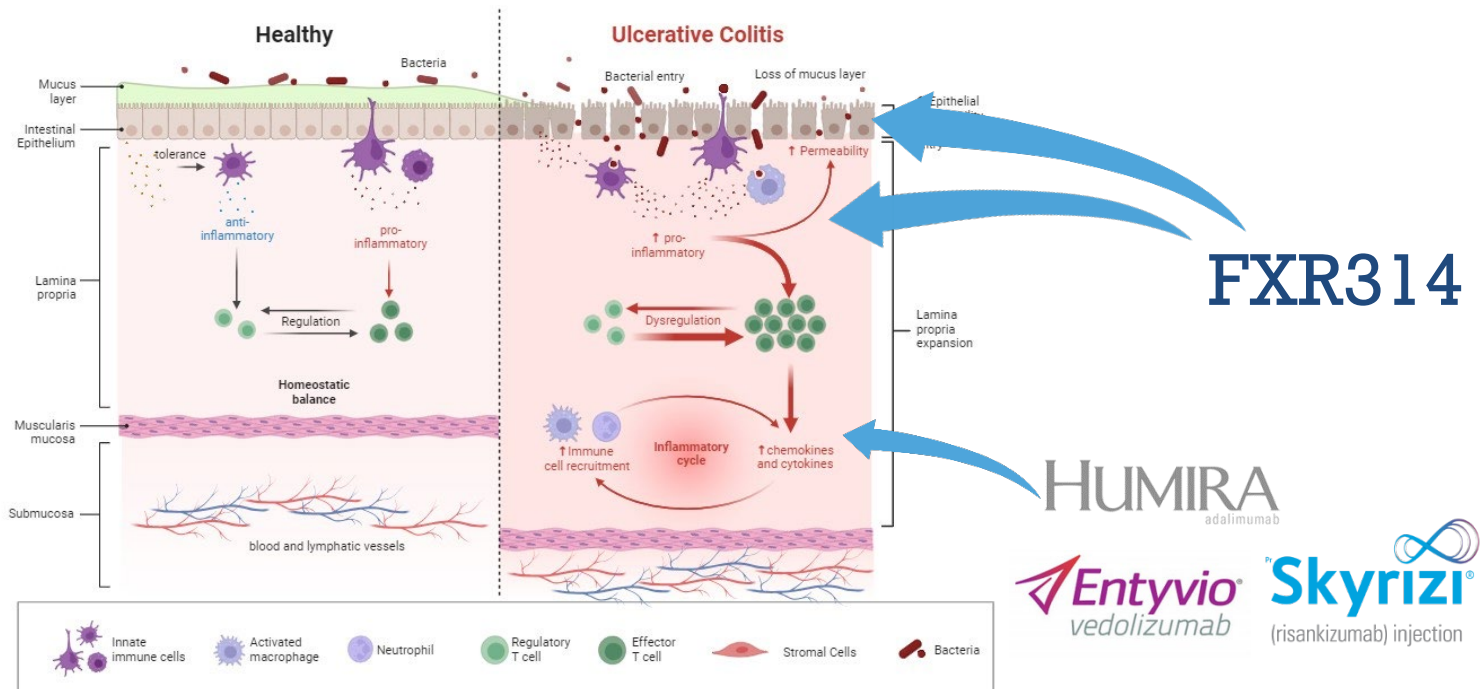
- FXR314 has excellent potency and specificity
- Specific to FXR, does not act as a bile acid, like Ocaliva (OCA) and some others
- Higher potency and specificity to FXR get around OCA liver tox concern

FXR314 Phase 2a Trial in Ulcerative Colitis

Open label study to demonstrate promise

- Target enrollment of 35 patients
- FXR314 6mg
- 12 weeks of treatment
- Diagnosis of moderate to severe UC \geq 3months prior to screening defined by clinical and endoscopic evidence
- Primary objective: improvement in UC severity and symptoms via the modified Mayo score (mMS)
- Clinical remission 25%+ targeted
- Initiating enrollment 2Q 2024
- Study readout 2Q 2025

