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): November 25, 2013

VENTRUS BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-35005	20-8729264
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer ID Number)
99 Hudson Street, 5th Floor, New York, New York	10013	
(Address of principal executive offices)	(Zip Code)	

Registrant's telephone number, including area code (646) 706-5208

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))

Item 8.01. Other Events.

Attached hereto as Exhibit 99.1 is a PowerPoint presentation that Ventrus Biosciences, Inc. will use for various conferences and investor presentations and which is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	PowerPoint presentation of November 2013.

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.

VENTRUS BIOSCIENCES, INC.

Date: November 25, 2013

/s/ David J. Barrett
David J. Barrett, Chief Financial Officer

Exhibit 99.1

Forward Looking Statements

This material contains estimates and forward-looking statements. The words "believe," "may," "might," "will," "aim," "estimate," "continue," "would," "anticipate," "intend," "expect," "plan" and similar words are intended to identify estimates and forward-looking statements. Our estimates and forward-looking statements are mainly based on our current expectations and estimates of future events and trends, which affect or might affect our businesses and operations. Although we believe that these estimates and forward-looking statements are based upon reasonable assumptions, they are subject to many risks and uncertainties and are made in light of information currently available to us. Our estimates and forward-looking statements may be influenced by the following factors, among others: risks related to the costs, timing, regulatory review and results of our studies and clinical trials; our ability to obtain FDA approval of our product candidates; differences between historical studies on which we have based our planned clinical trials and actual results from our trials; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; our liquidity and working capital requirements; our expectations regarding our revenues, expenses and other results of operations; the unpredictability of the size of the markets for, and market acceptance of, any of our products; our ability to sell any approved products and the price we are able realize; our need to obtain additional funding to develop our products, and our ability to obtain future funding on acceptable terms; our ability to retain and hire necessary employees and to staff our operations appropriately; our ability to compete in our industry and innovation by our competitors; our ability to stay abreast of and comply with new or modified laws and regulations that currently apply or become applicable to our business; estimates and estimate methodologies used in preparing our financial statements; the future trading prices of our common stock and the impact of securities analysts' reports on these prices; and the risks set out in our filings with the SEC, including our Annual Report on Form 10-K. Estimates and forward-looking statements involve risks and uncertainties and are not guarantees of future performance. As a result of known and unknown risks and uncertainties, including those described above, the estimates and forward-looking statements discussed in this material might not occur and our future results and our performance might differ materially from those expressed in these forward-looking statements due to, including, but not limited to, the factors mentioned above. Estimates and forward-looking statements speak only as of the date they were made, and, except to the extent required by law, we undertake no obligation to update or to review any estimate and/or forward-looking statement because of new information, future events or other factors.

Company Overview

- **A phase 3 specialty pharmaceutical company focused on neglected areas of drug development: primary focus is currently anorectal disorders**
- **Current portfolio**
  - **VEN 307: Diltiazem cream for anal fissures – 505(b)(2)**
    - Phase III data from first pivotal trial showed good tolerability and significant improvement in efficacy outcomes
    - Concentrated market driven by colorectal surgeons
    - Data readout from second phase III trial expected Q1 2014; NDA filing expected Q2 2014
  - **VEN 308: Topical phenylephrine for fecal incontinence – 505(b)(2)**
    - Published proof of concept trials in fecal incontinence associated with ileal pouch anal anastomosis (IPAA)
    - Orphan disorder treated in ~40 colorectal surgery centers nationwide
  - **VEN 310: Delivery platform**
    - Initial focus: C. difficile and vancomycin-resistant enterococcus (VRE)
- **Funded through key milestones**
  - Current cash believed sufficient to cover completion of the VEN 307 development program and one year of commercialization

VEN 307: Diltiazem Cream

Novel Treatment for Anal Fissures

Anal Fissures: Cause & Management

Cause

Increased sphincter tone

↓

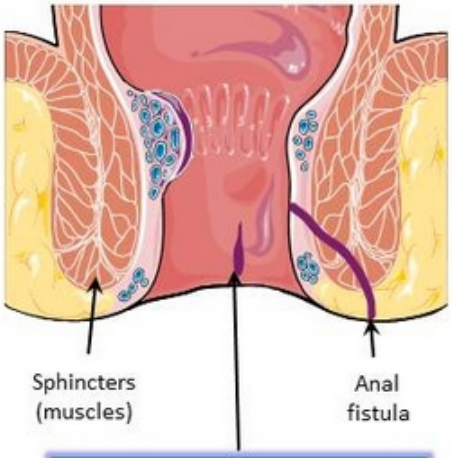
Local ischemia

↓

Tear (fissure) in anal canal

↓

Severe pain on defecation



Anal Fissure
1.1 million office visits/year[1]

Treatment Options

Control constipation, topical steroids

↓

Reduce sphincter tone

↓

Rectiv® **and compounded topical drugs**[2]**:**

- Nitroglycerin
- Calcium channel blockers

Botox → Surgery

1. Physician Drug & Diagnosis Audit (PDDA), 2010.
2. *Rectiv*® is a registered trademark of Aptalis; it launched Feb 2012.

VEN 307: Summary

2% Topical Diltiazem Cream Applied Peri-anally TID	
Mechanism of Action	➢ Calcium channel blocker ▪ Relaxes the internal anal sphincter, reduces pain, and increases tissue blood flow
Preclinical Safety	➢ Preclinical topical safety with 2% diltiazem twice daily for ninety days
Clinical Pharmacology	➢ Topical has < 10% of the systemic exposure as oral dosage but significantly greater effect on sphincter tone (i.e., blood levels do not predict activity). Low exposure = better tolerability than oral diltiazem
Clinical Data	➢ Numerous clinical trials with ~1,200 subjects ▪ Infrequent mild adverse events (AE) reported ▪ Similar or better reduction in pain, significantly better tolerability than with nitroglycerin (GTN) ➢ First pivotal trial complete: 465 subjects, significant improvement vs. placebo, tolerability confirmed

First Pivotal Phase III Trial

- **FDA (Analgesia Division) pre-IND meeting: August 2007**
  - Achieved clarity on primary endpoint: reduction in pain
  - Confirmed safety database and toxicology requirements
- **Phase III trial conducted by SLA Pharma (licensor)**
  - 3 arms with 155 patients per arm in 31 sites in Europe
  - 2% and 4% diltiazem three times a day (TID) and placebo in 31 sites across Europe
    - Romania (11 centers, 66%), Bulgaria, Spain, UK, Germany and Lithuania
    - 94.6% of subjects completed the 12-week study
  - Primary outcome: change from baseline in average of worst anal pain associated with or following defecation at Week 4 on an 11-point numerical rating scale (Likert-like scale)
  - Selected secondary outcomes:
    - Change from baseline in average of daily overall anal fissure-related pain at Week 4
    - Proportion of subjects who have complete healing of anal fissure at Week 8
    - Change in the Patient's Global Impression of Improvement (PGI-I) at Week 4

Study Hit Anal Fissure "Trifecta"

