UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 07, 2024

Organovo Holdings, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-35996**	**27-1488943**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11555 Sorrento Valley Rd
Suite 100
San Diego, California **92121**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 224-1000

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	ONVO	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Organovo Holdings, Inc. (the "Company") is furnishing a corporate presentation, attached as Exhibit 99.1 to this Current Report on Form 8-K (the "Corporate Presentation"), which the Company intends to post on the Company's website. The Corporate Presentation was presented at the Crohn's & Colitis Congress in January 2024. The Corporate Presentation is current as of January 25, 2024, and the Company disclaims any obligation to update this material in the future.

The information in this Item 7.01, including the Corporate Presentation attached hereto as Exhibit 99.1, is being furnished under Item 7.01 of Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits
(d) Exhibits.

Number	Description
99.1	Corporate Presentation, dated January 25, 2024
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL).

* * *

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Organovo Holdings, Inc.

Date: February 7, 2024

By: /s/ Keith Murphy

Name: Keith Murphy
Title: Executive Chairman

Exhibit 99.1

Evaluation of the Clinical Stage FXR Agonist FXR314 in Human Primary Cell 3D Models of Crohn's Disease and Ulcerative Colitis

Fabrice Piu, PhD
Vice President, Research & Development
Organovo Inc.

Crohn's & Colitis Congress
Jan 25-27, 2024 – Las Vegas, Nevada

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 July 14, 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.

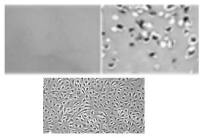
In presenting this material or responding to inquiries in connection with a presentation, management may refer to results, projections or performance measures that are not prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") as reported in the Company's SEC filings. These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

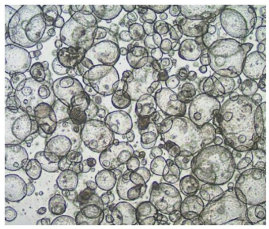
ONVO 3D Disease Models Can Enable Better Clinical Outcomes

- Organovo creates exceptional 3D models using bioprinting and other 3D tissue technologies
- Models created with cells isolated directly from IBD patients (Crohn's Disease or Ulcerative Colitis, biologic naïve or exposed, varying disease severity)
- Models faithfully replicate various aspects of the IBD disease process and human biology
- Models can be used to identify new mechanisms of action, validate novel targets via testing of various entities (chemicals, SiRNAs, …), and study the effects of clinically approved treatment paradigms
- Testing of broad donor sets from a biobank allows to understand population response to a drug or to target modulation

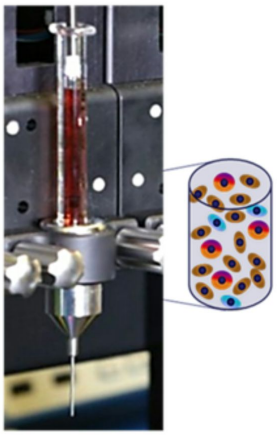
ONVO Bioprinting Inflammatory Bowel Disease Model

Cell expansion



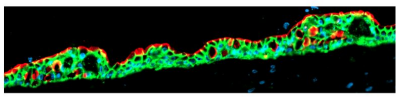


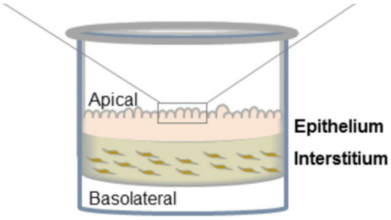
- Intestinal Crypts
- Endothelial cells
- Smooth muscle cells
- Fibroblasts



