

**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 10, 2017

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-33389
(Commission File Number)

94-3136179
(IRS Employer
Identification No.)

**900 E. HAMILTON AVENUE, SUITE 550
CAMPBELL, CA 95008**
(Address of principal executive offices, including zip code)

(650) 934-5200
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

- ☐ 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 7.01. Regulation FD Disclosure

In connection with the attendance of VIVUS, Inc., or the Company, at the 35th Annual J.P. Morgan Healthcare Conference, the Company will be distributing the slides attached hereto as Exhibit 99.1; such slides are incorporated by reference herein.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Slide presentation entitled "Corporate Update, January 2017"

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.

VIVUS, INC.

/s/ John L. Slebir

John L. Slebir

Senior Vice President, Business Development and General Counsel

Date: January 10, 2017

3

EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
99.1	Slide presentation entitled "Corporate Update, January 2017"

4



INNOVATIVE THERAPIES NOVEL PRODUCTS

Qsymia[®] 
(phentermine and topiramate
extended-release) capsules 

STENDRA[™] 
(avanafil) tablets

Corporate Update
January 2017

FORWARD LOOKING STATEMENT



This presentation contains "forward-looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "may," "believe," "expect," "forecast," "intend," "anticipate," "predict," "should," "planned," "likely," "opportunity," "estimated," and "potential," the negative use of these words or other similar words. All forward-looking statements included in this presentation are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to:

- the timing of initiation and completion of the post-approval clinical studies required as part of the approval of Qsymia by the U.S. Food and Drug Administration, or FDA;
- the response from the FDA to the data that we will submit relating to post-approval clinical studies;
- the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy requirements;
- that we may be required to provide further analysis of previously submitted clinical trial data;
- our ability to work with leading cardiovascular outcome trial experts in planning substantial revisions to the original design and execution of the clinical post-marketing cardiovascular outcomes trial, or CVOT, with the goal of reducing trial costs and obtaining FDA agreement that the revised CVOT would fulfill the requirement of demonstrating the long-term cardiovascular safety of Qsymia;
- our efforts with the European Medicines Agency, or EMA, relating to our CVOT, and the resubmission of an application for the grant of a marketing authorization to the EMA, the timing of such resubmission, if any, the results of the CVOT, assessment by the EMA of the application for marketing authorization, and their agreement with the data from the CVOT;
- our ability to successfully seek approval for Qsymia in other territories outside the U.S.;
- whether healthcare providers, payors and public policy makers will recognize the significance of the American Medical Association officially recognizing obesity as a disease, or the new American Association of Clinical Endocrinologists guidelines;
- our ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to retail distribution, the broadening of payor reimbursement, the expansion of Qsymia's primary care presence, and the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia;
- our ability to focus our promotional efforts on health-care providers and on patient education that, along with increased access to Qsymia and ongoing improvements in reimbursement, will result in the accelerated adoption of Qsymia;
- our ability to minimize expenses that are not essential to expanding the use of STENDRA and Qsymia or are related to product development;
- our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers;

FORWARD LOOKING STATEMENT



- risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA® (avanafil) or SPEDRA™ (avanafil) by our sublicensees;
- our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with Mitsubishi Tanabe Pharma Corporation in which we do not have a commercial collaboration, including Mexico and Central America;
- our ability to ensure that the entire supply chain for avanafil efficiently and consistently delivers avanafil to our sublicensees;
- the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand;
- our ability to accurately forecast Qsymia demand;
- our ability to commercialize Qsymia efficiently;
- the number of Qsymia prescriptions dispensed through certified pharmacies;
- the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods;
- our history of losses and variable quarterly results;
- substantial competition;
- risks related to our ability to protect our intellectual property and litigation in which we are involved or may become involved;
- uncertainties of government or third-party payor reimbursement;
- our reliance on sole-source suppliers, third parties and our collaborative partners;
- our ability to continue to identify, acquire and develop innovative investigational drug candidates and drugs;
- risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations;
- our ability to demonstrate through clinical testing the quality, safety, and efficacy of our investigational drug candidates;
- the timing of initiation and completion of clinical trials and submissions to foreign authorities;
- the results of post-marketing studies are not favorable;
- compliance with post-marketing regulatory standards, post-marketing obligations or pharmacovigilance rules is not maintained;
- the volatility and liquidity of the financial markets;
- our liquidity and capital resources;
- our expected future revenues, operations and expenditures;
- potential change in our business strategy to enhance long-term stockholder value;
- our ability to address or potentially reduce our outstanding debt balances;
- the impact, if any, of changes to our Board of Directors or management team; and
- other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission.

- **Qsymia (phentermine and topiramate extended-release) capsules CIV**
 - Treatment for chronic weight management for obese adult patients or overweight adult patients with one weight-related comorbidity
 - Approved by the FDA in July 2012
 - Commercialized by VIVUS in the U.S.
- **Avanafil**
 - Treatment of erectile dysfunction
 - Approved by the FDA in April 2012 under the commercial name STENDRA, approved by the EC in June 2013 under the commercial name SPEDRA
 - Commercialization rights licensed to third parties
- **Tacrolimus**
 - Investigational product candidate for the treatment of pulmonary arterial hypertension
 - In-licensed in January 2017

- Initiated business strategy review to reshape VIVUS' business model
- Received \$70 million for a license to commercialize STENDRA in the U.S., Canada, South America, and India
- In-licensed worldwide development and commercial rights for tacrolimus for the treatment of pulmonary arterial hypertension (PAH) and related vascular diseases
- Received favorable Markman ruling in Qsymia patent litigation
- Lawsuit against Hetero for infringement of STENDRA patents settled