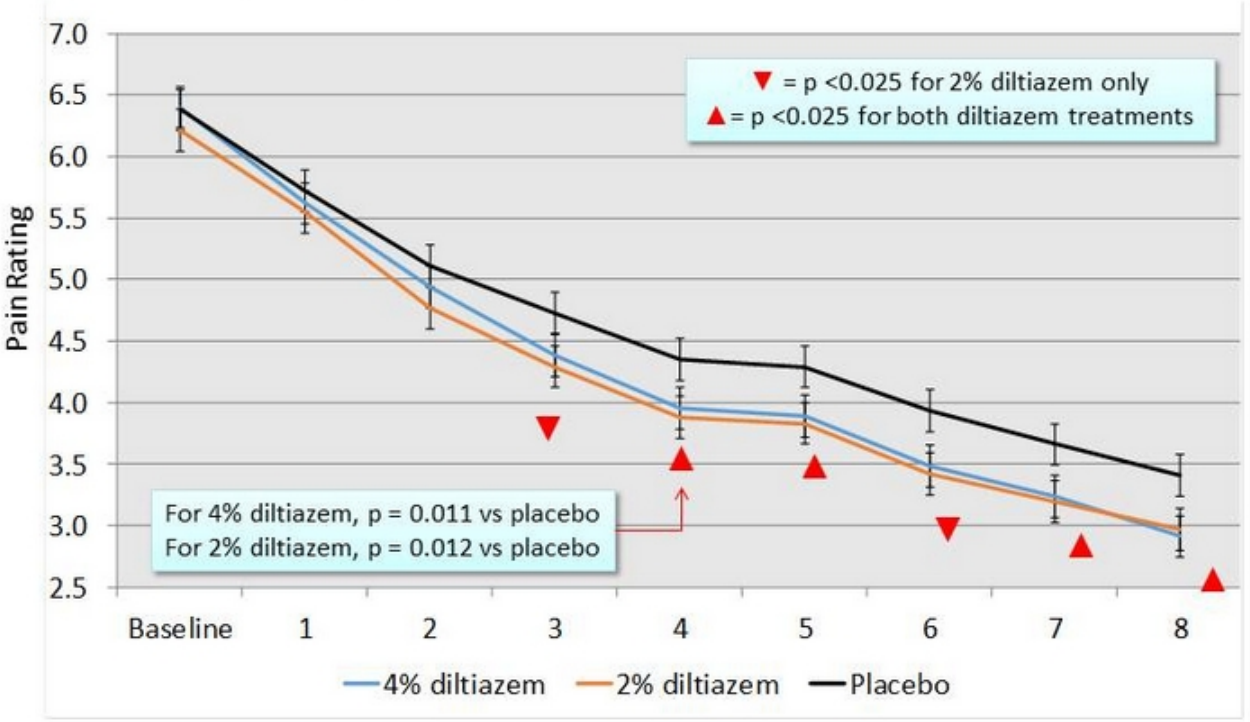
Outcome never before achieved in a single trial of a drug for AF

First Pivotal Phase III Trial: Summary of Results, May 14, 2012

- Double-blind, placebo-controlled clinical trial randomized 465 subjects to diltiazem hydrochloride 4% or 2% by weight (w/w) cream, or placebo, applied topically TID for 8 weeks, followed by a 4 week blinded observation period
- At 4 weeks, the 2% diltiazem treatment arm demonstrated improvements compared to placebo
  - Primary endpoint of average of worst anal pain associated with or following defecation: pain score improvement of 0.43 for 2% diltiazem (p=0.0122)
  - Secondary endpoint of overall anal-fissure-related pain: pain score improvement of 0.42 for 2% diltiazem (p=0.0143)
- Compared with placebo, 2% diltiazem significantly improved the PGI-I measure at Week 4 (p = 0.0084)
- At Week 8, healing was improved for the 2% diltiazem arm (31.2% healing, p=0.0426) compared to placebo (23.9%)
- Adverse events (e.g., incidence of headaches) were similar across all 3 treatment arms (4%, 2%, placebo)

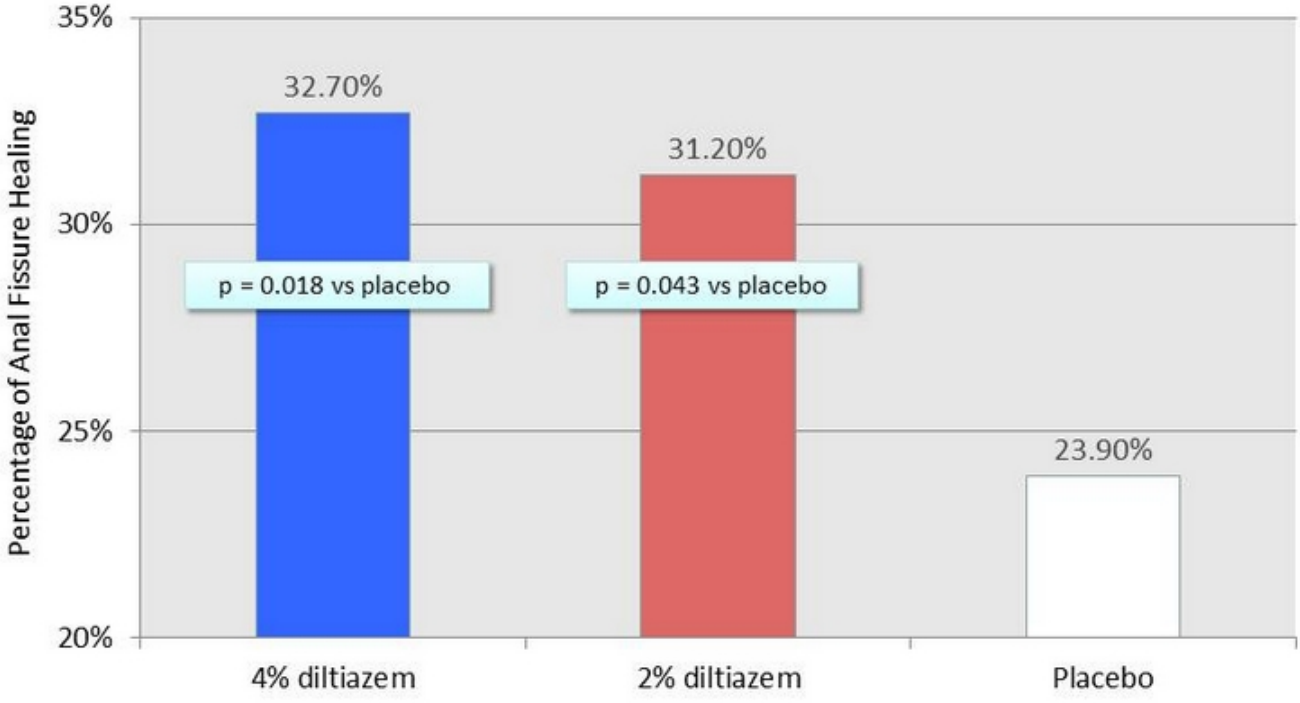
Primary Endpoint: Average Score of Worst Anal Pain Associated with or Following Defecation at Week 4

Compared with placebo, significant reductions with diltiazem from Week 3



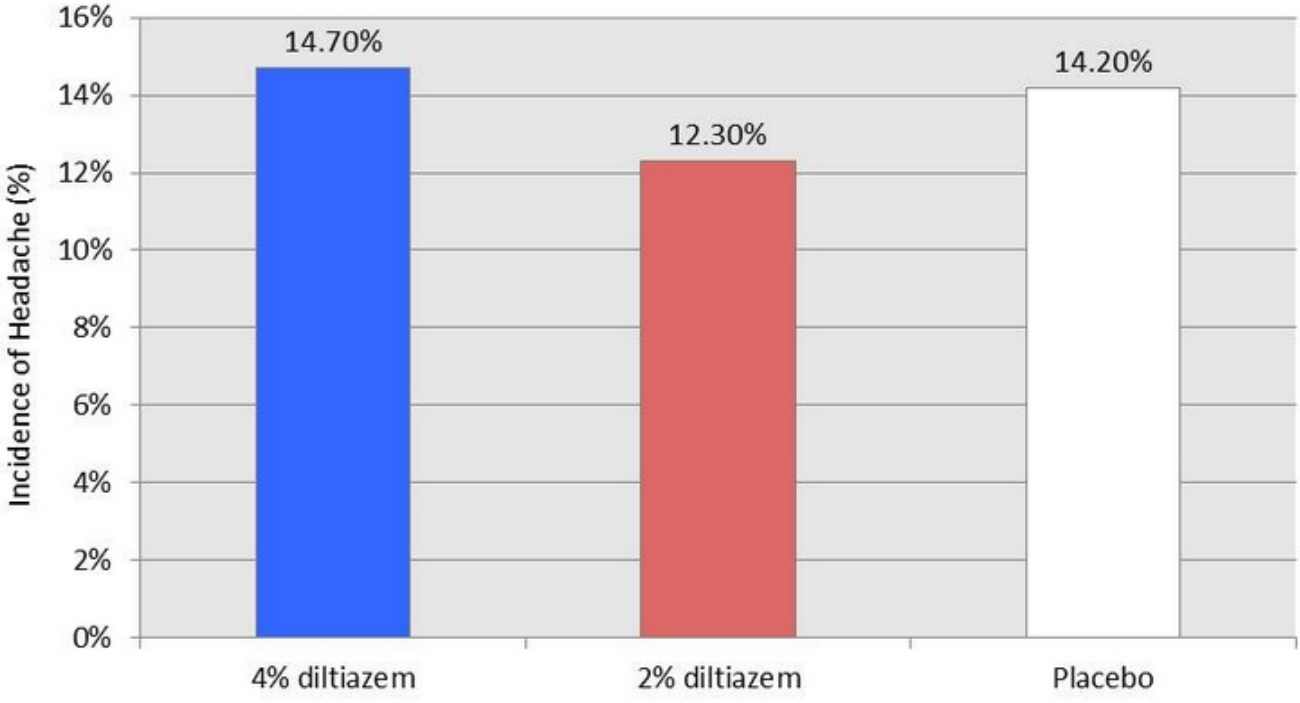
Secondary Endpoint: Healing of Anal Fissure at Week 8

