
**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)
August 21, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure

In connection with a series of meetings, VIVUS, Inc. will be distributing and presenting the slides attached hereto as Exhibit 99.1; such slides are incorporated by reference herein.

The information furnished under this Item 7.01, including the related exhibit, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by reference to such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Slide presentation entitled “Investor Presentation August 2018 — Reinvigorate, Deliver and Innovate — Nasdaq: VVUS”

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: August 21, 2018



Investor Presentation
August 2018

Reinvigorate, Deliver and
Innovate

Nasdaq: VVUS

Forward Looking Statements

Non-GAAP Financial Measures

Forward Looking Statements

Certain statements in this presentation are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to potential change in our business strategies for the Company and for each of our products; risks and uncertainties related to size and growth of the applicable markets, our expected future revenues, operations and expenditures; risks and uncertainties related to our history of losses and variable quarterly results; risks and uncertainties related to the timing, strategy, tactics and success of the marketing and sales of PANCREAZE; risks and uncertainties related to our, or our partner's, ability to successfully commercialize Qsymia; risks and uncertainties related to our ability to identify and acquire cash flow generating assets; risks and uncertainties related to our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for unpartnered territories under our license with MTPC; risks and uncertainties related to our ability to successfully develop or acquire a proprietary formulation of tacrolimus as a precursor to the clinical development process; risks and uncertainties related to our ability to address or potentially reduce our outstanding balance of the convertible notes due in 2020; risks and uncertainties related to our, or our current or potential partners', ability to gain approval for Qsymia in territories outside the U.S.; risks and uncertainties related to our ability to work with FDA to significantly reduce or remove the requirements of the clinical post-approval cardiovascular outcomes trial, or CVOT; risks and uncertainties related to the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy, or REMS, requirements; and risks and uncertainties related to our dialog with the European Medicines Agency, or EMA, relating to real world safety data for Qsymia and the resubmission of the marketing authorization application, and the assessment by the EMA of the marketing authorization application and the real world safety data. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2017 as filed on March 14, 2018, and as amended by the Form 10-K/A filed on April 26, 2018, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

Use of Non-GAAP Financial Measures

We supplement our condensed consolidated financial statements presented on a GAAP basis by providing additional measures which are considered non-GAAP under applicable SEC rules, such as EBITDA and Enterprise Value. We believe that the disclosure of these non-GAAP measures provides investors with additional information that reflects the basis upon which our management assesses and operates our business. This non-GAAP financial measure is not in accordance with GAAP and should not be viewed in isolation or as a substitute for GAAP net loss and is not a substitute for, or superior to, measures of financial performance performed in conformity with GAAP.

Investment Highlights and Recent Accomplishments

- Newly integrated management team
- Three approved products, one product in active development
 - Qsymia® – Body mass index management / Weight Loss
 - PANCREAZE® – Endocrine pancreatic insufficiency (EPI)
 - STENDRA®/SPEDRA® – Erectile dysfunction
 - VI-0106 – in development for Pulmonary Arterial Hypertension
- Restructured a portion of our convertible debt
 - Reduced convertible debt due in May 2020 from \$250M to \$190M
 - Added \$110M of Senior Secured Notes due in 2024
- Clear strategic path to positive operating cash flow and profitability
 - Expect to generate operating free cash flow by the first quarter of 2019 (a first for VIVUS, excluding one-time asset sales and before debt service)
 - May 2018 – Mar 2019: expected turnaround period
 - Apr 2019 – Dec 2019: anticipate modest growth with improved operations
 - Jan 2020 – Dec 2020: target improved growth of PANCREAZE and stability on Qsymia
- \$123.5M of cash and available-for-sale securities at June 30, 2018

Building a Premier Specialty Pharmaceutical Organization

- Drive significant growth through acquiring EBITDA positive brands, with a focus on the U.S. and Canadian markets (network of global partners for EX U.S. and Canada)
 - Acquired U.S. and Canadian rights to PANCREAZE® from Janssen in June 2018
- Leverage existing U.S. commercial infrastructure to expand market opportunity for current and future products
 - 18 sales representatives, 3 district managers
- Ignite organic growth through re-investing into in-line brands
 - PANCREAZE has not been actively promoted since 2012
 - Qsymia access for patients is currently limited to 11.25% of the total market. VIVUS is expanding access and believes it can potentially increase access up to 70% of the total market by 2020
- \$123.5 million in unrestricted cash and available-for-sale securities (June 30, 2018) to support acquisition of additional EBITDA-positive products

