

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 13, 2012

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 present at BIO CEO on February 13, 2012 and which is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Slide presentation of February 13, 2012 to be presented at BIO CEO.

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: February 13, 2012

/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; 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 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 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

Ventrus: Progress

➤ 2011:

- Completed \$20 mm IPO (overallocation) – Jan 2011
- Completed \$50mm marketed follow-on – July 2011

- Launched Pivotal PH III trial of iferanserin (VEN 309) in hemorrhoids based on FDA feedback in SPA process
 - 70+ centers in the US, 600 patients, August 2011
- Launched clinical pharmacology program VEN 309
- Submitted PH IIb trial for publication (published Clin Ther. January)
- Completed enrollment in pivotal trial of VEN 307 (diltiazem cream, anal fissures) December 2011
- Completed omnibus market research study in hemorrhoids (10,000 consumers, 800 Dr's)

Ventrus: 2012: 1st half *(estimated)*

➤ April 2012:

- **Completion of enrollment** in pivotal PH III US trial of iferanserin (**VEN 309**) in hemorrhoids: 600 patients, US

➤ May 2012

- **Data Readout** from 1st pivotal PH III trial of **VEN 307** (diltiazem cream) in anal fissures: 465 patients EU (2%, 4% and placebo cream t.i.d)

➤ June 2012

- **Data readout** from pivotal PH III US trial of iferanserin (**VEN 309**) in hemorrhoids: 600 patients, US: 14 d Rx vs 7d vs placebo, and recurrence rate
- **Data readout** from PK program **VEN 309**

Ventrus: 2012: 2nd half *(assuming positive trial data)*

➤ **July - September 2012:**

- FDA meetings re VEN 309 and VEN 308

➤ **Q3 – Q4 2012**

- Launch of next phase of VEN 309 studies
- launch of next phase of VEN 307 studies
- publication/presentations of VEN 309 and 307 data
- Ongoing recurrence data from 1st pivotal of VEN 309
- Results for new formulation of VEN 307

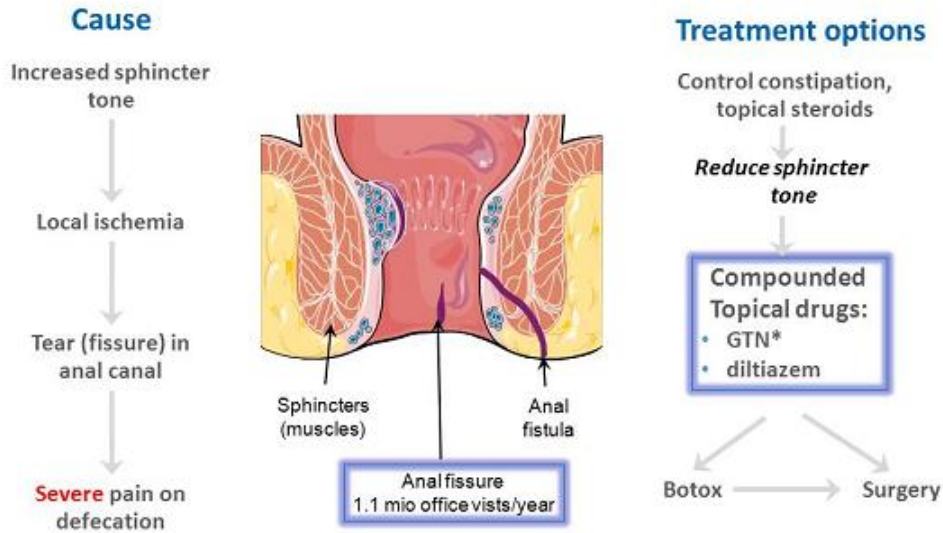


VEN 307: Diltiazem Cream

Novel Treatment for Anal Fissures



Anal Fissures: Cause and Management



*Rectiv (topical GTN) recently approved by FDA but not yet launched

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: First Pivotal Phase III Trial: Enrollment completed