Compared with placebo, significantly greater healing with diltiazem 4% at Week 8



Adverse Events: Incidence of Headache

No significant differences between diltiazem and placebo



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Second Pivotal Phase III Trial

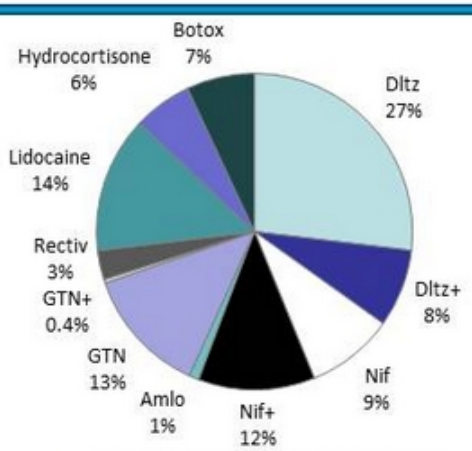
- **433 subjects enrolled: diltiazem 2% vs placebo**
- **72 sites in US, Canada, and Israel**
  - 338 subjects
- **18 sites in Bulgaria, Poland, Ukraine**
  - 95 subjects
- **Design and endpoints are the same as first phase III except the entry pain scores are higher (5 vs. 4)**
- **Data expected Q1 2014**
- **NDA filing expected Q2 2014**

Commercialization
VEN 307

Anal Fissures Market

Therapy by Colorectal Surgeons

- Colorectal surgeons (CRS) see 73% of the anal fissure patients in the United States[2]
- There are 1,357 CRS and are easily reached by a small dedicated sales force



Princeton Brand Econometrics (PBE), 2012.

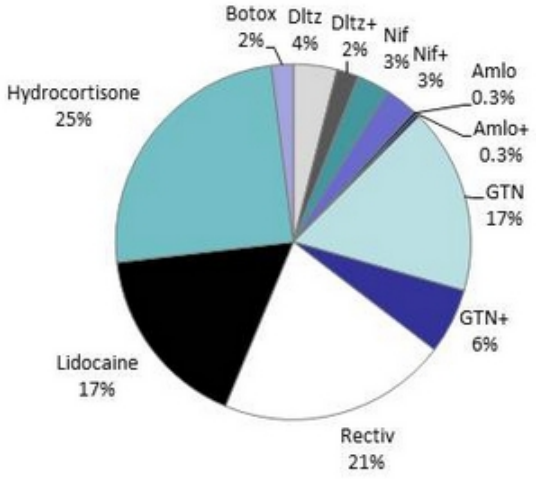
('000)	2015	2016	2017	2018	2019	2020
US Population[1]	325,344.0	328,421.5	331,528.0	334,664.0	337,829.6	341,025.1
Anal Fissures						
Patients[2]	767.3	774.5	781.9	789.3	796.7	804.3
Incidence[3]	0.24%	0.24%	0.24%	0.24%	0.24%	0.24%
Seen by CRS[2]	73.5%	73.5%	73.5%	73.5%	73.5%	73.5%
Patients	564.0	569.3	574.7	580.1	585.6	591.1
CRS that treat AF with Rx[4]	89.7%	89.7%	89.7%	89.7%	89.7%	89.7%
AF Patients on Rx	505.9	510.6	515.5	520.4	525.3	530.2

1. UN Department of Economic and Social Affairs (Population Division): US Population growth between 2000 and 2010 = 0.95%
2. AF Patients who visited a physician (SDI PDDA, 2010)
3. Incidence of people with AF who will visit a physician.
4. Princeton Brand Econometrics (PBE), 2012.

Anal Fissures Market

Therapy by Gastroenterologists

- Gastroenterologists (GI) see 5% of the anal fissure patients in the United States[1]
- Before Rectiv, 55% of patients were prescribed compounded GTN by Gastroenterologists[2]
- More recent market research demonstrates that physicians will switch from compounded to GMP treatment options



Princeton Brand Econometrics (PBE), 2012.

1. AF Patients who visited a physician (SDI PDDA, 2010).
2. Ventrus clinical trial site survey, 2012.

VEN 307

Target & Messaging Opportunity

- Customer target is concentrated
  - Primary focus: 1,357 colorectal surgeons
  - Secondary focus: call lists will include high Rectiv prescribing GIs and PCPs
- Message is simple
  - Quality and availability of GMP diltiazem exceeds compounded diltiazem
  - The AE profile of diltiazem is superior to that of GTN
- Customer target is receptive to the message
  - Colorectal surgeons already prefer compounded calcium channel blockers for anal fissures

VEN 307

Market Forecast: Upsides

- Issue: forecast only considers those AF patients seen by colorectal surgeons
  - Opportunity: calling on high decile gastroenterologists represents (1) an un-forecasted upside and (2) a market expansion assessment
- Issue: forecast assumes only one month of VEN 307 per patient
  - Opportunity: given a better adverse events profile (vs. GTN) and possibly lower cost to patients (vs. compounded), HCPs may write more than one month per patient

VEN 308: Topical Phenylephrine

Novel Treatment for Fecal Incontinence

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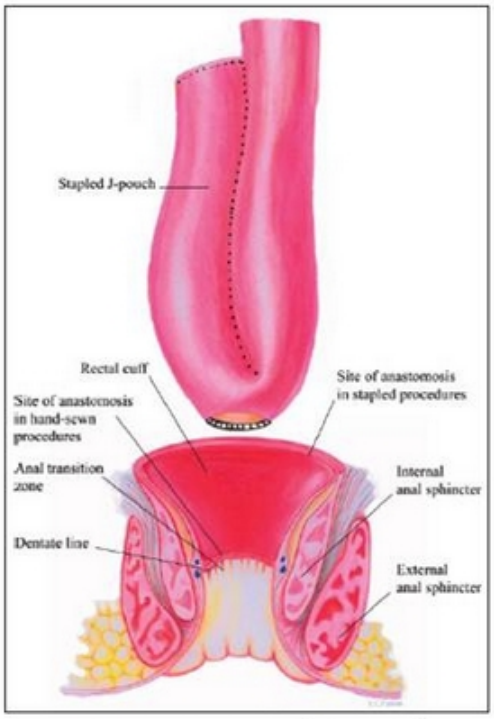
Fecal Incontinence: Summary



Most Common Pouch Procedures

Symptoms:

- IPAA – Frequent soiling and seepage (orphan indication)
- General – Mild soiling to severe urge incontinence

Causes:

- IPAA – Loss of muscle tone and sensation, liquid stool
- General – Multiple etiologies, including child birth, many GI disorders and other complications

Current Treatments:

- OTC – Bulking fiber, Imodium and pads
- Rx – No agents available
- Invasive – Dermal filler (*Solesta*®) and surgery to repair sphincter damage

Solesta® is a registered trademark of Salix.