Asset Acquisition Philosophy

- As a core VIVUS activity, we are evaluating additional in-licensing and acquisition candidates that would meet our goals of meeting patients' needs while working toward profitability and creating stockholder value.
- Our approach to evaluating these opportunities
 - The price of the target asset has to be defined early in the process as being in a range that would generate acceptable returns on invested capital.
 - While we utilize financial leverage, we will not financially engineer returns.
 - We need to see that the product has some market barriers to entry for at least a defined period of time, or that the market has flushed through a number of competitors.
 - Identify products that have a significant clinical following and are important in the treatment of the medical condition(s) for which the product is indicated.
 - Acquire assets that don't require heroic or large number of strategies to achieve our performance targets. Turnaround assets can become cash flow positive, but there are limits to the activities and initiatives we will undertake in the pursuit of value creation around an acquired product.

Pharmaceutical Assets

	Pre-Clinical	Phase 1	Phase 2	Phase 3	Approved
PANCREAZE®					
-EPI due to Cystic Fibrosis + other conditions					
-Pancreatitis					
Qsymia®					
-Obesity (Discussion with EU on refiling based on real world data)					
-Obstructive Sleep Apnea					
-NASH					
Avanafil (STENDRA®/SPEDRA®)					
-Erectile Dysfunction (Marketing authorization ongoing in MENA and Russia/CIS)					
VI-0106					
-Pulmonary Arterial Hypertension			Orphan Status Granted; VIVUS is seeking Fast Track and Breakthrough Therapy designation		

VIVUS objectives: 2018 and beyond

- Realize value of the PANCREAZE acquisition
- Expand the Qsymia opportunity through new sales and marketing initiatives in the U.S. and seek approval in the EU and other territories
- Explore opportunities to advance VI-0106 into the clinic in a manner consistent with capital objectives
- Acquire additional EBITDA-positive products that leverage VIVUS' commercialization infrastructure and expertise
- Continue to address the amount and structure of VIVUS' corporate debt
- Seek additional opportunities to monetize Avanafil

COMMERCIAL ASSETS

PANCREAZE Summary

- PANCREAZE is indicated for exocrine pancreatic insufficiency (EPI) due to cystic fibrosis or other conditions
 - Pancreatic enzyme preparation consisting of pancrelipase, an extract derived from porcine pancreas glands
 - Provides proven benefits to EPI patients
 - Indicated for both pediatric and adult EPI patients
- VIVUS holds PANCREAZE product rights in the United States and Canada
- Market for pancreatic enzyme replacement therapies (PERT) is in excess of \$1 billion annually
 - PANCREAZE holds approximately 3%* of the PERT market
 - Janssen ceased active promotion of PANCREAZE in 2012
 - VIVUS expects to increase PANCREAZE revenue/market share with re-investment in and active promotion of the brand

