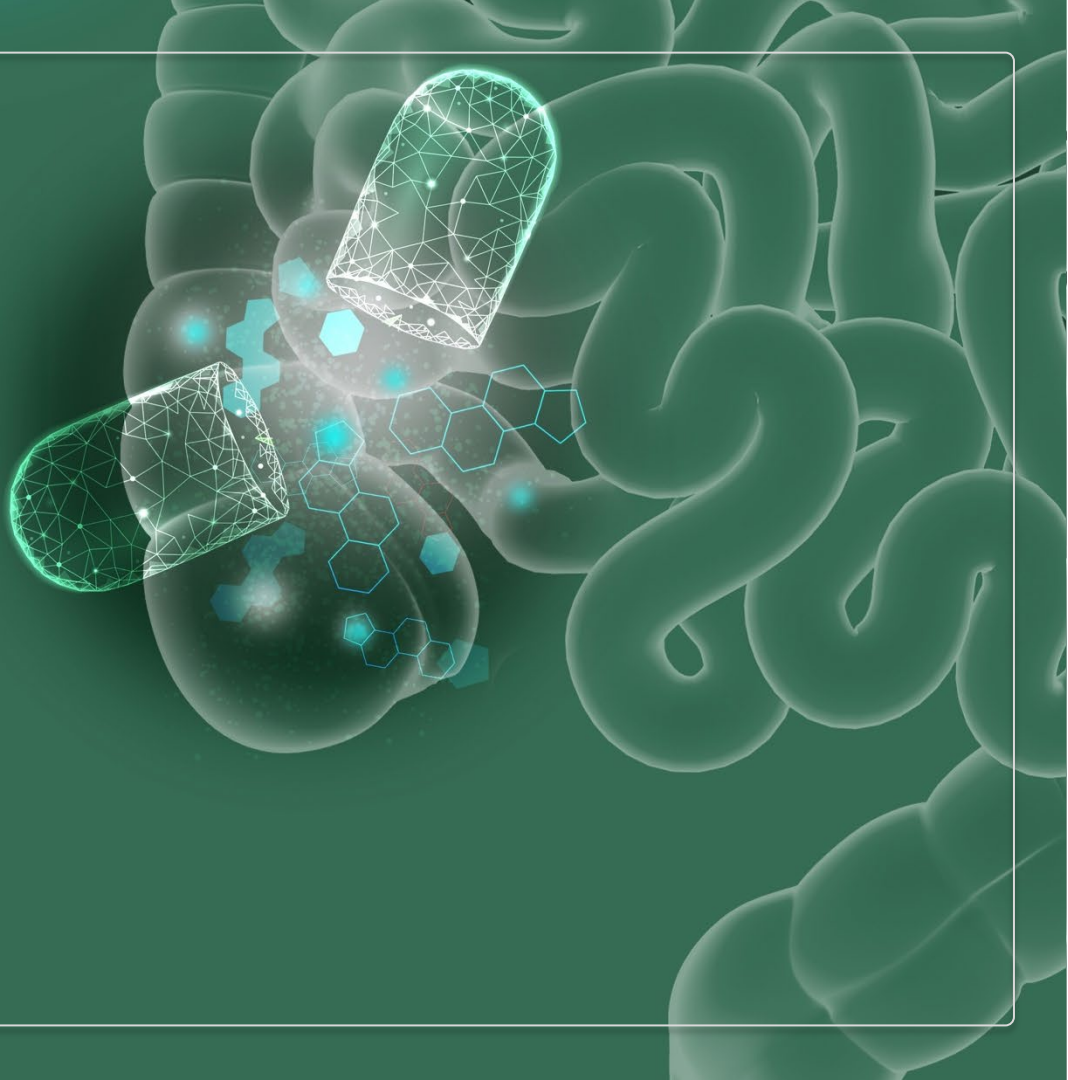
VISCERA LABS

NOVEMBER 2024



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Viscera Labs is developing a novel formulation of colesevelam (VL-001) for the treatment of bile acid diarrhea (BAD)

2.2 million people with BAD in the US	**There is no approved treatment**
BAD is managed by functional gastroenterologists	**Focused promotional effort**
Gastroenterologists prescribe colesevelam off-label to treat BAD	**Customer familiarity with the agent**
The tolerability and dosing of the current formulations of bile acid sequestrants can be limiting	**Need for a bile acid sequestrant that targets the terminal ileum**
VL-001 may have utility in glycemic control, pruritus associated with cholestatic liver disease, and statin-intolerant hypercholesterolemia	**Expands the clinical utility of VL-001**