VEN 308: Summary

Topical Phenylephrine Applied Peri-anally	
Mechanism of Action	➢ A selective alpha-1 agonist that causes internal sphincter contraction and elevates maximum resting anal sphincter pressure
Preclinical Safety	➢ Prescription phenylephrine already has carc and tox data ➢ Dermal sensitization and irritation in experimental formulation
Clinical Data	➢ Pharmacodynamic increase in maximum resting anal pressure ➢ Proof of concept in 12 IPAA patients over 28 day period ➢ >100 patients in multiple studies of passive FI with mixed results
Intellectual Property	➢ Patent on current formulation expires 2017 ➢ Orphan indication for IPAA: 7 years exclusivity ➢ New formulation may allow for up to 20 years exclusivity if patentable and enables expanded indications (e.g., mild FI)

VEN 308 Status

- **Constricts smooth muscle**
  - Introduced as a nasal decongestant (5-15 mg, QID, oral)
  - In 2006, there were 17 million TRx/year written in the United States
- **Efficacy in FI is related to improving external sphincter dysfunction**
  - Won't be effective in passive incontinence
- **Two clinical studies published in 2000**
  - Carapeti[1] – IPAA FI PE vs. PBO
    - PE improved 28 day FI scores (p=0.001)
    - PE improved patient subjective measure (p=0.04)
    - No reported side effects.
  - Carapeti[2] – General FI PE vs. PBO
    - No significant differences in FI scores
    - 6 PE and 2 Plc patient had >75 subjective improvement
    - 3 patients had mild local dermatitis
- **Pre-IND meeting June 21, 2007**
  - Confirmed orphan development plan for IPAA
  - Confirmed objectives of dose range study
- **CMC – Final formulation in development**

1. Carapeti E, et al, Randomized controlled crossover trial of topical phenylephrine for fecal incontinence in IPAA, Dis Colon Rectum (2000); 43(8), 1059-1063.
2. Carapeti E, et al, Randomized controlled crossover trial of topical phenylephrine for general fecal incontinence, BJS (2000); 87, 38-42.

VEN 310: Delivery Platform

Initial Focus: C. difficile and VRE

Role of the Microbiome

- The human gut is under perpetual threat from potentially damaging agents (bacteria, viruses, fungi and bacteriophage) and it therefore comes equipped with several protective mechanisms
  - Layers of impenetrable sticky mucus
  - A protective epithelium supported by an army of vigilant immune cells
  - Beneath this a complex support system of immune cells and signalling molecules
- Commensal bacteria have adapted to live in the gut through an active two-way "conversation":
  - The microbiota influence the host's immune system both at a local and systemic level
  - The host immune system influences the composition, diversity and even location of the microbiota in the gut
- Any disruption of this "conversation" can lead to predisposition to disease or to disease itself
  - A wide range of conditions, all known to be underpinned by immune dysfunction, now appear to have some link to dysbiosis

It is the absence of normal microflora rather than the presence of pathogenic microbes that seems to underlie immune dysfunction

Therabiome – Agreement

- Intellectual property relating to the oral delivery of bacteria, viruses, and drugs agents to specific sites in the intestine using a pH sensitive controlled release platform technology

- Rights to develop and commercialize the use of bacteria, viruses, proteins and small molecules by oral delivery in:
  - Gastrointestinal dysbiosis, including but not limited to C. difficile, irritable bowel syndrome, constipation and inflammatory bowel disease
  - Auto-immune disorders and autism, including but not limited to as controlled by bacteria or virus
  - Orally delivered vaccines, including viral and bacterial

Therabiome – Opportunities

- Therapeutic use of selected bacteria
  - To correct dysbiosis and increase colonization resistance (e.g., C. difficile, VRE, IBS-D, antibiotic-induced diarrhea)
  - To down-regulate the adaptive immune system (locally: IBD; systemically: other auto-immune disorders)
  - To correct metabolic dysregulation from dysbiosis, e.g., obesity, diabetes
  - Other: autisim
- Oral vaccines
  - Deliver antigens precisely and intact to ileal/colonic lymphoid tissue
- Small molecules
  - Optimize delivery for topical colonic activity
- Estimated initial target: phase II in CDAD and/or VRE by Q1 2016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Backup Slides

VEN 307

FDA Written Feedback from Pre-NDA Meeting August 30, 2012

- Planned NDA submission following completion of second Phase 3 study (expected Q4 2013)
- Second Phase 3 study design accepted
  - Randomized, double-blind, placebo-controlled, parallel-treatment group efficacy and safety study of topical diltiazem hydrochloride 2% cream in subjects with anal fissures
  - 400 subjects at approximately 120 clinical sites in the U.S., Canada and Israel
  - Primary endpoint is reduction of worst anal fissure-related pain associated with or following defecation when administered three times a day for 28 days
  - Secondary endpoints are reduction of (i) overall daily anal fissure-related pain and (ii) patient global impression of improvement (PGI-I) at day 29 in subjects with anal fissure-related pain
- NDA to include clinical cutaneous sensitization and irritation studies and PK study
- Confirmed with the FDA that there is no need for chronic studies (clinical or Tox)

First Phase 3 Trial: Enrollment Criteria

- **Inclusion Criteria**
  - Written informed consent
  - An average of ≥4 on the 11-point NRS during the screening phase for worst anal pain associated with, or following, defecation for the most recent 3 days of the 7-day screening period in which the subject has defecated
  - Evidence of anal fissure
  - Willingness to stop all concomitant topical preparations
  - Ability to use Interactive Voice Recognition System (IVRS) diary
- **Exclusion Criteria**
  - Use of opioids and other analgesics (except acetaminophen up to 4 g per day and ibuprofen up to 1.8 g per day)
  - Prior lateral sphincterotomy or other previous surgery
  - AF associated with other conditions
  - Cardiovascular disease
  - Pregnancy, lactation

VEN307-PK-001

- 12 subjects: sequential dosing of all subjects with diltiazem 2% topical single and multi-dose, and oral to determine PK in AF patients
- One site in US
- 12 subjects enrolled
- All PK parameters were as expected and the systemic exposure to diltiazem from topical diltiazem compared to oral diltiazem was confirmed at <10%

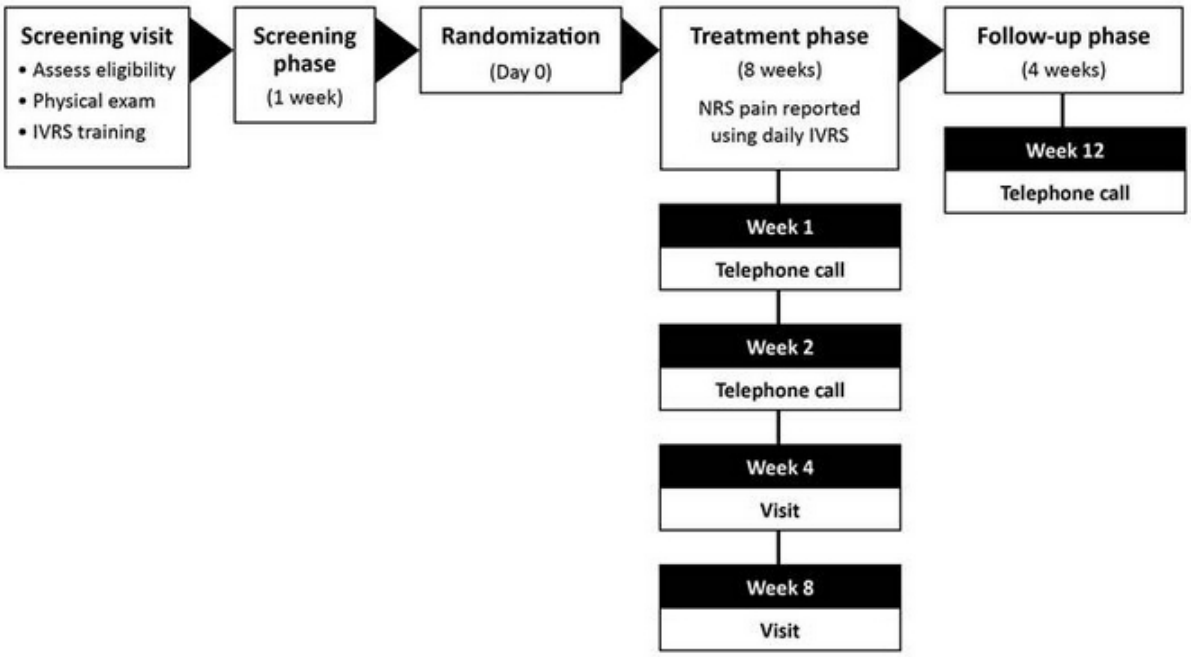
VEN307-DERM-001 and 002

- Sensitization and Irritation studies, 200 and 35 healthy volunteers respectively
  - Diltiazem 2%, vehicle , saline control, active control (SLS)
- The irritation scores were similar for diltiazem, placebo, and saline, all significantly better than SLS (active control)
- There were minimal AEs and no severe or serious AEs
- No irritation or sensitization potential with drug product or vehicle (placebo in PH III trials)

