

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 14, 2011

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))
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Item 8.01. Other Events.

Attached hereto as Exhibit 99.1 and 99.2 is a PowerPoint Presentation that Ventrus will present to investors and at various industry events and the hemorrhoid market survey Ventrus posted to its website. Exhibits 99.1 and 99.2 are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>ExhibitNo.</u>	<u>Description</u>
99.1	Slide presentation of November 2011 to be presented to investors.
99.2	Hemorrhoid market survey summary posted to Ventrus Biosciences, Inc. website.

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 14, 2011

By: /s/ David J. Barrett

David J. Barrett, Chief Financial Officer



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; the risks of not closing the acquisition of VEN 309 from Sam Amer & Co.; 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, including VEN 309; our ability to sell any approved products and the price we are able realize; our need to obtain additional funding 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 III biopharmaceutical company focused exclusively on gastroenterology; specifically, anal disorders - a neglected area of drug development
- Products address large, underserved, and untapped markets
- Late-stage products being studied for 3 of the top 10 GI disorders

Program (Pathway)	Indication	Clinical Phase			Potential NDA Filing	Next Milestone	Commercial Rights
		I	II	III			
VEN 309 Iferanserin (NCE)	Hemorrhoids				2014	Pivotal Phase III data read-out in 2Q 2012	World Wide
VEN 307 Diltiazem (505(b)2)	Anal Fissures				2013	Pivotal Phase III data read-out in 2Q 2012	North America
VEN 308 (505(b)2)	Fecal Incontinence				2015	Commence development in 2012	North America

- Near-term milestones with 2 pivotal Phase III read-outs expected in 2Q 2012

Experienced Management Team

Russell H. Ellison, MD, MSc: *Chief Executive Officer and Chairman of the Board*

30 yrs experience in pharmaceutical industry, most recently:

- EVP, **Paramount Biosciences** (2007-2010);
- VP Clinical Development, **Fibrogen Inc** (2005-2007)
- VP Medical Affairs and CMO, **Sanofi-Synthelabo US** (2002-2004);
- VP Medical Affairs and CMO, **Roche US** (1997-2002)
- Prior board member of **Cougar Biosciences Inc.**

David J. Barrett, CPA: *Chief Financial Officer*

- CFO, **NeuroHitech**, (2006-2009)
- CFO, **Overture Asset Managers & Overture Financial services** (hedge fund) (2003-2006)
- Manager **Deloitte & Touche** (1999-2003)
- Board member, **Coronado Biosciences**

Thomas Rowland, *Chief Business Officer*

- 20+ years of commercial pharmaceutical experience, 15+ in gastroenterology
- VP Commercial Development, **Alnara/Lilly** (2010 -2011)
- Founding CEO of **Ventrus** (2007 – 2010)
- VP GI/Women's Health Business Unit, **Solvay** (2000-2005)