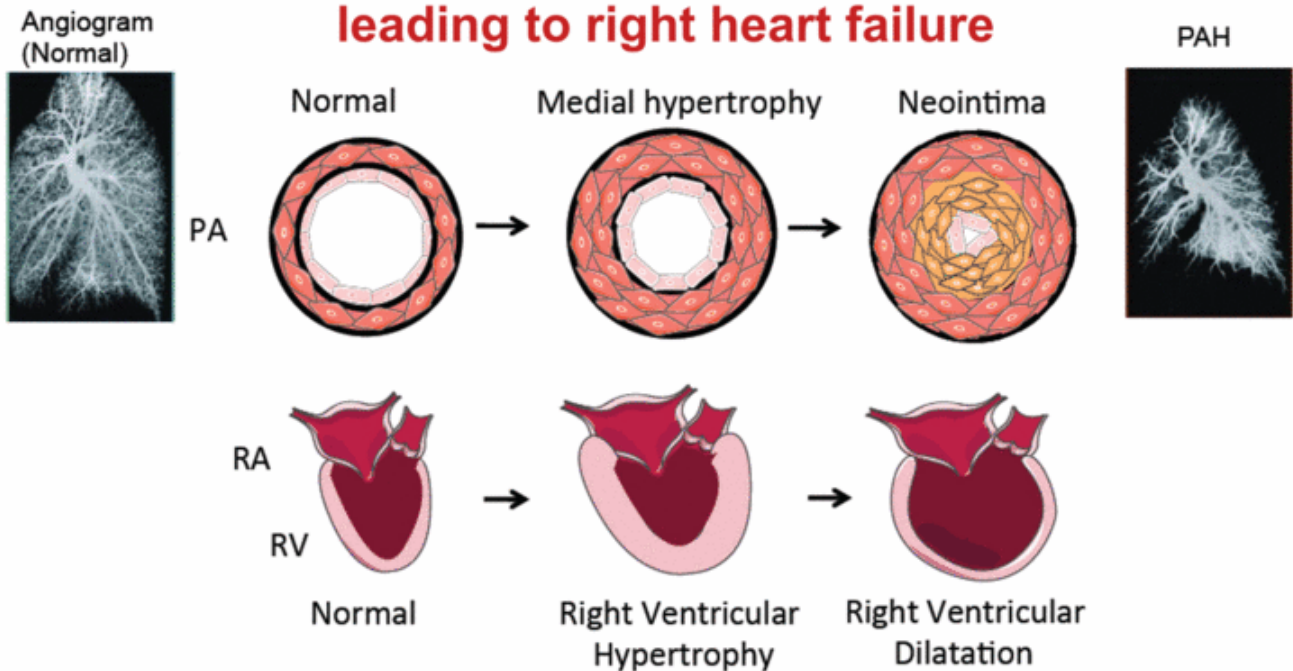
- Advance tacrolimus development, including the development of a proprietary formulation of tacrolimus
- Continue to efficiently monetize Qsymia in the U.S. and seek to monetize Qsymia and Avanafil outside of the U.S.
- Defend our Qsymia intellectual property rights for Qsymia
- Advance our efforts to address – in a cost-effective manner – the remaining Qsymia regulatory post-marketing requirements
- Evaluate additional potential in-licensing opportunities to build our portfolio of products and product candidates
- Address and potentially reduce our outstanding debt balances
- Effectively manage our cost structure

Pulmonary Arterial Hypertension

PULMONARY ARTERIAL HYPERTENSION (PAH): CLINICAL OVERVIEW



Progressive narrowing in pulmonary arteries leading to right heart failure



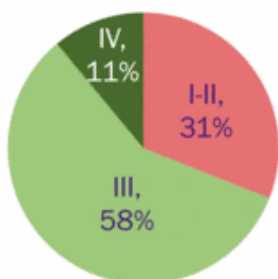
Unmet need with no cure

WHO FUNCTIONAL CLASSES FOR PAH

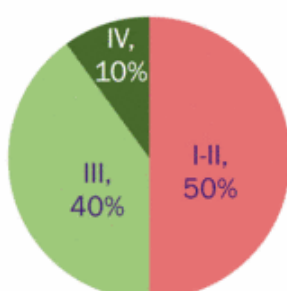


Class I	No symptoms with ordinary physical activity
Class II	Some symptoms with ordinary activity and slight limitation of physical activity
Class III	Symptoms with less than ordinary activity and increased limitation of physical activity
Class IV	Symptoms with any activity possibly even while at rest

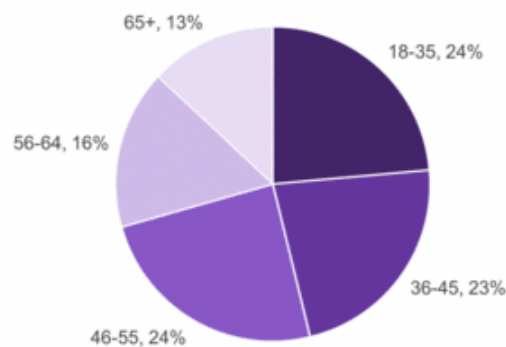
Data Monitor
Prevalent PAH Cases by WHO
Functional Class
(% of patients)



United Therapeutics
Prevalent PAH Cases by WHO
Functional Class
(% of patients)