VEN 307 Life Cycle Management: BID Formulation

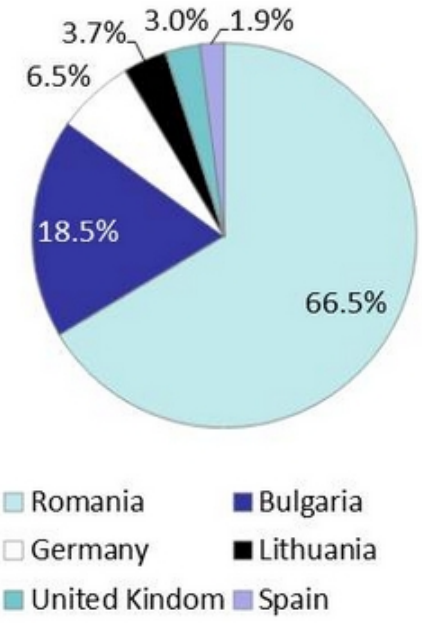
- Licensed from SLA Pharma for U.S. and Canada in return for single digit royalties and approval milestones
- U.S. patent protects IP through February 2018 and with HW extension to August 2019. Possible pediatric extension to Q2 2020.
  - After expiration, the Company expects generic approval to be difficult due to topical dosage, trade secret protection, re-formulation obstacles and the need for clinical study and comparative PK data in AF patients
- Have completed technical development of 4 extended release formulations
  - All patentable with expected protection through 2033
  - All B.I.D. or O.D.
  - At least one U.S. Phase 3 trial with one extended release formulation will be required (if one formulation is acceptable in manometry/PK studies).

Study Design



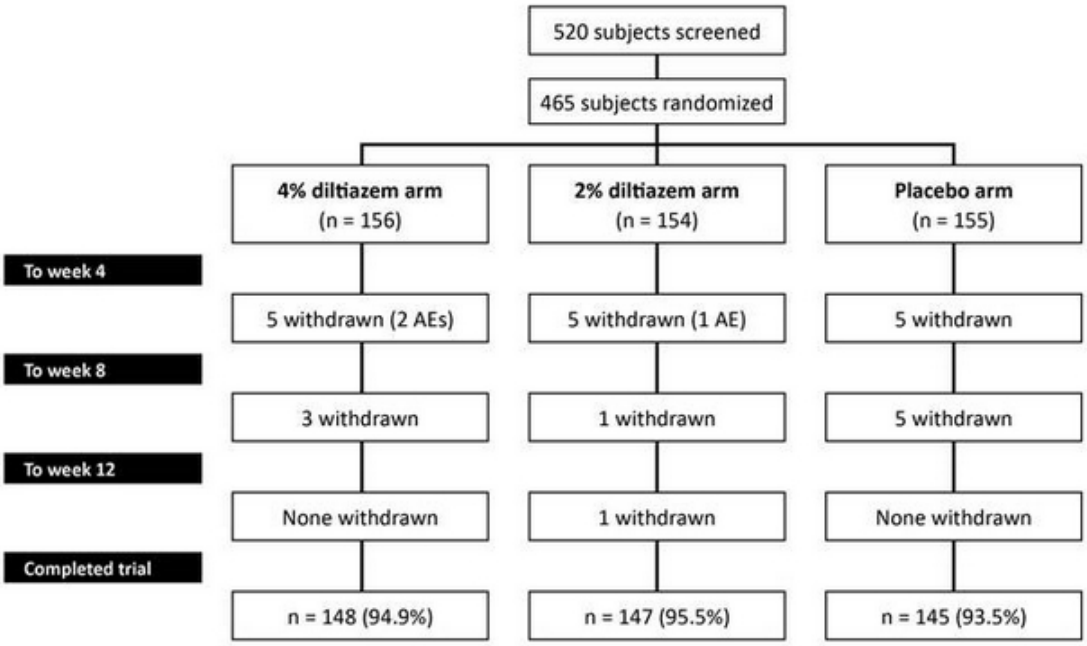
Baseline Demographics

Variable	4% diltiazem	2% diltiazem	Placebo
Age (years)	42.3 ± 13.6	44.2 ± 14.2	43.2 ± 12.5
Male	38.5%	48.1%	43.9%
Female	61.5%	51.9%	56.1%
Caucasian	100.0%	100.0%	99.4%
Height (cm)	169.3 ± 7.8	170.8 ± 9.1	168.9 ± 13.6
Weight (kg)	73.9 ± 16.6	77.5 ± 17.7	76.0 ± 18.1

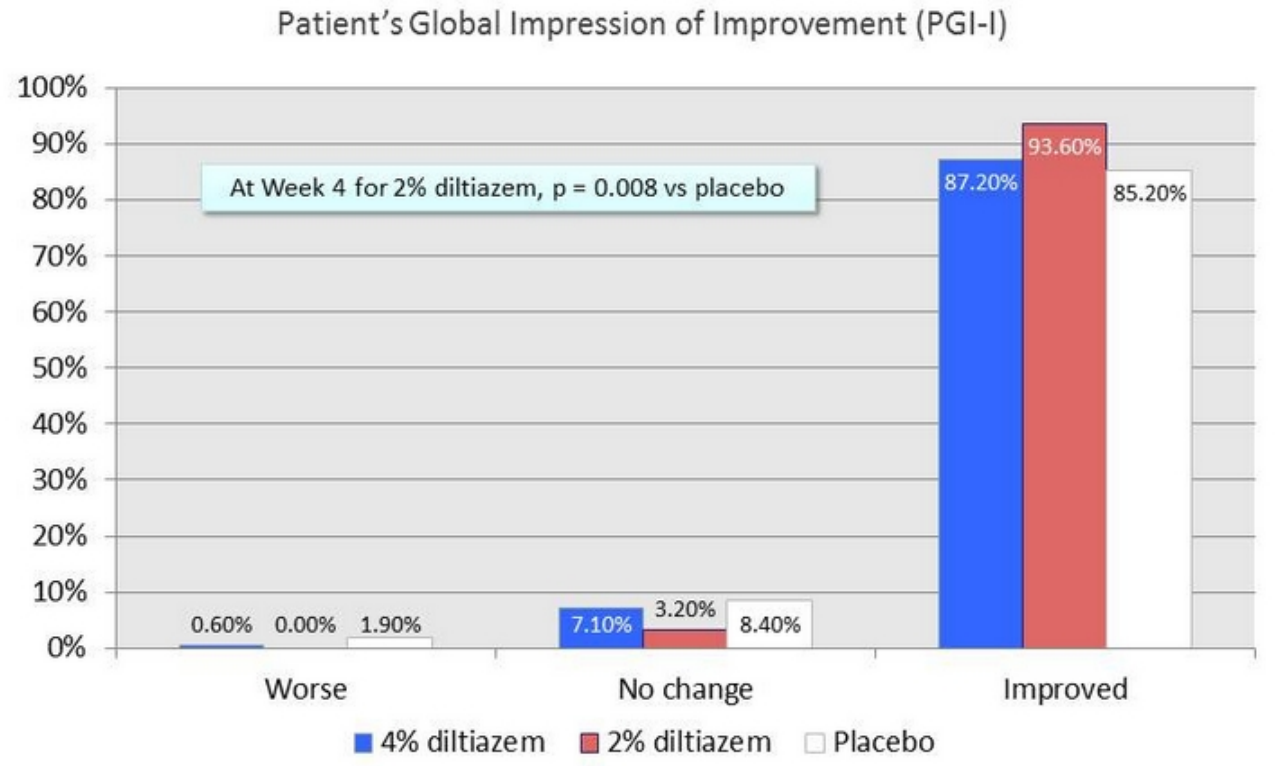


Geographic distribution of all 465 enrolled subjects

Patient Disposition



Secondary Endpoint: PGI-I at Week 4



Selected Adverse Events

Condition	4% diltiazem	2% diltiazem	Placebo
Gastrointestinal	65.4%	59.1%	54.2%
Proctalgia (anal pain)	42.3%	41.6%	45.2%
Nervous system	17.3%	13.0%	14.8%
Infections	8.3%	7.1%	3.9%
General disorders	3.8%	3.2%	5.2%
Musculoskeletal	2.6%	2.6%	1.9%
Metabolism	1.3%	3.9%	1.3%
Blood, lymphatic	1.9%	0.6%	1.9%
Hepatobiliary	1.3%	1.3%	1.3%
Psychiatric	1.9%	0.0%	1.3%
Respiratory	1.3%	0.6%	0.6%
Skin	1.3%	0.6%	0.6%
Cardiac	0.6%	0.0%	0.4%
Vascular	0.0%	0.6%	0.0%

