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): September 12, 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:

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 7.01. Regulation FD Disclosure.

Ventrus Biosciences, Inc. is furnishing as an exhibit to this Form 8-K a PowerPoint presentation that is to be made available during the presentation by the Company's Chief Executive Officer, Russell H. Ellison, at the Rodman & Renshaw 13th Annual Healthcare Conference being held in New York City on September 12, 2011.

The information furnished in this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Slide presentation of September 12, 2011.

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: September 12, 2011

/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: 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 and our estimates regarding our capital requirements; our liquidity and working capital requirements; our expectations regarding our revenues, expenses and other results of operations; 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; and the future trading prices of our common stock and the impact of securities analysts' reports on these prices. 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 1Q 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 1H 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

Hemorrhoids: Market Opportunity

Symptoms	➢ Bleeding, pain, itching, swelling, tenderness & difficult defecation
Patients	➢ Approx 12.5 million patients in U.S.
FDA-Approved Rx Drugs	➢ None
Current Treatment Options	➢ Invasive procedures (e.g., banding, sclerosing agents, surgery for prolapsed hemorrhoids) ➢ 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 ➢ > 4 million prescriptions of non-approved and non-DESI intra-anal steroids[3] ➢ Current products are not reimbursed
Drugs in Pipeline	➢ No other known drugs in development in U.S.

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

Hemorrhoids: Market Opportunity

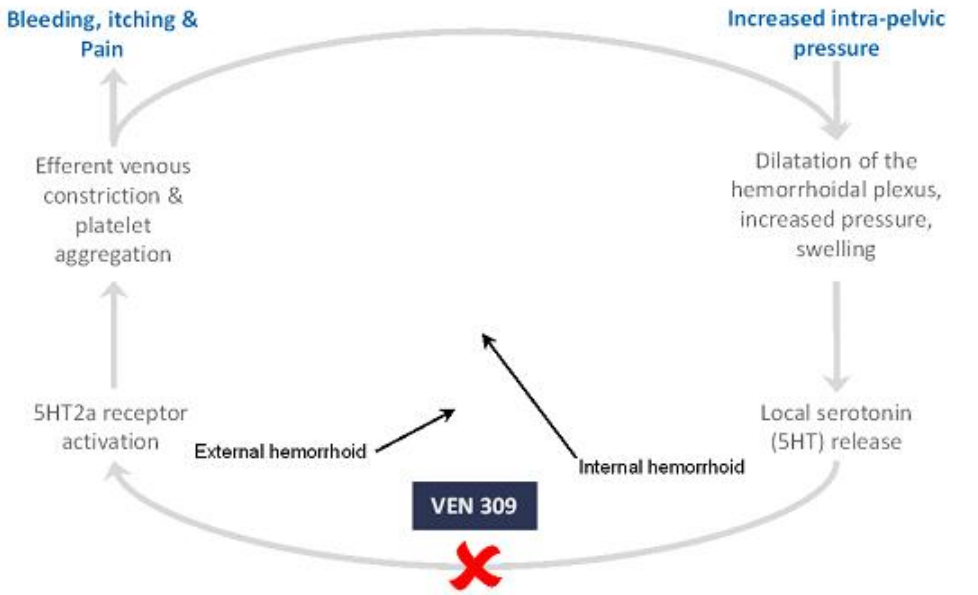
Highly prevalent, solution-seeking market with excellent demographics

In the last 52 weeks ending July 2nd 2011[1]

- **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**

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.

Physiology of Hemorrhoids



VEN 309 (Iferanserin) Summary

Topical rectal ointment applied intra-anally BID (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	➢ World-wide rights paying royalties between 1% and 4% (pending close of $12 mio asset purchase 11/2011 contingent on PH III safety profile)
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 II

