

**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): **June 19, 2020**

**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 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 (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.**

On June 19, 2020, VIVUS, Inc. posted to its website a corporate presentation. A copy of the corporate presentation is attached hereto as Exhibit 99.1.

The information in this Item 7.01 and the attached Exhibit 99.1 are being furnished and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall they be deemed to be incorporated by reference in any filing made by VIVUS, Inc. under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Corporate Presentation</a>

## 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

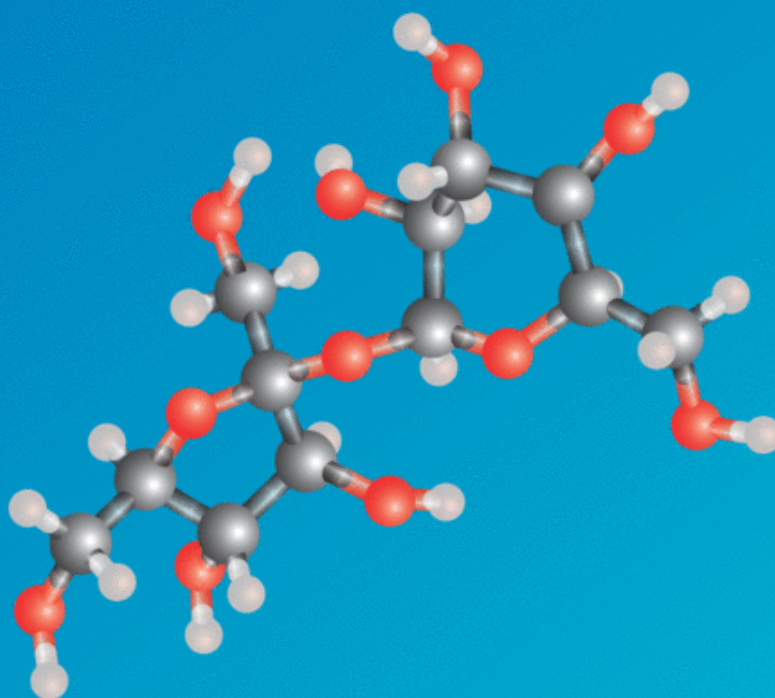
Senior Vice President, Business Development and General Counsel

Date: June 19, 2020

# VIVUS

Corporate Presentation  
June 2020

VIVUS Incorporated  
Nasdaq: VVUS



# Forward Looking Statements

## Non-GAAP Financial Measures




*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 our ability to execute on our business strategy to enhance long-term stockholder value; risks and uncertainties related to our ability to address our outstanding balance of the convertible notes due in May 2020, including our ability during the agreed upon 30-day grace period to work with IEH Biopharma LLC to restructure the outstanding principal amount of the convertible notes; risks and uncertainties related to the timing, strategy, structure and implementation of any restructuring transaction with IEH Biopharma LLC; risks and uncertainties related to a bankruptcy filing absent an agreement on a restructuring transaction in the short term; risks and uncertainties related to the effect of the recent coronavirus (COVID-19) outbreak on our business and the businesses of our partners; risks and uncertainties related to our liquidity and capital resources; risks and uncertainties related to our history of losses and variable quarterly results; risks and uncertainties related to our expected future revenues, operations and expenditures; risks and uncertainties related to the effectiveness of the VIVUS Health Platform, including its adoption by healthcare providers and its ability to improve patient outcomes and, if applicable, access to Qsymia® and PANCREAZE®; risks and uncertainties related to the timing, strategy, tactics and success of the marketing and sales of PANCREAZE, including our ability to improve patient access to PANCREAZE; risks and uncertainties related to our, or our current or potential partner's, ability to successfully commercialize Qsymia, including our ability to improve patient and physician access to Qsymia; risks and uncertainties related to our ability to sell through the Qsymia retail pharmacy network and the Qsymia Advantage Program; risks and uncertainties related 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 ("FDA"), including the Phase 4 post-marketing study of Qsymia in obese adolescents; risks and uncertainties related to the response from FDA to any data and/or information relating to post-approval clinical studies required for Qsymia; risks and uncertainties related to the impact of any possible future requirement to provide further analysis of previously submitted clinical trial data; risks and uncertainties related to the design and outcome of any clinical study required by FDA to expand the Qsymia label; 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; risks and uncertainties related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; risks and uncertainties related to our dialog with certain concerned member states in Europe relating to the pending decentralized Marketing Authorization Application, the timing and scope of the assessment by such Concerned Member State health authorities of our Marketing Authorization Application, and ultimately the decision of such Concerned Member State health authorities whether to grant Marketing Authorization for Qsymia in such EU countries; risks and uncertainties related to our ability to successfully develop or acquire a proprietary formulation of tacrolimus; risks and uncertainties related to our ability to identify, acquire and develop new product pipeline candidates; risks and uncertainties related to our ability to demonstrate through clinical testing the quality, safety, and efficacy of our current or future investigational drug candidates or approved products; risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA/SPEDRA (avanafil) by our current or potential collaborators; risks and uncertainties related to our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with MTTC in which we do not have a commercial collaboration; and risks and uncertainties related to the impact, if any, of changes to our Board of Directors and senior management team. 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, 2019 as filed on March 3, 2020 and as amended on Form 10-K/A on April 29, 2020, 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 Snapshot

