

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, DC 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 5, 2019**

VIVUS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33389
(Commission
File Number)

94-3136179
(I.R.S. Employer
Identification No.)

900 E. Hamilton Avenue, Suite 550
Campbell, CA 95008
(Address of Principal Executive Offices, and Zip Code)

(650) 934-5200
Registrant's Telephone Number, Including Area Code

N/A
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	VVUS	The Nasdaq Global Select Market
Preferred Share Purchase Rights		

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 communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communication 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 presentations by VIVUS, Inc. (the “Company”) at the RHK Capital 4th Annual Disruptive Growth Conference hosted by ReedSmith at 10:20 A.M. ET on Thursday, September 5, 2019 in New York and at the 21st Annual H.C. Wainwright Global Investment Conference at 1:45 P.M. ET on Monday, September 9, 2019 in New York, the Company 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.

Exhibit No.	Description
99.1	Slide presentation entitled “Investor Presentation September 2019 — Innovate, Deliver and Grow — 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: September 5, 2019

VIVUS

September 2019

Innovate, Deliver and Grow

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 discussions with the European Medicines Agency, or EMA, relating to the resubmission of the marketing authorization application for Qsymia, and the assessment by the EMA of the marketing authorization application. 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, 2018 as filed on February 26, 2019, 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

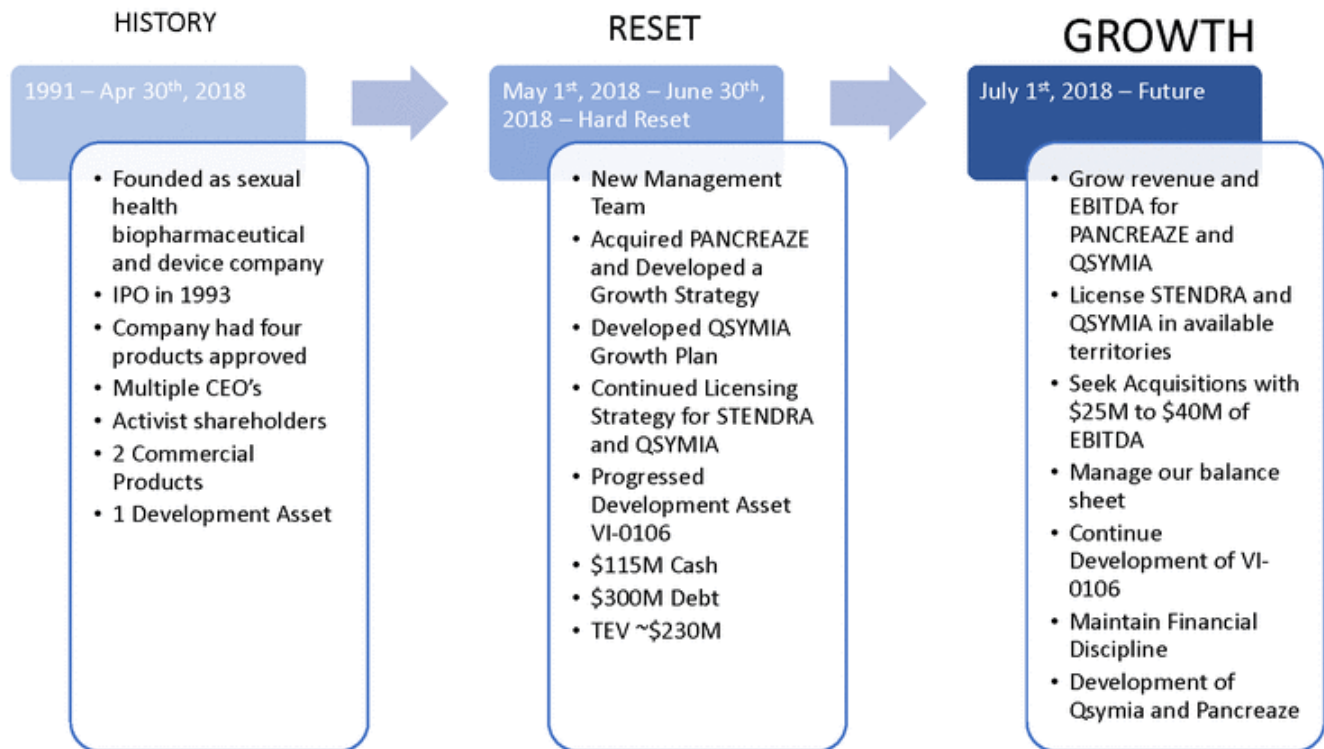
We supplement our condensed consolidated financial statements presented on a GAAP basis by providing additional measures which are considered non-GAAP under applicable SEC rules, such as EBITDA and Enterprise Value. We believe that the disclosure of these non-GAAP measures provides investors with additional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