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A Unique Market Opportunity by Managing Risk

Regulatory

Although no product for BAD is yet approved by FDA:

- Viscera will leverage the development efforts of competing assets when filing the IND for VL-001

Clinical

While VL-001 has yet to be evaluated in humans:

- VL-001 has shown efficacy in pre-clinical models
- The current formulation of colesevelam has demonstrated efficacy in the treatment of BAD

Commercial

VL-001 will compete with generic colesevelam, however:

- VL-001 is designed to be more tolerable
- The ASP of VL-001 will only be 2x generic colesevelam
- Initial reaction from GI associations (e.g., GIHF, GHAPP) is positive

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The BAD Market & VL-001

- 2.2 million Americans aged 20-64 suffer from BAD
- It's estimated that only 33% of them get a confirmatory diagnosis[1]
  - It's projected that five years post-launch Viscera will drive the diagnosis rate to 43%
- In 2023, 46.6% of those diagnosed with BAD were prescribed a bile acid sequestrant (BAS) by a GI[2]
  - It's projected that five years post-launch 50.6% of those diagnosed will be prescribed a BAS

Projected annual net retail sales: **~$750M**

Key Forecast Assumptions

Populations, 2024 ('000)	
Prevalent patients	2,206.6
Diagnosed patients	728.2
Prescribed patients	339.2
Key Assumptions	
Diagnosis rate – 2024	33.0%
Diagnosis rate – year 5 post-launch	43.0%
Prescription rate – 2024	46.6%
Prescription rate – year 5 post-launch	50.6%
Share, demand – year 5 post-launch	25.0%
Pricing	
Launch price/year – WAC	$4,380
Launch price/year – ASP	$2,208

1. Bannaga A, et al. BMJ Open Gastroenterol. 2017 Jan 19;4(1). **2**. Definitive Healthcare

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The Viscera Labs Management Team has decades of experience in all aspects of the pharmaceutical industry

JP Benya
President & CEO

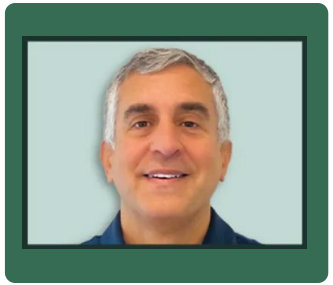
assemblybio
sanofi aventis
Schering-Plough

Steve Petruccelli
EVP, Secretary

Daiichi-Sankyo
Schering-Plough

Lisa Pedicone PhD
VP, Chief Scientific Officer

MERCK
Schering-Plough



Paul Ursino
VP, Chief Development Officer

VINCHEM

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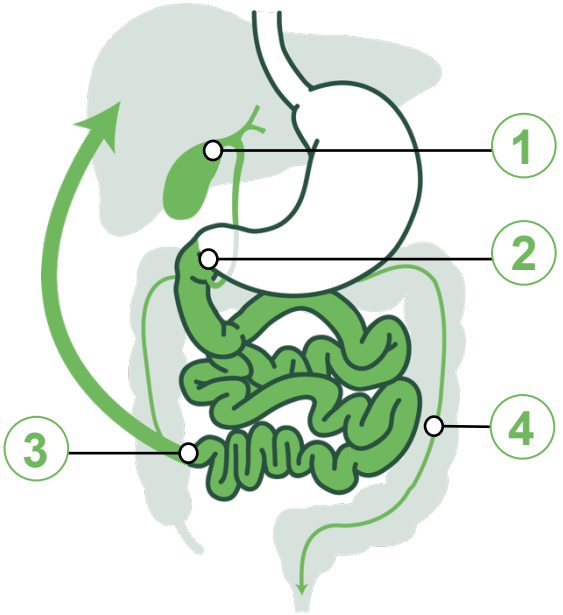
The bile acid (BA) pool remains constant in healthy persons

After traveling through the small intestine and aiding in digestion, **~95% of BAs are reabsorbed from the terminal ileum** and recycled back to the liver.[1-3]



1. BAs are produced in the liver and stored in the gallbladder.[1,2]
2. During digestion, BAs are expressed from the common bile duct into the duodenum.[1,2]
3. **~5% of BAs are not reabsorbed** and are excreted in the feces.[1,2]

1. Farrugia A, Arasaradnam R. *Frontline Gastroenterol*. 2021;12:500-507. **2.** Marasco G et al. *J Clin Med.* 2022;11:3102.
3. Camilleri M, Nurko S. *Neurogastroenterol Motil.* 2022;34:e14287.