- **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
 - **NDA filing possible 2013**

- **Phase III trial initiated (November 2010) with *data anticipated in 2Q 2012***
 - Licensor (SLA) is conducting trial. Initiated in November 2010
 - 3 arms, 155 pts per arm: 2% 4% diltiazem t.i.d., and placebo in 31 sites in Europe
 - Primary endpoint: reduction in pain on defecation using a validated scale (Likert, NRS)
 - Ventrus review of blinded data and study operations 10/2011: Correct patients enrolled, data compliance and GCRP are good, data are being reviewed continuously.
 - Enrollment completed; ***data readout expected in May 2012***

- **Planned Second Phase III trial(s):**
 - Developing 4 possible extended release formulations: may test some or all in human manometry trial in 2012. Next phase could be 2 PH III trials with extended release formulation if one is acceptable, or 1 with original formulation

Competitive Treatments for Anal Fissure

- **Topical Nitroglycerine (GTN): Rectiv 0.4% GTN ointment BID**
 - Recently approved in the U.S. for moderate and severe pain of chronic anal fissure (June 22 2011): ProStrakan/Kirin: **Launch expected 1Q 2012 by Aptalis**
 - improved pain but difficult side effect profile: high rate of headaches (often severe), flushing, nausea and dizziness
 - FDA PPI: 1 pivotal trial: total headache = 64% of patients; 938 headaches in 79 patients. 3 week treatment
- **Medical associations' guidelines** have consistently directed physicians to topical Diltiazem over GTN as 1st line therapy
 - The Association of Coloproctology of Great Britain and Ireland (2008)⁽¹⁾
 - The American Gastroenterology Association (2003)⁽²⁾
- **Other Calcium Channel Blockers**
 - Compounded Nifedipine is used to a lesser extent than Diltiazem; less literature available
- **Botox**
 - Out of pocket cost for patients
- **Surgery**
 - Forcible dilatation and sphincterotomy: most often curative, but fecal incontinence is a problem