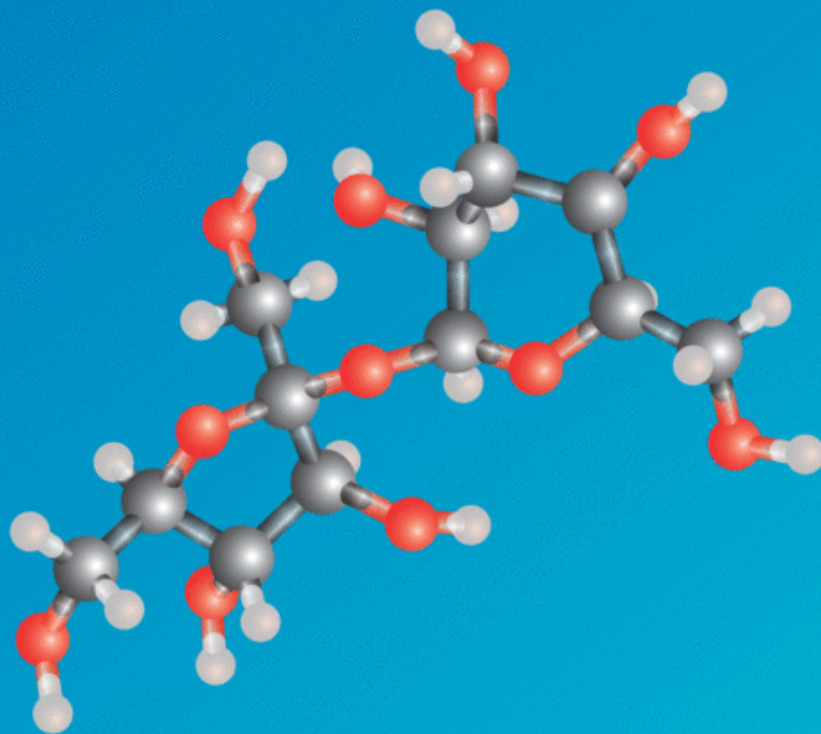
*Leading Biopharmaceutical Company with Unique Commercial Stage Products, a Promising Pipeline and a State-of-the-Art Technology Platform for Outcome Management*

	<b>VI-0106</b> <small>(FK-506, Tacrolimus)</small>	<b>Qsymia</b> <small>(phentermine and topiramate extended-release) capsules</small>	 <small>(pancrelipase)</small>		
<b>Indication / Application</b>	Pulmonary Arterial Hypertension	High BMI Management in Adult Patients	Exocrine Pancreatic Insufficiency	BMI Management, CF Management Inclusive of COVID-19 Tracking	Erectile Dysfunction  Royalty and Supply Revenue Only
<b>Description</b>	Proprietary once-daily, extended-release oral formulation of low dose Fk-506	Proprietary once-daily, of low doses of phentermine and extended-release topiramate	Porcine-derived lipase, protease, and amylase	State of the art telemedicine system coupled with Bluetooth device enables 24x7 patient monitoring	Oral PDE-5 inhibitor
<b>Mechanism of Action</b>	Enhancement of BMPR2 signaling with FK-506 may address a fundamental cause of PAH	Quick-release phentermine starts working immediately to reduce appetite, while extended-release topiramate works throughout the day to help patients feel full	Acts as a replacement for the missing digestive enzymes produced by the pancreas to help patients digest food normally	Monitors and measures up to 8 vitals including: blood glucose, heart rate, O2 readings and blood pressure utilizing passive data collection	Triggers relaxation of arterial smooth muscle, leading to arterial dilation, venous constriction, and erection
<b>Approved / Development Stage</b>	Phase 2B Trial Anticipated Enrollment 1 <sup>st</sup> Half 2021	July 2012 USA Sep 2019 S Korea Submitted EU Oct 2019	April 2010 USA	Technology Launched Apr 2020	April 2012 - USA Jan 2015 - EU