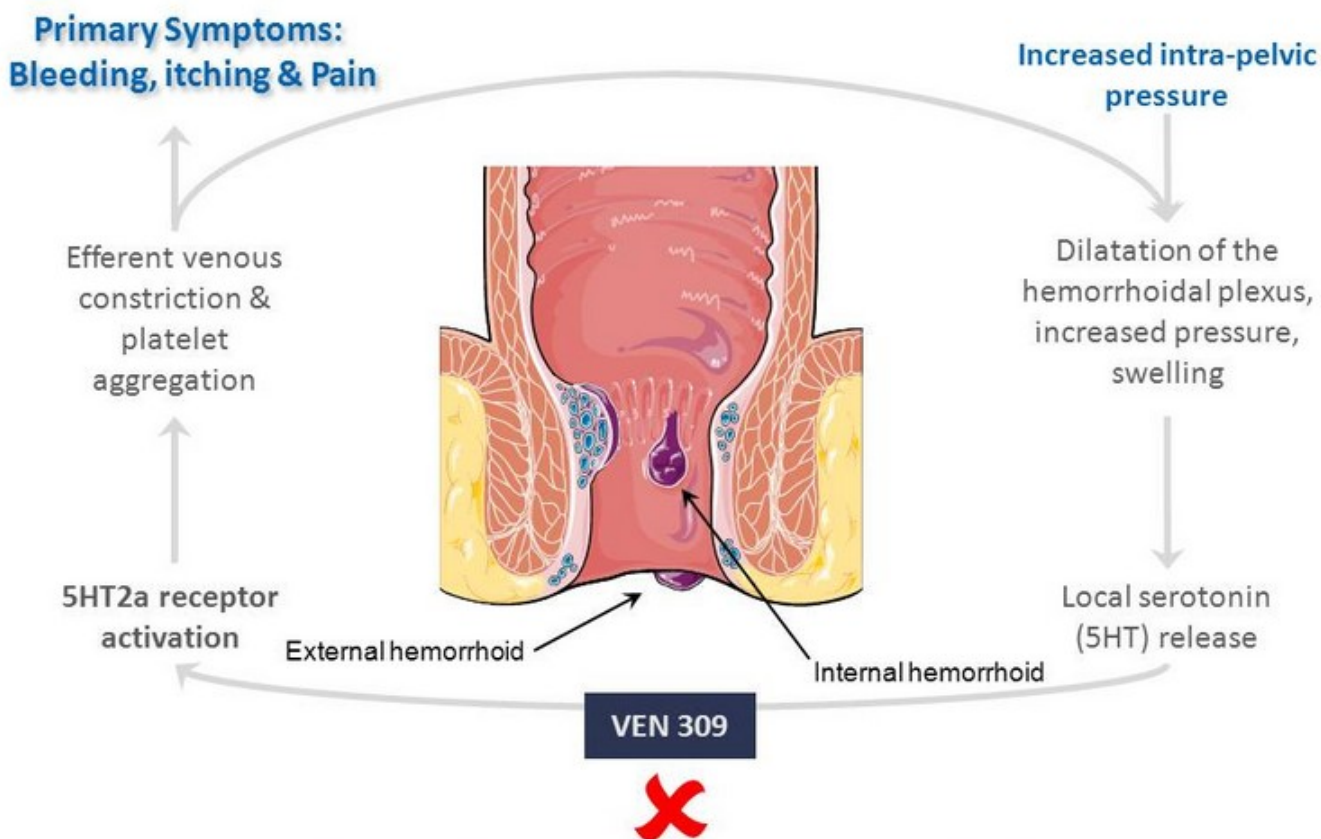


VEN 309: Iferanserin

NCE for Hemorrhoids



Physiology of Hemorrhoids



Hemorrhoids: 21.7 mio patients/year[^]: treatment options:

- **Invasive procedures (e.g., banding, sclerosing agents, surgery for prolapsed hemorrhoids)**

- **Rx:**
 - No FDA approved Rx drugs. Only Rx topical steroid containing products approved in EU, Japan*
 - > 4 million prescriptions of non-approved and non-DESI intra-anal steroids³
 - Current products have minimal to no reimbursement

- **OTC:**
 - 20-22 million^{1,2} OTC units sold annually in U.S. (e.g., “Preparation H”) – combinations of protective ointments, low-strength steroid, topical anaesthetics

- **No other known drugs in development in U.S, EU or Japan.**

1. Nielsen Homescan and retail scan July 2011 2. IMS 2003 3. IMS 2009

* Oral Daflon has a hemorrhoid indication in France ^ PBE survey of 10,250 consumers 2011

Hemorrhoids: Current OTC use:

In the last 52 weeks ending July 2nd 2011¹

- **9.5 million unique households purchased 1 or more OTC hemorrhoid preps**
(Representing 1 in 12 households)
- **On average each purchasing household bought 1.7 units per year**
 - 30% of purchasing households bought 2 or more units per year (ie: chronic or recurrent use); average time for repeat purchases was 2 months
- **77% of purchasers were 45 years old or older**
 - 55% of all ambulatory care visits are for patients 45 years of age or older - (ie 600 mio. visits/yr, 5 visits/person) ²
- **55% of households had income >\$50,000/year**

A highly prevalent solution seeking population with favorable demographics

1. Nielsen Homescan July 2011

2. Schappert SM. Ambulatory medical care utilization estimates for 2007. National Center for Health Statistics. Vital Health Stat 13(169). 2011.

VEN 309 (Iferanserin) Summary

Topical rectal ointment applied intra-anally BID x 2 weeks (with proprietary single-use applicator)

Mechanism of Action	<ul style="list-style-type: none">➤ Selective 5HT2a antagonist➤ Does not cross the blood brain barrier except at doses much higher than to be used therapeutically
Preclinical Safety	<ul style="list-style-type: none">➤ Systemic exposure is < 10%➤ Therapeutic ratio is > 17x
Clinical Pharmacology	<ul style="list-style-type: none">➤ Metabolized by CYP2D6 in liver (similar to Prozac)➤ No accumulation of the drug on twice daily dosing
Clinical Data	<ul style="list-style-type: none">➤ Seven clinical trials in 359 subjects (220 exposures)➤ No SAEs, limited AEs (mainly GI), similar AE profile vs placebo➤ Significant improvements in symptoms related to hemorrhoids including bleeding, pain and itching
Rights	<ul style="list-style-type: none">➤ Scheduled to acquire world-wide rights paying royalties between 1% and 4% <i>(closing expected Nov 14 2011)</i>
Market and Data Exclusivity	<ul style="list-style-type: none">➤ Filed a new concentration range patent (August 2010)➤ Composition of matter expires August 2015 in the U.S. - 5 years and 10 years of data exclusivity in the U.S. and E.U. under Hatch-Waxman Act, respectively➤ Topical GI Product with low bioavailability