- Cell Mixture
- Proprietary Media
- Matrix

- Multimodal
- Biocompatible
- Spatial control
- Complex Geometries

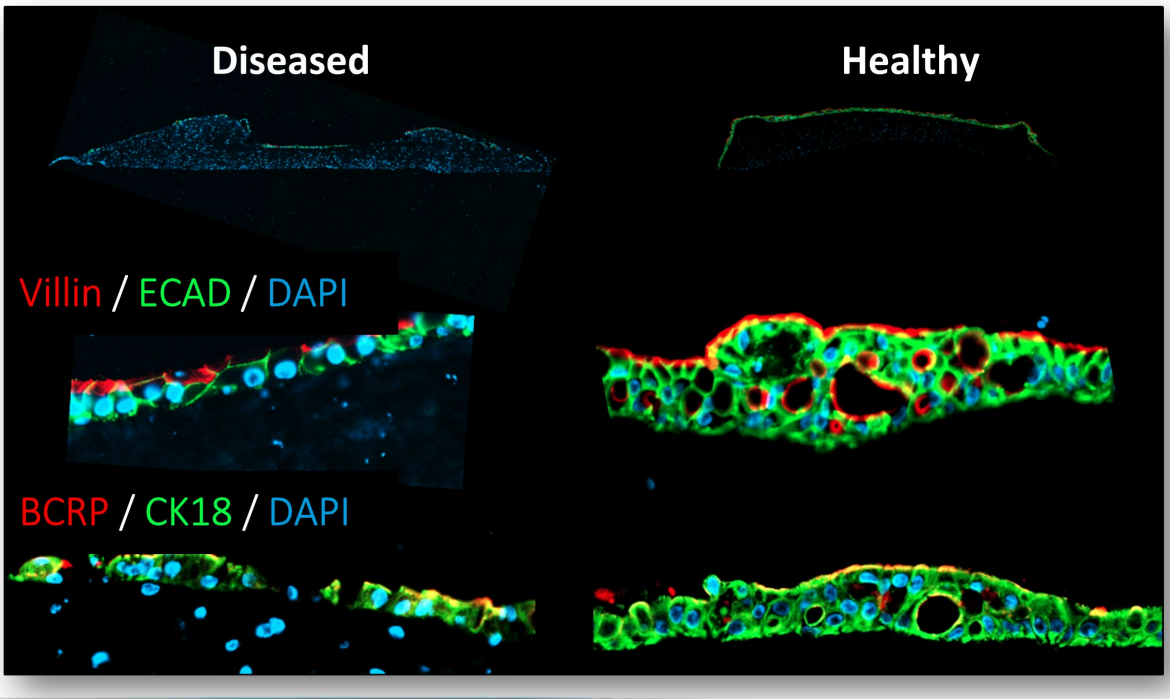




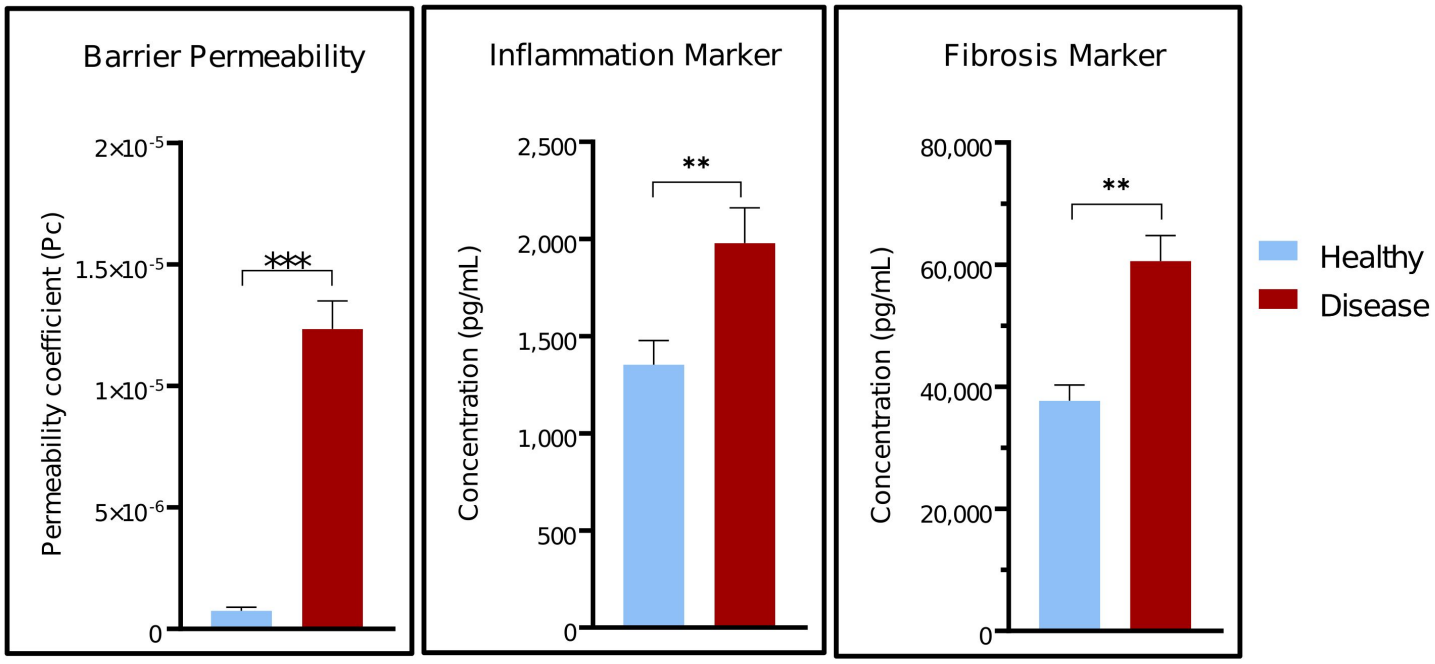
- Reproducible
- Scalable
- Cell dense
- Physiologically accurate biology