VIVUS is a technology enabled
biopharmaceutical company that specializes in
the commercialization of innovative therapies
that focus on advancing treatments for patients
with serious unmet medical needs

Overview

- **VIVUS Health Platform** - developing and bringing an integrated approach to care utilizing software integrated with clinical processes to achieve better health outcomes to drive savings in the healthcare system
- **Commercialized Pharmaceuticals**
 - Qsymia (phentermine and topiramate extended-release) – a safe and effective pharmaceutical therapy for body mass index management
 - PANCREAZE – a biopharmaceutical indicated for exocrine pancreatic insufficiency (EPI) due to cystic fibrosis or other conditions
- **Development Pharmaceutical**
 - VI-0106 – for the treatment of pulmonary arterial hypertension; orphan drug designation, seeking Fast Track and Breakthrough Therapy designation
- **Out-Licensed Pharmaceutical**
 - STENDRA (avanafil) – treatment of erectile dysfunction
- **Completed four quarters of a 10-quarter turnaround**

Brief History



Completed Four Quarters of a 10-Quarter Turnaround

- LTM Q2 2019 Generated \$72.7M of revenue and \$14.4M of EBITDA
 - First time since 1997 that VIVUS has generated recurring positive EBITDA
 - Excluding discretionary R&D expense, VIVUS generated \$19.2M of EBITDA
- Relaunched Qsymia and PANCREAZE
 - Qsymia Advantage on the VIVUS Health Platform
 - PANCREAZE Advantage on the VIVUS Health Platform

Seizing Opportunity in an Evolving Healthcare Landscape

- The consolidation of PBM's, health plans, pharmacy chains, wholesalers and data platforms has created a significant chasm between the patient and the pharmaceutical manufacturer
- The self-insured employer, physician and patient marketplaces have been incredibly responsive and accepting of new business models that address and disrupt this consolidation
- Gateway to allow VIVUS to partner with Doctors, Dieticians, Nutritionists, Self-Insured Employers, Private and Public Insurers and most importantly Patients to achieve their healthy weight goals
- The VIVUS HEALTH PLATFORM integrates medical, pharmaceutical, nutritional and information technology and has the potential to generate revenue on a subscription basis while delivering solid economic ROI's to key stakeholders

LEGEND

Reusable

Needs
Modification for
Each ProductUnique to Each
Product

Q4 2019

VIVUS Health Platform



Patient




Healthcare Provider

Qsymia and PANCREAZE Advantage Programs

Co Pay Card

Sampling Program

Patient Assistance
ProgramVIVUS HEALTH Store
Vitamins and
Supplements Through
AmazonDirect-to-Patient
Medicine Delivery
 Physician Engagement
Telemedicine
HIPAA Compliance /
Identity ManagementPatient Data
Engagement3PL Logistics
Management