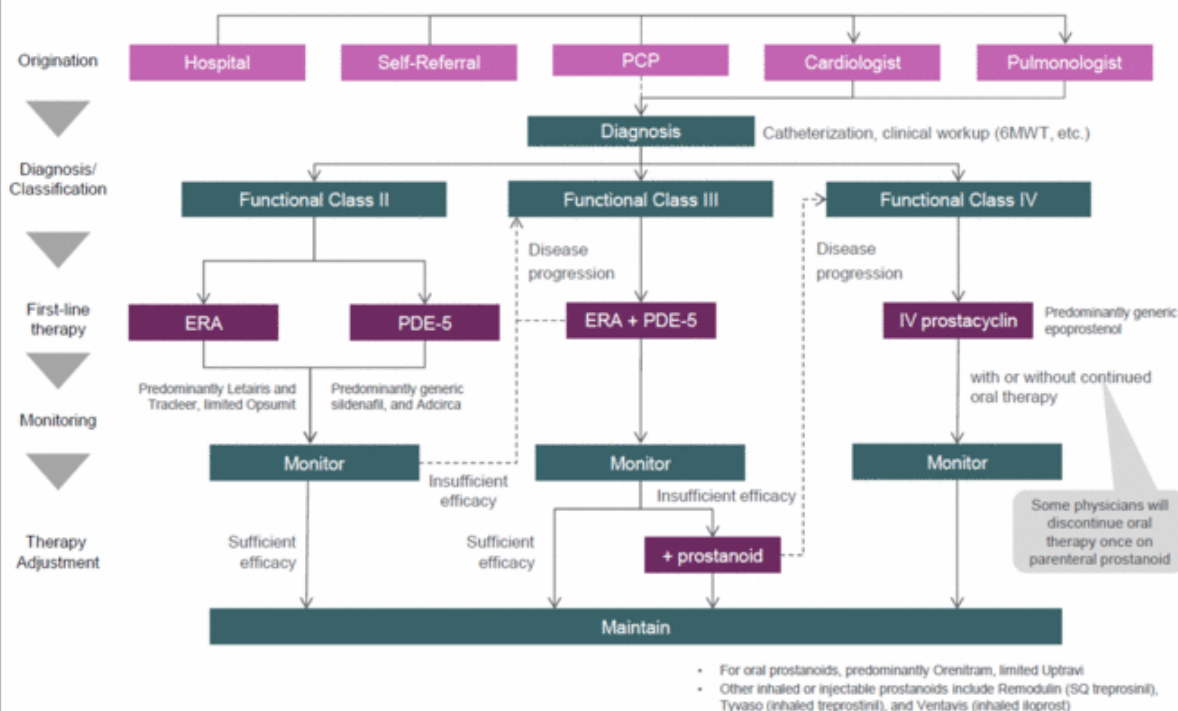


Data Monitor
Age Distribution of
U.S. PAH Patients - 2012



Based on modification of New York Heart Association (NYHA) functional classification

Most physicians initiate the class II patients with either an ERA or PDE5 inhibitor and add therapies as the disease progresses

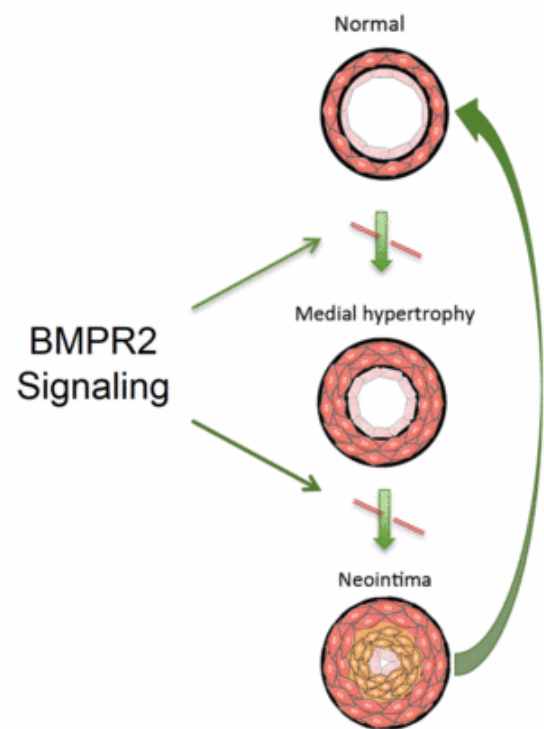


Current treatments all target vasoconstriction
Pricing ranges from \$30K - \$180K per year

Type of Treatment	MOA	Currently Available Medications	Medications In Development
Endothelin receptor antagonists (ERAs)	Inhibit vasoconstrictive effects of endothelin	<ul style="list-style-type: none"> • Tracleer (bosentan) • Opsumit (macitentan) • Letairis (ambrisentan) 	<ul style="list-style-type: none"> • Ambrisentan / tadalafil combination
Phosphodiesterase-5 (PDE-5) inhibitors	Inhibit degradation of cGMP, an important intracellular 2 nd messenger promoting vasodilation	<ul style="list-style-type: none"> • Revatio (sildenafil) • Adcirca (tadalafil) 	
Prostacyclins	Stimulate production of cAMP, an important intracellular 2 nd messenger promoting vasodilation	<ul style="list-style-type: none"> • Uptravi (selexipag) • Flolan (epoprostenol) • Remodulin (treprostinil) • Tyvaso (treprostinil) • Orenitram (treprostinil) • Veletri (epoprostenol) • Ventavis (iloprost) 	<ul style="list-style-type: none"> • Ralinepag • Berapost 314d • TransCon Treprostinil
sGC stimulator	Stimulate production of cGMP	<ul style="list-style-type: none"> • Adempas (riociguat) 	<ul style="list-style-type: none"> • Citrupress • IK-7002