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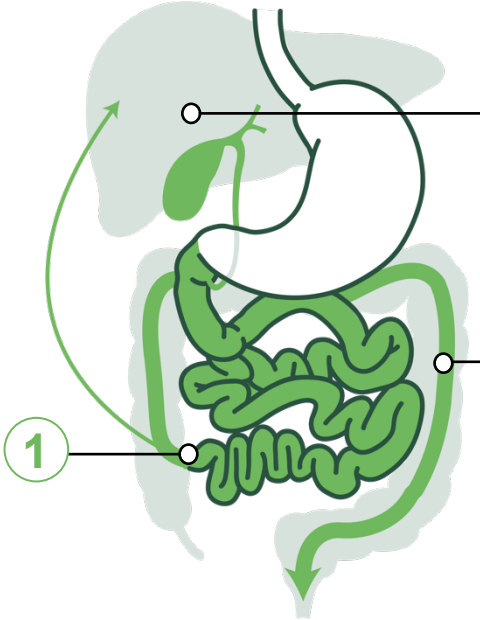
In BAD, excess BAs reach the colon and cause diarrhea

BAs are not reabsorbed efficiently.[1-3]



Synthesis of BAs in the liver is increased, leading to increased BAs in the systemic circulation and

Excess BAs reach the colon, increasing secretion and motility

Diarrhea, abdominal cramping, urgency, bloating

1. Farrugia A, Arasaradnam R. *Frontline Gastroenterol*. 2021;12:500-507. **2.** Marasco G et al. *J Clin Med.* 2022;11:3102.
3. Camilleri M, Nurko S. *Neurogastroenterol Motil.* 2022;34:e14287.

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BAD has substantial negative impact on patients' lives

>90% of patients were **nervous leaving home** and were often or sometimes **embarrassed** by symptoms.[1]

40% of patients experienced **extreme tiredness.**[1]

30% of patients reported **frequent work absences** because of their symptoms.[1]

NEARLY **50%** of patients **worried about losing bowel control** quite a bit or a great deal.[2]

75% of patients considered **proximity to a toilet** moderately to extremely important.[2]

Data from 100 patients with BAD responding to an online survey from BAM Support UK.[2]

Data from an observational study of 44 patients at Mayo Clinic in Rochester, Minnesota, with Rome III-diagnosed IBS-D and BAD.[2]

1. Bannaga A et al. *BMJ Open Gastroenterol*. 2017;19;4(1): **2.** BouSaba J et al. *Clin Gastroenterol Hepatol*. 2022;20:2083-2090.

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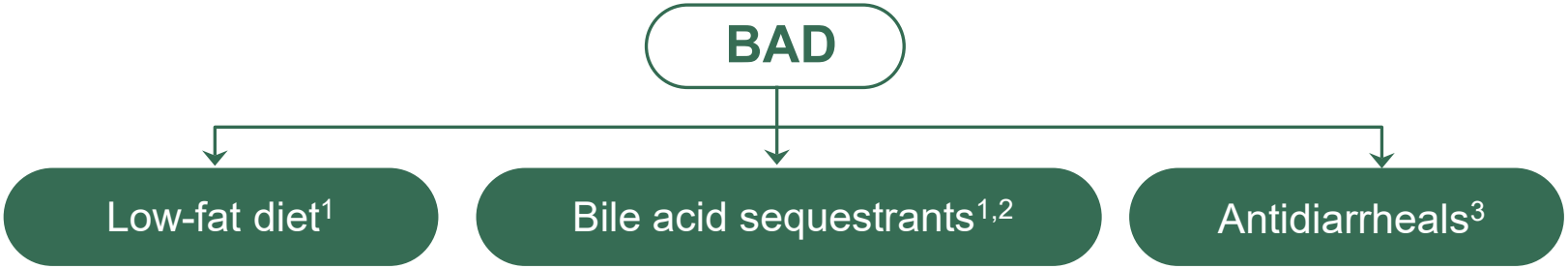
Treatment options for BAD are limited



There are no FDA approved treatments for BAD.