(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

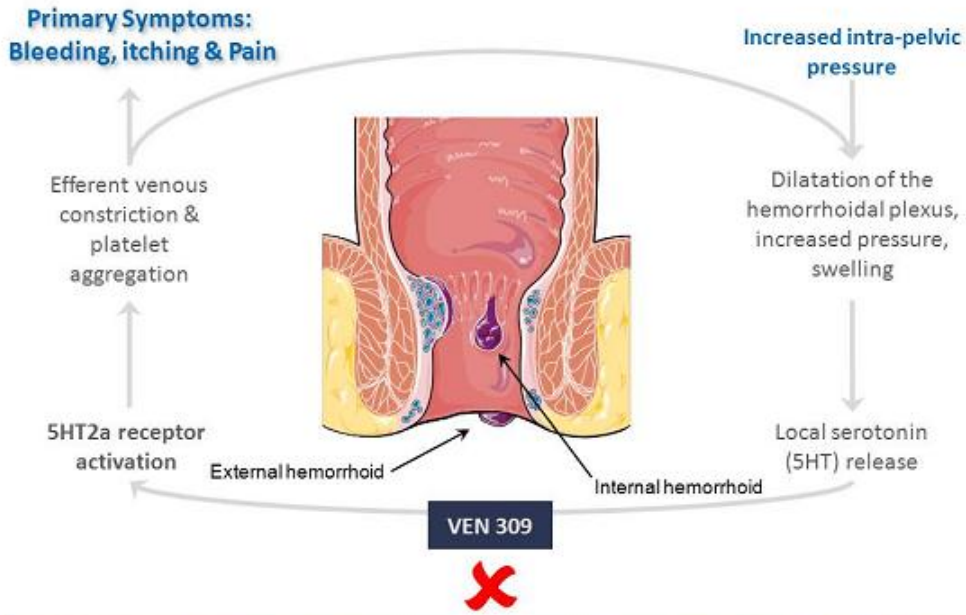


VEN 309: Iferanserin

NCE for Hemorrhoids



Physiology of Hemorrhoids



VEN 309 (Iferanserin) Summary

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

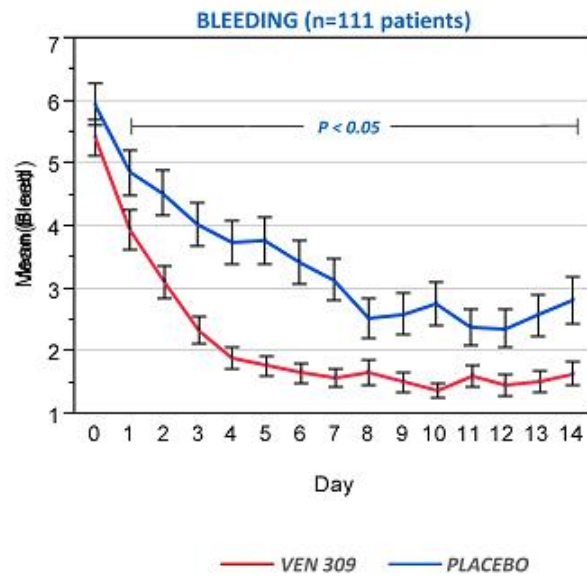
| | |
|------------------------------------|---|
| Mechanism of Action | <ul style="list-style-type: none">➤ Selective 5HT_{2a} antagonist➤ Does not cross the blood brain barrier except at doses much higher than to be used therapeutically |
| Preclinical Safety | <ul style="list-style-type: none">➤ Systemic exposure is < 10%➤ Therapeutic ratio is > 17x |
| Clinical Pharmacology | <ul style="list-style-type: none">➤ Metabolized by CYP2D6 in liver➤ 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">➤ Ventrus has all rights and title, World-wide, paying royalties between 1% and 4% |
| 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 (German study¹)

- 121 patients randomized to lferanserin 0.5% BID vs. placebo ointment x 14 days
- Weekly visits for 2 week treatment; follow-up at 45 days
- Symptoms recorded in daily diaries (scale of 1-10; 1 = no symptoms)
- Statistically significant improvement in symptoms: bleeding, itching, pain

➤ Primary endpoint

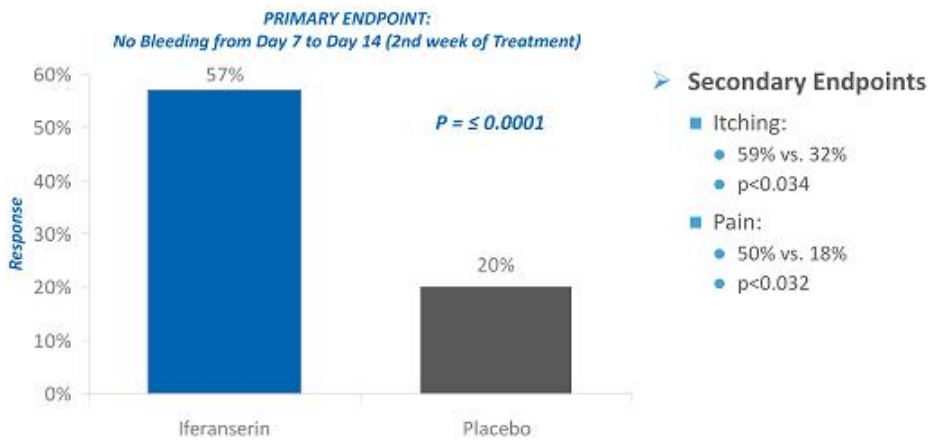
- Bleeding: rapid sustained effect
 - Day 7 VEN 309 vs. placebo $p < 0.0001$
 - Day 14 VEN 309 vs. placebo $p < 0.0075$