Gastrointestinal Adverse Events

Condition	4% diltiazem	2% diltiazem	Placebo
Gastrointestinal	**65.4%**	**59.1%**	**54.2%**
Proctalgia (anal pain)	42.3%	41.6%	45.2%
Anal pruritus	14.7%	14.9%	7.7%
Anorectal discomfort	15.4%	13.6%	5.8%
Abdominal pain	3.2%	2.6%	5.2%
Anal haemorrhage	2.6%	3.2%	5.2%
Constipation	3.2%	0.6%	3.2%
Abdominal pain upper	2.6%	1.9%	1.3%
Diarrhoea	2.6%	0.6%	0.6%
Faeces hard	1.9%	0.6%	0.6%
Toothache	1.3%	1.3%	0.6%
Haemorrhoids	1.9%	0.6%	0.6%
Anal inflammation	1.3%	1.3%	0.0%
Rectal haemorrhage	0.6%	0.6%	1.3%

Gastrointestinal Adverse Events (Cont.)

Condition	4% diltiazem	2% diltiazem	Placebo
Gastrointestinal	**65.4%**	**59.1%**	**54.2%**
Nausea	0.6%	0.0%	1.9%
Anal fissure	0.6%	0.6%	0.6%
Dyspepsia	1.9%	0.0%	0.0%
Anal fistula	0.6%	0.0%	0.6%
Anal spasm	0.0%	1.3%	0.0%
Periproctitis	0.6%	0.0%	0.6%
Abdominal pain lower	0.6%	0.0%	0.0%
Haematochezia	0.0%	0.6%	0.0%
Abdominal distension	0.6%	0.0%	0.0%
Anal polyp	0.6%	0.0%	0.0%
Anal prolapse	0.6%	0.0%	0.0%
Anal ulcer	0.6%	0.0%	0.0%
Faecal incontinence	0.0%	0.6%	0.0%
Flatulence	0.6%	0.0%	0.0%
Gingival bleeding	0.6%	0.0%	0.0%
Irritable bowel syndrome	0.6%	0.0%	0.0%
Painful defaecation	0.0%	0.6%	0.0%
Pancreatitis	0.0%	0.0%	0.6%
Perianal erythema	0.6%	0.0%	0.0%

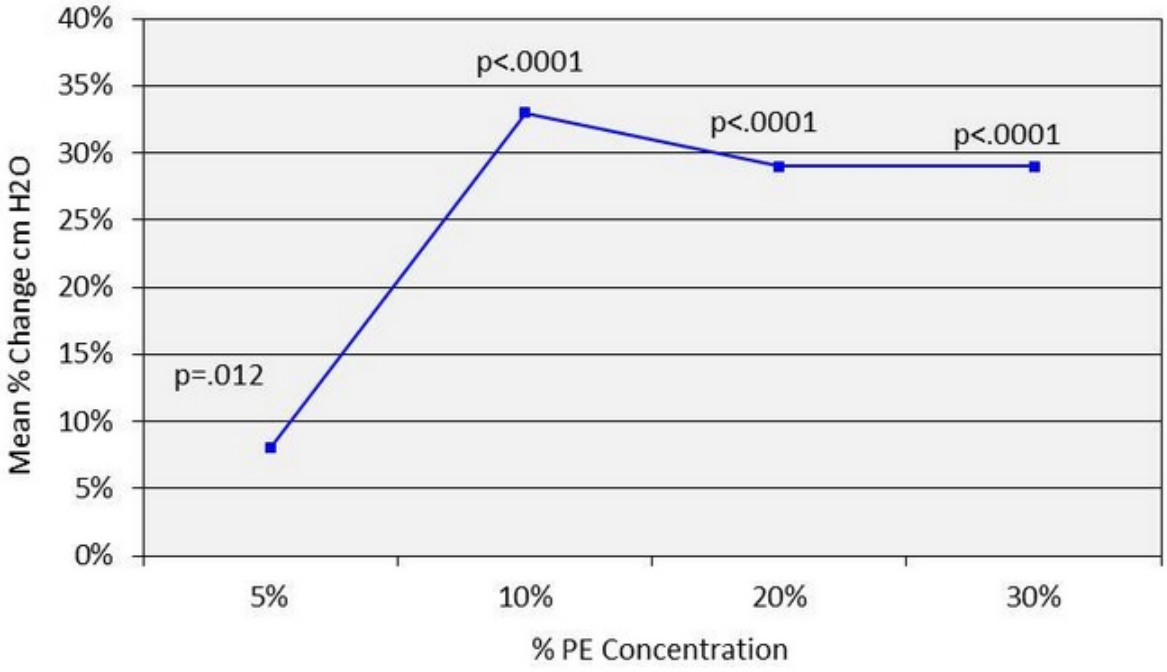
Infections Adverse Events

Condition	4% diltiazem	2% diltiazem	Placebo
Infections	**8.3%**	**7.1%**	**3.9%**
Nasopharyngitis	2.6%	3.2%	1.9%
Influenza	2.6%	0.6%	1.9%
Sinusitis	0.6%	0.6%	0.0%
Cystitis	0.6%	0.0%	0.0%
Acute tonsillitis	0.0%	0.6%	0.0%
Gastroenteritis	0.0%	0.6%	0.0%
Pneumonia	0.0%	0.6%	0.0%
Respiratory tract infection	0.6%	0.0%	0.0%
Tonsillitis	0.6%	0.0%	0.0%
Tooth abscess	0.0%	0.6%	0.0%
Vulvovaginal candidiasis	0.6%	0.0%	0.0%
Vulvovaginal mycotic infection	0.0%	0.6%	0.0%

Metabolic and Nutritional Adverse Events

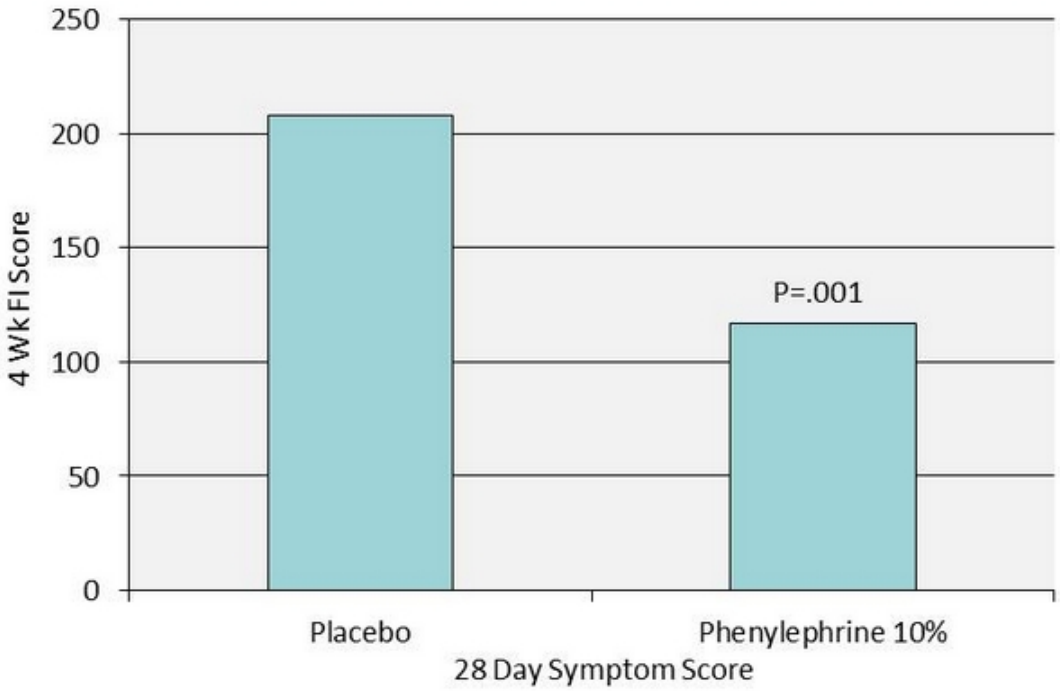
Condition	4% diltiazem	2% diltiazem	Placebo
Metabolism and Nutrition Disorders	**1.3%**	**3.9%**	**1.3%**
Dyslipidaemia	0.6%	1.3%	0.6%
Hypertriglyceridaemia	0.0%	1.9%	0.6%
Hypercholesterolaemia	0.0%	0.6%	0.0%
Hyperglycaemia	0.6%	0.0%	0.0%

Phenylephrine Gel Increases Maximum Anal Resting Pressure



Sample Size = 12 healthy patients.
Carapeti, E, Topical phenylephrine increases anal sphincter resting pressure, British Journal of Surgery (1999); 86, 267-270.