1. Watson L et al. *Clin Med.* 2015;15(6):536-540. **2.** Camilleri M, Nurko S. *Neurogastroenterol Motil.* 2022;34:e14287.
3. Mottacki N et al. *Aliment Pharmacol Ther.* 2016;43:884-898.

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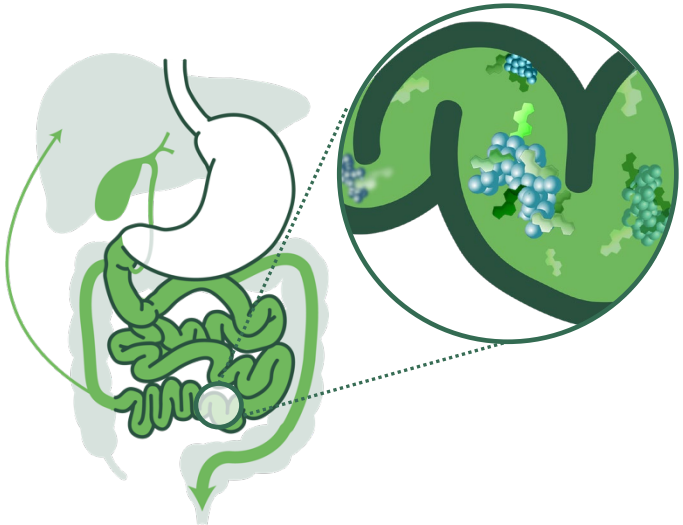
BA sequestrants bind BAs in the small intestine and reduce their delivery to the colon[1]

Mechanism of BA sequestrants in BAD



Cholestyramine
(Questran®, generic)[2]

- Most studied of the BA sequestrants for BAD[3]

Colestipol
(Colestid®, generic)[2]

- Few data in BAD[3]

Colesevelam
(Welchol®, generic)[2]

- Stronger binding affinity for BA than cholestyramine and binds a broader spectrum of BAs[4]
- Better tolerated than cholestyramine and colestipol[4]

1. Camilleri M, Nurko S. *Neurogastroenterol Motil.* 2022;34:e14287. **2.** NIH. Accessed April 13, 2023. dailymed.nlm.nih.gov.
3. Wilcox C et al. *Aliment Pharmacol Ther.* 2014;39:923-939. **4.** Borup C et al. *Lancet Gastroenterol Hepatol.* 2023;8u:321-331

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Many patients do not tolerate current formulations of BA sequestrants

Poor tolerability

UP TO **70%** patients discontinue BA sequestrants due to AEs, usually nausea.[1]

Poor palatability

due to the taste and/or texture often limit compliance[1,2]

POTENTIAL FOR **Drug-drug interactions**

must be considered in patients taking multiple medications[2,3]

1. Vijayvargiya P et al. *Clin Gastroenterol Hepatol.* 2020;18(13):2962-2970. **2**. Appleby RN et al. *United European Gastroenterol J.* 2017;5(3):380-388. **3.** Wilcox C et al. *Aliment Pharmacol Ther.* 2014;39:923-939.

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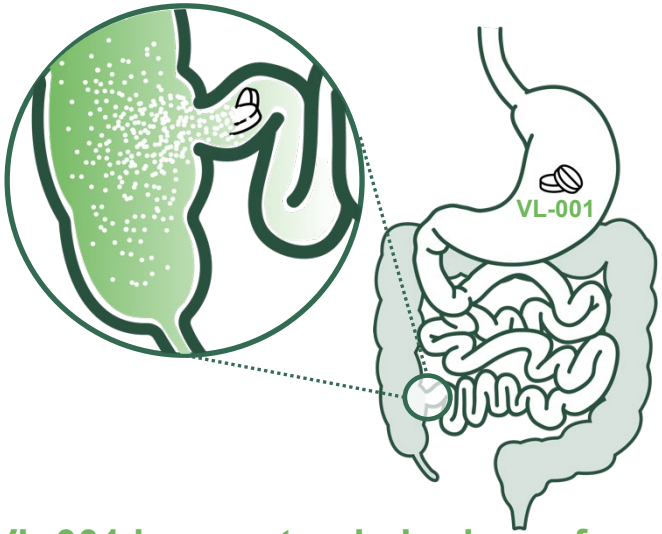
VL-001 is designed to target colesevelam release in the terminal ileum