FXR314 MoA Linked to Epithelial Repair, Upstream of Anti-inflammatory Treatments



- Potential to achieve priority utilization over anti-inflammatory therapies
- Epithelial repair would negate cytokine release
- Preference for safety (no immunosuppression) & convenience (oral once daily)

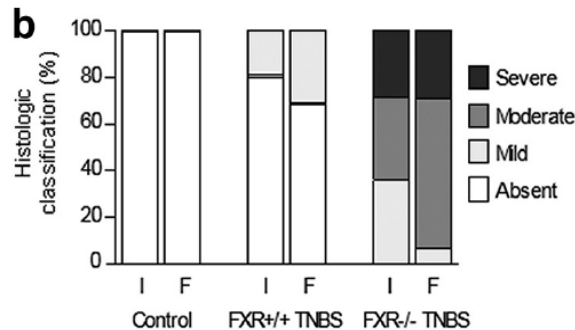


FXR314 Preclinical Support

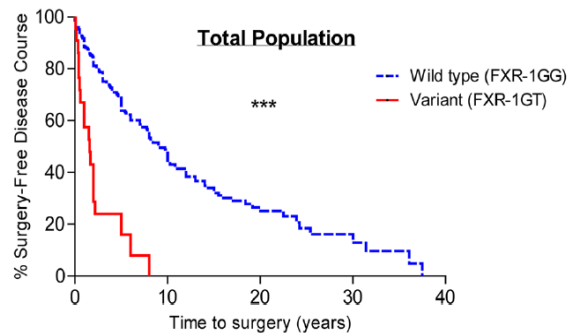
Evidence for a Role of FXR Agonism in Inflammatory Bowel Disease (IBD)

- FXR is a nuclear hormone receptor critical for maintaining bile acid, lipid and intestinal homeostasis
- Studies in null mice demonstrate a protective role of FXR in IBD
- FXR SNP associated with IBD
 - FXR SNP rs56163822 (FXR-1G->T) leads to reduced protein expression
 - Patients with Crohn's disease (CD) carrying the FXR-1G->T variant exhibit greater disease severity and earlier progression to surgery
- The biomarker of intestinal FXR activity, FGF-19, is reduced in CD patients

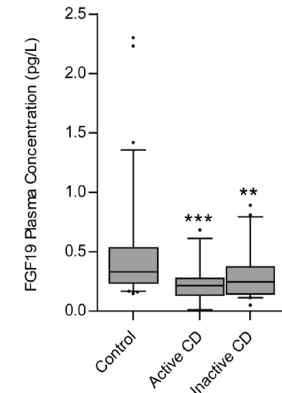
FXR protects mice from TNBS-induced colonic inflammation