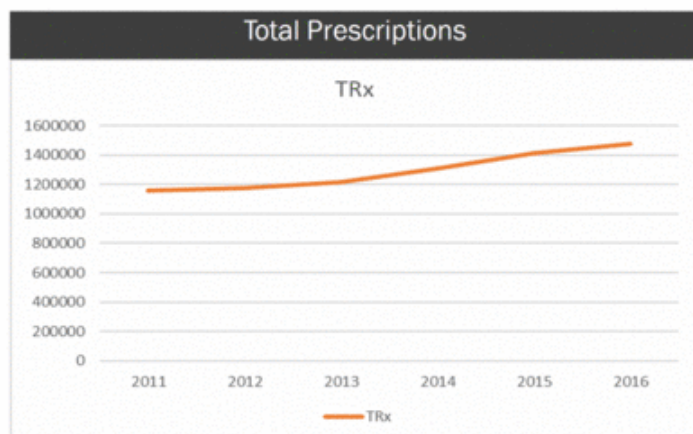
* Derived from IMS data

Overview of PANCREAZE

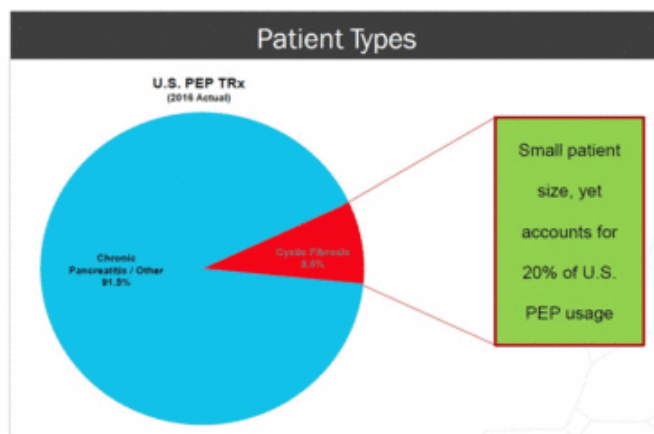
- **Established Brand**
 - In market since 1988
 - PANCREAZE is not interchangeable with other PERTs in market
 - Has demonstrated steady volume post competitor entry
- **Known Competitive Landscape**
 - Potential new entrants must conduct clinical trial to receive NDA approval
 - Sollpura (synthetic) failed Phase 3 study for 3rd time
- **Stable Market Dynamics**
 - PERT utilization is growing as the incidence and prevalence of Cystic Fibrosis and Chronic Pancreatitis continues to grow
 - Brands are not interchangeable
- **Demonstrated Safety and Efficacy**
 - Prescribed by doctors for more than 20 years
 - Demonstrated significant symptom improvement
- **Reliable Supply Chain**
 - Fully integrated supply chain from Active Pharmaceutical Ingredients to finished product
 - Same manufacturer since launch of brand in 1988
 - Leading third party logistics providers

PERT Market Overview*

- Stable market with 9,000 new patient starts on therapy per month
- PERT market growing at a rate of 5% (2016 actual) and expected to grow at a rate of 4% in 2017
- Cystic Fibrosis and Chronic Pancreatitis patients drive PERT prescriptions



Source: IMS and Janssen



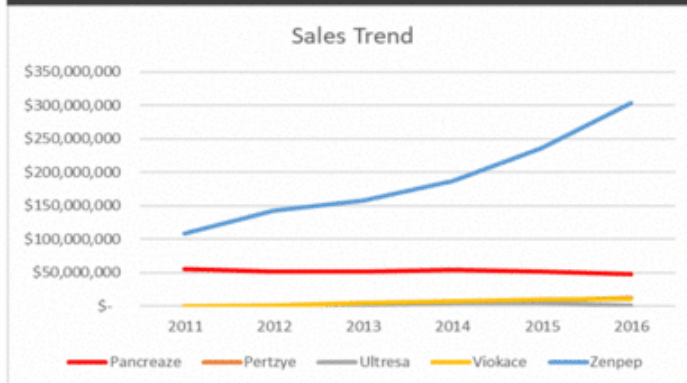
PERT market has demonstrated stable utilization for patients requiring pancreatic enzyme replacement

* Derived from IMS data

PERT Market Overview*

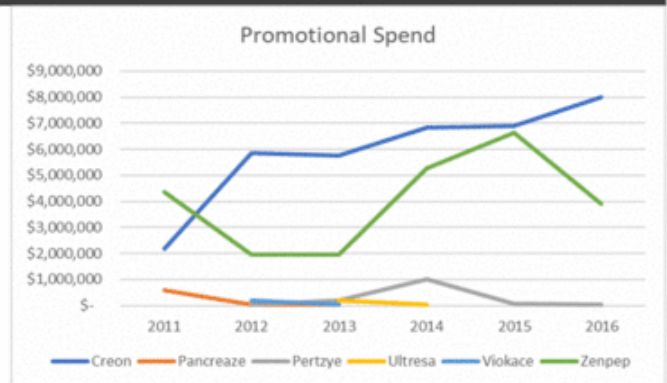
- PANCREAZE sales stable with mild annual decrease without any promotional investment
- Creon and Zenpep are market leaders with continued promotional investment
- PANCREAZE performance expected to improve with promotional investment by VIVUS

PERT Sales – 2011 to 2016



Creon not represented in the above pane
Creon generates ~ \$750M USD annually

Promotional Spend – 2011 to 2016



PERT market has demonstrated stable utilization for patients requiring pancreatic enzyme replacement

* Derived from IMS data

PANCREAZE Commercial Strategy

- Planned “Relaunch” of PANCREAZE in the fourth quarter of 2018
 - Focus on two key market segments in the U.S. and Canadian markets
 - Cystic fibrosis centers of excellence
 - High-treating physicians within the chronic pancreatitis market
 - Engage with payors to provide better PANCREAZE access to patients
 - Re-establish patient support program to facilitate usage of and compliance with PANCREAZE therapy
 - Establish strong presence among key EPI thought leaders
 - Work with manufacturer to introduce new forms and dosage strength
- Leverage VIVUS’ demonstrated commercial infrastructure and expertise to expand market footprint
 - Two competitors currently control approximately 90%* of the market with minimal commercial investment
 - VIVUS believes that proactive sales and marketing efforts can drive greater adoption of PANCREAZE as the EPI therapy of choice