VL-001 is an extended-release formulation designed to pass through the upper GI tract and release colesevelam in the terminal ileum.[1]

Potential advantages of VL-001 over current colesevelam formulations[2,3]

- Improved efficacy due to more rapid sequestration of bile acids
- Improved tolerability (i.e., nausea)
- Lower drug burden, lower pill count, and smaller tablet size
- Fewer drug-drug interactions (e.g., oral contraceptives)

1. Data on file. Viscera Labs. **2**. Appleby RN et al. *United European Gastroenterol J*. 2017;5(3):380-388. **3.** Vijayvargiya P et al. *Clin Gastroenterol Hepatol.* 2020;18(13):2962-2970.

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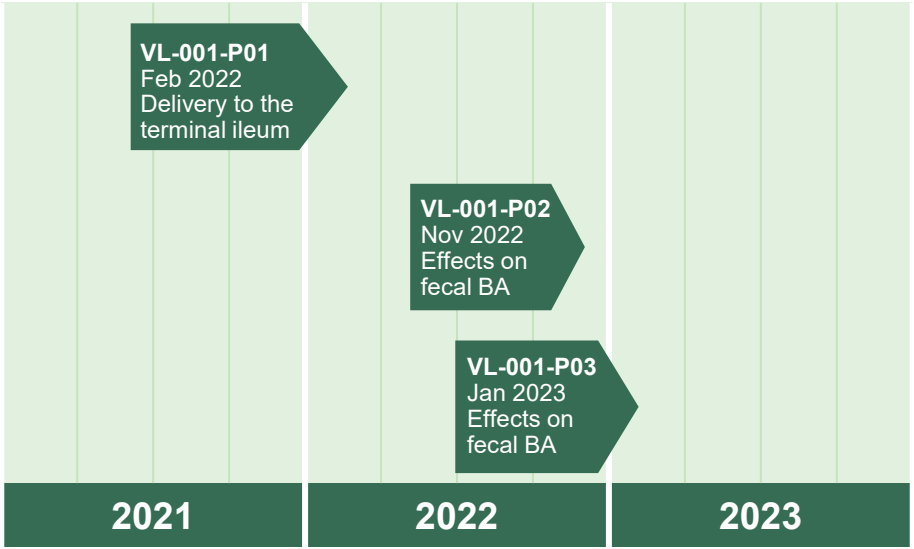
VL-001 preclinical development



Data on file. Viscera Labs.

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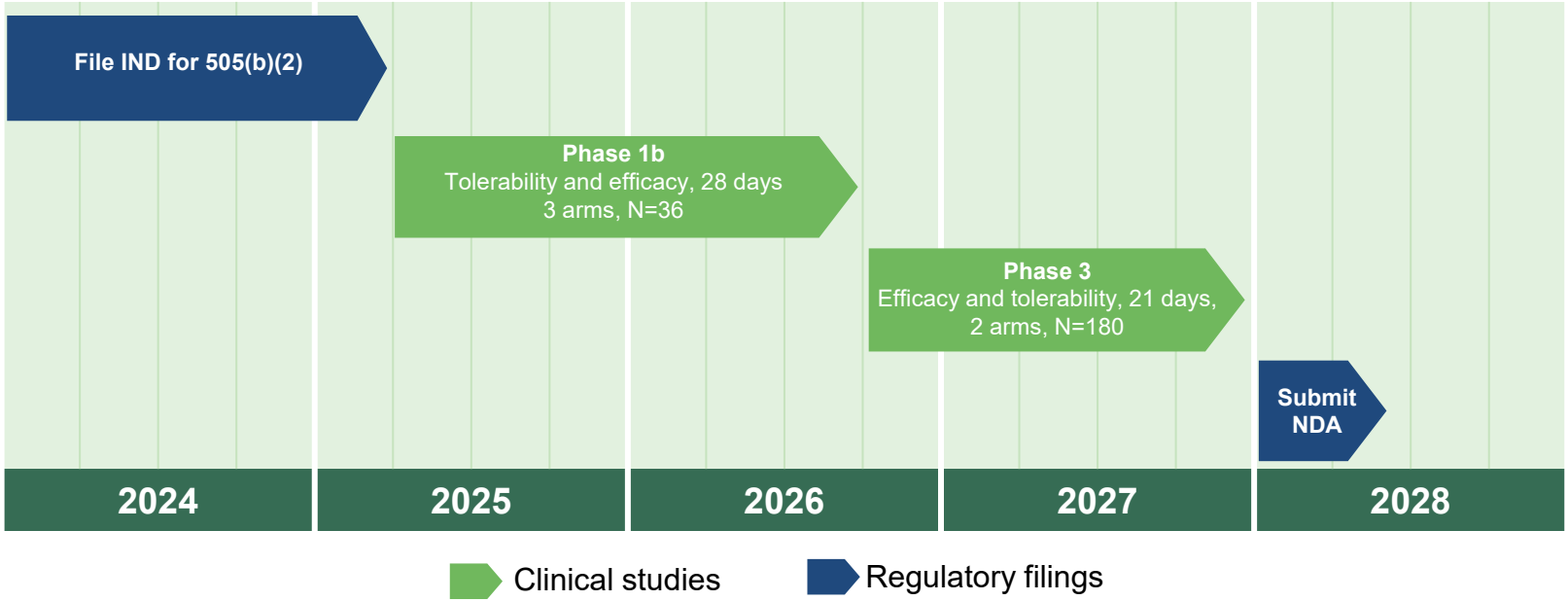
VL-001 clinical development