3D Bioprinting Recapitulates Cellular Organization of Diseased and Healthy Intestinal Cell Donors

- Polarized epithelium with functional tight junctions, transporters (P-gp, BCRP)
- Specialized epithelial cell types
- Physiological barrier function



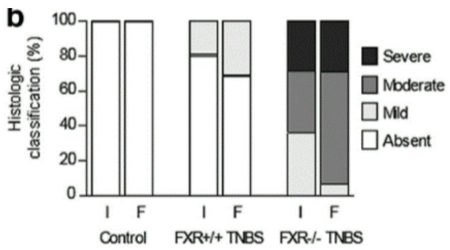
3D Models from IBD Patients Demonstrate Impaired Epithelial Barrier Function and Increased Inflammation and Fibrosis



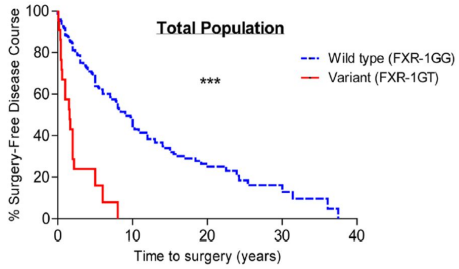
FXR Agonism Is An Important Effector in IBD

- 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
- Human genetics studies have reported the existence of FXR SNP associated with intrahepatic cholestasis of pregnancy and IBD
  - FXR SNP rs56163822 (FXR-1G->T) leads to reduces 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, FGF19, is reduced in CD patients

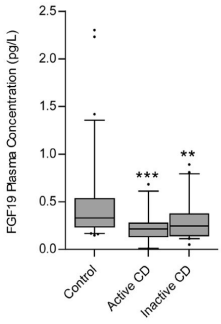
FXR protects mice from TNBS-induced colonic inflammation



FXR variant causes increased disease severity



Biomarker of FXR activity reduced in CD patients



FXR314 Potential Role in IBD – Study Design

- Evaluation of FXR314, a potent and selective non-bile acid FXR agonist

- Conducted in 3D models of IBD:
  - Crohn's disease: 5 human diseased donors
  - Ulcerative colitis: 3 human diseased donors

