
**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)
November 27, 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	<u>Slide presentation entitled “Investor Presentation November 2018 — Reinvigorate, Deliver and Innovate — Nasdaq: VVUS”</u>

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: November 27, 2018



November 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. 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.

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Investment Highlights

- Generated recurring positive non-GAAP EBITDA of \$4.8M in Q3 2018. This is the first quarter VIVUS has generated positive EBITDA based on recurring revenue in the last ten years
- Repurchased/restructured \$68.6M of the May 2020 \$250M convertible bond almost two years ahead of schedule
- Between cash on hand and debt capacity from forecasted EBITDA performance, VIVUS expects to be able to address the remaining \$181.4M of debt due May 2020
- Building sales force to launch PANCREAZE in Q1 of 2019
- Completed pilot programs for QSYMIA relaunch coupled with a newly structured sales force
- Active discussion with additional partners on STENDRA/SPEDRA
- Continued Progress on VI-0106 PAH Therapeutic Program

Management Focus Next 24 Months

- Drive Qsymia revenue and profitability with the Transformative Pharmaceutical Operating Model
- Re-launch PANCREAZE in Q1 2019
 - New sales team and excellent market insights
 - Leverage the Transformative Pharmaceutical Operating Model
- Continue addressing the \$181.4M of convertible notes due in May 2020 by driving operating performance and maintaining financial discipline
- Accelerate development of VI-0106
- Obtain additional regulatory approvals and partners in open territories for STENDRA/SPEDRA and certain strategic territories for Qsymia
- Acquire additional cash flow positive healthcare/pharmaceutical assets

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 Kline, ICC, Novartis
Santosh Varghese, M.D. 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

Pharmaceutical Assets

	Pre-Clinical	Phase 1	Phase 2	Phase 3	Approved
PANCREAZE®					
-EPI due to Cystic Fibrosis + other conditions					
-Pancreatitis					
Qsymia®					
-Obesity (Discussions 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		

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

3-month data also support short-term use, with weight loss reductions of 15-19 pounds and reductions of 2-3 inches from waist

93.3M Americans are living with a BMI greater than 30 according to CDC	Approximately 10-17% of the 93.3M Americans are willing to take a daily pill to help manage their weight	In 2011, the American Board of Obesity Medicine (ABOM) was established	In 2013, 587 Physicians were certified as ABOM Physicians, by 2018, 2,656 physicians have been certified as ABOM Physicians https://www.abom.org/stats-data/
All States have populations with 20% or greater with >30 BMI 7 states have populations with 35% or greater with >=30 BMI		Based on 2008 dollars the cost of obesity in the American Healthcare system is \$147B per annum	In 2017 the total weight loss market was \$66B, a combination of OTC diet pills, diet foods, counseling centers and pharmaceuticals
To address this market, VIVUS has reorganized the sales team of 18 reps to focus on high value territories and modified the sales compensation model, additionally we are now employing a call center model	We are streamlining the product acquisition process for the patient based on results of two successful pilot programs that we ran in Texas and Georgia	We are integrating wearables technology, nutritional science, on-line prescribing and VIVUS pharmaceutical technology to create the Transformation Pharmaceutical Operating Model	Qsymia has been used to treat over 600K Americans. We believe with the changes that we are making we will be able to treat closer to 6M to 11M Americans



- 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 market place in the US for therapies that treat EPI and growing at 6% per annum	20% of the market is generated by Cystic Fibrosis patients	51% of the market is generated by acute pancreatitis patients	11% of the market is generated by pancreatic cancer patients
VIVUS is providing support for investigator sponsored trials in pancreatic cancer	Q1 2019 the new PANCREAZE focused sales force will address the top 1,500 prescribers. These prescribers represent 35% of the total market	We believe our 2,600 unit dose is optimal size for the pediatric Cystic Fibrosis patient	Due to the FDA requirements for the approval of animal based API products, we believe the entire EPI class has a significant barrier to entry
We intend to support our patient support program with a best in class nutritional supplements program	Our comprehensive patient centered EPI patient experience is being developed to be unique in the EPI market place	We are integrating wearables technology, nutritional science, on-line prescribing and VIVUS pharmaceutical technology to create the Transformation Pharmaceutical Operating Model	We believe that our sales and marketing programs related to PANCREAZE will allow us to grow market share in the EPI space