VEN 309 Clinical Data: Efficacy Phase IIb

➤ **5 sites in Germany, conducted in 2003/2004**

- 121 patients randomized to Iferanserin 0.5% BID vs. placebo ointment x 14 days
- Baseline and weekly visits for 2 week treatment; follow-up at 45 days
- Symptoms recorded in daily diaries (scale of 1-10; 1 = no symptoms)

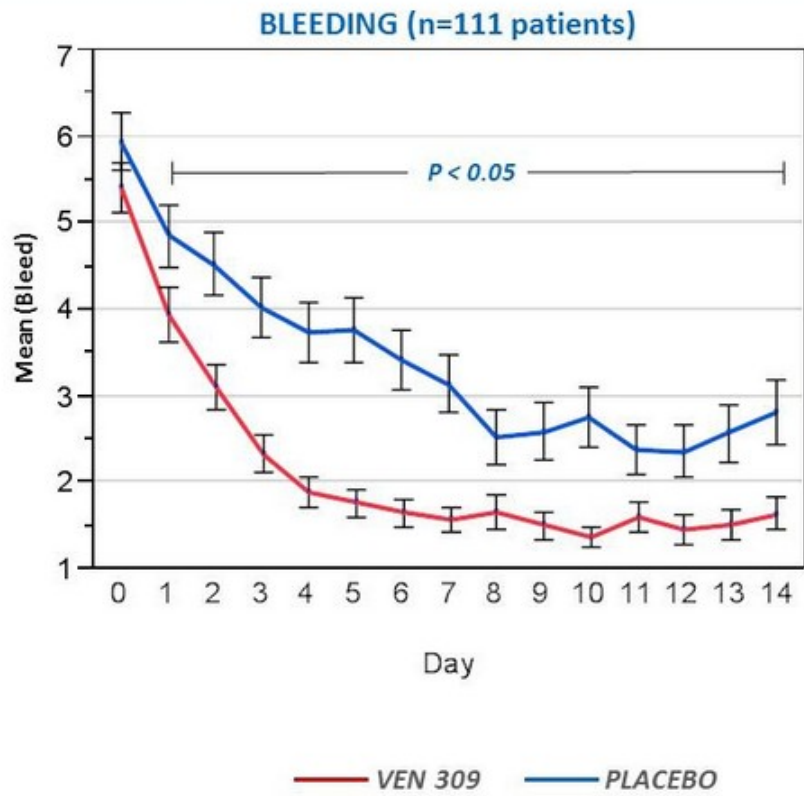
➤ **Endpoints**

- Primary - bleeding scale at Day 7 and Day 14; 111 evaluable patients
- Secondary - itching and pain scales at Day 7 and Day 14; 60 evaluable patients with itching, 40 evaluable patients with pain
- Other - tenderness, fullness, throbbing, gas, difficulty in defecation and physician's assessment