505(b)(2) pathway and existing supply of VL-001 drives rapid NDA submission



Data on file. Viscera Labs.

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VL-001 intellectual property & regulatory exclusivity

3 issued patents

US 11,590,161
Notice of Allowance issued Oct 5, 2022
Claims directed to an
oral drug delivery system

US 11,524,029
Notice of Allowance issued Oct 5, 2022
Claims directed to a
method of treating BAD

US 11,813,283
Notice of Allowance issued Nov 14, 2023
Claims directed to a
method of treating insufficient glycemic control

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3 YEARS

of data exclusivity
from FDA

30-month stay
after filing of first ANDA

Freedom to operate in BAD

February 11, 2020

"Viscera's activities would not infringe any valid claim of any unexpired U.S. patent, or any claims that might issue as currently pending in any published U.S. patent application, or international patent application designating the U.S."

Data on file. Viscera Labs.

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Investigational agents for BAD

Agent	Mechanism	Development phase			
		1	2	3	4
Eluxadoline (Viberzi® , Allergan)[1,2]	Mixed μ- and κ-opioid receptor agonist and δ-antagonist				
A3384 (Albireo)[1,3,a]	Colonic-release cholestyramine				
Aldafermin (NGM Biopharmaceuticals)[1,4]	FGF-19 analogue				
LJN452 (Novartis)[1,5,a]	FXR agonist				

FGF, fibroblast growth factor; FXR, farnesoid X.
[a]Development status uncertain.
1. Clinicaltrials.gov. Accessed May 1, 2023. https://www.clinicaltrials.gov. **2.** Vijayvargiya P et al. *Dig Dis Sci.* 2022;67(8):3911-3921. **3.** Appleby RN et al. *United European Gastroenterol J.* 2017;5(3):380-388. 4. BouSaba J et al. *Gastroenterology.* 2023 Apr 19:S0016-5085(23)0062102. Online ahead of print. **5.** Camilleri M et al. *Aliment Pharmacol Ther.* 2020;52(5):808-820.

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Uses of funds

Viscera Labs is seeking $6.0M in equity financing[1] to file an IND and undertake the phase 1b clinical trial

(thousands)	2025	2026[2]	Total	Share
G&A[3]	$346.6	$278.7	$625.3	12%
Legal	20.0	57.5	77.5	1%
Development	6.0	227.0	233.0	4%
Regulatory	506.9	45.0	551.9	10%
Clinical	1,889.5	1,889.5	3,779.0	72%
Total	**$2,769.0**	**$2,497.7**	**$5,266.7**	**100%**

Notes
1. Assumes financing closes December 31, 2024
2. Viscera Labs will seek an exit 4Q'26
3. Viscera Labs will use consultants for the CFO, CIO, CMO, and CDO roles as these roles do not require FTEs in the 2024-2026 period