TACROLIMUS: TARGETING PROLIFERATION

- Bone Morphogenic Protein receptor 2 (BMPR2) signaling inhibits vascular smooth muscle proliferation
- Reduced BMPR2 expression, including loss-of-function mutations in BMPR2, is prevalent in PAH patients, and may contribute to smooth muscle proliferation
- Phase 1 studies of low dose tacrolimus demonstrate the ability to restore BMPR2 signaling
- Low dose tacrolimus reverses neointimal hypertrophy in animal models of PAH
- Enhancement of BMPR2 signaling may address one of the causes of PAH
- Not mutation dependent



TACROLIMUS EXPERIENCE IN PAH PATIENTS (STANFORD)



- **Phase 2a study**

- Randomized, double-blind study
- 23 WHO class 1-2 patients titrated to target blood levels
- All target blood levels well tolerated
 - No drug related SAEs, nephrotoxicity or incident diabetes
 - GI complaints (nausea, diarrhea) may provide useful tolerability marker
- Study population precluded useful efficacy assessments

- **Compassionate use**

- 3 end-stage patients, functional class III and IV
- Positive impact on clinical outcomes
 - Dramatically reduced rate of hospitalizations
 - Functional class improvements observed

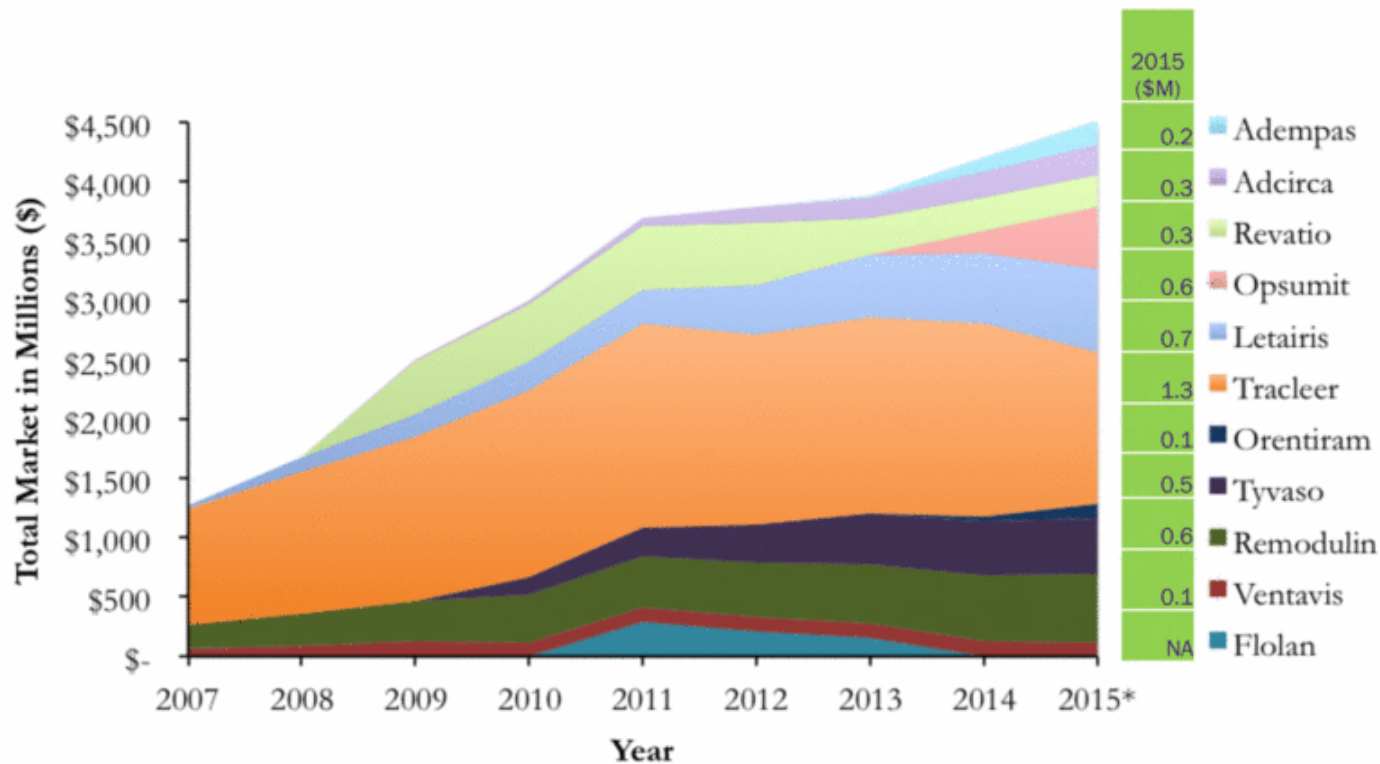
COMPASSIONATE USE STUDY: SYMPTOMS AND CLINICAL PARAMETERS



Figure 1. Timeline of symptoms, clinical parameters, events, and therapies for patients 1–3 before and after initiation of FK506. Registry to Evaluate Early and Long-Term PAH Disease Management (REVEAL) risk score, %1-year survival: score 1–7 = 95–100% (low risk), 8 = 90–95% (average risk), 9 = 85–90% (moderately high risk), 10–11 = 70–85% (high risk), and 12 or above = <70% (very high risk) (3). Events reported as those related to pulmonary arterial hypertension (PAH): RHF, HepF, Sync, Tx List, and Tx Hold. Dop = dopamine; ERA = endothelin receptor antagonist; HepF = hepatic failure; NYHA = New York Heart Association functional class; PDE-I = phosphodiesterase-5 inhibitor; Prost = prostacyclin; RHF = right heart failure; Sync = syncope; Tx Hold = placed on hold for transplantation because of clinical improvement; Tx List = listed for heart and/or lung transplantation.