# VIVUS

About VI-0106

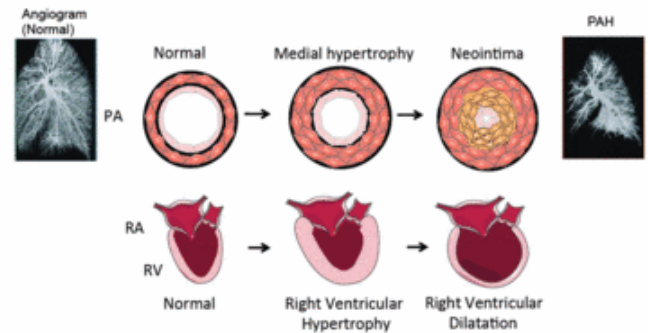


# Pulmonary Arterial Hypertension

## Disease Characterizations and Current Treatments

Progressive narrowing of the pulmonary arteries leading to right heart failure

Current therapies only slow disease progression or provide symptom relief



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"> <li>Tracleer (bosentan)</li> <li>Opsumit (macitentan)</li> <li>Letairis (ambrisentan)</li> </ul>	<ul style="list-style-type: none"> <li>Ambrisentan / tadalafil combination</li> </ul>
Phosphodiesterase-5 (PDE-5) inhibitors	Inhibit degradation of cGMP, an important intracellular 2 <sup>nd</sup> messenger promoting vasodilation	<ul style="list-style-type: none"> <li>Revatio (sildenafil)</li> <li>Adcirca (tadalafil)</li> </ul>	
Prostanoids/ Prostacyclins	Stimulate production of cAMP, an important intracellular 2 <sup>nd</sup> messenger promoting vasodilation	<ul style="list-style-type: none"> <li>Uptravi (selexipag)</li> <li>Flolan (epoprostenol)</li> <li>Remodulin (treprostinil)</li> <li>Tyvaso (treprostinil)</li> <li>Orenitram (treprostinil)</li> <li>Veletri (epoprostenol)</li> <li>Ventavis (iloprost)</li> </ul>	<ul style="list-style-type: none"> <li>Ralinepag</li> <li>Berapost 314d</li> <li>TransCon Treprostinil</li> </ul>
sGC stimulator	Stimulate production of cGMP	<ul style="list-style-type: none"> <li>Adempas (riociguat)</li> </ul>	<ul style="list-style-type: none"> <li>Citrapress</li> <li>IK-7002</li> </ul>



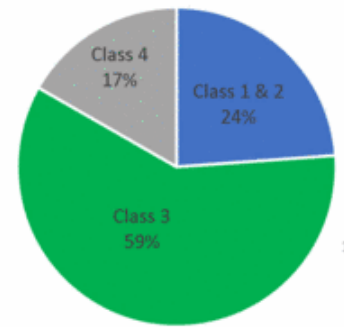
### Pulmonary Arterial Hypertension

Is abnormally high blood pressure in the arteries of the lungs. Because symptoms may develop very gradually, patients may delay seeing a physician for years. Common symptoms are shortness of breath, fatigue, non-productive cough, angina pectoris, fainting or syncope, peripheral edema (swelling around the ankles and feet), and rarely hemoptysis. PAH is a serious, rare, and progressive disease which results in right heart failure and ultimately death.

### Opportunity for VI-0106

~70K Patients EU (57%) , USA (42%), Japan (1%)  
 VI-0106 Potential Treats 76% of Patient Population  
 Class 3, 4  
 Gross Revenue Potential (inclusive of differentiated pricing)  
 We believe the gross revenue potential is up to \$750M or more annually in the U.S. and up to \$500M or more annually in the EU.

### WHO Patient Classification

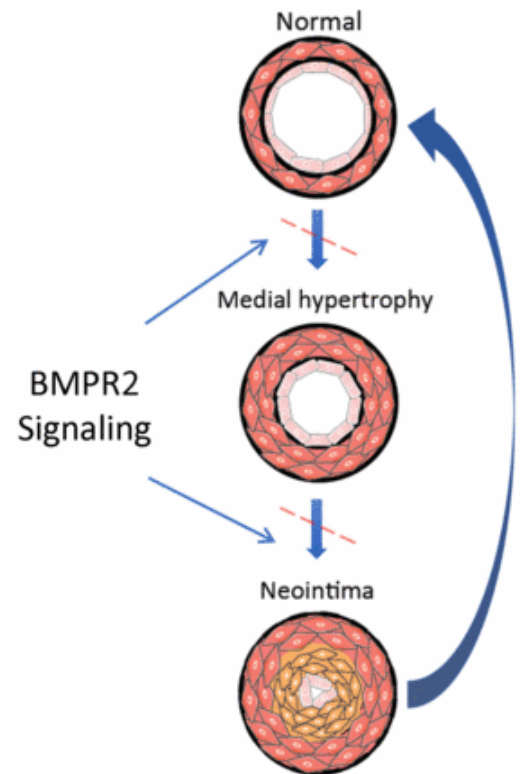


Class I	No symptoms with ordinary physical activity 6 Min Walk 572 yds <sup>(2)</sup>
Class II	Some symptoms with ordinary activity and slight limitation of physical activity 6 Min Walk 472 yds <sup>(2)</sup>
Class III	Symptoms with less than ordinary activity and increased limitation of physical activity 6 Min Walk 324 +-99 yds <sup>(2)</sup>
Class IV	Symptoms with any activity possibly even while at rest 6 Min Walk 140 +- 83 yds <sup>(2)</sup>

1,2 <https://erj.ersjournals.com/content/50/2/1700740>

\* Fk-506 is the original designation for Tacrolimus by Fujisawa Pharmaceutical Company (now Astellas Pharma)