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Viscera Labs Consultants

Brooks Cash, MD
Chief, Division of Gastroenterology, Hepatology, and Nutrition
University of Texas Health Science Center at Houston

Ken Cusi, MD
Chief, Division of Endocrinology, Diabetes & Metabolism
Department of Medicine
University of Florida

Kris V. Kowdley, MD
Elson S. Floyd College of Medicine
Washington State University
Liver Institute Northwest

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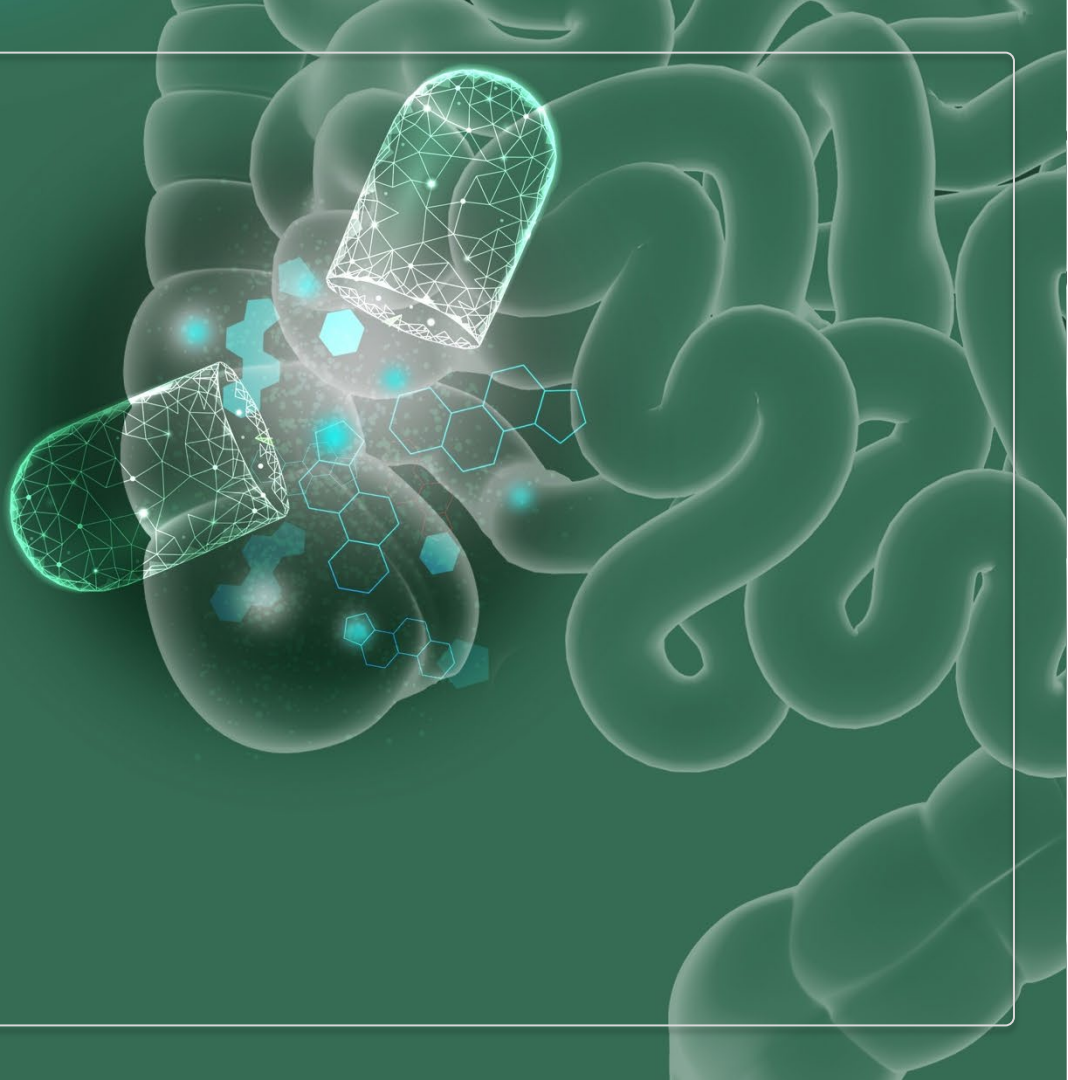
THANK YOU !



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