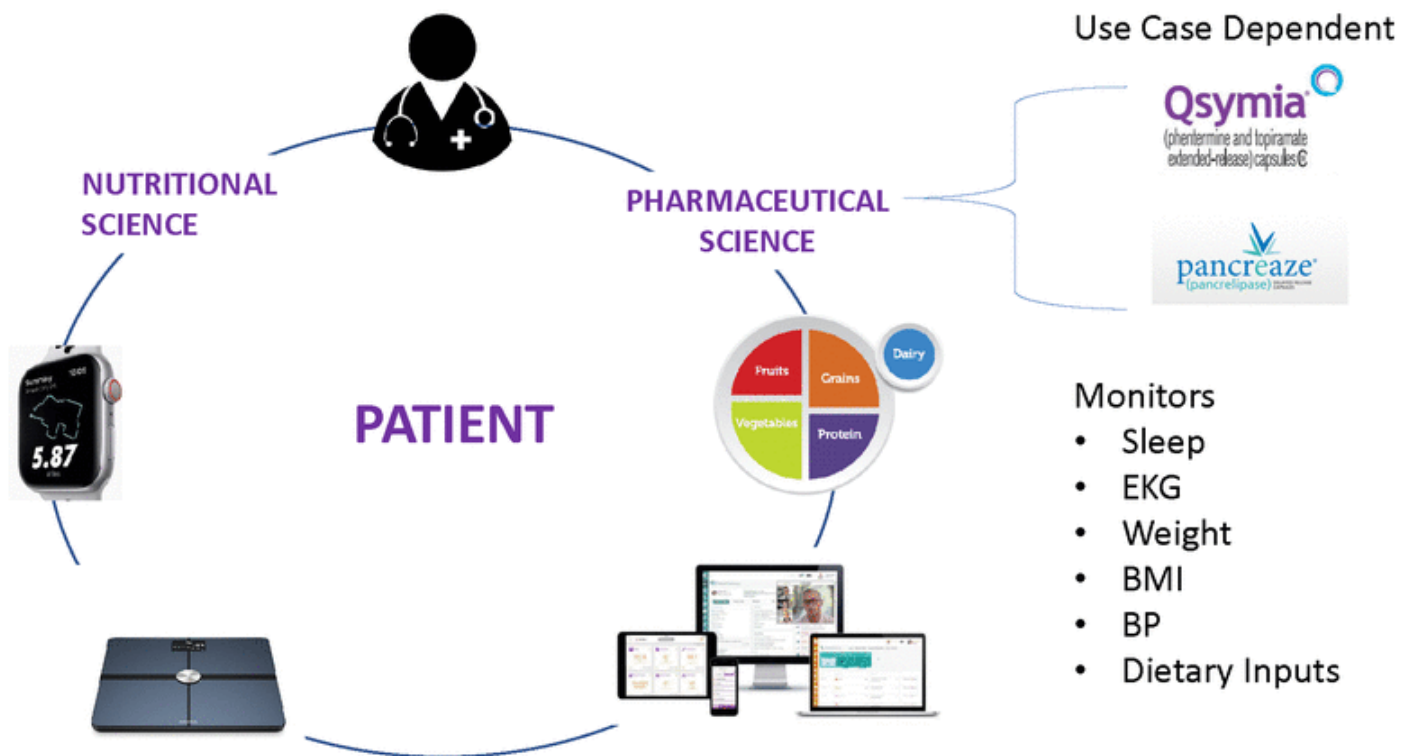
Sales Force Systems

Analytics and Machine
Learning

Digital Marketing

Payer Reimbursement
ManagementFinance and Legal
ProcessesClinical Marketing and
Sales ForcePharmaceutical
Manufacturing

VIVUS HEALTH PLATFORM



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

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

VIVUS believes the 3-month data from its CONQUER study supports short-term use, demonstrating weight loss reductions of 15-19 pounds and reductions of 2-3 inches from waist

~130M Americans are living with a BMI greater than 30 according to CDC	Somewhere between 13M and 22M Americans are willing to take a pharmaceutical or a daily supplement to aid in their weight loss	44% of Patients Aged 18-64 have one or more comorbidities in addition to have a BMI ≥ 30	In 2017, the total weight loss market was \$66B, a combination of OTC diet pills, diet foods, counseling centers and pharmaceuticals
All States have at least 20% of their population with a >30 BMI 7 of which have over 35% of their population with ≥ 30 BMI	Between 24% and 27% of all medical expenditures in the United States are related to obesity and obesity related diseases	The annual medical cost for a person with a healthy BMI is ~\$3,500 in contrast with a person with a BMI greater than 30 the annual medical cost is closer to ~\$10,000	Qsymia has been used to treat over 600K Americans. VIVUS believes with the changes it has made, VIVUS will be able to treat closer to 6M to 11M Americans generating annual revenue in the \$50M to \$120M range