- US and foreign applications pending
 - Filing date is April 30, 2012 so patent term to April 30, 2032
 - US patent allowed
 - Issued as US9474745 on Oct. 25, 2016
 - Continuation filed
 - 8 claims
 - EP, AU, CA, and JP are filed

\$4.5 BILLION GROWTH MARKET - WORLDWIDE (2015)



U.S. market estimated at \$2.7B

- **PAH is a serious, rare, and progressive disease**
 - Progressive narrowing in pulmonary arteries
 - Resulting in right heart failure and ultimately death
 - Median life expectancy: 5 years from diagnosis (~45 years old, class III/IV)
- **Unmet need**
 - Existing drug therapies ONLY target symptoms and slow progression of disease
 - Lung transplantation only option for advanced patients not responsive to drug therapies
- **Large growth market: ~\$4.5B worldwide, \$2.7B U.S. in 2015**
 - Treatment supports multiple "layering" therapies
- **Orphan drug designation received**
 - Potential for "Breakthrough Therapy" designation
 - Potentially class modifying, extending life expectancy
- **Patent issued**

AVANAFIL

STENDRA™ *(avanafil) tablets*

A red graphic element consisting of several horizontal lines of varying lengths, creating a stylized arrow or 'S' shape.

About STENDRA™

STENDRA is a prescription medicine used to treat erectile dysfunction (ED). STENDRA (avanafil) is licensed from Mitsubishi Tanabe Pharma Corporation. VIVUS has development and commercial rights to STENDRA for the treatment of sexual dysfunction worldwide with the exception of certain Asian Pacific Rim countries.

Important Safety Information

Do not take STENDRA if you take nitrates, often prescribed for chest pain, as this may cause a sudden, unsafe drop in blood pressure. Tell your healthcare provider about all the medicines you take and discuss your general health status to ensure that you are healthy enough to engage in sexual activity. If you experience chest pain, nausea, or any other discomforts during sex, seek immediate medical help.

In the rare event of an erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury. STENDRA in combination with other treatments for erectile dysfunction is not recommended. STENDRA does not protect against sexually transmitted diseases, including HIV.

The most common side effects of STENDRA are headache, flushing, runny nose and congestion.

- Only erectile dysfunction treatment with a clinically proven 15 minute onset-of-action
- Able to be taken with food and alcohol
- Strong safety profile

- Signed in July 2013
- 40 Countries in Europe + AUS/NZ
 - As of December 2016, SPEDRA available in 30 countries in the Menarini territories
 - Additional launches expected in 2017
- Upfront and potential milestone payments of 71M Euros
 - 41M Euros earned to date
- Flat royalty on net sales



- Signed in September 2016
- United States, Canada, South America, and India
- Upfront payment of \$70M
- Product sold through Mist Pharmaceuticals
- Metuchen is responsible for obtaining and maintaining regulatory approvals in its territory

- Signed in December 2013
- Africa, Middle East, Turkey, CIS countries
- Upfront and potential milestone payments of \$61M
 - \$5M earned to date
- Tiered royalty on net sales
- Sanofi is responsible for obtaining and maintaining regulatory approvals in its territory

- ANDA Filer: Hetero USA, Inc.
 - Paragraph IV certifications for Orange Book listed patents
- Notice received on June 20, 2016
- VIVUS filed a patent infringement lawsuit on July 27, 2016 on the basis of Hetero's ANDA submission
- Lawsuit settled in January 2017 – Hetero granted license to enter market no earlier than six months prior to expiration of last to expire patent

Qsymia



About Qsymia

Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related medical condition such as high blood pressure, type 2 diabetes, or high cholesterol.

Important Safety Information

Qsymia (phentermine and topiramate extended-release) capsules CIV is contraindicated in pregnancy; in patients with glaucoma; in hyperthyroidism; in patients receiving treatment or within 14 days following treatment with monoamine oxidase inhibitors (MAOIs); or in patients with hypersensitivity to sympathomimetic amines, topiramate, or any of the inactive ingredients in Qsymia.

Qsymia can cause fetal harm. Females of reproductive potential should have a negative pregnancy test before treatment and monthly thereafter and use effective contraception consistently during Qsymia therapy. If a patient becomes pregnant while taking Qsymia, treatment should be discontinued immediately, and the patient should be informed of the potential hazard to the fetus.

The most commonly observed side effects in controlled clinical studies, 5% or greater and at least 1.5 times placebo, include paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth.