Phenylephrine Gel Improves 28 Day Symptom Scores in IPAA Patients



Sample size = 12 IPAA FI patients.
Carapeti E, et al, Randomized controlled crossover trial of topical phenylephrine for fecal incontinence in IPAA, Dis Colon Rectum (2000); 43(8), 1059-1063.

Fecal Incontinence Market Summary

- **Patient Population**
  - Orphan: 50MM – 100MM
    - 25% of Ulcerative Colitis patients undergo surgical resection procedures such as IPAA
  - General Population: 9MM
    - 63% female
- **Competitive Landscape**
  - Bulking fiber and pads are the current standard of care
  - No approved products in the U.S./E.U.
  - Solesta® dermal filler: No data regarding applicability in this population
  - IPAA population focused in gastroenterologists and colorectal surgeons

Therabiome – Terms

- For the license, Ventrus paid Therabiome an upfront non-refundable license fee of $ 300,000
- Ventrus must pay Therabiome:
  - Clinical and regulatory milestones for each product or therapy advanced from the platform for U.S. regulatory milestones
  - Lesser amounts for foreign regulatory milestones, which vary by country and region
  - Royalties on annual net sales of a product in the low to mid-single digit percentages plus, once annual net sales exceed two certain thresholds, a one-time cash payment upon reaching each threshold
- Therabiome must pay Ventrus:
  - Royalties on annual net sales of any product it develops, using the intellectual property, in the low double to mid-double percentages, depending on the level of development or involvement Ventrus had in the product

Appendix Commercialization Slides

PBE Market Research

- Market research conducted by Princeton Brand Econometrics to better understand the drivers needed to size the current prescription market for anal fissures
- Conducted Q4 2012 via the internet

Physicians responding to the primary research	
Colorectal Surgeons	98
Gastroenterologists	500
General Surgeons	87
PCPs	101
All Others	119
Total	**905**

7.2% of all CRS

- 731 invites were sent to CRS to secure the 98 respondents
- 5,857 invites were sent to GI to secure the 500 respondents

PDDA Data

- SDI's Physician Drug & Diagnosis Audit is a monthly survey that monitors disease states and the physician intended associated drug and non-drug therapy
- Over 3,200 office-based physicians (including 375 surgeons) representing 30 specialties across the United States report all patient activity during one typical workday per month
- SDI recruits physicians based on an AMA mailing list which is arranged by region and specialty

Forecast Model

('000)	2015	2016	2017	2018	2019	2020
U.S. Population[1]	325,344.0	328,421.5	331,528.0	334,664.0	337,829.6	341,025.1
Anal Fissures						
Patients[2]	767.3	774.5	781.9	789.3	796.7	804.3
Incidence[3]	0.24%	0.24%	0.24%	0.24%	0.24%	0.24%
Seen by CRS[2]	73.5%	73.5%	73.5%	73.5%	73.5%	73.5%
Patients	564.0	569.3	574.7	580.1	585.6	591.1
CRS That Treat AF with Rx[4]	89.7%	89.7%	89.7%	89.7%	89.7%	89.7%
AF Patients on Rx	505.9	510.6	515.5	520.4	525.3	530.2
Surgical Intervention[4]	33.7%	33.7%	33.7%	33.7%	33.7%	33.7%
AF Surgeries	190.1	191.8	193.7	195.5	197.3	199.2
Rx Before Surgery[4]	85.9%	85.9%	85.9%	85.9%	85.9%	85.9%
Patients Rx Before Surgery	163.3	164.8	166.4	167.9	169.5	171.1

1. UN Department of Economic and Social Affairs (Population Division): US Population growth between 2000 and 2010 = 0.95%
2. AF Patients who visited a physician (SDI PDDA, 2010)
3. Incidence of people with AF who will visit a physician.
4. Princeton Brand Econometrics (PBE), 2012.

VEN 307 Go To Market Plan

Launch Objectives

1. Raise the awareness of the "branded, FDA-approved, GMP topical diltiazem"
   - Develop core group of 10-15 CRS and GI KOLs 12 months prior to launch
   - Increase the awareness by 100% of all CRSs from the pre-launch (baseline) ATU to the first post-launch ATU
   - Convert 50% of all CRSs prescribing compounded diltiazem for their AF patients to VEN 307 by end of Year 1
   - Convert 75% of all HCPs prescribing Rectiv to VEN 307 by end of Year 1

2. Ensure early MHC reimbursement
   - Ensure that VEN 307 is Tier 2 for 10% and Tier 3 for 90% of covered lives in managed healthcare plans by Year 1
   - Ensure that VEN 307 is Tier 2 for 25% and Tier 3 for 75% of covered lives in managed healthcare plans by Year 2

3. Implement LCM plan
   - Qualify two suppliers
   - Develop a meter dose pump for launch 4Q'15/1Q'16
   - Ensure a BID formulation is ready for phase 3 trials by the end of 2015

Ventrus Team Meeting, Apr 26, 2012.

Sequence of Objectives

- Q1 2015: convert compounded diltiazem and Rectiv Rx to VEN 307
  - Cost effective targeting via a specialty sales force
  - Employ sales force-directed activities (e.g. samples, etc.) and non-personal promotion (e.g., internet, journal ads, etc.)
- Q1 2016: expand the market
  - Implement "remind and maintain" with prescribers of VEN 307
  - Expand Rx volume via lower decile GIs

VEN 307 Go To Market Plan

Segmentation & Targeting

- Healthcare providers
  - All colorectal surgeons
  - First decile GIs who manage and/or refer AF patients
- Patients
  - Existing and newly presenting AF patients
    - To ensure the initial HCP experience with VEN 307 is positive, the appropriate patient type per the PI should be targeted
- Payors
  - Pharmacy Directors: drive early coverage of VEN 307
  - Medical Directors: drive awareness of viable non-surgical option

Managed Healthcare Coverage Objectives

- Assumes VEN 307 ultimately ends up as branded preferred (Tier 2) in the majority of plans
- It is assumed that MHC plans will not step patients through compounded options, given the relatively small total cost burden; medical loss ratio targets @ 80%, and evolving compounding concerns
- While off-label use isn't expected with VEN 307, a few prior authorizations are nevertheless expected at launch

(% of patients)	2015	2016	2017	2018	2019+
Copay					
Tier 1 ($20)	0%	0%	0%	0%	0%
Tier 2 ($50)	10%	25%	40%	55%	60%
Tier 3 ($75)	90%	75%	60%	45%	40%
Restrictions					
No restrictions	80%	90%	100%	100%	100%
Step edit	0%	0%	0%	0%	0%
Prior authorization	20%	10%	0%	0%	0%
Step + PA	0%	0%	0%	0%	0%

VEN 307 Go To Market Plan

Physician Calls by Decile

- Decile options: Rectiv Rx, surrogate markers (e.g., lidocaine), self-reported AF patient population or compounding activity
- Call activity: 2,593 HCPs
  - 100% of CRS every 3 to 4 weeks
  - 10% of GIs every 4 weeks

Call Capacity (yearly)	
Days/year	365
Weekend days	104
Holidays and vacations	20
Working days/rep	241
Calls/day	8
Call capacity/rep	1,928
Call capacity, Ventrus/CSO	38,560