* Derived from IMS data

Qsymia Summary

- Qsymia is a safe and effective therapy for body mass index management
 - Proprietary extended-release formulation combining low doses of active ingredients from two previously approved compounds, phentermine and topiramate
 - 3-month data also support short-term use, with weight loss reductions of 15-19 pounds and reductions of 2-3 inches from waist
- Marketed in the U.S. utilizing a dedicated in-house sales force covering the highest-volume prescribers of anti-obesity medications
- Opportunity for growth and expansion outside the U.S.

U.S. Qsymia Commercial Results

- Qsymia scripts have been declining

	2014	2015	2016	2017	6 Mos 2018
Low	151,719	135,946	86,646	71,496	32,700
Mid	284,005	277,503	207,113	180,800	84,219
3/4	51,311	76,667	69,556	64,174	32,012
High	46,801	75,936	78,695	78,059	39,345
Total	533,835	566,052	442,010	394,529	188,276

- Possible reasons include:
 - Access to product
 - Pricing compared to competition
 - Profitability
 - Perception of obesity as chronic
 - Competitive commercial spending
 - Perception of Clinical Risk (CVOT overhang)

Qsymia Opportunities - U.S.

- Potential for label change with approval of sNDA
 - Discussions ongoing with FDA
 - Possible change to a “Short-term” label (approximately 12 weeks)
 - Possible elimination of CVOT
 - Only product with 12 week clinically meaningful efficacy data
- Enhanced promotion to patient in-need through adoption of a specialty pharmaceutical distribution model
 - Provides opportunity for pricing flexibility
- Adolescent market
 - Adolescent Safety/Efficacy Study (OB-403)
 - To start enrollment in the fourth quarter of 2018 or the first quarter of 2019

Qsymia Opportunities - Ex U.S.

- EU
 - Re-engaged with EU regulators following evaluation of post-launch safety data in U.S. patients
 - MAA submission planned by the end of 2018
 - Exploring partnership opportunities
- Rest of World
 - Licensed in South Korea to Alvogen
 - High-potential geographies being explored include: Latin America, Russia/CIS, Asia (excluding South Korea), and MENA

Qsymia Development Opportunities

- OSA: Obstructive Sleep Apnea
 - Positive Phase 2 study results published in SLEEP (2012;35(11):1529-1539)
 - Obtained FDA feedback to allow finalization of pivotal trial protocol
- NASH: Nonalcoholic Steatohepatitis
 - Significant unmet medical need in NASH, with no FDA-approved therapies available
 - Favorable biomarker data in Phase 3 Clinical studies
 - STAM mouse model study suggests benefit on NASH endpoints/fibrosis independent of weight loss
 - Ongoing protocol development for an exploratory human study
- Extension beyond obesity market will require resolution of cardiovascular outcomes trial (CVOT) requirement

Avanafil Summary

- Approved as STENDRA in the U.S. and as SPEDRA in the EU
- Compelling clinical data
 - Only erectile dysfunction treatment with a clinically proven 15-minute onset-of-action
 - Able to be taken with food and alcohol
 - Strong safety and side-effect profile
- Product is out-licensed in the United States and other territories
- Regulatory approvals in process in key countries within the MENA and Russia/CIS

Avanafil Partnerships

	Menarini	Metuchen Pharmaceuticals (Mist Pharmaceuticals)
Effective Date	July 2013	September 2016
Territories	EU, Australia and New Zealand	United States, Canada, South America and India
Upfront and Milestones	71M Euros (41M received to date)	\$70M upfront
Royalty	Yes	No

Available Territories: MENA/Turkey, Russia/CIS, and Mexico/CENAM

PIPELINE OPPORTUNITY:

VI-0106 - Tacrolimus for the
Treatment of Pulmonary Arterial
Hypertension (PAH)