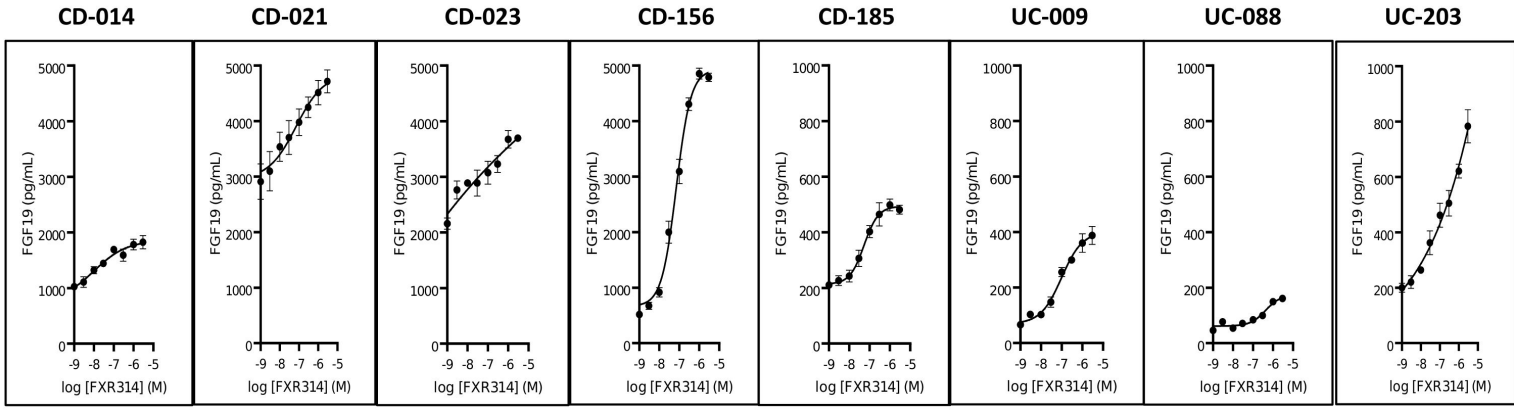
- Endpoints:
  - Target engagement: intestinal biomarker FGF19
  - Barrier permeability: FITC-Dextran 4 kDa (FD-4)
  - Fibrosis: Procollagen type I N-terminal propeptide (P1NP)

Demonstrated Target Engagement by FXR314 in CD and UC

- Evaluated FGF19 a direct biomarker of intestinal FXR activity
- Potent and dose-dependent activation of FGF19 by FXR314 in all CD and UC donors
- Degree of activation varies between the different donors

	CD-014	CD-021	CD-023	CD-156	CD-185
Fold Act.	1.8	1.6	1.7	9.3	2.4
EC50 (nM)	100	70	54	71	53

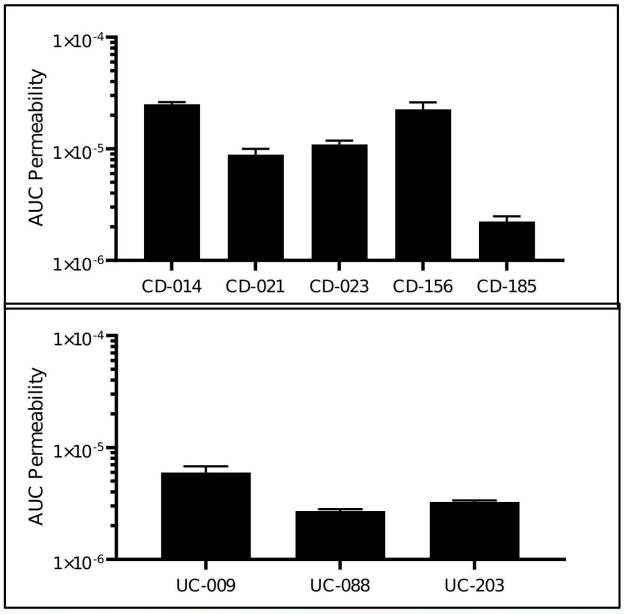
	UC-009	UC-088	UC-203
Fold Act.	5.9	3.4	3.9
EC50 (nM)	98	427	200