VEN 309 Clinical Data: Efficacy Phase IIb

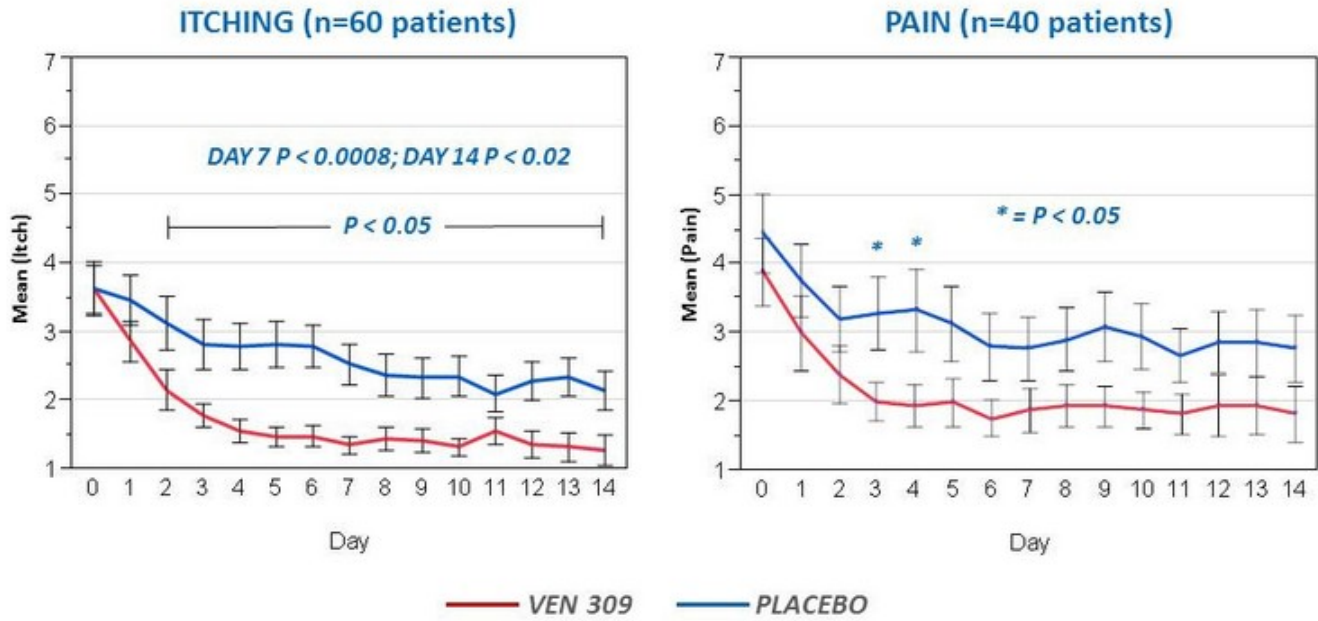
➤ Primary endpoint

- Bleeding: rapid sustained effect
 - Day 7 VEN 309 vs. placebo $p < 0.0001$
 - Day 14 VEN 309 vs. placebo $p < 0.0075$



VEN 309 Clinical Data: Efficacy Phase IIb

Secondary endpoints: rapid, sustained effect



EFFICACY ENDPOINTS FOR PHASE III

- **Primary endpoint: no bleeding Day 7 - Day 14 (2nd week of treatment).**

- **Secondary endpoints: no pain, no itching Day 7 - Day 14**
 - Unusual for symptomatic drugs – usually reduction in a scale – ie mitigation vs cessation

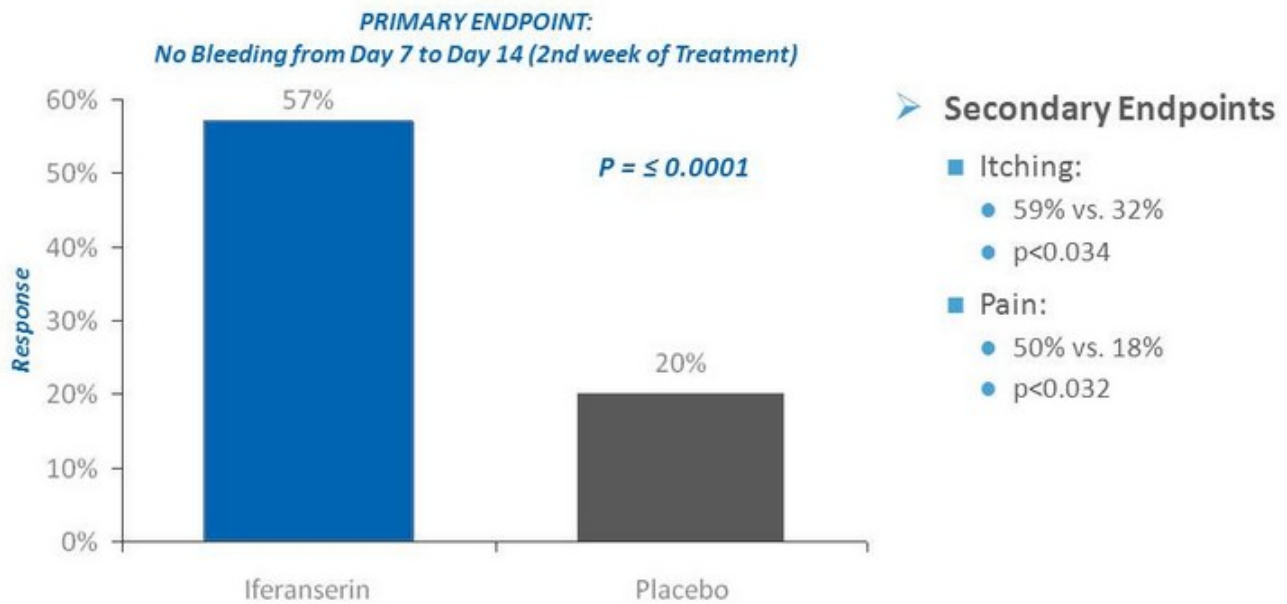
 - Clearly clinically relevant (FDA)

 - Compelling for patients and physicians vs OTC products (marginal transient effect) or intra-anal steroids (no data)

- **Proposed by FDA**

Modeling of Phase IIb Data for Phase III Endpoints*

Absence of symptom Day 7 through Day 14
n = 111 with bleeding, n = 60 with itching; n = 40 with pain, at entry