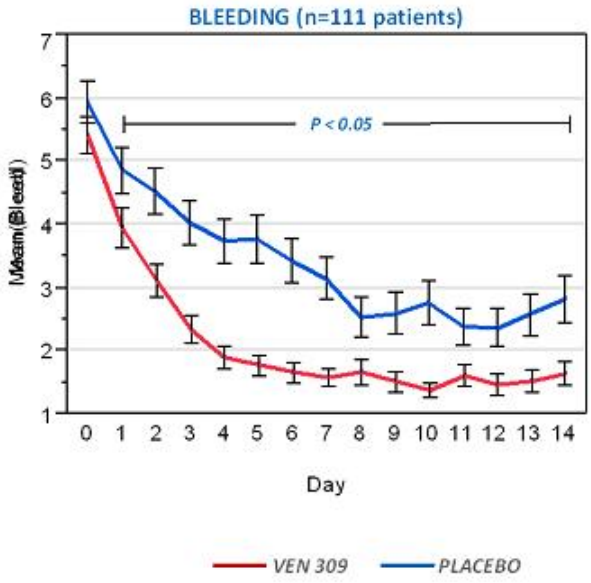
	Proof of Concept Study (Racemate) Arizona	Early Phase II (S-isomer) Japan	Late Phase II (S-isomer) Japan
Dosing and Administration	➢ 1% TID vs. placebo	➢ 0.25% vs. 0.5% vs. 1% BID	➢ 0.25% vs. 0.5% vs. 1% BID
Number of Patients	➢ 26 patients	➢ 72 patients	➢ 104 patients
Duration of Therapy	➢ 5 days	➢ 14 days	➢ 28 days
Results and Clinical Benefits	➢ Significant improvement in symptoms, including bleeding ➢ Rapid onset, effects maintained	➢ 0.5% significantly better than other concentrations ➢ Improvements in symptoms and size, rapid onset	➢ 0.5% and 1.0% consistent improvements in symptoms

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

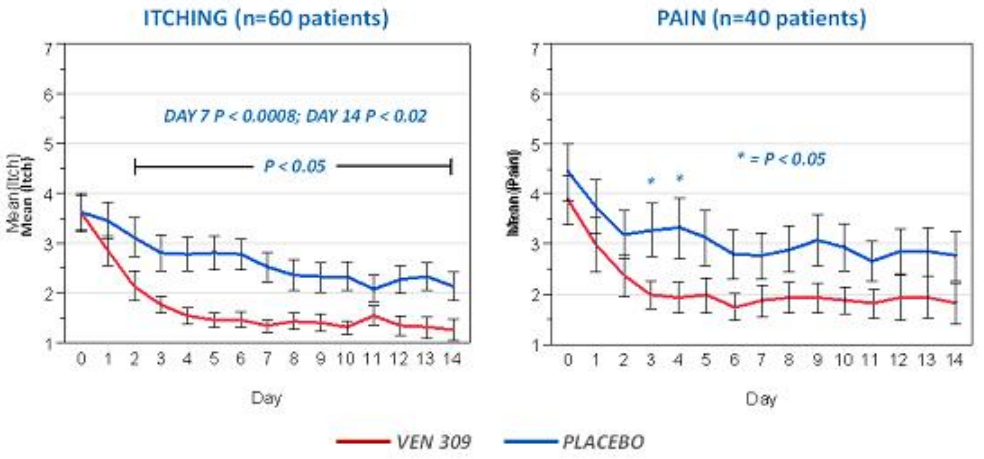
VEN 309 Clinical Data: Efficacy Phase IIb

- **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



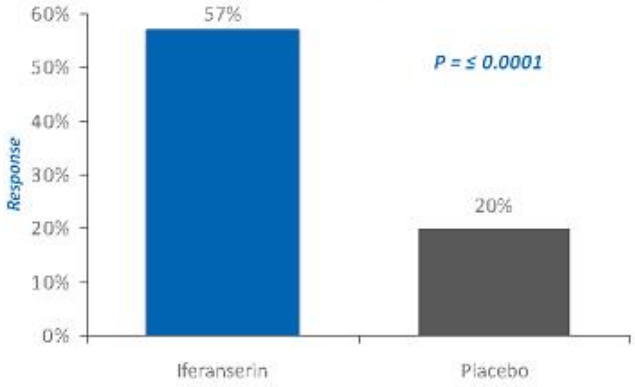
EFFICACY ENDPOINTS FOR PHASE III

- **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

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

First Pivotal Phase III Trial Initiated

- **Initiated on schedule August 2011, double blind data anticipated Q1 2012**
  - Approximately 600 patients (> 99% power for primary and >95% for secondary endpoints)
  - 3-arm study (200 patients/arm), double blind, b.i.d:
    - Placebo ointment vs Iferanserin 0.5% x 14 days vs Iferanserin 0.5% x 7 days
  - Approximately 70 sites (U.S.): 65 sites are active; screening and enrollment
  - 14 days treatment with follow-up at 28 days; all patients roll over to 12 month extension follow-up to assess recurrence (open label treatment with Iferanserin if recurrence)
  - Endpoints collected by daily patient diaries (IVRS system)