- Mechanism of Action
- Disease Modifying
- Reduced expression of Bone Morphogenetic Protein Receptor 2 (BMPR2), is prevalent in PAH patients
  - Not mutation dependent
- BMPR2 signaling inhibits vascular smooth muscle proliferation, and loss of signaling may contribute to pathology of PAH
- Low doses of FK-506 shown to restore BMPR2 signaling
- Low dose FK-506 reverses neointimal hypertrophy in animal models of PAH
- Enhancement of BMPR2 signaling with Fk-506 may address a fundamental cause of PAH



\* FK-506 is the original designation for Tacrolimus by Fujisawa Pharmaceutical Company (now Astellas Pharma)

### IP and Patient Data

PAH needs multiple "layering" therapies

VIVUS has Received Orphan Drug Designation for both US and EU

US Patent 9,474,745 expires Dec 29, 2032

Unique proprietary formulation for once daily dosing without the need for blood level monitoring

Potential for "Breakthrough Therapy" designation and potential for "Class Modifying" or "Disease Modifying" designation for extending life expectancy

Established Regulatory Pathway with FDA & EMA

- US FDA IND submission estimated timing: 2H 2020
- Phase 2B & 3 protocols are near final
- Anticipated first patient enrolled 1H 2021
- Companionate Use Data for Three Patients
  - Functional class 3 and 4 100% Response Rate
  - Significant impact on clinical outcomes life expectancy well above mean for high risk PAH patients
  - Dramatically reduced rate of hospitalizations
  - Functional class improvements observed

### TransformPAH Clinical 2A Study

Purpose: To evaluate the feasibility, safety, and tolerability of 3 different exposure levels of tacrolimus

Double-blind, randomized, placebo-controlled study of 23 subjects with stable PAH. Subjects were randomized to target trough blood levels of tacrolimus

Placebo

Low: 0 to <2 ng/mL

Mid: 2 to <3 ng/mL

High: 3 to <5 ng/mL

Treatment period of 14 weeks

Titration was managed by unblinded study personnel

Product was safe and well tolerated in subjects

### Additional Data

Tacrolimus at both immunosuppressive and low doses

Mimics BMP signaling in mvPAECs Promotes PAEC survival and increases tube formation, functions essential for preventing loss of vessels and PAH associated remodeling

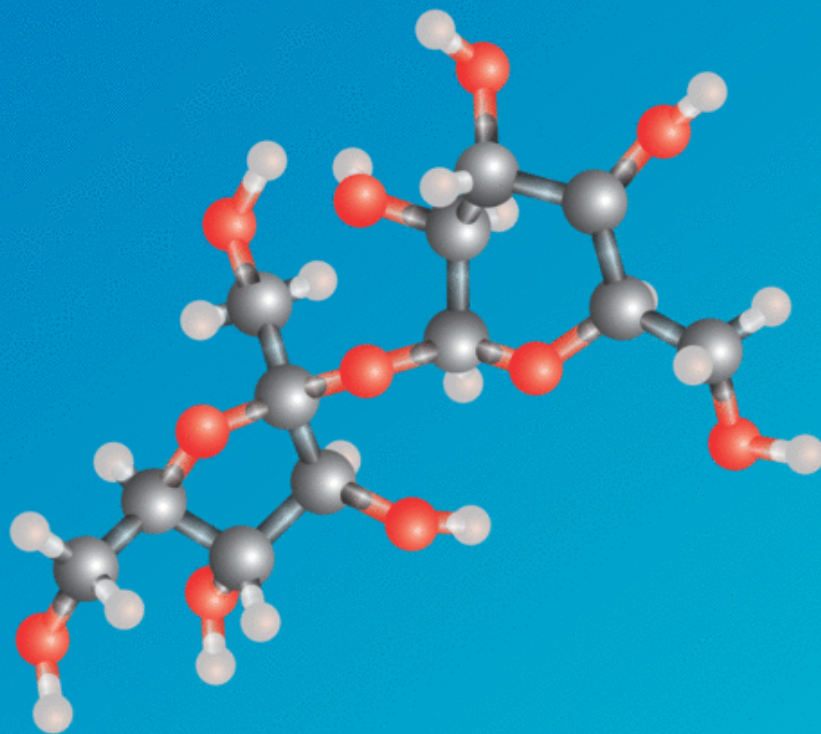
In in-vivo studies, tacrolimus

Prevented hypoxia-induced PAH in mice with BMPR2 knockout Reduced RVSP and inhibited PASMC proliferation in rats with monocrotaline-induced PAH Reversed severe established PAH and neointima formation in the SU5416/hypoxia rat model



# VIVUS

About Qsymia



### Mechanism of Action

Qsymia utilizes a combination of phentermine and extended release topiramate to suppress appetite, increase metabolism and control cravings, though the exact mechanism of Qsymia is unknown

### Size of Market

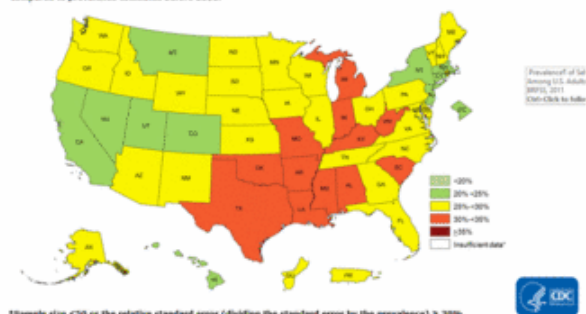
As of 2020, 138M Americans have self-reported a BMI greater than 30 Inclusive of 13.7M Americans aged 2-19 have self-reported a BMI greater than 30

