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): January 9, 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:

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

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

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

o 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 to investors and at various industry events and which is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Slide presentation of January 2012.

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: January 9, 2012

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


ventrus
BIOSCIENCES

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

VEN 309: Iferanserin

NCE for Hemorrhoids

Physiology of Hemorrhoids

Primary Symptoms: Bleeding, itching & Pain

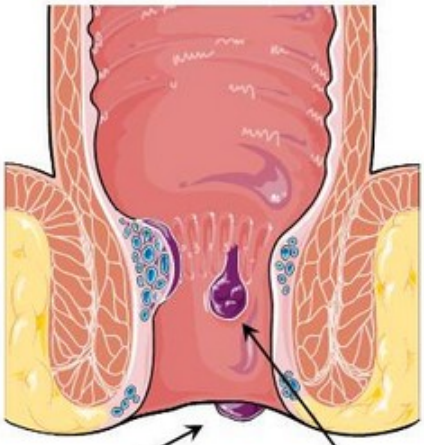
Increased intra-pelvic pressure

Dilatation of the hemorrhoidal plexus, increased pressure, swelling

Local serotonin (5HT) release

5HT2a receptor activation

Efferent venous constriction & platelet aggregation



External hemorrhoid

Internal hemorrhoid

VEN 309

VEN 309 (Iferanserin) Summary

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

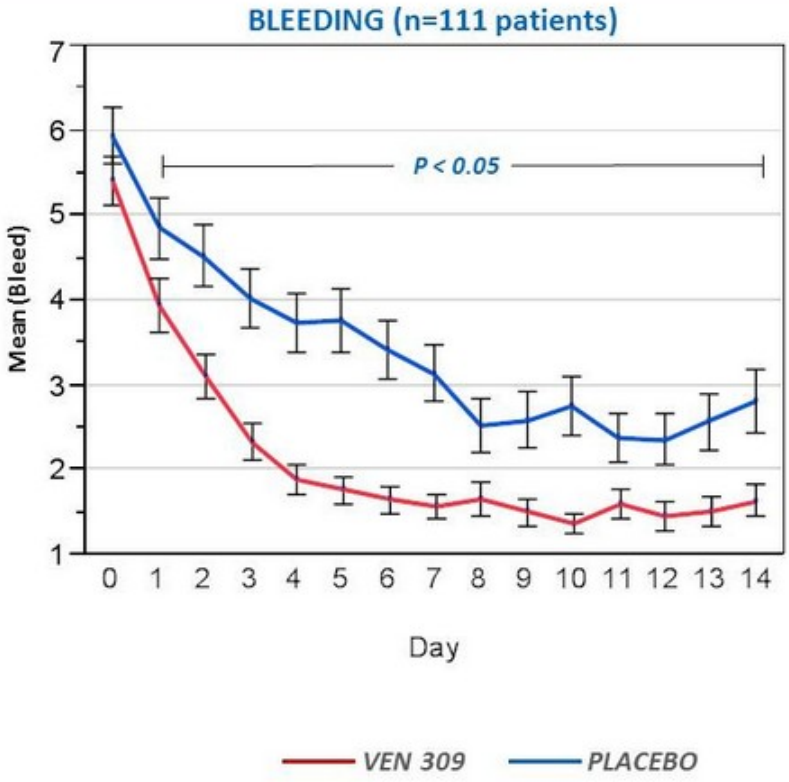
Mechanism of Action	➢ Selective 5HT2a antagonist ➢ Does not cross the blood brain barrier except at doses much higher than to be used therapeutically
Preclinical Safety	➢ Systemic exposure is < 10% ➢ Therapeutic ratio is > 17x
Clinical Pharmacology	➢ Metabolized by CYP2D6 in liver ➢ No accumulation of the drug on twice daily dosing
Clinical Data	➢ 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	➢ Ventrus has all rights and title, World-wide, paying royalties between 1% and 4%
Market and Data Exclusivity	➢ 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 study)

- 121 patients randomized to Iferanserin 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