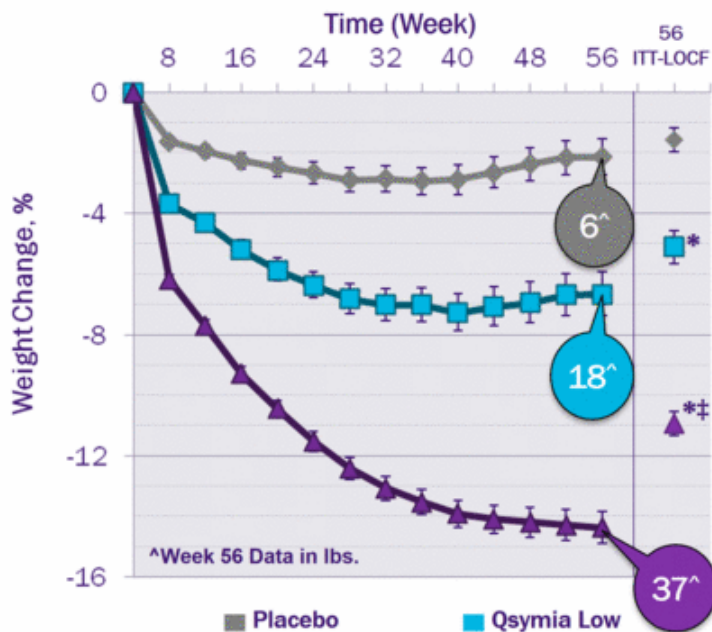
- Qsymia is a safe and effective therapy for chronic weight management
 - Proprietary extended-release formulation combining low doses of active ingredients from two previously approved compounds, phentermine and topiramate
- Marketed in the U.S. utilizing a dedicated in-house sales force covering the most productive prescribers of anti-obesity medications
 - Available in over 40,000 retail pharmacies nationwide or via a certified mail order pharmacy network
- Opportunity for growth and expansion outside the U.S.
 - VIVUS holds global rights to Qsymia
 - High potential geographies include the EU, CIS, Japan/China/Korea and the Middle East/North Africa

QSYMIA MAGNITUDE OF EFFECT

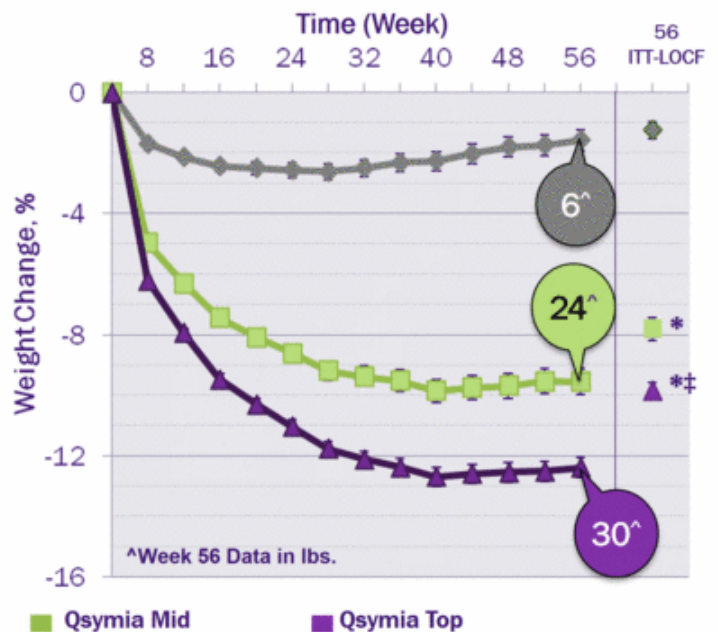
PIVOTAL 1-YEAR STUDIES: WEIGHT LOSS OVER TIME (OBSERVED/ITT DATA)



Study 1 (EQUIP¹)



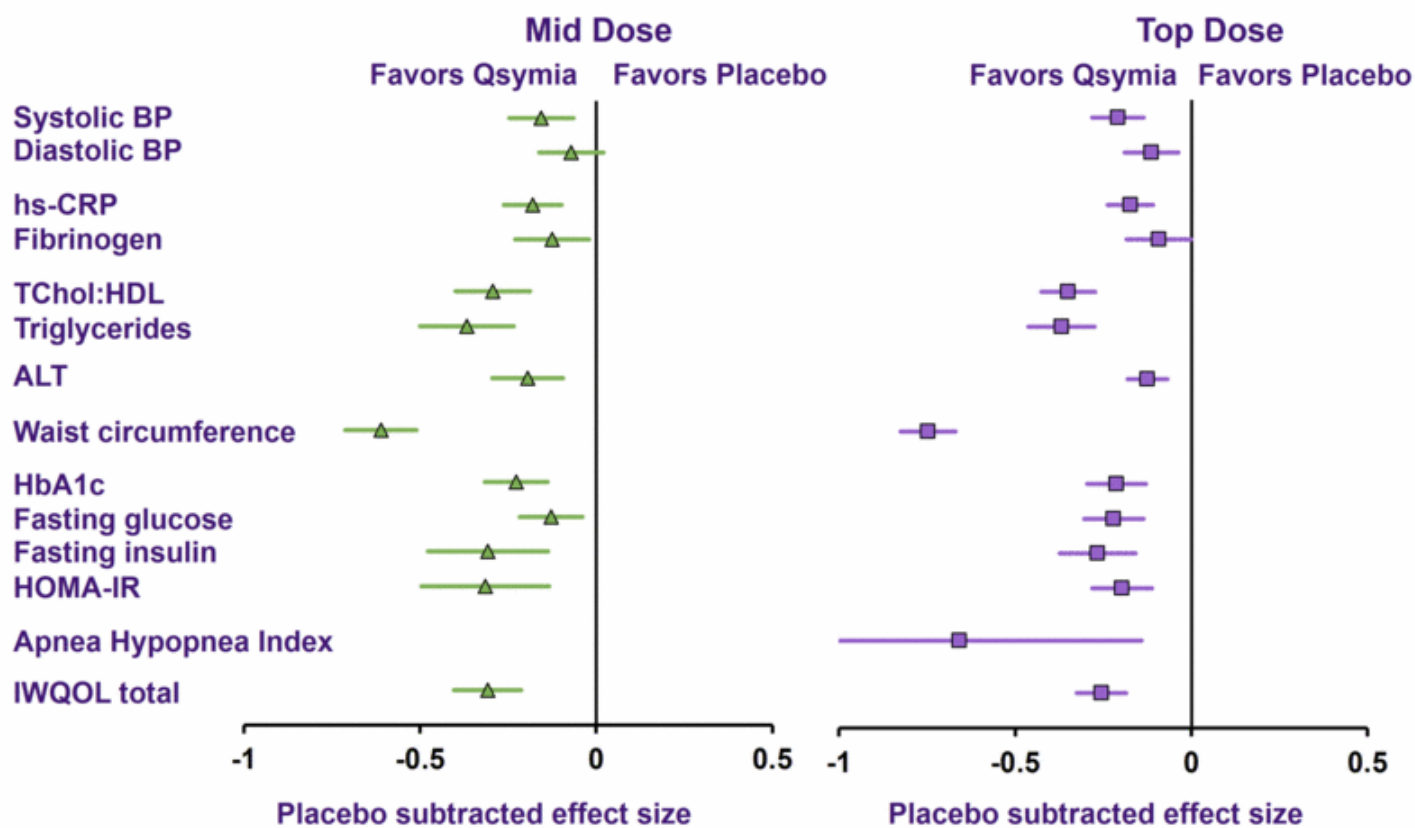
Study 2 (CONQUER²)