### Indication

Qsymia is intended to be used as an adjunct to a reduced-calorie diet along with increased physical activity in patients with a body mass index (BMI) greater than 30 kg/m<sup>2</sup> or a BMI of 27 kg/m<sup>2</sup> or greater and who have at least one weight-related comorbidity (e.g., hypertension, dyslipidemia, diabetes or prediabetes, or abdominal obesity)

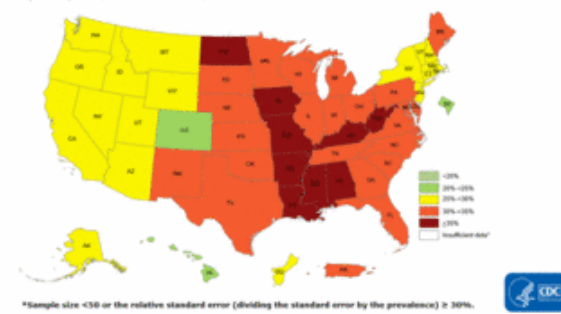
### Prevalence<sup>1</sup> of Self-Reported Obesity Among U.S. Adults by State and Territory, BRFSS, 2011

<sup>1</sup> Prevalence estimates reflect BRFSS methodological changes started in 2011. These estimates should not be compared to prevalence estimates before 2011.



### Prevalence<sup>1</sup> of Self-Reported Obesity Among U.S. Adults by State and Territory, BRFSS, 2018

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<https://www.cdc.gov/obesity/data/prevalence-maps.html>  
<https://www.cdc.gov/obesity/data/adult.html>  
<https://www.cdc.gov/obesity/data/childhood.html>

### Qsymia EQUIP Study

15mg/92mg Achieves >14% Weight Loss at 1 Year

693 Patients Completed Study

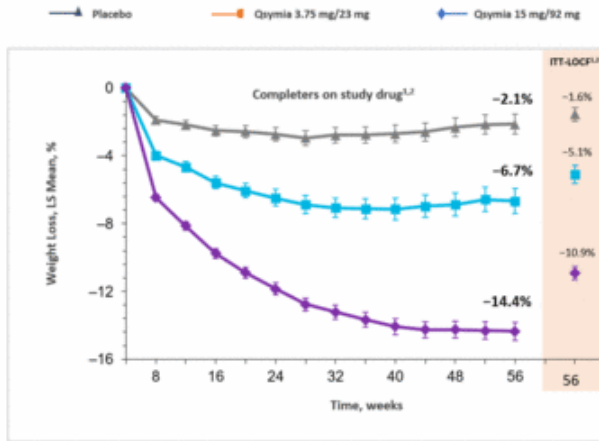
Patients selection criteria inclusive of patients with a BMI  $\geq 35$

### Qsymia CONQUER Study

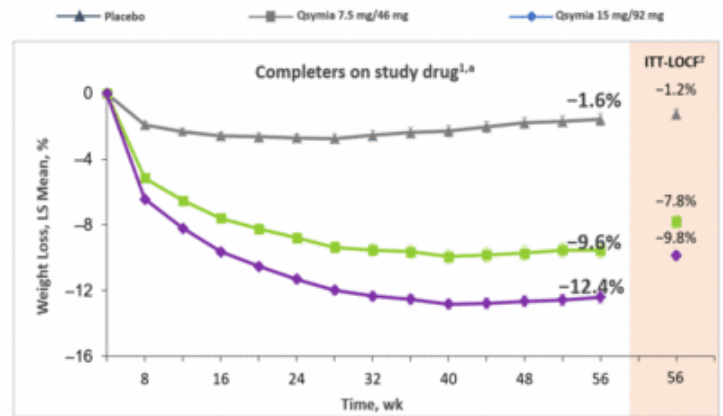
Overweight and Obese Patients With Comorbidities Experienced Significant Weight Loss

84% of Patients Responded to Treatment at 12 Weeks

1532 Patients Completed Study



<sup>1</sup>  $P < .0001$  for both doses vs placebo, and 15 mg/92 mg vs 3.75 mg/23 mg at all time points for both completers and ITT-LOCF. L.S., least-squares.  
<sup>2</sup> Qsymia Full Prescribing Information, Campbell, CA: VIVUS, Inc; 2017. 2. Allison DB et al. Obesity (Silver Spring). 2012;20(2):330-342.



<sup>1</sup>  $P < .0001$  for both doses vs placebo, and 15 mg/92 mg vs 7.5 mg/46 mg at all time points for both completers and ITT-LOCF. <sup>2</sup> Data on file. VIVUS, Inc. 2. Qsymia Full Prescribing Information, Campbell, CA: VIVUS, Inc; 2017.