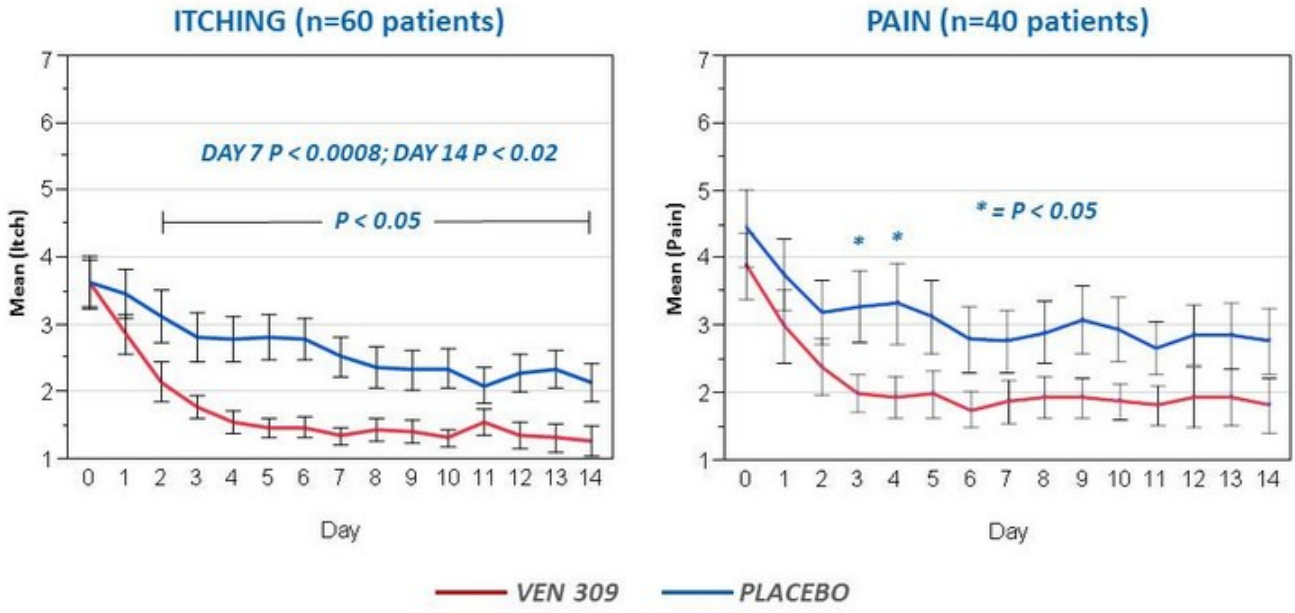
Primary endpoint

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



VEN 309 Clinical Data: Efficacy Phase IIb

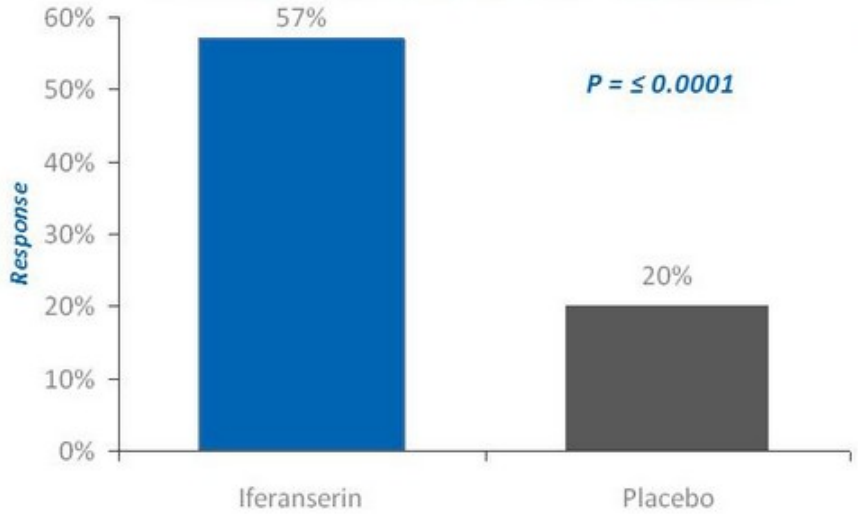
Secondary endpoints: rapid, sustained effect



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

PRIMARY ENDPOINT:
No Bleeding from Day 7 to Day 14 (2nd week of Treatment)



- **Secondary Endpoints**
  - Itching:
    - 59% vs. 32%
    - p<0.034
  - Pain:
    - 50% vs. 18%
    - p<0.032

Majority of responders in the treatment arm respond by Day 3

*Post hoc

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)**

VEN 309: The Market

Hemorrhoids: 21.7 mm 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 steroids[3]
  - 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
  - **9.5 million unique households purchased 1 or more OTC hemorrhoid preps[1]** (Representing 1 in 12 households)

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 10,202 consumers 2011

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 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*

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

Quantitative Prescriber Hemorrhoid Market Survey

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*

** PBE factored*

VEN 307: Diltiazem Cream

Novel Treatment for Anal Fissures

ventrus BIOSCIENCES

Anal Fissures: Cause and Management

Cause

Increased sphincter tone

↓

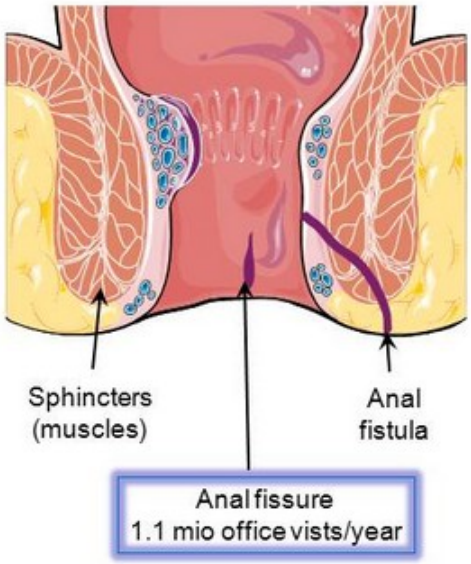
Local ischemia

↓

Tear (fissure) in anal canal

↓

Severe pain on defecation



Treatment options

Control constipation, topical steroids

↓

Reduce sphincter tone

↓

Compounded Topical drugs:

- GTN*
- diltiazem

↓

Botox → Surgery

*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	➢ Calcium channel blocker ▪ Relaxes the internal anal sphincter, reducing pain and increasing tissue blood flow
Preclinical Safety	➢ Preclinical topical safety with 2% Diltiazem twice daily for ninety days
Clinical Pharmacology	➢ 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	➢ Ten clinical trials in 453 individuals ➢ Infrequent mild AEs reported ➢ Similar or better reduction in pain, significantly better tolerability than GTN
Rights	➢ North American rights paying mid to upper single digit royalties
Market and Data Exclusivity	➢ 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 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
  - **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

- **Planned Second Phase III trial(s):**
  - 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

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
  - Extensive literature reporting 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]
- **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

- 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

(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*

Financial Overview, Milestones

Expected Milestones: VEN 309 and VEN 307

H1 2012	H2 2012

VEN 309

- Publication of PH 2b trial (January)
- 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

- Completion of enrollment (Jan) and Data read-out from first pivotal Phase III trial (May)
- Go/no go decision and selection of extended release formulation
- Launch of second pivotal(s)

Q3-2011 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