All observed data; *p<0.0001 vs placebo; †p<0.0001 vs. Qsymia Mid or Low

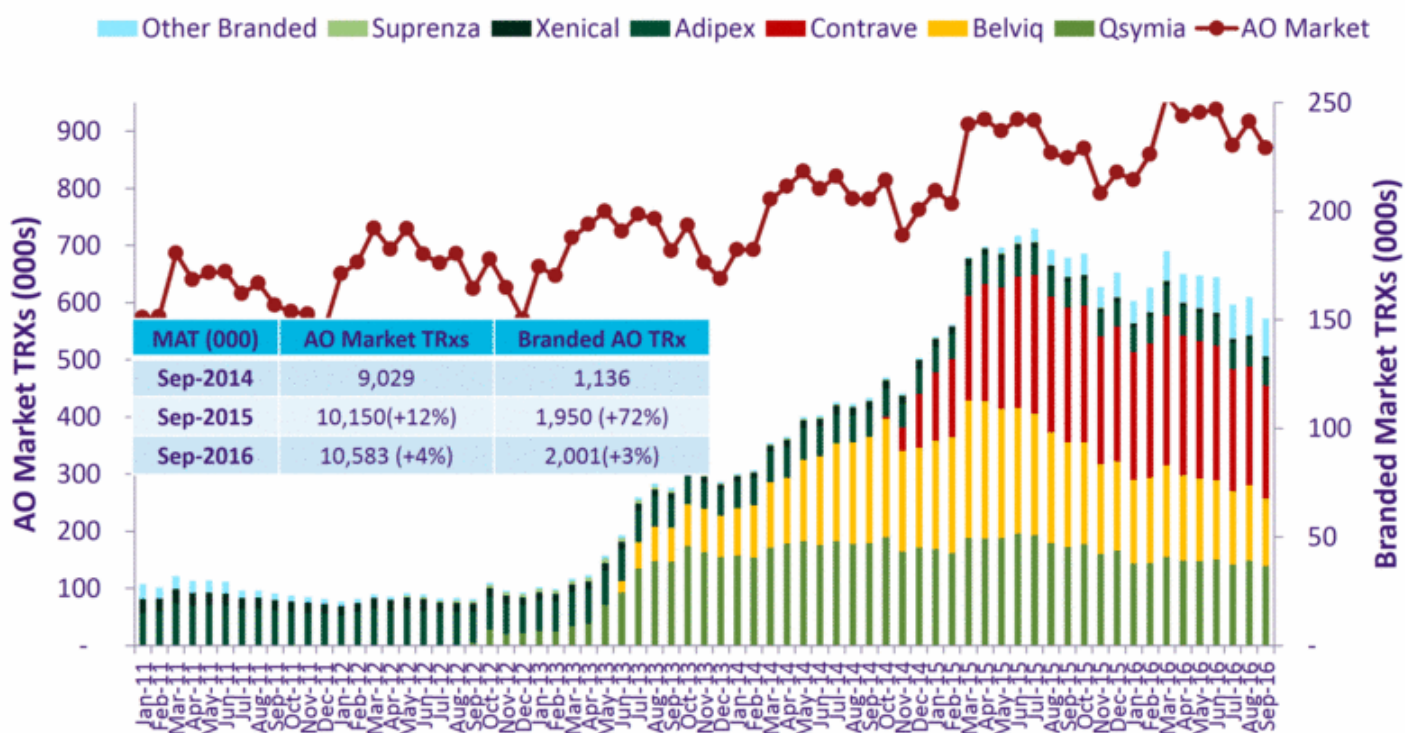
The most commonly observed side effects in controlled clinical studies, 5% or greater and at least 1.5 times placebo, include paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth.