Majority of responders in the treatment arm respond by Day 3

*Post hoc

Development Plan

- Chronic repeated use product (FDA definition – may or may not be the case in Japan and EU)
- 1,500 subjects needed for complete safety profile (US and possibly EU)
- Two pivotal Phase III trials (and one double blind Phase III recurrence trial to determine safety/efficacy and treatment for recurrence for the US)
- Clinical pharmacology program including: DDI, PK in poor metabolizers, QT and special populations (to start Q4 2011)
- Preclinical:
 - 2 species 6 & 9 mo. Chronic tox
 - Carcinogenicity studies in two species exposed for 104 weeks and dose ranging study and chronic tox in rats and dogs (only for FDA?)
 - Carcinogenicity is critical path for NDA, clinical trials can be done serially without losing time
- Potential FDA approval 2015 (if no carc required, ROW 2014)

VEN309 (Iferanserin) for the Treatment of Hemorrhoids

➤ Ongoing Phase III trial: iferanserin 0.5% ointment b.i.d.

■ Design

- 3 arms, 200 patients per arm (placebo, 14 day treatment, 7 day treatment), total 600 patients, 70 sites
- 2 week treatment followed by 2 week observation, double-blind
- 1 year open-label extension (treatment for recurrence of symptoms)
- **Primary endpoint, cessation of bleeding day 7– 14; secondary endpoints, cessation of pain, itching day 7-14.** Endpoints collected daily using Integrated Voice Response System (IVRS)
 - ▶ Patients need 2 consecutive days of bleeding and either pain or itching at randomization: *meaningful symptoms to get meaningful improvement*
- Due to 1 year open-label extension
 - ▶ Colonoscopy required pre-randomization if > 3 yrs ago
 - ▶ No DDI data re CYP2D6: exclude history of and current depression, SSRI's
 - ▶ Exclude history of heart disease, BMI > 36, other chronic diseases
- **Discussion with FDA on all major elements of the protocol**

■ Progress

- Initiated early August with 65 sites; currently all 70 sites screening
- Enrolling correct patients, minimal loss of key outcome data on IVRS, continuous data review
- Large number of patients entering screening as expected

VEN309 (Iferanserin) for the Treatment of Hemorrhoids

■ Estimated timelines

- Updated guidance
 - ▶ Enrollment complete: April 2012
 - ▶ Double-blind data and available open-label recurrence data: **around June 2012**
 - ▶ Factors driving updated timelines
 - Screen failure rate higher than expected due primarily to
 - Need for 2 symptoms x 2 consecutive days , thus patients staying in screening longer than expected and large number eventually failing
 - History of depression, need for colonoscopy, chronic disease, BMI
 - ▶ **No effect on NDA filing timelines**

■ Impact on future studies (2nd pivotal and double-blind recurrence trial)

- Screen failure rate expected to decrease
 - ▶ Neither has open-label extension, and DDI studies will be available:
 - colonoscopy post treatment, no depression exclusion, minimal chronic/ high morbidity disease exclusions

VEN309 (Iferanserin) for the Treatment of Hemorrhoids

➤ Pharmacology program: CYP2D6 metabolism

- Iferanserin is dependant on CYP2D6 for metabolism and inhibits CYP2D6 in the liver (Prozac)
 - Advantage: GI topical drug with low systemic exposure
- Program designed to generate following data
 - Poor metabolizers (missing genes): safety and exposure, needed for QT study
 - ▶ One poor metabolizer (2 genes missing) in Ph I had no adverse events
 - Drug interaction with CYP2D6 dependant/inhibiting drugs (Cymbalta [duloxetine], dextromethorphan)
- Data anticipated Q2 2012 (when pivotal trial data expected)
 - *Allow less restrictions in exclusion criteria* for the next studies
 - Provide high dose arm for QT study
 - De-risk safety profile

Hemorrhoid Rx Commercial Potential: Study

- **Ventrus commissioned an omnibus survey and predictive modeling market research in September 2011 of 800 physicians and 1,125 hemorrhoid patients**
 - Physician project is beginning the analysis stage
 - Consumer project is in analysis stage and initial results are available

- **Study Approach**
 - Each respondent sees only one profile
 - PBE *factors* (discounts) the self-stated survey responses regarding VEN 309 adoption to accurately reflect real world behavior, based on extensively validated in-market models

- **Princeton Brand Econometrics**
 - Founded in 1991 and has worked for 9 of the top 10 pharmaceutical companies
 - Chosen based on their track record of accurately predicting physician and consumer behavior given a range of product profiles and promotional levels
 - Mean absolute percentage error over 31 validated forecasts is 2.68%