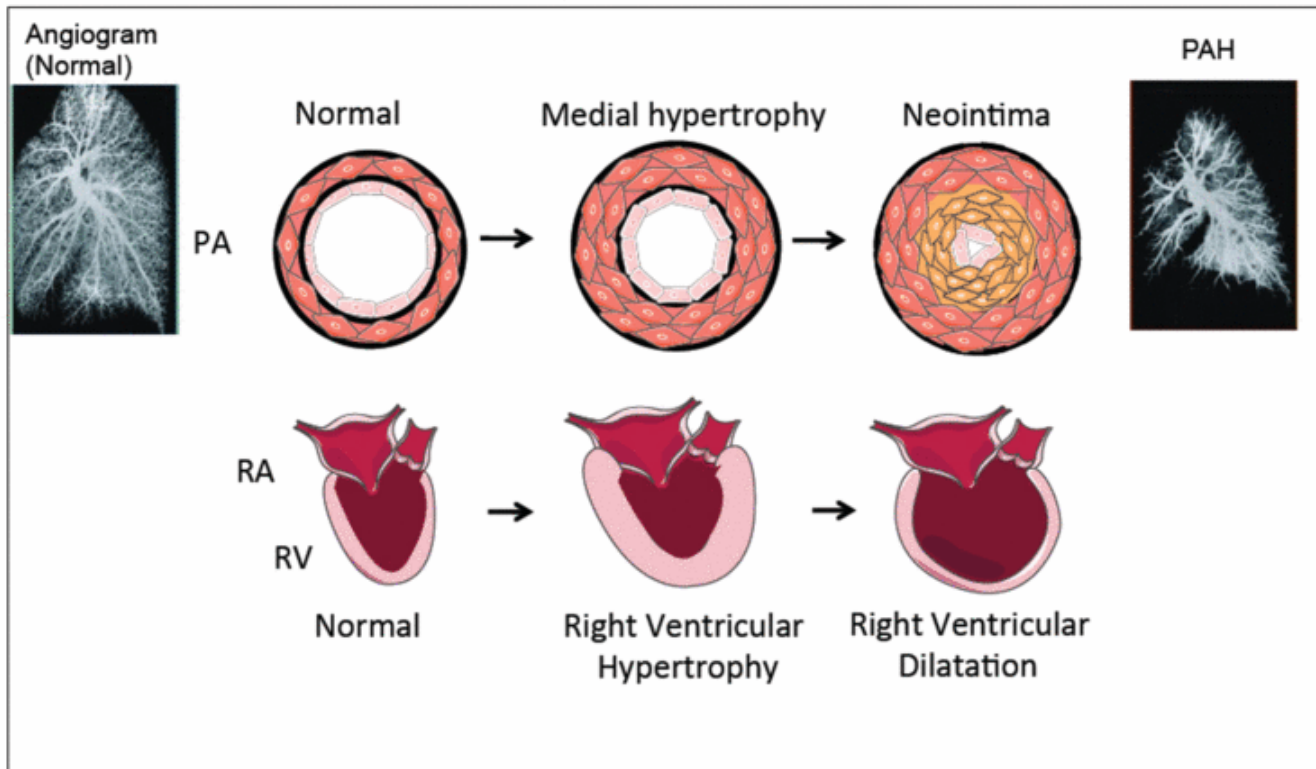
VI-0106 PAH Opportunity

- 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, while failing to substantially modify the disease course
 - Lung transplantation only option for advanced patients not responsive to drug therapies
- Tacrolimus, a drug approved in multiple organ transplant settings, has demonstrated efficacy in PAH and could be an important new class of therapy that addresses the underlying cause of disease
- Large growth market: ~\$4.5B* worldwide, \$2.7B* U.S. in 2015
 - Treatment supports multiple “layering” therapies
- Orphan drug designation received
 - Potential for “Fast Track” and/or “Breakthrough Therapy” designation
 - Potentially class/disease modifying, extending life expectancy
- VIVUS is exploring opportunities to advance the development of VI-0106, a proprietary formulation of tacrolimus, in a manner consistent with its capital objectives