BENEFICIAL EFFECTS OF WEIGHT LOSS WITH QSYMIA



SEP'16: BRANDED MARKET SHOWS A DECREASE OF (-15%) VS. SEP'15

QSYMIA (-20%); BELVIQ (-35%); CONTRAVE (-16%)



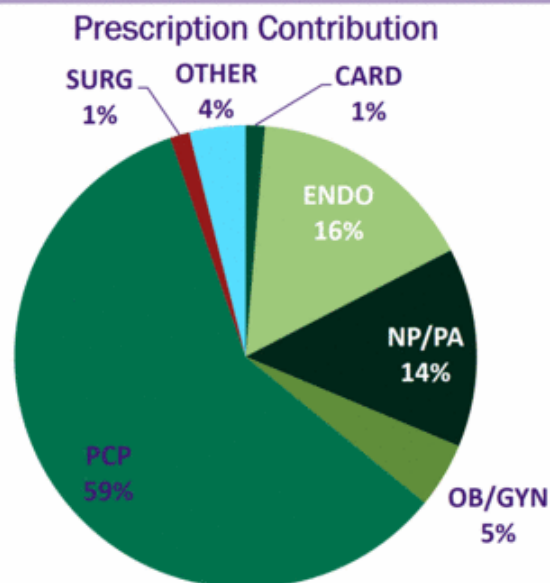
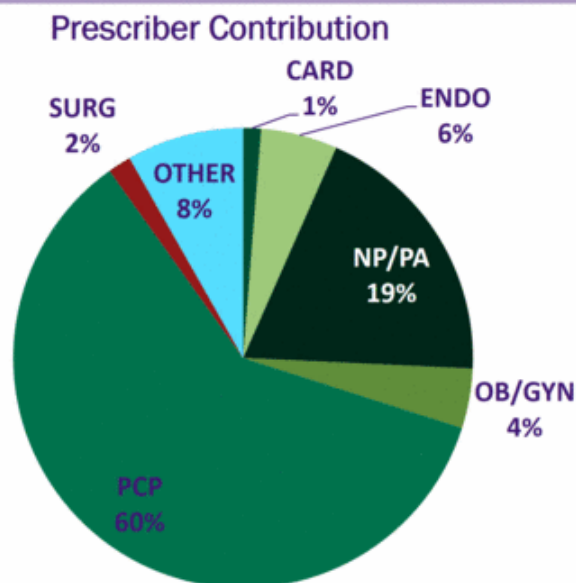
Note: Growth adjusted per IMS adjustment for AO market MAT (Moving Annual Total). All data IMS including Qsymia.

Source: Jan-2011 through Sep-2013 AO Market based on IMS NPA, Oct-2013 through present AO Market based on IMS Xponent.

©2017 VIVUS Inc. All rights reserved | www.vivus.com

QSYMIA TRxs BY SPECIALTY – 2015

ENDO IS TOP SPECIALTY BY PRODUCTIVITY



Specialty	CARD	ENDO	NP/PA	OB/GYN	PCP	SURG	OTHERS
Avg Rx/MD	15.5	43.6	10.6	15.9	14.3	12.2	7.0

Source: VIVUS Data on file- 1/23/2016 file. Data includes MO+PR Retail.

- **Status of ongoing FDA discussions**
 - CVOT remains a post-marketing requirement (PMR)
 - FDA requested potential new timeline to fulfil CVOT PMR
 - FDA needs new data to consider any modification of CVOT PMR
 - Company's position: There has been no indication throughout Qsymia clinical development nor in postmarketing experience of any increase in adverse CV events to warrant the CVOT PMR
- **CV Advisory Group**
 - Agreed on absence of CV risk signal to justify the current CVOT
 - Suggested performing a retrospective study of healthcare claims database to provide FDA new data for consideration
- **Retrospective Study**
 - Retrospective study to evaluate CV events in patients using phentermine, topiramate, Qsymia, or phentermine plus topiramate compared to non-users
 - Data expected in the first quarter of 2017

Additional VIVUS patents issued with claims covering QSYMIA and extending patent coverage by nine years

- U.S. Patent No. 8,580,298 issued in 2013
 - Dosage form claims
 - Continuations 8,895,058 and 9,011,905 issued in 2014 and 2015
- U.S. Patent No. 8,580,299 issued in 2013
 - Method-of-use claims for effecting weight loss
 - Continuations 8,895,057 and 9,011,906 issued in 2014 and 2015
- Continuation applications pending
- VIVUS has 11 patents listed in the Orange Book for Qsymia
- Patents pending in EP, AU, BR, CA, MX, IN, IL, CN, CL, JP, KR
- Patents granted in EP, JP, MX, ZA, AU and CA

- **ANDA Filers: Teva; Dr. Reddy's**
 - Paragraph IV certifications for 10 of 11 Orange Book listed patents
- **1st Notice received**
 - From TEVA (via Actavis) on 07-May-2014
 - From Dr. Reddy's (via TEVA) on 05-March-2015
- **Received favorable Markman ruling**
 - Adopted VIVUS' proposed constructions for all but one of the disputed claim terms
 - Adopted a compromise construction that was acceptable to VIVUS for the final claim term

Financial Summary

- **Company Name:** VIVUS, Inc.
- **Ticker:** VVUS (NASDAQ Global Market)
- **Share Price:** \$1.27 (1/5/2017)
- **Market Capitalization:** \$133 million (1/5/2017)
- **Cash and investments:** \$283.6 million (9/30/2016)
- **Debt principal balance:** \$284.6 million (9/30/2016)



INNOVATIVE THERAPIES NOVEL PRODUCTS

Qsymia[®]

(phentermine and topiramate
extended-release) capsules ©



STENDRA[™]

(avanafil) tablets



Corporate Update
January 2017