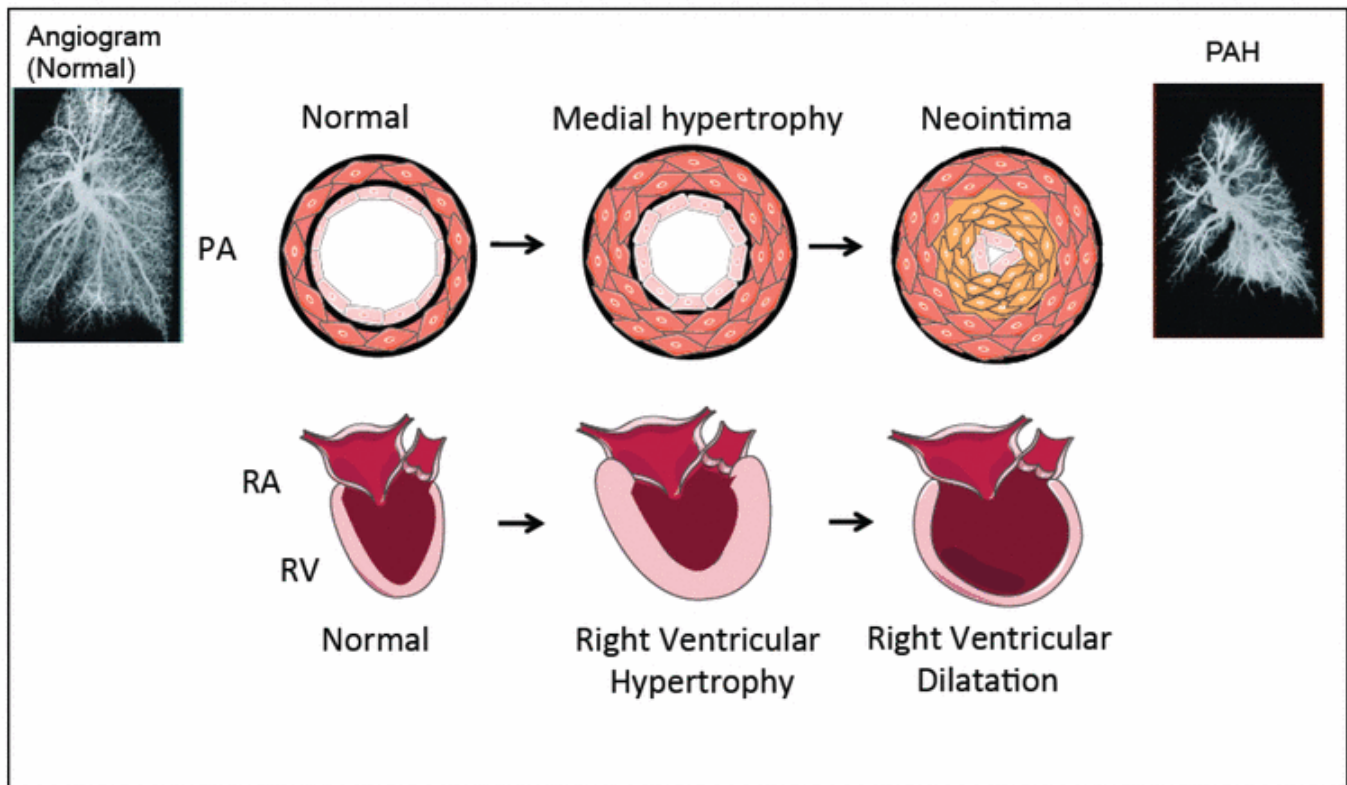
VI-0106 PAH

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

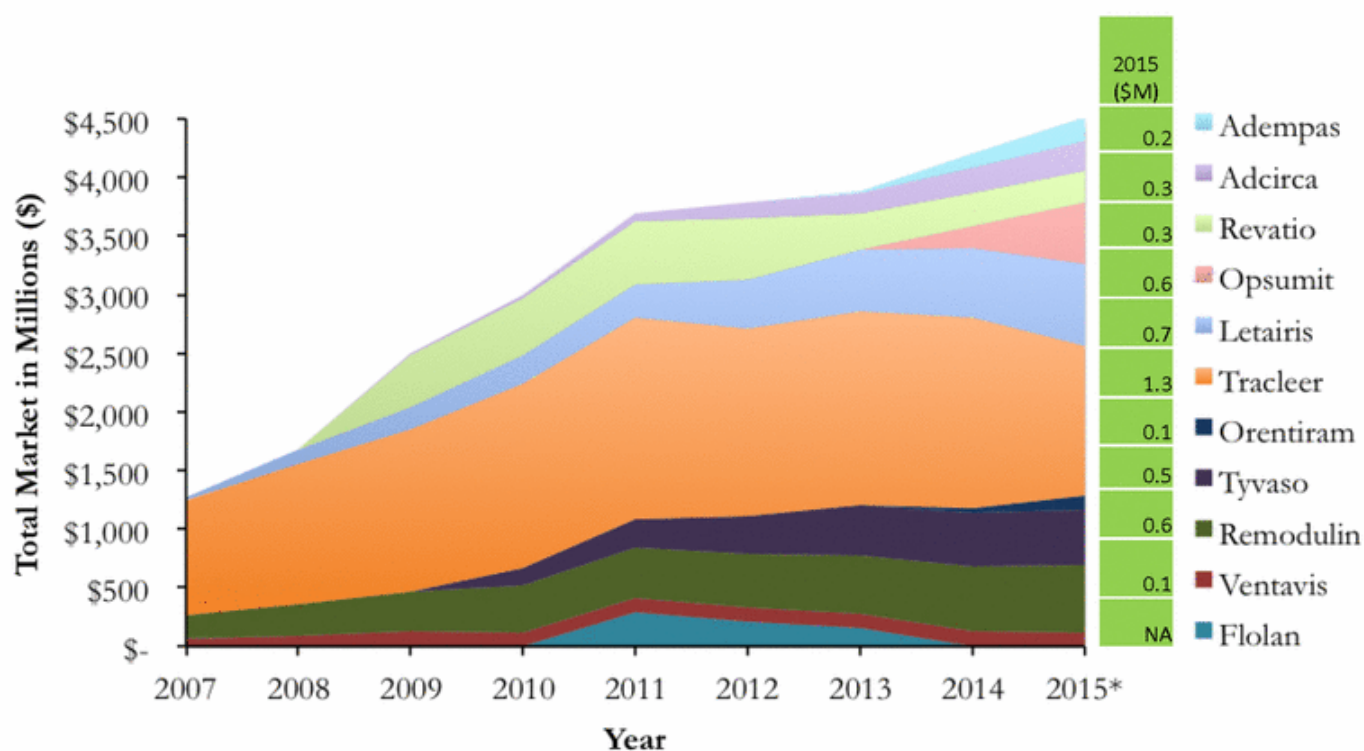
PAH is a serious, rare, and progressive disease	Progressive narrowing in pulmonary arteries, resulting in right heart failure and ultimately death	5 Year survival rate is ~22.8% assuming WHO class III/IV patients	Existing drug therapies ONLY target symptoms and slow progression of disease, while failing to substantially modify the disease course
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	Potential for “Fast Track” and/or “Breakthrough Therapy” designation	Potentially class/disease modifying, extending life expectancy