Study Results

- 10,202 adult consumers were screened (designed to match US demographics)
- 1,125 (11%) consumers reported suffering from hemorrhoids within the last two years...ie: *hemorrhoid patients*
 - 2010 US Adult population – 234,564,000 (2010 US census)
- **Period prevalence:**
 - 2 years: 11% - 25.8 million
 - 1 year: 9.3% - 21.7 million
 - 1 month: 6.0% - 14.0 million
 - Day of survey: 2.9% - 6.7 million
- **Treatments**
 - 15% reported never using OTC or Rx treatment
 - Of those treating, 86% reported using an OTC preparation or 14% Rx as their last treatment
 - 10% of all patients reported having an invasive procedure (61% surgery) with 75% reporting recurrence of symptoms after surgery

Patient response to VEN 309 DTC/PR concept

➤ Strong willingness to ask their doctor for VEN 309 at the next visit

- In the whole sample: (complete range of current satisfaction, severity frequency of hemorrhoids, time of last episode, and income):
 - 75% stated* that they would request a prescription at the next visit
 - 25% would actually request a prescription (75% factored by PBE algorithm)
 - 66% receiving a prescription would fill the Rx at a \$35 patient out-of-pocket co-pay^
 - ▶ 78% with household income above \$50k/year would fill the Rx at a \$35 copay^
- For patients who are having symptoms now, (estimated at 6.7 mm)
 - 88% stated* they would request a prescription and
 - 80% would actually request it (PBE factored)

*Stated includes "Definitely, Probably and Might"

^ PBE factored



VEN 307: Diltiazem Cream

Novel Treatment for Anal Fissures



Anal Fissures: Cause and Management

Cause

Increased sphincter tone



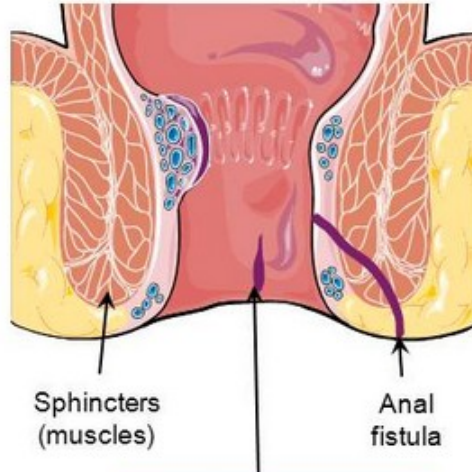
Local ischemia



Tear (fissure) in anal canal



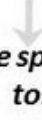
Severe pain on defecation



Anal fissure
1.1 mio office vists/year

Treatment options

Control constipation,
topical steroids

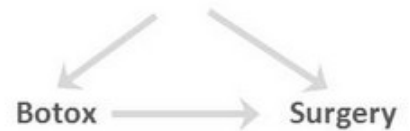


Reduce sphincter tone



Topical drugs:

- GTN
- diltiazem



Anal Fissures: Patient Options

FDA-Approved Rx Drugs	<ul style="list-style-type: none">■ Rectiv (GTN Topical) FDA approved 6/22/2011 but not launched yet<ul style="list-style-type: none">■ Relaxes anal sphincter; effective in pain relief■ Systemic exposure gives \geq exposure as an anti anginal dose■ Flushing and headaches limit use;<ul style="list-style-type: none">○ US PI: 938 headaches in 79 patients○ overall headache rate (US PI; SMPC) > 60%
Current Drug Treatments	<ul style="list-style-type: none">■ Fiber, sitz baths, steroids first line■ Compounded Diltiazem, Nifedipine, and some GTN are already used by specialists and PCP's■ Medical associations' guidelines have consistently directed physicians to topical Diltiazem over GTN as 1st line therapy<ul style="list-style-type: none">○ The Association of Coloproctology of Great Britain and Ireland (2008)⁽¹⁾○ The American Gastroenterology Association (2003)⁽²⁾
Drugs in Pipeline	<ul style="list-style-type: none">■ RDD Pharma completed a Phase Ib clinical trial of Nifedipine for the treatment of chronic anal fissures

(1) Cross, KLR., et al., (2008) *The Management of Anal Fissure: ACPGBI Position Statement*. *Colorectal Disease*, 10 (Suppl. 3), 1-7.