# COVID-19 Observations

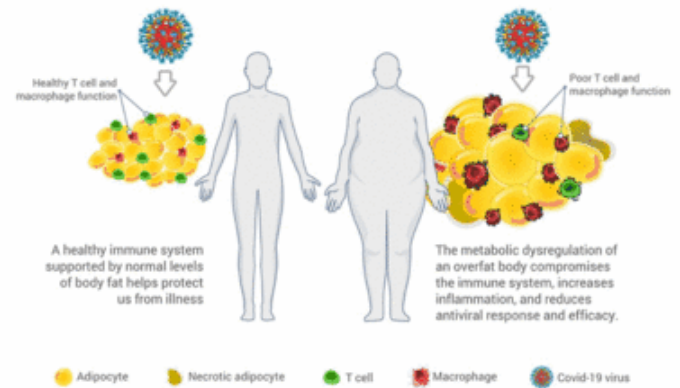
## BMI Appears to be a Singular Risk Factor for COVID-19 Outcomes

- In the United States, 42 percent of adults have a BMI over 30, the threshold for obesity, and more than 9 percent are classified as severely obese with a BMI over 40, according to the CDC. People with obesity can have other high-risk health conditions, such as hypertension or diabetes (SN: 3/20/20). But some doctors suggest a high BMI should be a risk factor in itself
- Studies have found that patients under 60 with a BMI over 35 were at least twice as likely to be admitted to the ICU for coronavirus than patients with healthy BMIs, the researchers report April 9 in *Clinical Infectious Diseases*. Those same patients were three times more likely to die from the infection than those with a lower BMI
- A study tracked 3,615 people who tested positive for SARS-CoV-2, the virus that causes COVID-19, at a New York City hospital from March 4 to April 4. Of those, 1,370, or 38 percent, were obese. In patients over 60, weight did not appear to be a factor in hospital admission or the need for intensive care
- A hospital in Lille, France, also found that the higher the BMI, the more likely a patient needed to be ventilated. Of 124 patients admitted to intensive care for COVID-19, almost half were obese or severely obese, researchers report April 9 in *Obesity*. Of the 85 patients who were intubated, nearly 90 percent had a BMI over 35, the data show.

### ACE2 and COVID 19 Interaction

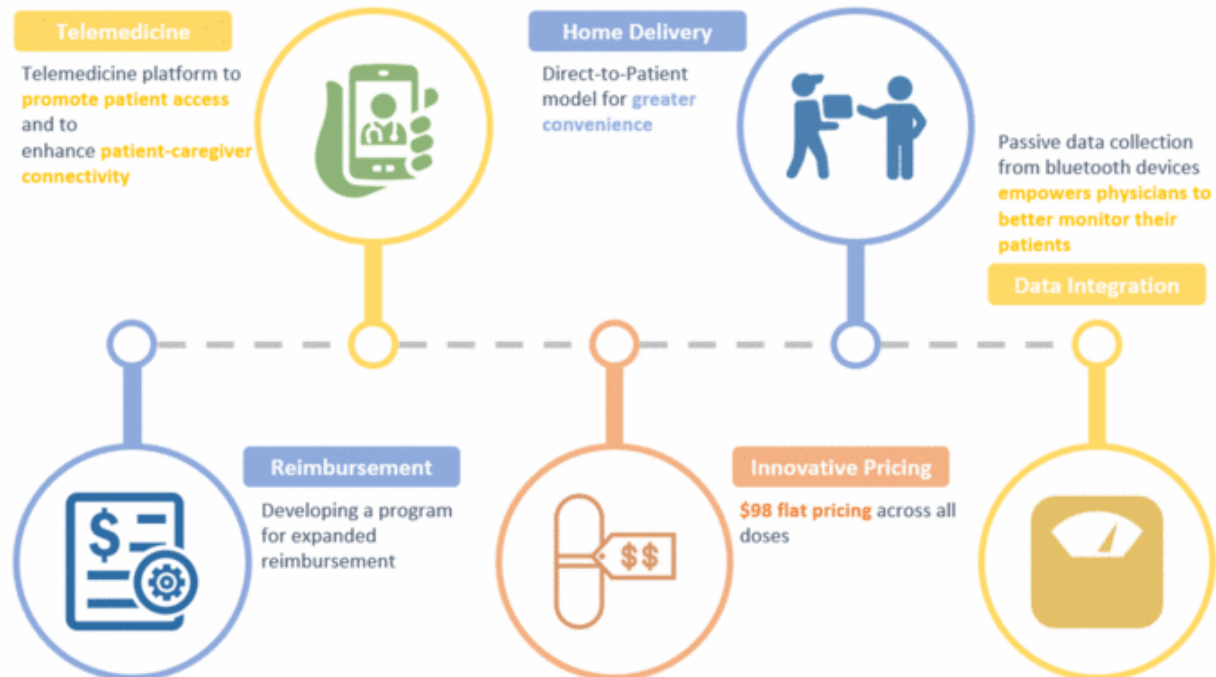
#### Covid-19: Death through virally-driven hyperinflammation.

Adipose tissue is populated by a number of immune cells including T cells and macrophages.