Approximately 217K Patients are currently living with PAH, 70% to 80% of these patients are female	Assuming Clinical Breakthrough designation VI-0106 could be approved in 2021	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, our UK based Phase 1 trial and Investigator led Phase 2 data, we remain bullish on this program and technology

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

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 (Area Under the Curve) compared to available immediate release tacrolimus.

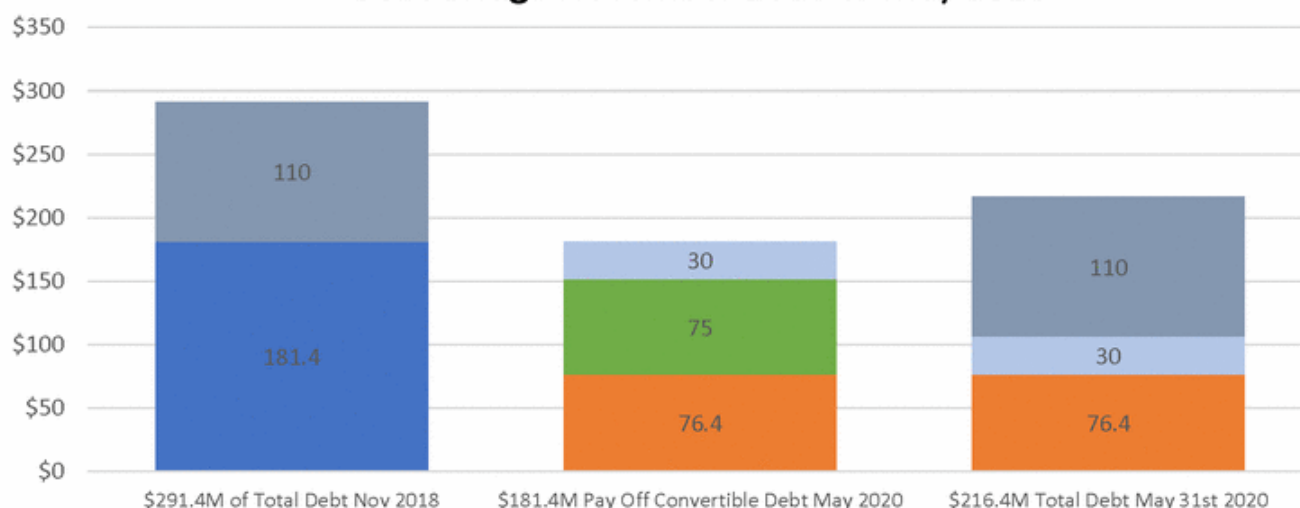
Asset Acquisition Philosophy

- 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.