- 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

Approximately \$1B marketplace in the US and Canada for therapies that treat EPI and growing at 6% per annum

Market breakdown:

- 51% acute pancreatitis
- 20% Cystic Fibrosis
- 11% pancreatic cancer

VIVUS believes its 2600-unit dose is optimal size for the pediatric Cystic Fibrosis patient

VIVUS believes the EPI class has a significant barrier to entry with the FDA requirements for the approval of animal-based EPI products

VIVUS is providing support for investigator sponsored trials in pancreatic cancer

VIVUS supports its patient support program with a best in class nutritional supplements program

VIVUS intends to integrate wearables technology, nutritional science, on-line prescribing and VIVUS pharmaceutical technology to create the Transformational Pharmaceutical Operating Model

VIVUS believes that its sales and marketing programs will allow it to grow share in the EPI space to generate annual revenue of \$60M - \$90M

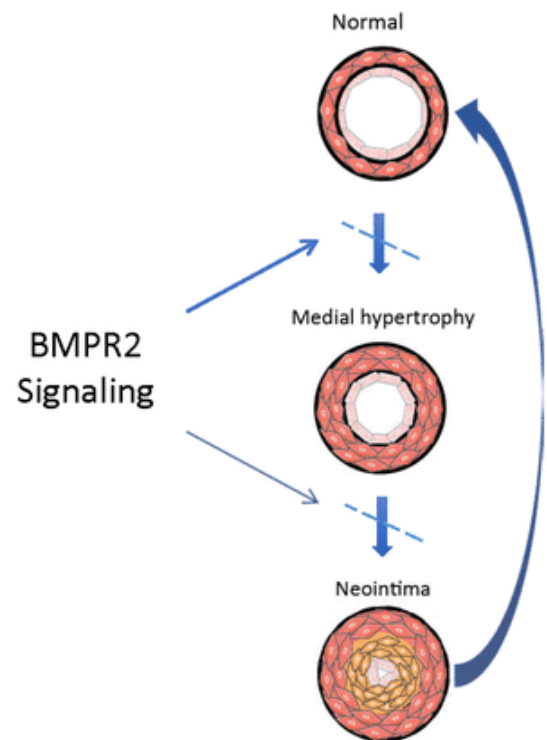
VI-0106 PAH

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

PAH is a serious, rare, and progressive disease with a 5 Year survival rate of ~22.8% assuming WHO class III/IV patients	Large growth market ~\$4.5B worldwide ~\$2.7B U.S. in 2015	Approximately 217K Patients are currently living with PAH, 70% to 80% of these patients are female	Tacrolimus has demonstrated efficacy in PAH and could be an important new class of therapy that addresses the underlying cause of the disease
Potentially class/disease modifying, extending patients' life expectancy	Potential for "Fast Track" and/or "Breakthrough Therapy" designation	VIVUS is exploring opportunities to advance the development of VI-0106, a proprietary formulation of tacrolimus, in a manner consistent with its capital objectives	Based on compassionate use data, VIVUS' UK based Phase 1 trial and Investigator led Phase 2 data, VIVUS remains bullish on this program and technology

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

- **Compassionate use**
 - 3 end-stage patients, WHO 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 functional class 1 and 2 patients titrated to target blood levels
 - All target blood levels well tolerated
 - No drug-related Serious Adverse Events, 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 (Area Under the Curve) compared to available immediate release tacrolimus.