FXR variant causes increased disease severity

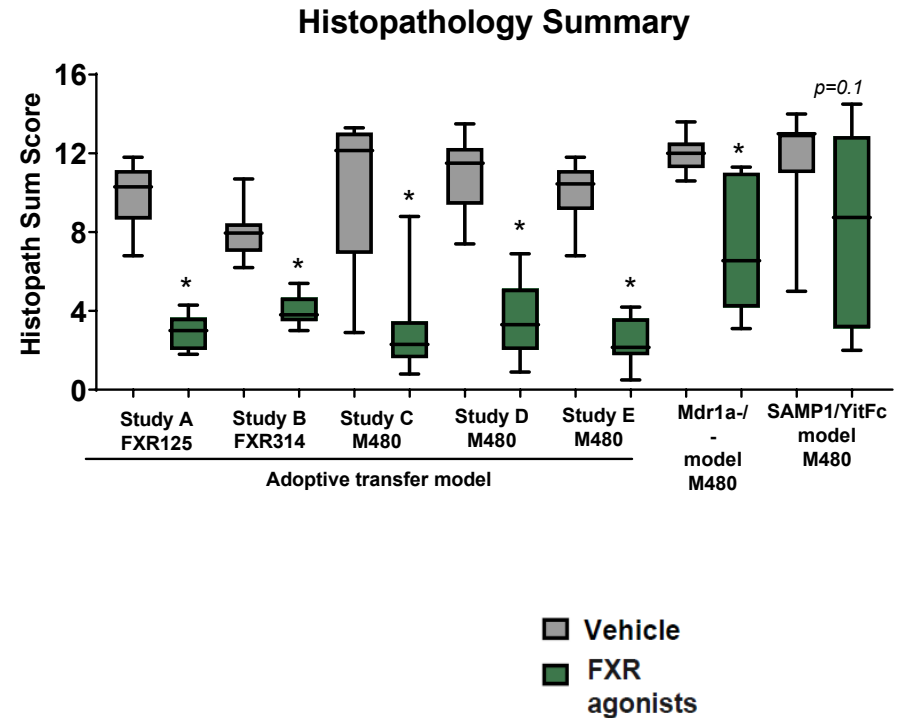


Biomarker of FXR activity reduced in CD patients



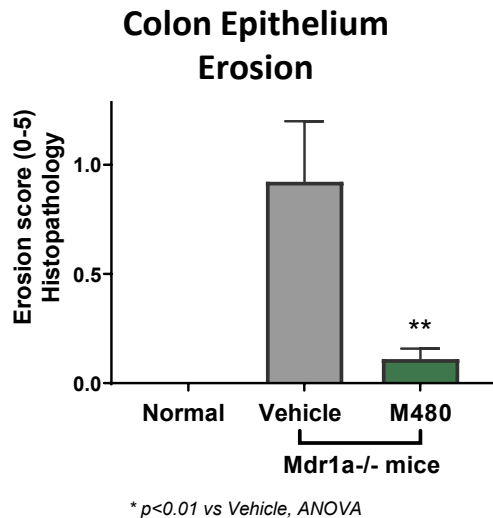
FXR314 and Analogs Improve Colitis in Multiple Chronic IBD Models

- Efficacy demonstrated in various chronic IBD models of different modalities
- All studies conducted in treatment mode
- Adoptive transfer model: colitis triggered by abnormal T-cell activation
- Mdr1a null model: colitis triggered by disrupted gut barrier function
- SAMP1/YitFc model: spontaneous Crohn's disease-like ileitis



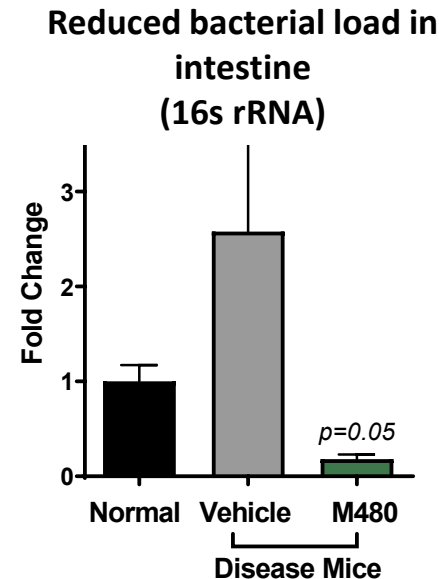
FXR Agonists Improve intestinal lining

Protection of intestinal barrier



Mdr1 null colitis model

Direct anti-bacteria effects



adoptive T-Cell transfer model

Market Opportunities for FXR 314

Ulcerative Colitis (UC)

- 13 M prevalent cases of UC globally in 2022, 2.1 M in NA ¹
- Global market size in 2021 \$6.6B²
- Anticipated to reach \$12 billion by 2032, growing steadily at a CAGR of 6.0%²
- Driven by the increasing prevalence of ulcerative colitis, and introduction of several new therapies