1. Herold et al *Cin Ther* online January 2012

Modeling of Phase IIb¹ 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

1. Herold et al *Cin Ther* online January 2012

VEN309 (Iferanserin) for the Treatment of Hemorrhoids

- Ongoing Phase III trial: iferanserin 0.5% ointment b.i.d.
 - Endpoints: *meaningful improvement (proposed by FDA)*
 - Primary endpoint, cessation of bleeding day 7– 14;
 - Secondary endpoints, cessation of pain, itching day 7-14.
 - Design
 - 3 arms 200 pts per arm: 7d vs 14 d vs placebo; 70 US sites
 - Open label extension to 1 year to treat recurrence
 - Inclusion requires meaningful symptoms
 - Restrictive inclusion criteria may be less in next studies
 - Discussion with FDA on all major elements of the protocol
 - Progress
 - Initiated early August with 65 sites; currently all 70 sites active
 - Enrolling correct patients, minimal loss of key outcome data, continuous data review
 - Large number of patients entering screening as expected
 - New Guidance for expected timelines:
 - ▶ Completion of enrollment around April 2012
 - ▶ Reporting of top line results around June 2012
 - ▶ Timelines impacted by need for 2 days of symptoms and exclusion criteria

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**
 - One is ongoing now; top line results expected around June 2012
- **one double blind Phase III recurrence trial to determine safety/efficacy and treatment for recurrence for the US)**
- **Clinical pharmacology program**
 - DDI, PK in poor metabolizers: results expected in 2nd quarter 2012
 - QT and special populations
- **Preclinical: Chronic Tox and Carcinogenicity studies (two species for 2 yrs)**
- **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)**

Hemorrhoids: The market:

- **Patients:** 10,202 adult consumers surveyed (designed to match US demographics): consumers reporting suffering from hemorrhoids ¹:
 - within the last two yrs: 11% 25.8 million people²; **last yr; 9.3% 21.7 mio**
 - Past 1 month: 6.0% - 14.0 million; **Day of survey: 2.9% - 6.7 million**
- **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. No other known drugs in development in U.S, EU or Japan.
 - **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

1. Princeton Brand Econometrics Survey 2011. 2: calculated from the 2010 US Adult population – 234,564,000 (2010 US census)
2. IMS 2003 3. IMS 2009 * Oral Daflon has a hemorrhoid indication in France ^ PBE survey of 10,202 consumers 2011

Patient response to VEN 309 DTC/PR concept

➤ Use of Current 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

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

- 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)
- In the whole sample: (complete range of current satisfaction, severity frequency of hemorrhoids, time of last episode, and income):
 - ▶ 78% with household income above \$50k/year ***would fill*** the Rx at a \$35 copay^

*Stated includes "Definitely, Probably and Might"

^ PBE factored

Quantitative Prescriber Hemorrhoid Market Survey

- 795 Health Care Providers (physicians and mid-level prescribers) were surveyed¹,
- Based on this primary research and prescriber level data from Wolters Kluwer, approximately 170,000 HCP directly generate over 6 million prescriptions and OTC recommendations
 - Of these 170,000 HCPs:
 - 40% only treat with prescription products (primarily topical 2.5% hydrocortisone)
 - 20% only recommend OTC products (primarily Preparation H)
 - 40% treat with either prescription or OTC products dependant on the individual patient
 - Approximately 21,000 HCP account for 50% of the this unit activity generated in physician offices

When exposed to the VEN 309 base case product profile and a wide range of co-pay scenarios:

- HCPs showed high willingness to prescribe and minimal co-pay price sensitivity
 - **Probability of HCPs to grant a patient Rx request ranged from .88 -.92***

1: Princeton Brand Econometrics Survey 2011

Commercialization Strategy

The nature of the markets we target provide Ventrus with optimal strategic flexibility

➤ Specialty sales force and DTC 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
- Our market research indicates that Direct To Consumer (DTC) advertising¹ could be highly impactful in the launch of VEN 309 for hemorrhoids