(2) Madoff, RD., & Fleshman, JW. (2003) *AGA Technical Review on the Diagnosis and Care of Patients With Anal Fissure*. *Gastroenterology*, 124, 235-245

VEN 307 (Diltiazem) Summary

2% Topical Diltiazem cream applied peri-anally TID

Mechanism of Action	<ul style="list-style-type: none">➤ Calcium channel blocker<ul style="list-style-type: none">■ Relaxes the internal anal sphincter, reducing pain and increasing tissue blood flow
Preclinical Safety	<ul style="list-style-type: none">➤ Preclinical topical safety with 2% Diltiazem twice daily for ninety days
Clinical Pharmacology	<ul style="list-style-type: none">➤ Topical has < 10% systemic exposure as oral dose but significantly greater effect on sphincter tone – i.e., blood levels do not predict activity. Low exposure = better tolerability than oral Diltiazem
Clinical Data	<ul style="list-style-type: none">➤ Ten clinical trials in 453 individuals➤ Infrequent mild AEs reported➤ Similar or better reduction in pain, significantly better tolerability than GTN
Rights	<ul style="list-style-type: none">➤ North American rights paying mid to upper single digit royalties
Market and Data Exclusivity	<ul style="list-style-type: none">➤ Method of use patent expires Feb 2018➤ Topical GI product; systemic levels do not predict efficacy and will not guarantee generic drug approval➤ Extended Release formulations (b.i.d.) under development to extend exclusivity

VEN 307: Clinical Trial Data

➤ Early Phase II study (2% BID)

- Primary endpoint of *healing* not met due to high placebo response (similar to GTN studies); other endpoints measured at end of study

➤ Multiple investigator-initiated trials

- Most comparing Diltiazem topical with GTN, and a few vs. standard care; using gels/creams; BID and TID
- Almost all reported equal or better *pain* results than GTN with fewer side effects; one with somewhat better effects on pain vs. GTN and substantially better than placebo, e.g.,
 - Shrivastava⁽¹⁾ (2007)- Diltiazem superior pain relief @ 6 weeks, no AEs in Diltiazem treated patients; 67% of GTN patients had headaches $n = 90$
 - Kocher⁽²⁾ (2002)- Diltiazem lower side effects than GTN, no differences in healing or pain $n = 60$

(1) Shrivastava BK, et al, Randomized clinical trial GTN vs. Diltiazem vs. Fiber Only, *Surgery Today* (2007); 37: 482-485

(2) Kocher, H, et al, Randomized double-blind clinical trial comparing side effects GTN vs. Diltiazem, *British Journal of Surgery* (2002); 89, 413-417

VEN 307: First Pivotal Phase III Trial Initiated

- **FDA (analgesia division) pre-IND meeting conducted in August 2007**
 - Confirmed Phase III multi-dose plan; *505b(2) status*
 - Achieved clarity on primary endpoint: reduction in pain
 - Confirmed safety database and tox requirement

- **Phase III trial initiated (November 2010) with *data anticipated around May 2012***
 - Licensor (SLA) is conducting trial
 - 465 patients in 30 sites in Europe; initiated in November 2010
 - Treated for 2 months: randomized 1:1:1 double blind; fiber plus 2%, 4% VEN 307, and placebo; primary endpoint at 1 month
 - NRS scale, daily diaries
 - 1 week observation to ensure sufficient pain prior to randomization
 - Primary endpoint: reduction in pain on defecation using a validated scale (Likert, NRS)
 - Ventrus did detailed review of blinded data and study operations 10/2011: Correct patients enrolled, IVRS compliance is good, data are being reviewed continuously

- **Planned Second Phase III trial(s):**
 - We intend to conduct enabling toxicity
 - Developing 4 possible extended release formulations: may test some or all in human manometry trial in 2012
 - Could be 2 trials with extended release formulation if one is acceptable, or 1 with original formulation

Expected Milestones: VEN 309 and VEN 307



VEN 309

- Publication of German PH II study
- Additional results from market research
- Completion of PH 3 trial enrollment (April) and results from PH 3 trial (June)
- Clinical pharmacology results
- Publication of preclinical pharmacology
- Recurrence data read-outs from 1st pivotal; launch of second pivotal and recurrence trial

VEN 307

- Progress update on a new Diltiazem extended release formulation with extended IP
- Completion of enrollment (Jan) and Data read-out from first pivotal Phase III trial (May)
- Selection of extended release formulation
- Launch of second pivotal(s)



Corporate Overview



Future Scenarios: VEN 309 and VEN 307

After data readouts expected in 2Q 2012:

➤ Strategic options

- In 2012, 5-6 major pharma companies with primary care and/or GI products and field forces
- Four with an OTC division
- 2-3 GI specialty companies

➤ Partnerships

- We intend to seek a marketing partner for VEN 309 for ex-U.S. territories (EU, Asia)
- Co-promotion opportunities exist for broader PCP coverage of VEN 309 and VEN 307 in US

➤ Estimated continued development of products by Ventrus:

- **VEN 309** US filing 2H 2014 approval possible 2015; may be earlier in EU, and/or Japan (PH I and II done in Japan)
- **VEN 307** diltiazem cream filing 2H 2013; approval possible 2014 (later if extended release)

Possible Commercialization Strategy

The nature of the markets we target provide Ventrus with the option of US commercialization