Asset Acquisition Philosophy

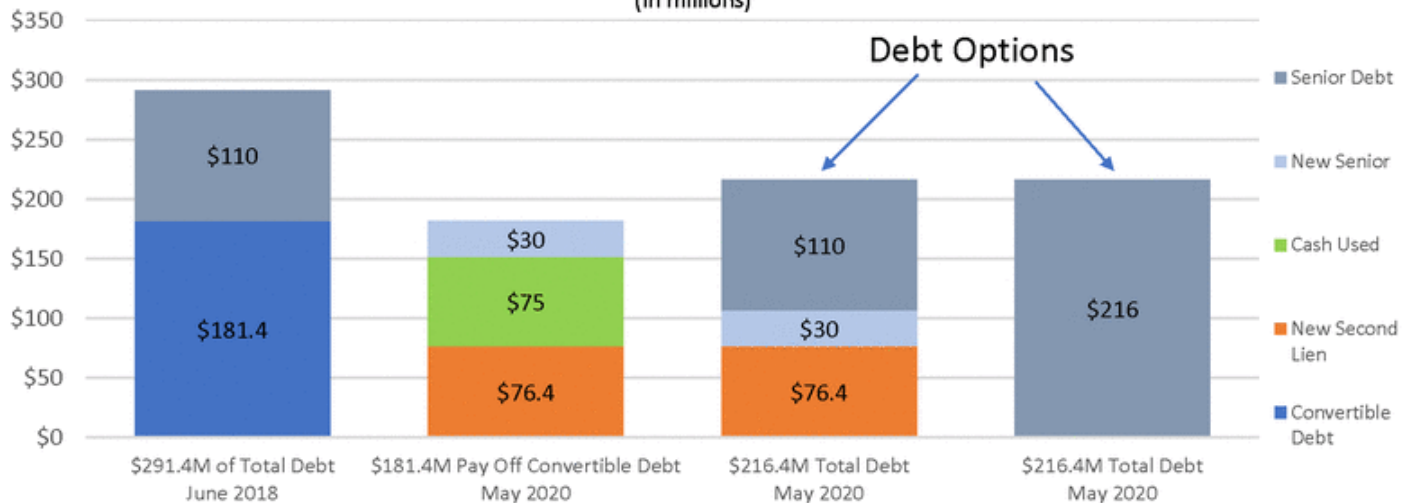
- VIVUS is evaluating additional in-licensing and acquisition candidates that would meet its goals of meeting patients' needs while working toward profitability and creating stockholder value.
- VIVUS' approach to evaluating these opportunities
 - The price of the target asset has to be defined early in the process as being in a range that would generate acceptable returns on invested capital.
 - While VIVUS utilizes financial leverage, it will not financially engineer returns.
 - The product must have some market barriers to entry for at least a defined period of time, or show 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 performance targets.

Corporate Debt Alternatives

	In order of current preference
1a	Improve operating performance to generate enough recurring cash flow to pay down and refinance debt
1b	Acquire asset(s) that generate \$25M - \$40M of annual non-GAAP EBITDA and refinance entire debt balance along with financing for acquisition
2	Borrow high yield debt / Raise cash through a preferred non-voting stock instrument
3	Raise cash through issuance of equity

Debt Bridge June 2019 to May 2020

(in millions)



<ul style="list-style-type: none"> • Total Debt as of June 30, 2019 • \$181.4M of Convertible Debt at 4.5% Interest Rate • \$110M of Senior Debt at 10.375% Interest Rate with Athyrium Capital • Total Annual Interest Expense of \$19.6M 	<ul style="list-style-type: none"> • Use \$75M of \$94M of VIVUS Cash • Borrow \$30M of Senior Debt Pari Passu to Athyrium Capital Terms • Raise \$76.4M of Second Lien at ~12% 	<ul style="list-style-type: none"> • Total Debt as of May 2020 - \$216.4M • \$140M – \$216.4M of Senior Debt at Market Rates • May have a combination of senior and second lien debt in the capital stack • Total Annual Interest Expense of \$21M - \$23.48M
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- As of May 2020, based on current internal projections of EBITDA, VIVUS should be able to support senior secured debt amounts between \$200M and \$250M and support second lien debt in the range of \$75M to \$125M based on industry standard credit metrics as of August 2019
- VIVUS believes we will have a debt cushion of approximately \$23M to \$118M as of May 2020