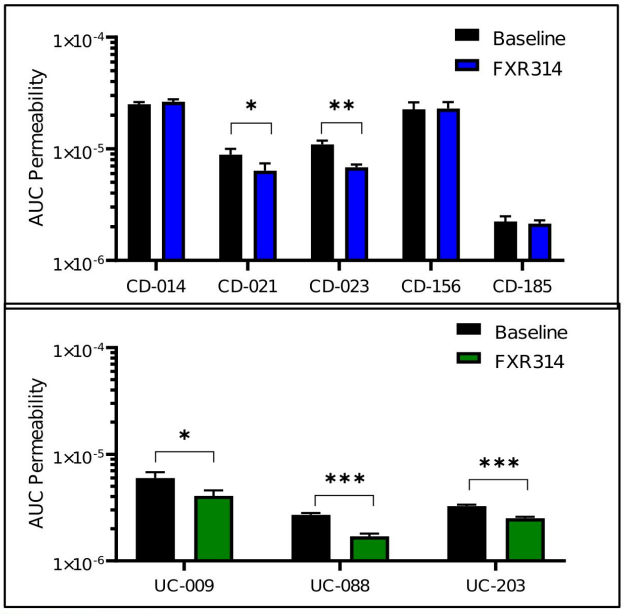
FXR314 Improves Barrier Integrity in CD and UC donors

- Intestinal permeability is determined by FD4 assay
- Diseased tissues (CD and UC) have intrinsically different baseline permeability values reflective of the disease state
- FXR314-induced decrease in barrier permeability observed in a subset of CD donors, and all UC donors

Baseline Barrier Integrity



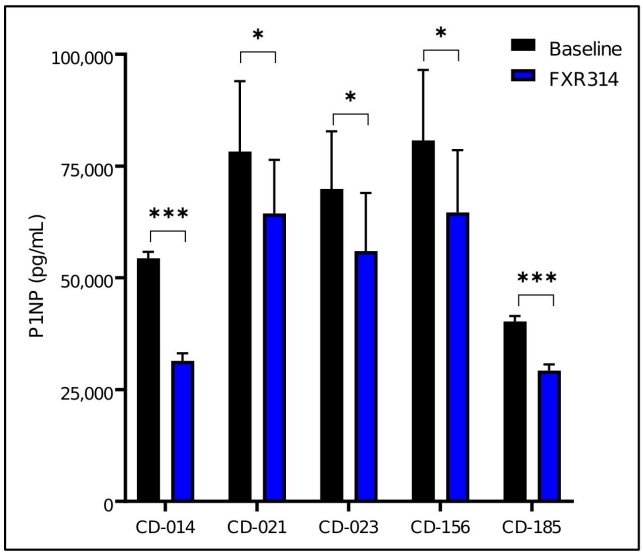
FXR314 Treated Donors



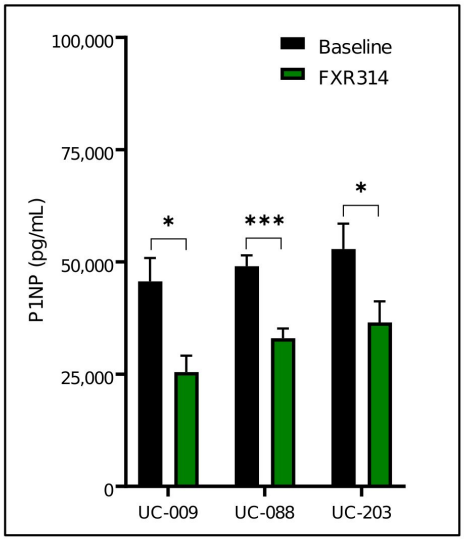
FXR314 Improves Fibrosis in CD and UC donors

- Evaluated P1NP as a marker of fibrosis
- FXR314-induced decrease in fibrotic marker observed in all CD and UC donors