- **Inclusion criteria**
  - Symptomatic grade I to III internal hemorrhoids
  - Bleeding from hemorrhoids 2 consecutive days immediately prior to randomization, with pain or itching accompanying the bleeding for the 2 days

- **Primary endpoint: no bleeding Day 7 - Day 14 (2nd week of treatment). Secondary endpoints: no pain, no itching Day 7 - Day 14**

- **Discussion with FDA on all major elements of the protocol**

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, intensive PK, QTc 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)

VEN 307: Diltiazem Cream

Novel Treatment for Anal Fissures

Anal Fissures: Cause and Management

Cause

Increased sphincter tone

↓

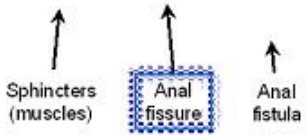
Local ischemia

↓

Tear (fissure) in anal canal

↓

Severe pain on defecation



Treatment options

Control constipation, topical steroids

↓

Reduce sphincter tone

↓

Topical drugs

Botox → Surgery

Anal Fissures: Medical Need and Market Opportunity

	Anal Fissures
Symptoms	■ Ischemic tears in the anus ■ Severe pain
Market	■ 1.1 million office visits per year
FDA-Approved Rx Drugs	■ Rectiv (GTN Topical) FDA approved 6/22/2011 but not launched yet ■ Relaxes anal sphincter; effective in pain relief ■ Systemic exposure gives ≥ exposure as an anti anginal dose ■ Flushing and headaches limit use; ○ US PI: 938 headaches in 79 patients ○ overall headache rate (US PI; SMPC) > 60%
Current Drug Treatments	■ 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 ○ The Association of Coloproctology of Great Britain and Ireland (2008)[1] ○ The American Gastroenterology Association (2003)[2]
Drugs in Pipeline	■ RDD Pharma completed a Phase Ib clinical trial of Nifedipine for the treatment of chronic anal fissures

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

(2) Madoff, R.D., & Fleshman, J.W. (2003) AGA Technical Review on the Diagnosis and Care of Patients With Anal Fissure. Gastroenterology, 124, 235–245

VEN 307 (Diltiazem) Summary

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

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 triol 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 recently initiated (November) with *data anticipated in 2Q 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)
- **Planned Second Phase III trial(s):**
  - We conduct enabling toxicity
  - We may compare with Rectiv for AEs in PH III or PH IV
  - Could be 2 trials with extended release formulation or 1 with original

Market Strategy, Financial Overview

Commercialization Strategy

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

- **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
- **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

Summary Financial Overview

(000's)	
Cash & Equivalents @ June 30, 2011	$11,369
Cash Proceeds July 2011 Raise	$47,500
VTUS has sufficient cash into 2014	

	Dilutive Securities (millions)
Common Stock	12.4
Warrants ($1.24 - $66.46)[1]	.9
Options ($6.30)[2]	1.9
Total	15.2

(1) Range of exercise prices at June 30 2011
(2) Weighted average exercise price, at June 30 2011

Expected Milestones

4Q 2011 /1Q 2012	1Q / 2Q 2012	H2 2012
VEN 309		
➢ Completion of Phase III trial enrollment	➢ Data read-out from first pivotal Phase III trial (1Q 2012)	➢ Recurrence read-out from 1st pivotal; data read-outs from pharmacology program; launch of second pivotal and/or recurrence trial
➢ Publication of German PH IIB trial and preclinical pharmacology review	➢ Data from clin. pharm program	
VEN 307		
➢ Selection of a new Diltiazem extended release formulation with extended IP (3Q/4Q 2011)	➢ Data read-out from first pivotal Phase III trial (2Q 2012)	➢ Launch of second pivotal(s)
➢ Completion of enrollment of European Phase III		

Key Takeaways

The Products

- VEN 309 believed to be the first and ONLY FDA-approved Rx drug for hemorrhoids, with a market of approximately 12.5 million patients 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
- Cash sufficient through Q1 2014 under most scenarios
- Multiple scenarios are possible for further development and commercialization of the products after the data read-outs
- Experienced team with a history of success