Experienced Management Team

Name /Role	Experience
John Amos Chief Executive Officer	<ul style="list-style-type: none"> • 25+ 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 Kline, ICC, Novartis
Santosh Varghese, M.D. Chief Medical Officer	<ul style="list-style-type: none"> • 20+ years in Healthcare as Senior Executive • Elan, Merck, Schering Plough, Sanofi Aventis
Scott Oehrlein Chief Operations Officer	<ul style="list-style-type: none"> • 30+ years in Healthcare as Senior Executive • The Upjohn, Sanofi, Novartis, Willow

Management's Focus

- Drive Qsymia and PANCREAZE revenue and profitability
 - Qsymia: expand the Qsymia Advantage Program direct-to-patient pharmacy model and launch telemedicine
 - PANCREAZE: continue momentum generated from the Q1 2019 re-launch
 - Growth expected in Q3 2019
- Continue addressing outstanding debt
 - Drive operating performance and maintain financial discipline while carefully considering financing alternatives
- Accelerate development of VI-0106
- Acquire additional cash flow positive healthcare/pharmaceutical assets
- Obtain additional regulatory approvals and partners in open territories for STENDRA/SPEDRA and certain strategic territories for Qsymia
- Enhance and expand the VIVUS HEALTH PLATFORM (VHP)
 - Qsymia Advantage Program powered by VHP
 - PANCREAZE Advantage Program by VHP

Financial Snapshot

Company Overview	
Company Name	Vivus, Inc
Ticker	VVUS
Current Share Price (8/23/2019)	\$ 4.32
52 Week High	\$ 7.10
52 Week Low	\$ 2.15
Market Capitalization (in MM)	\$ 45.8
Plus: Debt (Principal value)	
Convertible Notes, due 2020	181.4
Senior Secured Notes, due 2024	110.0
Less Cash and Investments	(94.4)
Enterprise value	\$ 242.8

Balance Sheet, June 30, 2019 (in \$MM)			
Assets		Liabilities	
Cash and Investments	\$ 94.4	Accounts Payable	\$ 3.8
Receivables	24.6	Accrued Expenses	34.4
Inventory	30.1	Current Portion of LT Debt	185.4
Other Current Assets	6.9	Other Current Liabilities	1.9
Total Current Assets	156.0	Total Current Liabilities	225.5
Property & Equipment, Net	0.3	Long-Term Debt	107.0
Other Non-Current Assets	128.4	Other Non-Current Liabilities	4.6
Total Other Assets	128.7	Total Liabilities	337.1
		Total Equity	(52.4)
Total Assets	\$ 284.7	Total Liabilities and Equity	\$ 284.7