➤ Specialty sales force can be highly effective

- Diltiazem is the established gold-standard treatment for anal fissures among GIs and the launch of Rectiv will allow cost effective targeting of prescribers, with the AE advantage of VEN 307 and already established preference
- Highly selective specialty sales force targeting of prescribers of the 4 million prescriptions of steroids for hemorrhoids (using IMS data), to convert these to VEN 309
 - No data to support the use of intra anal steroids as effective treatment; not approved
- Yearly DTC campaign (cost efficient with this indication)

➤ Co-promotion possibilities with existing primary care field forces for broad coverage

➤ Pricing and Reimbursement

- VEN 309: No other drugs in class or indication: Medicare Part D and managed care implications (anticipate blended 2nd tier/3rd tier formulary)
- VEN 307: Anticipate 2nd tier/3rd tier formulary. Anticipate Medicare part D (side effect difference vs GTN).

Q3-2011 Financial Update

➤ Cash balance

■ Cash and cash equivalents at Sept 30, 2011	\$ 53.3 Mil
■ Expected cash burn next 12 months*	\$ 12 -\$ 16 Mil
■ Cash and cash equivalents YE 2011 end guidance	\$ 34-\$ 36 Mil

➤ Stock data

■ Fully diluted shares outstanding	15.3 Mil
■ Shares outstanding	12.4 Mil

➤ Sources of funding 2007 to present

■ Funding pre-IPO	\$ 10 Mil
■ IPO December 2010	\$ 18 Mil
■ Secondary public offering July 2011	\$ 47.5 Mil

- * Excludes payment to acquire rights to Amer: estimates - our operation expenditures could change

Key Takeaways

➤ The Products

- VEN 309 believed to be the first and ONLY FDA-approved Rx drug for hemorrhoids, with a market of approximately 21.7 million patients/yr in the US and proportional markets in ROW
- VEN 307 believed to be a superior product to the only approved drug for anal fissures (Rectiv), with a market of approximately 1.1 million office visits per year
- VEN 309 and 307: validated Phase III endpoint that has already demonstrated efficacy in multiple Phase II trials
- Good safety profile - limited side effects from topical administration

➤ The Company

- 2 high-value pivotal data read-outs expected in H1 2012
- Multiple scenarios are possible for further development and commercialization of the products after the data read-outs
- Experienced team with a history of success

www.ventrusbio.com update

Landmark Market Research

In September 2011, Ventrus commissioned Princeton Brand Econometrics (PBE) to conduct a landmark omnibus survey of consumers and physicians. From these data, PBE is developing a predictive model to forecast physician and patient behavior in response to various product profiles and promotional levels. In addition to the predictive modeling, these data are providing some important insights into the natural history of hemorrhoids and the actions physicians and patients take seeking to alleviate this highly symptomatic disorder.

Hemorrhoid Patient Survey

A total of 10,202 consumers were screened from a robust preexisting panel of 50,000 consumers developed to replicate the US population on major demographic parameters. Of the over 10,000 consumers screened 1,125 reported having hemorrhoids within the last two years, which represents approximately 11% of the US adult population (25.8 million of 234 million people).

Summary of survey period prevalence:

- 2 years: 11% - 25.8 million patients
- 1 year: 9.3% - 21.7 million patients
- 1 month: 6.0% - 14.0 million patients
- Day of survey: 2.9% - 6.7 million patients

The survey showed a very active patient population with 85% reporting having had either over the counter (OTC) or prescription treatment at some point and 10% had had an invasive procedure (banding, injection, surgery) at some time.

Of those patients having an invasive procedure:

- 61% had surgery
- 26% had banding
- 75% of patients who had had an invasive procedure reported a recurrence

Of those patients having OTC or prescription treatment:

- 86% reported using OTC as their last treatment
 - 14% reported using prescription products as their last treatment
-

Patients had a strong response to the product concept of VEN 309 as a treatment for their hemorrhoids. Of the 1,125 surveyed:

- 75% stated* that they would request a prescription at their next physician visit
- 25% would** actually request a prescription (75% factored by PBE algorithm)

At a \$35 co-pay:

- 66% of patients receiving a prescription would fill the Rx
 - o 78% with household income above \$50,000 per year would fill the Rx

Among patients reporting having symptoms now

- 88% stated* that they would request a prescription at their next physician visit.
- 80% would** actually request a prescription (PBE factored)

About Princeton Brand Econometrics

Princeton Brand Econometrics (PBE) is a marketing engineering consultancy headquartered in Princeton, NJ, that builds models which simulate the cause and effect dynamics of market environments of interest, based on extensive and rigorous quantitative research. PBE's average forecast error across 31 published validations is $\pm 2.68\%$ of actual in-market outcomes, and its forecasting methodology has been utilized by 9 of the 10 top pharmaceutical companies.

*Stated responses include: definite, probably and might

**Assumes industry standard promotion levels