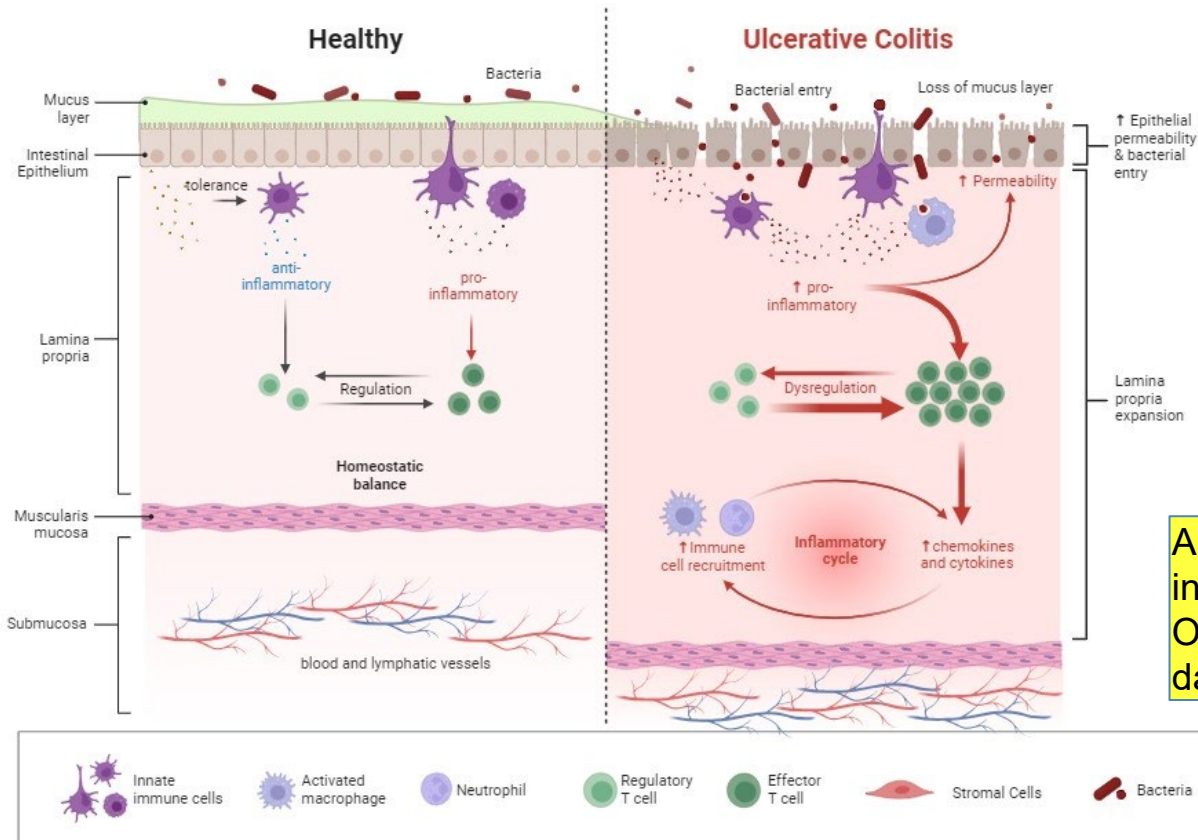
¹ iHealthcareAnalyst, Inc.

² Future Market Insights



Organovo's 3D Human Inflammatory Bowel Disease Model and the Path to FXR314

IBD Is Characterized by Epithelial Barrier Breakdown and Inflammatory Response



- Intestinal epithelium damage
- Gaps between epithelial cells
- Bacterial ingress into tissue
- Inflammatory response
- Cytokine release, T cell recruitment

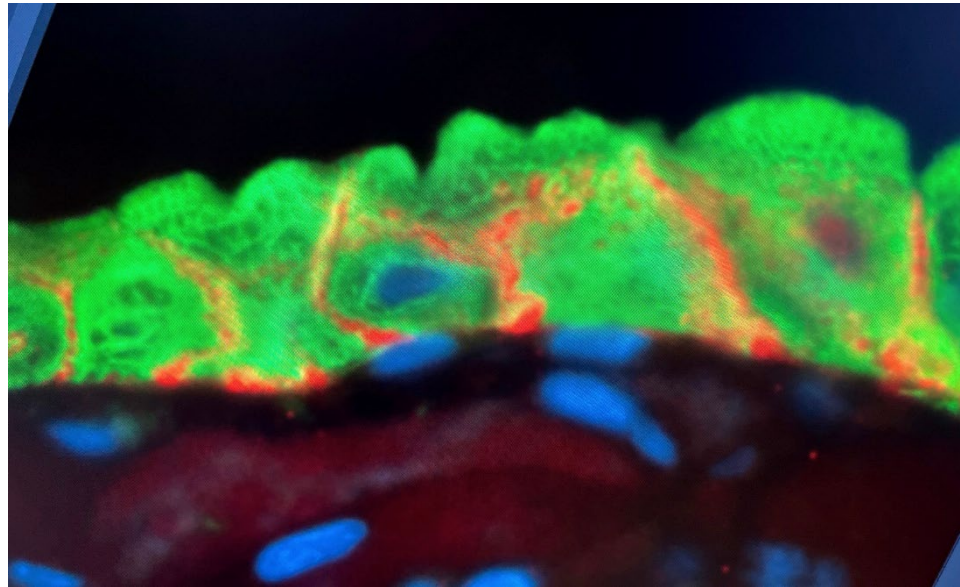
Approved treatments address the inflammatory response, but Organovo seeks to avoid epithelial damage, work earlier in disease