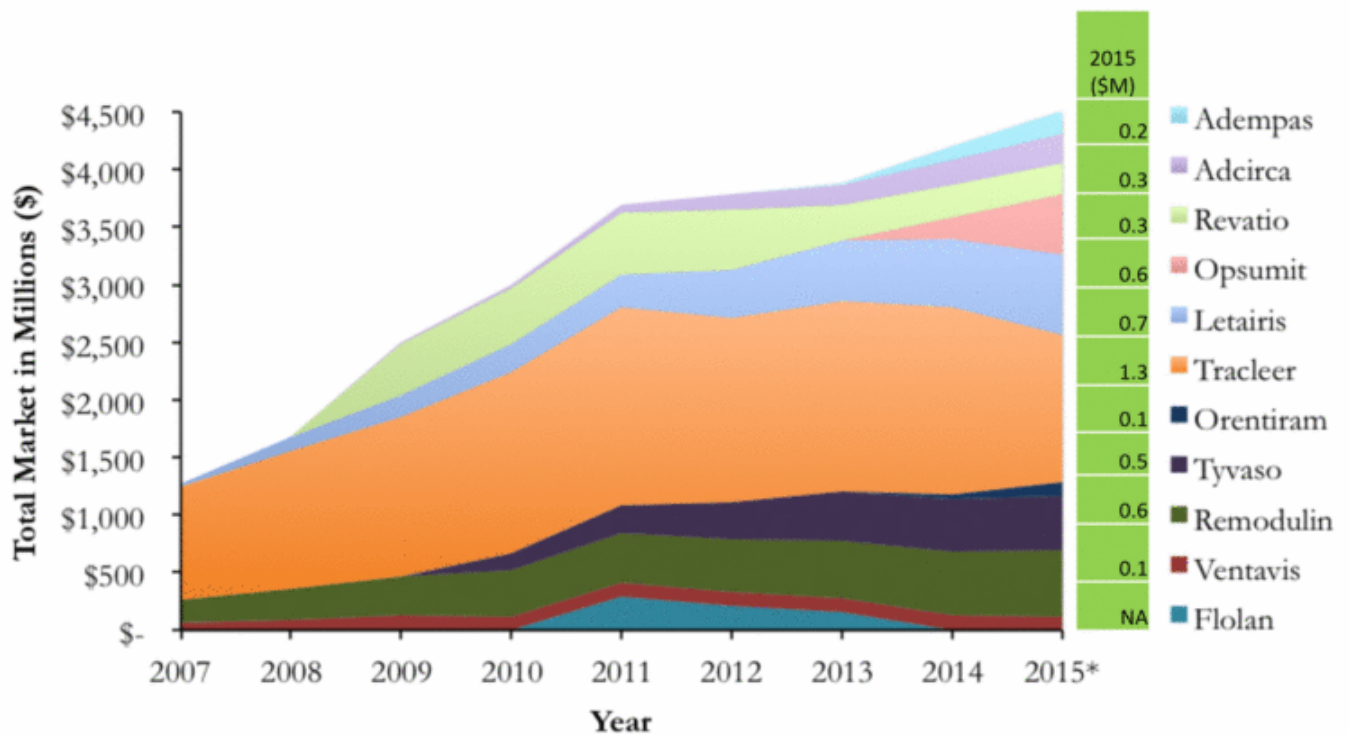
*LifeSci Capital, Sector Analysis, Feb 4, 2016

PAH Clinical Overview

The progressive narrowing in pulmonary arteries leading to heart failure



Worldwide Market for PAH Therapies

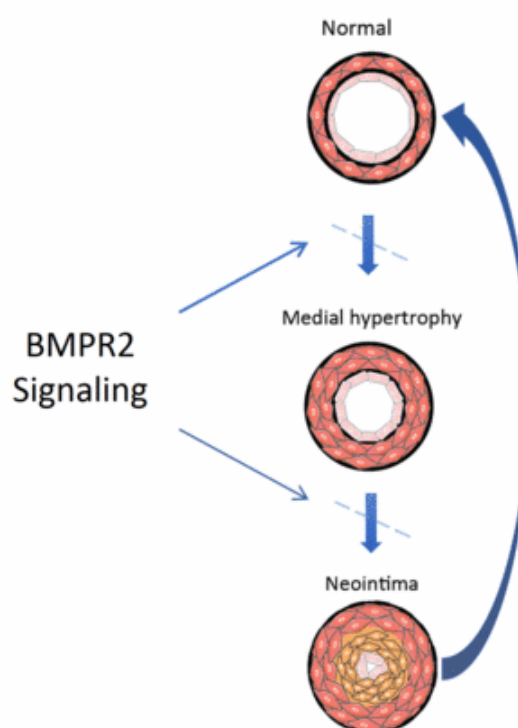


VI-0106 Revenue Potential \$750M to \$1B Globally

Graph: LifeSci Capital, Sector Analysis, Feb 4, 2016

VI-0106: Targeting Proliferation

- Bone Morphogenetic 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 of the currently approved tacrolimus formulation demonstrate the ability to restore BMPR2 signaling
- Low dose of currently approved tacrolimus formulation 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

- **Compassionate use**
 - 3 end-stage patients, functional class 3 and 4
 - Positive impact on clinical outcomes
 - Dramatically reduced rate of hospitalizations
 - Functional class improvements observed
- **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 a useful tolerability marker
 - Study population precluded useful efficacy assessments
- **Phase 1 PK Study**
 - Evaluate the pharmacokinetic (PK) profile of VI-0106 in healthy volunteers
 - Results showed prototype formulations had PK profiles consistent with earlier in-vitro evaluations, namely an extended Tmax, a lowered Cmax, and an increased AUC compared to available immediate release tacrolimus.