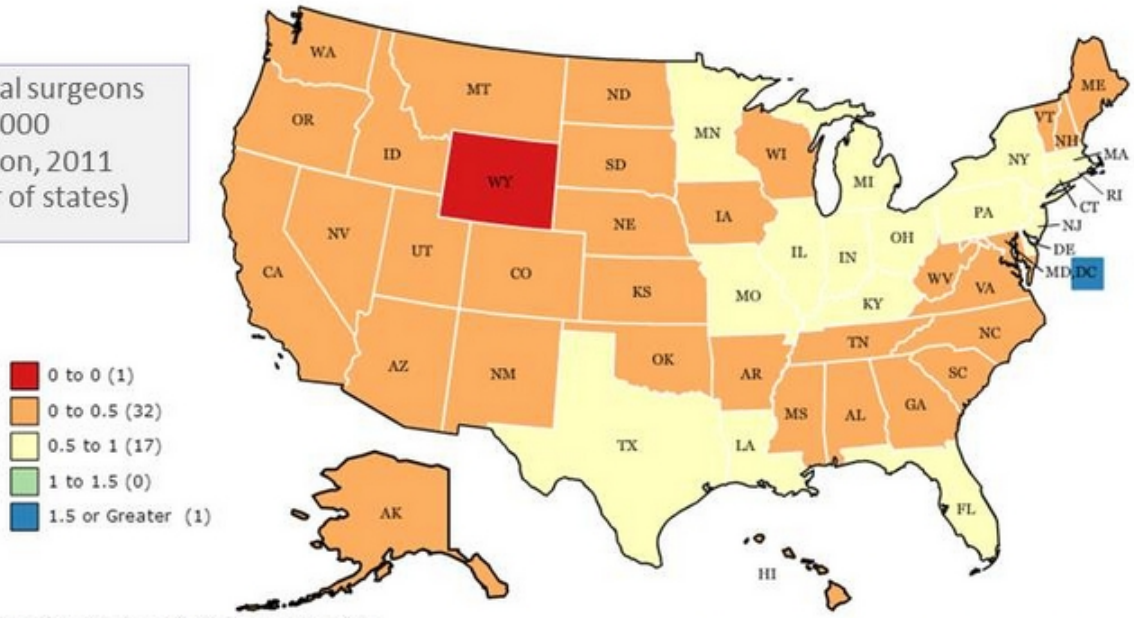
Decile	Colorectal Surgeons[1]				Gastroenterologists[2]				Total Calls/ Decile
	HCPs/ Decile	Cumulative HCPs	Calls/HCP (yearly)	Calls/ Decile	HCPs/ Decile	Cumulative HCPs	Calls/HCP (yearly)	Calls/ Decile	
1	136	136	18	2,443	1,236	1,236	12	14,836	17,278
2	136	271	18	2,443	1,236	2,473	-	-	2,443
3	136	407	18	2,443	1,236	3,709	-	-	2,443
4	136	543	18	2,443	1,236	4,945	-	-	2,443
5	136	679	18	2,443	1,236	6,182	-	-	2,443
6	136	814	18	2,443	1,236	7,418	-	-	2,443
7	136	950	18	2,443	1,236	8,654	-	-	2,443
8	136	1,086	18	2,443	1,236	9,890	-	-	2,443
9	136	1,221	12	1,628	1,236	11,127	-	-	1,628
10	136	1,357	12	1,628	1,236	12,363	-	-	1,628
Total	1,357	N/A	N/A	20,355	12,363	N/A	N/A	14,836	37,633

1. American College of Surgeons Health Policy Research Institute, Jan 2009.
2. American Board of Internal Medicine, Feb 2011.

Colorectal Surgeons

- Colorectal surgeons are not smoothly distributed in the United States and may impact targeting and call activity
  - Gastroenterologist targets will ensure complete territories

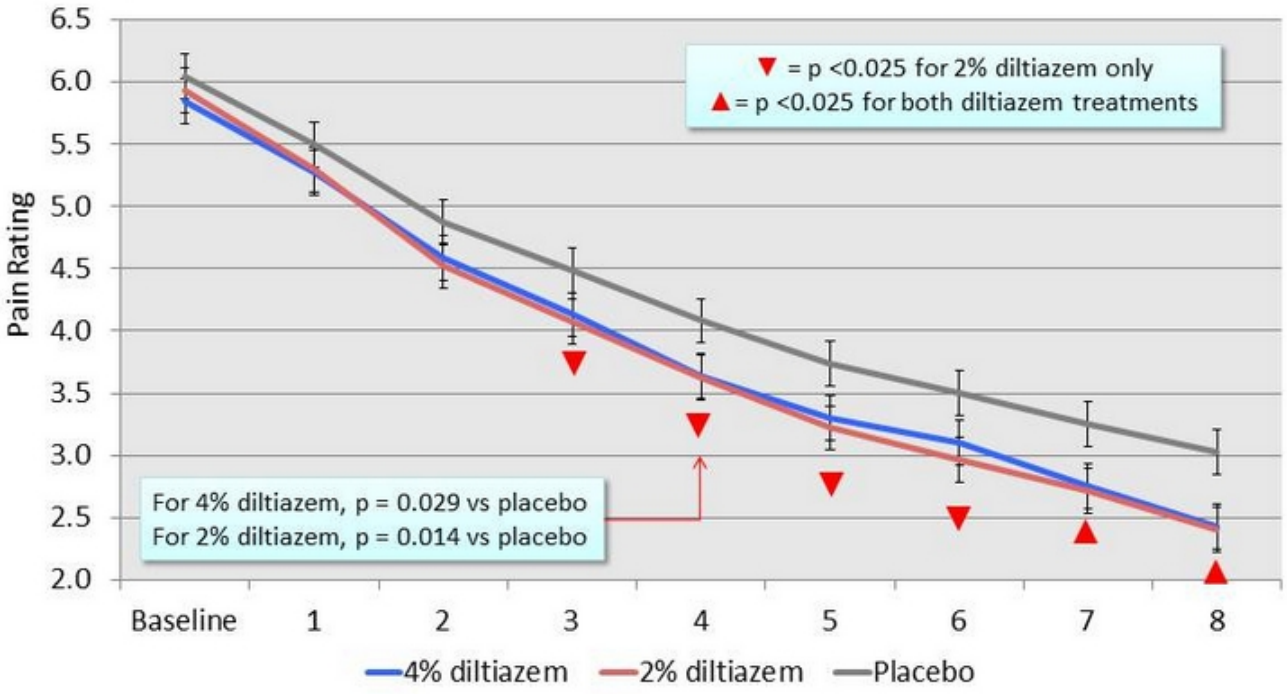
Colorectal surgeons per 100,000 population, 2011 (number of states)



American College of Surgeons Health Policy Research Institute.

Secondary Endpoint: Average Score of Daily AF Pain at Week 4

Compared with placebo, significant reductions with diltiazem from Week 3



VEN 307 Go To Market Plan

Executive Summary

- Launch VEN 307 in Q2 2015 to specialty physicians (colorectal surgeons and gastroenterologists) with a contract sales force of 20 sales representatives

- Minimize financial risk by aligning the majority of commercial expenses with FDA filing and approval

Preliminary Positioning

For your patients with anal fissures, VEN 307 is the first and only FDA-approved GMP prescription product proven to decrease the pain of anal fissures with **minimal adverse events**

- Note: The positioning and messaging for VEN 307 will be finalized following the submission of the NDA

Key Model Variables

- Population driven
  - Captures natural growth of anal fissures (AF) patient population
- Uses audited third party patient data (Physician Drug & Diagnosis Audit, PDDA) as surrogate for incidence of anal fissures
- Assesses the market that is driven by colorectal surgeons (CRS)
- Leverages market research (Princeton Brand Econometrics, PBE) about prescribing behavior of CRS with AF patients

Market Forecast

Key Assumptions for 2015

- US population = 325MM
  - Increasing at 0.95% per year
- Anal fissure patients = 767M unique patients who will visit a physician in 2015
  - Population-based projection of 2010 PDDA data
- Incidence = 0.24%
- AF patients that are seen by colorectal surgeons = 73.5%[1]
- CRS that treat AF with a prescription = 89.7%[2]
- AF patients being treated by CRS with a prescription = 506M

1. Physician Drug & Diagnosis Audit (PDDA), 2010.
2. Princeton Brand Econometrics (PBE), 2012.