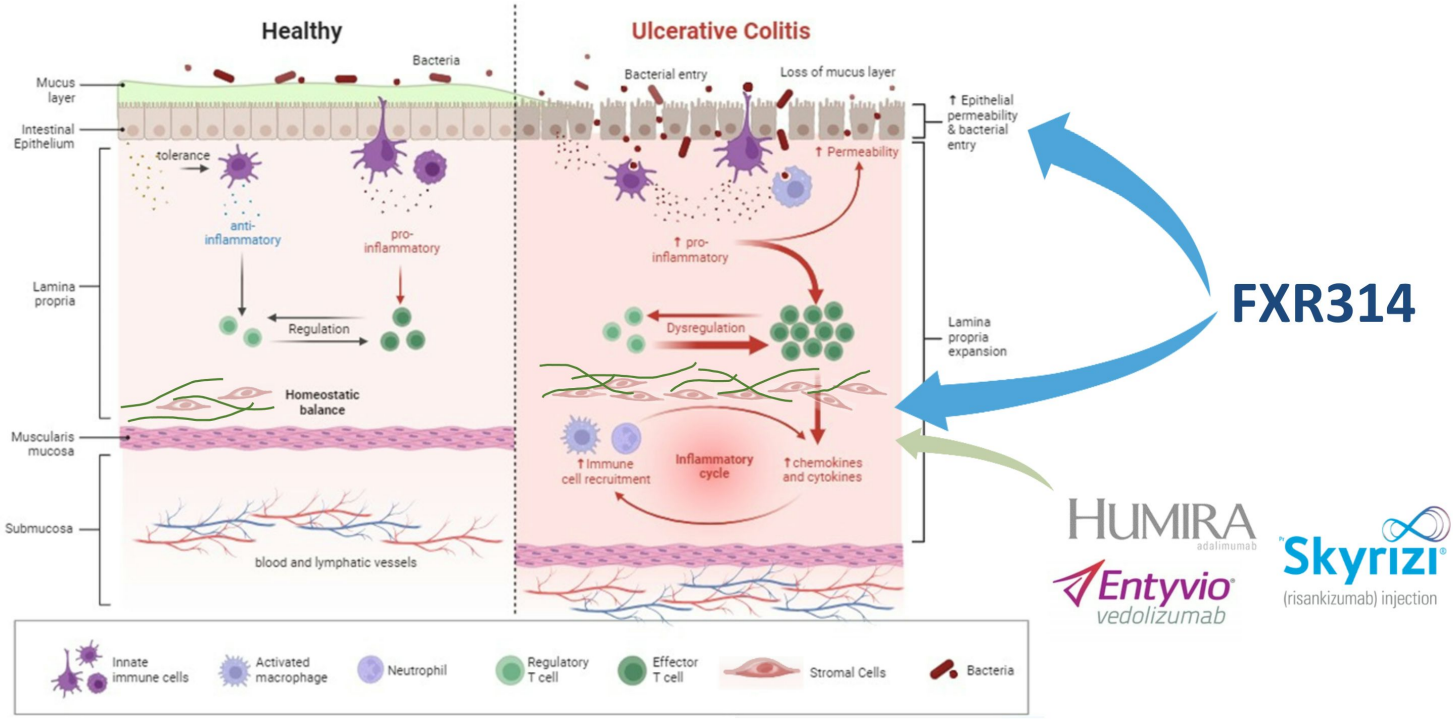
CD Donors



UC Donors



FXR314 MOA Linked to Epithelial Repair and Fibrosis Resolution Upstream of Anti-inflammatory Treatments



Conclusions

- Organovo 3D models (bioprinting and other tissue technologies) replicate various aspects of the IBD disease process and human biology
- 3D Models can be used to identify new mechanisms of action, validate novel targets, study the effects of clinically approved treatment paradigms and understand population response
- The potent non-bile acid FXR agonist FXR314 is effective in 3D models of Crohn's Disease and Ulcerative Colitis:
  - Demonstrated target engagement (FGF19) in all CD and UC donors
  - Improvement of intestinal barrier function in a subset of CD donors, and all UC donors
  - Improvement of fibrosis (P1NP marker) in all CD and UC donors
- A Phase 2 trial in Ulcerative Colitis is being planned