Organovo 3D Disease Models Can Enable Better Clinical Outcomes

- Organovo creates exceptional 3D models using bioprinting and other 3D tissue technologies
- 3D Tissue models created with cells taken directly from patients (UC or CD patients, biologic naïve or exposed, varying disease severity)
- Models can be used to test compounds, siRNA, etc. to validate targets or study drug effects
- Testing broad donor sets from a biobank allows us to understand population response to a drug or to target modulation

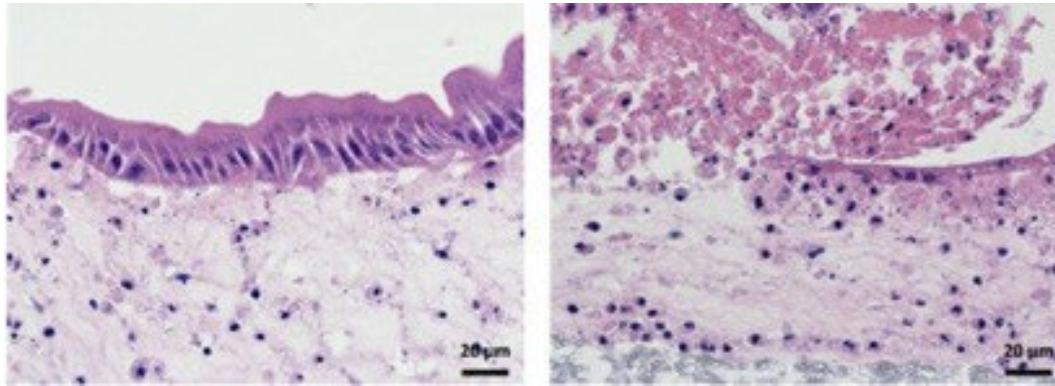
3D Tissue Intestinal Wall Model Has Accurate Structure with Intact Epithelium

- Polarized epithelium
- Interstitial layer with sm. muscle, fibroblast, capillaries
- Tight junctions – cadherin (orange)
- Specialized epithelial cell types
- Expresses functional, inducible CYP450 enzymes
- Physiological barrier function
- Functional P-gp and BCRP transporters



Tissue consists of human primary epithelial, sm. muscle, fibroblast, endothelial cells, either from healthy donor (shown) or diseased

3D tissue from diseased donor cells correctly demonstrates disease phenotype



Healthy donor cells

Diseased cells

- Our ability to see the earliest changes in the intestinal epithelial lining in the model led us to see value of FXR agonism in our tests
- FXR314 significantly reduces epithelial disruption in 3D disease donor model
- FXR314 similarly reduces epithelial disruption in preclinical animal models (Slide 11)
- Prevention of bacterial ingress and cytokine release, acts earlier in disease course
- May prevent need for inflammatory cytokine blockade, resulting in superior safety

Stock and Financial Information

Stock & Financial Information

Share & Stock Price Summary

Ticker	Nasdaq: ONVO
Shares Outstanding	8.72 M
Avg Daily Volume	87,237
52-Week Range	\$1.05 - \$3.20
Year End	March 31st

Financial Summary

Cash (as of 9/30/23)	\$7.6 M
Cash Burn (6 mo. ended 9/30/23)	\$8.5 M
Debt	None

Thank You!

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