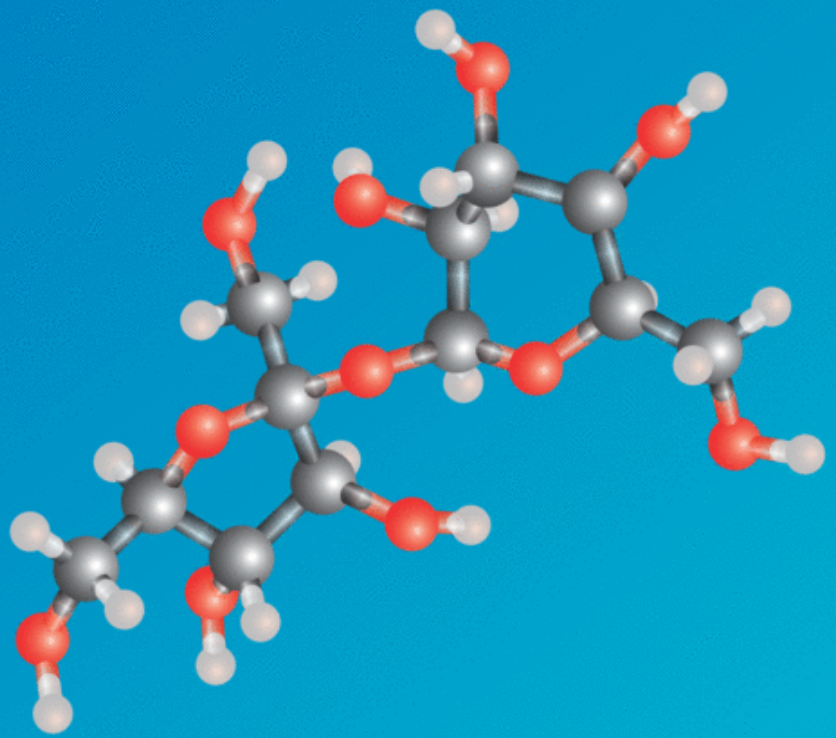
<https://www.sciencenews.org/article/coronavirus-covid19-obesity-risk-factor>  
<https://www.frontiersin.org/articles/10.3389/fpubh.2020.00135/full#B50>

- COVID -19 Coupled with the Self-Insured Employers Significantly Better Understanding of the Cost of Obesity is Starting to Revisit Anti-Obesity Coverage Decisions potentially lowering patients out of pocket expense for Qsymia specifically
- Qsymia prescription volume has demonstrated pricing sensitivity, VIVUS lowered the out of pocket patient expense resulting in improved volume growth through our Qsymia Advantage Program
- We believe the Gross Revenue Opportunity for Qsymia is up to \$80M per annum



# VIVUS

About Pancreaze



# Pancreaze

## Pharmaceutical Product Description

### Mechanism of Action

The pancreatic enzymes in PANCREAZE catalyze the hydrolysis of fats to monoglyceride, glycerol and free fatty acids, proteins into peptides and amino acids, and starches into dextrin and short chain sugars such as maltose and maltotriose in the duodenum and proximal small intestine, thereby acting like digestive enzymes physiologically secreted by the pancreas.

EPI caused by  
pancreatic disorders

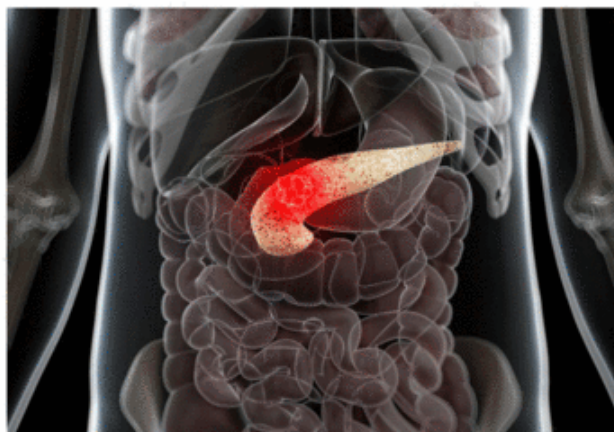
Chronic pancreatitis  
Acute pancreatitis  
Autoimmune pancreatitis  
Cystic Fibrosis

EPI caused by non-  
pancreatic disorders

Diabetes I & 2  
Inflammatory bowel disease  
Celiac disease

### Indication

PANCREAZE (pancrelipase) is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions inclusive of chronic pancreatitis





### Prevalence

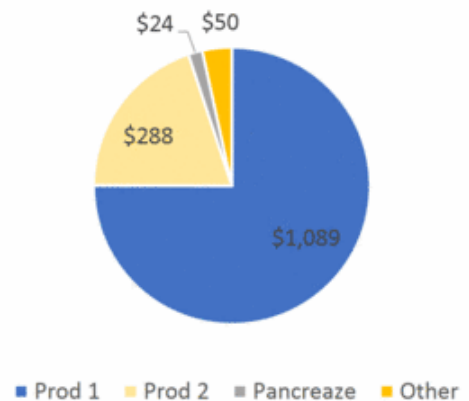
Exocrine Pancreatic Insufficiency affects at least 230,000 patients in the United States each year\*