Corporate Debt Alternatives

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

Debt Bridge November 2018 to May 2020



<ul style="list-style-type: none"> • Total Debt as of Nov 2018 • \$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 \$115M 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 31st 2020 • \$140M of Senior Debt at 4.5% Interest Rate • \$110M of Senior Debt at 10.375% Interest Rate with Athyrium Capital • Raise \$76.4M of Second Lien at ~12% per annum • Total Annual Interest Expense of \$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 \$165M and \$210M and support second lien debt in the range of \$75M to \$125M based on industry standard credit metrics as of Nov 2018
- Thus as of May 2020 VIVUS believes we will have a debt cushion of approximately \$23M to \$118M

Financial Snapshot

Company Overview	
(in \$MM, except per share data)	
Company Name	Vivus, Inc
Ticker	VVUS
Current Share Price (11/26/2018)	\$ 2.90
52 Week High	\$ 9.90
52 Week Low	\$ 3.30
Market Capitalization	\$ 30.8
Plus: Debt (Principal value)	
Convertible Notes, due 2020	190.0
Senior Secured Notes, due 2024	110.0
Less Cash and Investments	(115.1)
Enterprise value	\$ 215.7

Balance Sheet, September 30, 2018 (in \$MM)			
<u>Assets</u>		<u>Liabilities</u>	
Cash and Investments	\$ 115.1	Accounts Payable	\$ 4.5
Receivables	23.6	Accrued Expenses	31.9
Inventory	21.6	Other Current Liabilities	2.2
Other Current Assets	7.8	Total Current Liabilities	38.6
Total Current Assets	168.1		
Property & Equipment, Net	0.4	Long-Term Debt	300.2
Other Non-Current Assets	137.9	Other Non-Current Liabilities	3.9
Total Other Assets	138.3	Total Liabilities	342.7
		Total Equity	(36.3)
Total Assets	\$ 306.4	Total Liabilities and Equity	306.4

Operating Results

	2017	2017 Q4	2018 Q1	2018 Q2	2018 Q3	LTM
(in \$MMs, except per share data)						
Revenue:						
Net product revenue	\$ 44,983	\$ 8,934	\$ 9,632	\$ 13,250	\$ 16,484	\$ 48,300
License and milestone revenue	7,500	-	-	-	-	-
Supply revenue	10,407	2,343	1,683	1,042	478	5,546
Royalty revenue	2,483	664	585	668	1,126	3,043
Total revenue	65,373	11,941	11,900	14,960	18,088	56,889
Operating expenses:						
Cost of goods sold, excluding amortization	16,643	3,845	2,630	3,286	3,484	13,245
Amortization of intangible asset	544	91	91	1,273	3,638	5,093
Research and development	5,263	1,204	1,403	2,042	2,102	6,751
Selling and marketing	16,638	2,959	4,279	3,521	3,096	13,855
General and Administrative	23,492	5,722	5,789	8,190	5,360	25,061
Total operating expenses	62,580	13,821	14,192	18,312	17,680	64,005
Income (loss) from operations	2,793	(1,880)	(2,292)	(3,352)	408	(7,116)
Interest and other expense (income):						
Interest expense (income), net	33,231	8,109	7,900	8,696	9,616	34,321
Other expense (income), net	71	81	449	522	(21)	1,031
Total interest expense and other expense (income), net	33,302	8,190	8,349	9,218	9,595	35,352
Income (loss) before income taxes	(30,509)	(10,070)	(10,641)	(12,570)	(9,187)	(42,468)
Provision for (benefit from) income taxes	2	5	12	4	36	57
Net income (loss)	\$ (30,511)	\$ (10,075)	\$ (10,653)	\$ (12,574)	\$ (9,223)	\$ (42,525)
Basic and diluted net loss per share:	\$ (2.89)	\$ (0.95)	\$ (1.00)	\$ (1.18)	\$ (0.87)	\$ (4.01)
EBITDA adjustments to operating income/loss						
Depreciation/amortization	811	155	157	1,338	3,702	5,352
Stock Compensation	2,942	721	925	1,049	676	3,371
EBITDA	6,546	(1,004)	(1,210)	(965)	4,786	1,607
Less non-recurring (revenue)/expenses	(7,500)	-	-	2,034	-	2,034
Recurring EBITDA	(954)	(1,004)	(1,210)	1,069	4,786	3,641

Management Focus Next 24 Months

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- Re-launch PANCREAZE in Q1 2019
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- Continue addressing the \$181.4M of convertible notes due in May 2020 by driving operating performance and maintaining financial discipline
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Thank You