➤ Partnerships

- We intend to seek a marketing partner for VEN 309 for ex-U.S. territories
- Co-promotion opportunities exist for broader PCP coverage of VEN 309 and VEN 307

➤ Pricing and Reimbursement

- VEN 309: No other drugs in class or indication: Medicare Part D and managed care implications
- VEN 307: Expect major share of existing compounded Rx plus additional patients

¹Princeton Brand Econometrics forecast model 2012

2011 Financial Update

➤ Cash balance

| | |
|--|-----------------|
| ■ Cash and cash equivalents at Sept 30, 2011 | \$ 53.3 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 |

- * Includes payment for 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



BACKUP SLIDES



Hemorrhoid Rx Commercial Potential Study: Findings

- Omnibus survey and predictive modeling market research in September 2011: 800 physicians and 10,202 adult consumers surveyed (designed to match US demographics)

- 1,125 (11%) consumers reported suffering from hemorrhoids within the last two years...ie: *hemorrhoid patients – 25.8 million people*¹
 - 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

1 calculated from the 2010 US Adult population – 234,564,000 (2010 US census)

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 copay^
 - ▶ 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)

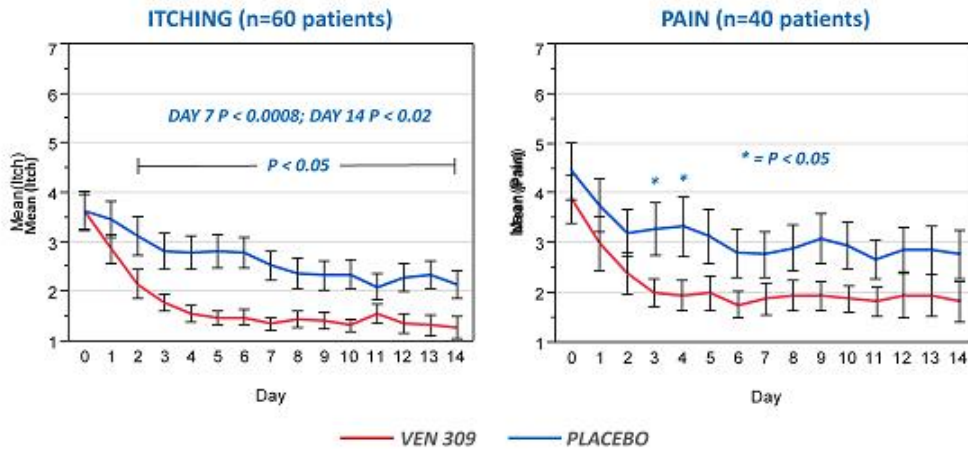
*Stated includes "Definitely, Probably and Might" ^ PBE factored

Quantitative Prescriber Hemorrhoid Market Survey

- 795 Health Care Providers (HCPs - physicians and mid-level prescribers) were surveyed, which included sampling from every meaningful specialty and Rx level, utilizing proprietary methodology of Princeton Brand Econometrics
- Based on this primary research and prescriber level data from Wolters Kluwer, approximately 170,000 HCP directly generate over 6 million prescriptions and OTC recommendations
 - Of these 170,000 HCPs:
 - 40% only treat with prescription products (primarily topical 2.5% hydrocortisone)
 - 20% only recommend OTC products (primarily Preparation H)
 - 40% treat with either prescription or OTC products dependant on the individual patient
 - Approximately 21,000 HCP account for 50% of the this unit activity generated in physician offices
 - PCPs and Gastroenterologists initiate the majority of RXs and OTC recommendations
 - PCP/OBG/Mid – 63% of treatment initiation
 - Gastro – 20% of treatment initiation
 - CRS/GS – 10% of treatment initiation
 - Other – 7 % of treatment initiation

VEN 309 Clinical Data: Efficacy Phase IIb¹

Secondary endpoints: rapid, sustained effect



1. Herold et al *Cin Ther* online January 2012