- Chronic pancreatitis patients (~144,000)
- Pancreatic cancer patients (~55,000)
- Cystic Fibrosis patients (~30,000)
- Newly diagnosed CF patients (1,000 newly diagnosed annually)

### PANCREAZE Opportunity

- Pancreatic Enzyme Replacement Therapy is ~\$1.4B annual market
- Annual historical growth of 6% per annum
- Product Life Cycle Improvements 12-month shelf life extended to 36-month shelf life with launch of new formulation in Nov 2020
- Unit of Measure extension for high dose planned launch in Q1 2021
- Improved Pharmacy Benefit Management Coverage
- Annual cost of therapy ranges from \$20K per annum to \$2K per annum
- We believe that PANCREAZE can grow gross revenue up to \$100M per annum over the next three years

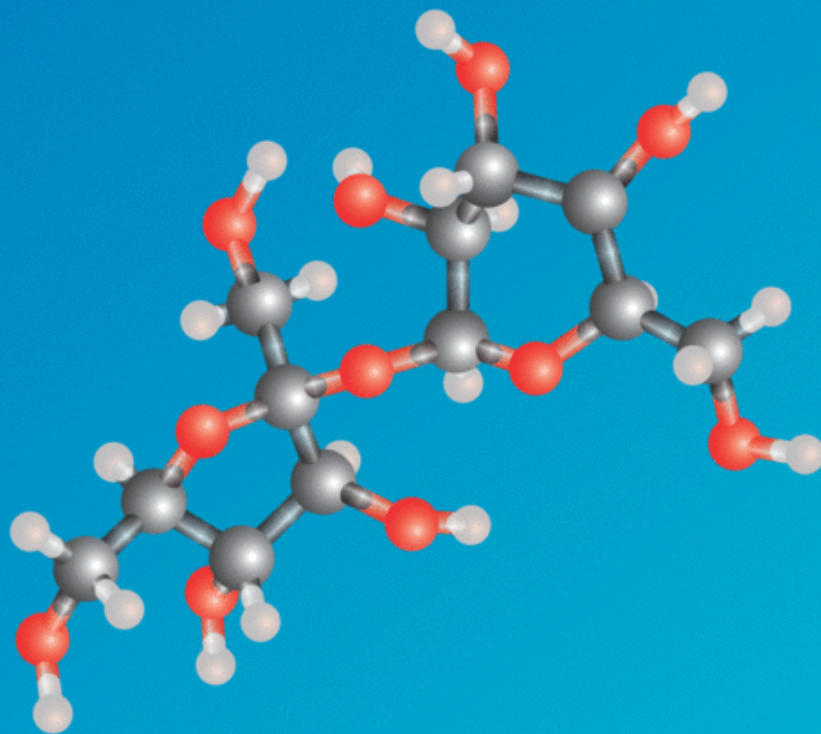
2019 Annual Net Sales in \$M



\*Othman et al, 2017, Internat J Clin Practice.  
DOI:10.1111/ijcp.13066.

# VIVUS

About VIVUS Health Platform





## State of the Art Telehealth Systems

- Diseases Specific Monitoring Tools
- Patient Communications Capabilities  
Teleconference virtual visits
- Seamless Coding and Billing integration
- Simple and Fast HCP Enrollment
- No additional Time Commitment for Office
- Easy Access for Patients
- Bluetooth enabled health devices to
  - Weight
  - BMI
  - Blood Pressure
  - Lung Function
  - EKG
  - Sleep Monitoring
  - Dietary Inputs
- Apple Health Kit integration



## Commercial Metrics

- Launched Apr 1, 2020
- Current Potential Physician Monitoring Coverage nine states and Washington DC
- Physician Per Month Pricing \$26
- Patient Monitoring Monthly Fees \$15 -\$40
- Group Employee Monitoring Fee Per Month \$0.5 - \$1.25

# Final Observations

## Sources and Uses

### Observations

- VIVUS has generated positive EBITDA in each of the past two fiscal years along with positive EBITDA for Q1 of 2020
- The company is significantly over levered with ~\$231M of total debt on the business
- Following the \$175M raise proceeds will be used for the pay down of certain debt and fees to create a properly leveraged balance sheet
- VIVUS has commercial products that we believe can generate up to \$180M per annum pharmaceutical revenue on approved products over the next three years
- VIVUS VI-0106 has the potential to be a first of its kind therapeutic agent for the reversal of the core cause of Pulmonary Arterial Hypertension
- The VIVUS Health Platform will change the way Cystic Fibrosis and High BMI patients are monitored and managed in the US while delivering a profitable and clinically meaningful business line

Sources		Uses	
S-1 Offering	\$175	Principal Payment	\$169.2
Cash on Hand	\$14.1M of \$32M Current Cash on Hand	Interest Payment	\$1.6
		Fees and Expenses	\$18.3
Total Sources	\$189.1	Total Uses	\$189.1