Operating Results

	31-Mar-18	30-Jun-18	30-Sep-18	31-Dec-18	2018	31-Mar-19	30-Jun-19	2019 YTD	LTM
	QTD	QTD	QTD	QTD	(in 000s)	QTD	QTD		
Revenue:									
Net product revenue	\$ 9,632	\$ 13,250	\$ 16,484	\$ 17,418	\$ 56,784	\$ 13,497	\$ 15,104	\$ 28,601	\$ 62,503
License and milestone revenue	-	-	-	-	-	-	-	-	-
Supply revenue	1,683	1,042	478	1,660	4,863	1,604	1,780	3,384	5,522
Royalty revenue	585	668	1,126	1,036	3,415	1,045	1,506	2,551	4,713
Total revenue	11,900	14,960	18,088	20,114	65,062	16,146	18,390	34,536	72,738
Operating expenses:									
Cost of goods sold, excluding amortization	2,630	3,286	3,484	5,213	14,613	4,308	4,377	8,685	17,382
Amortization of intangible asset	91	1,273	3,638	3,638	8,640	3,638	3,638	7,276	14,552
Research and development	1,403	2,042	2,102	1,800	7,347	2,469	2,352	4,821	8,723
Selling and marketing	4,279	3,521	3,096	3,074	13,970	4,534	4,607	9,141	15,311
General and Administrative	5,789	8,190	5,360	4,632	23,971	5,284	5,463	10,747	20,739
Inventory impairment and other non-recurring charges	-	-	-	-	-	-	-	-	-
Total operating expenses	14,192	18,312	17,680	18,357	68,541	20,233	20,437	40,670	76,707
Income (loss) from operations	(2,292)	(3,352)	408	1,757	(3,479)	(4,087)	(2,047)	(6,134)	(3,969)
Interest and other expense (income):									
Interest expense (income), net	7,900	8,696	9,616	7,664	33,876	3,805	3,763	7,568	24,848
Gain on extinguishment of debt	-	-	-	(1,427)	(1,427)	-	-	-	(1,427)
Other expense (income), net	449	522	(21)	20	970	65	117	182	181
Total interest expense and other expense (income), net	8,349	9,218	9,595	6,257	33,419	3,870	3,880	7,750	23,602
Income (loss) before income taxes	(10,641)	(12,570)	(9,187)	(4,500)	(36,898)	(7,957)	(5,927)	(13,884)	(27,571)
Provision for (benefit from) income taxes	12	4	36	-	52	(8)	8	-	36
Net income (loss)	\$ (10,653)	\$ (12,574)	\$ (9,223)	\$ (4,500)	\$ (36,950)	\$ (7,949)	\$ (5,935)	\$ (13,884)	\$ (27,607)
Basic and diluted net loss per share:	(1.00)	(1.18)	(0.87)	(0.42)	(3.48)	(0.75)	(0.56)	(1.31)	(2.59)
EBITDA	(1,210)	(965)	4,786	7,497	10,108	56	2,095	2,151	14,434
Recurring EBITDA	(1,210)	1,069	4,786	6,070	10,715	56	2,095	2,151	13,007

Thank You

Appendix

The Next 6 Quarters of Work Underway

Achievements	Next Steps
PANCREAZE <ul style="list-style-type: none"> • Relaunched in Q1 2019 with a 10-person sales force • Introduced co-pay card and sampling programs • Launched the VIVUS Health Store through Amazon • Launched the Patient Assistance Program 	<ul style="list-style-type: none"> • Enhance and expand the PANCREAZE Advantage Program <ul style="list-style-type: none"> • Direct-to-patient delivery • Telemedicine • Improve formulation for greater shelf life and expanded dose range • Improve reimbursement
Qsymia <ul style="list-style-type: none"> • Initiated Direct-to-Patient pharmacy model • Reduced and simplified pricing for patients • Launched online and telephonic ordering • Added two inside sales reps to address “white space” • Launched the VIVUS Health Store through Amazon • Obtained approval in South Korea 	<ul style="list-style-type: none"> • Enhance and expand Qsymia Advantage Program <ul style="list-style-type: none"> • Telemedicine • Integrate information technology and nutraceuticals • Improve reimbursement (i.e. self-insured employers) • Partner in strategic available countries
STENDRA/SPEDRA <ul style="list-style-type: none"> • Additional approvals in Russia, Saudi Arabia and Jordan 	<ul style="list-style-type: none"> • Partner in available countries (i.e. Central America, Mexico, Russia, MENA)
VI-0106 <ul style="list-style-type: none"> • Developed potential proprietary formulation • Identified clinical pathway to approval (potential breakthrough designation) 	<ul style="list-style-type: none"> • Complete stability on formulation • File IND • Initiate Phase 2 clinical trial

The Next 6 Quarters of Work Underway

Achievements	Next Steps
Debt <ul style="list-style-type: none">Repurchased \$68.6M of Convertible Notes due May 2020	<ul style="list-style-type: none">Address remaining \$181.4M of Convertible Notes Due May 2020
Corporate <ul style="list-style-type: none">Adjusted cost structure to become EBITDA generatingAdded staffing to build platform to support multiple products	<ul style="list-style-type: none">Acquire additional cash flow generating assetsDrive value through increased EBITDA generation