VI-0106 IP status

- U.S. and foreign applications pending
- Method of Use Patents
 - Patent term to April 30, 2032
- U.S. patent allowed
 - Issued as US9474745, term to December 29, 2032
 - Continuation filed
- 8 claims
- EP, AU, CA, and JP are filed

VIVUS objectives: 2018 and beyond

- Realize value of the PANCREAZE acquisition
- Expand the Qsymia opportunity through new sales and marketing initiatives in the U.S. and seek approval in the EU and other territories
- Explore opportunities to advance VI-0106 into the clinic in a manner consistent with capital objectives
- Acquire additional EBITDA-positive products that leverage VIVUS' commercialization infrastructure and expertise
- Continue to address the amount and structure of VIVUS' corporate debt
- Seek additional opportunities to monetize Avanafil

FINANCIAL AND OTHER INFORMATION

Management Team

Name /Role	Experience
John Amos Chief Executive Officer	<ul style="list-style-type: none"> • 24+ years in Healthcare as CEO, Investor, Board Member and Executive • McKesson, BMS, OTN, BVCF, ORIX, Willow
Ken Suh President	<ul style="list-style-type: none"> • 20+ years in Healthcare as CEO and Executive • Johnson & Johnson, Novartis, KRIM, Willow
Mark Oki Chief Financial Officer	<ul style="list-style-type: none"> • 20+ years in Healthcare as CFO and Finance Executive • Deloitte and Touche, Alexza Pharmaceuticals, Pharmacyclics, Incyte,
John Slebir General Counsel / SVP Business Development	<ul style="list-style-type: none"> • 25+ years in Healthcare as GC, Business Development, Corporate Secretary • Wilson, Sonsini, Goodrich and Rosati P.C.
Deborah Larsen Chief Strategy Officer (Commercial Ops)	<ul style="list-style-type: none"> • 25+ years in Global Marketing Roles • Glaxo Smith Klein, ICC, Novartis
Dr. Santosh Varghese Chief Medical Officer	<ul style="list-style-type: none"> • 20+ years in Healthcare as CEO and Executive • Elan, Merck, Schering Plough, Sanofi Aventis
Scott Oehrlein Chief Operations Officer	<ul style="list-style-type: none"> • 30+ years in Healthcare as CEO and Executive • The Upjohn, Sanofi, Novartis, Willow

Financial Snapshot

Company Overview	
Company Name	VIVUS, Inc.
Ticker	VVUS
Current Share Price (8/10/2018)	\$ 0.65
52 Week High	\$ 1.04
52 Week Low	\$ 0.33
Market Capitalization	\$ 68.9
Plus: Debt (Principal value)	300.0
Less Cash and Investments	123.5
Enterprise value	\$ 245.4
Balance Sheet, June 30, 2018 (in \$MM)	
Assets	Liabilities
Cash and Investments \$ 123.5	Accounts Payable \$ 4.3
Receivables 11.1	Accrued Expenses 26.9
Inventory 22.3	Other Current Liabilities 1.9
Other Current Assets 6.4	Total Current Liabilities 33.1
Total Current Assets 163.3	Long-Term Debt 295.5
Property & Equipment, Net 0.5	Other Non-Current Liabilities 4.6
Other Non-Current Assets 141.5	Total Liabilities 333.2
Total Other Assets 142.0	Total Equity (27.9)
Total Assets \$ 305.3	Total Liabilities and Equity \$ 305.3

Operating Results

	6 Mos			
	2015	2016	2017	2018
Revenue:				
(In thousands, except per share amounts)				
Net product revenue	\$ 54,622	\$ 48,501	\$ 44,983	\$ 22,882
License and milestone revenue	11,574	69,400	7,500	-
Supply revenue	26,674	2,291	10,407	2,725
Royalty revenue	2,560	4,066	2,483	1,253
Total revenue	95,430	124,258	65,373	26,860
Operating expenses:				
Cost of goods sold, excluding amortization	33,432	9,877	16,643	5,916
Amortization of intangible assets	725	725	544	1,364
Research and development	10,102	5,592	5,263	3,445
Selling and marketing	52,988	21,775	16,638	7,800
General and Administrative	26,399	30,604	23,492	13,979
Inventory impairment and other non-recurring charges	32,061	-	-	-
Total operating expenses	155,707	68,573	62,580	32,504
Income (loss) from operations	(60,277)	55,685	2,793	(5,644)
Interest and other expense (income):				
Interest expense (income), net	33,317	32,888	33,231	16,596
Other expense (income), net	(490)	(575)	71	971
Total interest expense and other expense (income), net	32,827	32,313	33,302	17,567
Income (loss) before income taxes	(93,104)	23,372	(30,509)	(23,211)
Provision for (benefit from) income taxes	3	70	2	16
Net income (loss)	\$ (93,107)	\$ 23,302	\$ (30,511)	\$ (23,227)
Basic and Diluted Net Income (Loss) per share	\$ (0.90)	\$ 0.22	\$ (0.29)	\$ (0.22)

IMPORTANT SAFETY INFORMATION

Important Safety Information

PANCREAZE

What is the most important information I should know about PANCREAZE?

- PANCREAZE may increase your chance of having a serious, rare bowel disorder called fibrosing colonopathy that may require surgery.
- The risk of having this condition may be reduced by following the dosing instructions that your healthcare provider gave you.

Call your doctor right away if you have any unusual or severe stomach area (abdominal) pain, bloating, trouble passing stool (having bowel movements), nausea, vomiting, or diarrhea. Take PANCREAZE exactly as prescribed by your doctor. Do not take more or less PANCREAZE than directed by your doctor.

What are the possible side effects of PANCREAZE?

PANCREAZE may cause serious side effects, including:

- A rare bowel disorder called fibrosing colonopathy.
- Irritation of the inside of your mouth. This can happen if PANCREAZE is not swallowed completely.
- Increase in blood uric acid levels. This may cause worsening of swollen, painful joints (gout) caused by an increase in your blood uric acid levels.
- Allergic reactions including trouble with breathing, skin rashes, or swollen lips.

Call your doctor right away if you have any of these symptoms. The most common side effects include pain in your stomach (abdominal pain) and gas. Other possible side effects: PANCREAZE and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs people eat as pork. These pigs may carry viruses. Although it has never been reported, it may be possible for a person to get a viral infection from taking pancreatic enzyme products that come from pigs. These are not all the side effects of PANCREAZE. Talk to your doctor about any side effect that bothers you or does not go away. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What should I tell my doctor before taking PANCREAZE?

Tell your doctor if you:

- are allergic to pork (pig) products.
- have a history of blockage of your intestines, or scarring or thickening of your bowel wall (fibrosing colonopathy).
- have gout, kidney disease, or high blood uric acid (hyperuricemia).
- have trouble swallowing capsules.
- have any other medical condition.
- are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

The Product Information and Medication Guide for PANCREAZE is available at www.pancrease.com.

Important Safety Information

Qsymia

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; 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.

Important Safety Information

STENDRA

STENDRA® (avanafil) is prescribed to treat erectile dysfunction (ED).

Do not take STENDRA if you take nitrates, often prescribed for chest pain, as this may cause a sudden, unsafe drop in blood pressure.

Discuss your general health status with your healthcare provider 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.

STENDRA may affect the way other medicines work. Tell your healthcare provider if you take any of the following; medicines called HIV protease inhibitors, such as ritonavir (Norvir®), indinavir (Crixivan®), saquinavir (Fortavase® or Invirase®) or atazanavir (Reyataz®); some types of oral antifungal medicines, such as ketoconazole (Nizoral®), and itraconazole (Sporanox®); or some types of antibiotics, such as clarithromycin (Biaxin®), telithromycin (Ketek®), or erythromycin.

In the rare event of an erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including STENDRA) reported a sudden decrease or loss of vision. It is not possible to determine whether these events are related directly to these medicines or to other factors. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including STENDRA, and call a doctor right away.

Sudden decrease or loss of hearing has been rarely reported in people taking PDE5 inhibitors, including STENDRA. It is not possible to determine whether these events are related directly to the PDE5 inhibitors or to other factors. If you experience sudden decrease or loss of hearing, stop taking STENDRA and contact a doctor right away. If you have prostate problems or high blood pressure for which you take medicines called alpha blockers or other anti-hypertensives, your doctor may start you on a lower dose of STENDRA.

Drinking too much alcohol when taking STENDRA may lead to headache, dizziness, and lower blood pressure.

STENDRA in combination with other treatments for ED 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.

Please see full patient prescribing information for STENDRA (50 mg, 100 mg, 200 mg) tablets.