



VIVUS Reports First Quarter 2020 Financial Results

Company to host conference call today at 4:30pm ET

CAMPBELL, Calif., May 06, 2020 (GLOBE NEWSWIRE) -- VIVUS, Inc. (Nasdaq: VVUS) (the "Company"), a biopharmaceutical company, today reported financial results for the quarter ended March 31, 2020 and provided a business update.

"Our ability to respond quickly to the COVID-19 pandemic by successfully accelerating the launch of our telemedicine and remote monitoring modules through the VIVUS Health Platform reflects our commitment to providing patients and physicians with real-world solutions that can improve health outcomes," said John Amos, VIVUS' Chief Executive Officer. "Results in the quarter were minimally impacted by the pandemic as we generated quarter-over-quarter revenue growth of 13.8% and increased prescriptions dispensed through the Qsymia Advantage Program's Direct-to-Patient model. We continue to work closely with our debtholders to identify and execute a fair restructuring of our corporate debt that will provide a more secure capital structure on which we can continue the significant progress already made in our ten-quarter turnaround strategy."

Recent Business Highlights

- **Announces Agreement with IEH Biopharma LLC**
In May 2020, VIVUS announced an agreement regarding its corporate debt with IEH Biopharma LLC, whereby the Company will pay IEH Biopharma \$3.8 million in accrued and unpaid interest on the Convertible Senior Notes and IEH Biopharma will grant the Company a 30-day grace period (if not terminated sooner pursuant to the terms of the agreement), beginning on May 1, 2020, for payment of the principal amount of the Convertible Senior Notes, during which the two parties will work exclusively to attempt to restructure the outstanding principal amount of the Convertible Senior Notes. As part of the agreement, VIVUS retired the remaining \$11.3 million in principal and \$253,373 in accrued interest held by other holders that was due on May 1, 2020.
- **Raises Additional Capital**
In April 2020, VIVUS completed a registered direct offering of 7,218,750 shares of its common stock at a purchase price of \$1.60 per share for proceeds of \$10.5

million, net of placement agent's fees and other offering expenses.

- Accelerates Launch of Telemedicine and Remote Monitoring Modules**
 In March 2020, VIVUS announced the accelerated launch of the telemedicine and remote monitoring modules of the VIVUS Health Platform. Participating physicians will be able to use the VIVUS Health Platform to conduct virtual office visits, regardless of whether the patient is prescribed a VIVUS product. The VIVUS Health Platform is designed to integrate pharmaceutical solutions, technology and clinical stakeholders to improve patient outcomes through increased information capture, resulting in enhanced patient access, increased adoption, and treatment durability.
- Completes Enrollment of Phase 4 Safety and Efficacy Study of Qsymia® in Adolescents**
 In March 2020, completed patient enrollment in VIVUS' Phase 4 clinical study designed to evaluate the safety and efficacy of Qsymia (phentermine and topiramate extended-release) capsules CIV in obese adolescents between the ages of 12 and 17 years.

2020 First Quarter vs 2019 Fourth Quarter Financial Results

Revenue consisted of the following:

	(In thousands)	
	Three Months Ended	
	March 31, 2020	December 31, 2019
Qsymia net product revenue	\$ 8,914	\$ 9,750
PANCREAZE/PANCREASE MT, net product revenue	5,783	5,849
Milestone revenue	2,000	-
Supply revenue	1,823	1,186
Royalty revenue	1,111	469
Total revenue	<u>\$ 19,631</u>	<u>\$ 17,254</u>

Qsymia net product revenue was \$8.9 million and \$9.8 million in the first quarter of 2020 and the fourth quarter of 2019, respectively. The decrease in net revenue was due to the seasonal decrease in shipments to wholesalers in the first quarter of 2020 compared to the fourth quarter of 2019. In the first quarter of 2020 and the fourth quarter of 2019, we had approximately 83,000 scripts. The Company continues to migrate Qsymia patients from the traditional retail pharmacy model to the Qsymia Advantage Program that improves access to Qsymia through, among other things, direct-to-patient distribution and improved pricing. During the first quarter of 2020, 36% of Qsymia scripts were dispensed through the Qsymia Advantage Program's

Direct-to-Patient model, up from 31% and 22% in the fourth and third quarters of 2019, respectively.

PANCREAZE®/PANCREAZE® MT net product revenue was \$5.8 million in both the first quarter of 2020 and the fourth quarter of 2019. The first quarter of 2020 and the fourth quarter of 2019 results included \$0.7 million and \$0.9 million, respectively, of Canadian sales of PANCREAZE® MT. The Company began to recognize sales revenue from Canadian sales in the third quarter of 2019. Total U.S. scripts were 5,685 and 5,735 during the first quarter of 2020 and the fourth quarter of 2019, respectively.

Milestone revenue in the first quarter of 2020 represented the payment related to Alvogen, VIVUS' Korean marketing partner, beginning commercialization of Qsymia in South Korea.

Supply revenue in the first quarter of 2020 consists of sales of STENDRA®/SPEDRA™ to our licensees for sales in the EU and U.S. Supply revenue in the fourth quarter consists of sales of Qsymia to Alvogen to support the launch of Qsymia in South Korea in the first quarter of 2020. Supply revenue varies based on the timing of orders from our licensees and consists of minimum order requirements and such purchases do not correspond to end user demand.

Royalty revenue was \$1.1 million and \$0.5 million in the first quarter of 2020 and the fourth quarter of 2019, respectively. These amounts consist of royalties earned on SPEDRA European revenues and, in 2020, also included royalties earned on Qsymia South Korean revenues.

Total cost of goods sold, excluding amortization, was \$4.6 million and \$4.0 million in the first quarter of 2020 and the fourth quarter of 2019, respectively. The increase was primarily due to the increase in supply revenue over the fourth quarter of 2019.

Amortization of intangible assets was \$3.6 million in both the first quarter of 2020 and the fourth quarter of 2019. The amount primarily consisted of amortization expense of costs capitalized related to the acquisition of PANCREAZE.

Selling, general and administrative expense was \$11.0 million in the first quarter of 2020 and \$10.9 million in the fourth quarter of 2019, respectively, and included selling and marketing expense of \$4.2 million and \$4.3 million, respectively. The increase in general and administrative costs was primarily due to expenses related to our efforts to refinance our outstanding debt.

Research and development expense was \$2.4 million in both the first quarter of 2020 and the fourth quarter of 2019, respectively. In these two periods, research and development efforts primarily consisted of activities related to the Qsymia adolescent and efficacy study (OB-0403), PANCREAZE post-marketing requirements assumed from Janssen and PANCREAZE product improvement initiatives. Research and

development expenses will fluctuate based on the timing of enrollment of the OB-0403 study and activities associated with the development of VI-0106.

Total interest and other expense was \$3.2 million in the first quarter of 2020 and \$2.9 million in the fourth quarter of 2019, respectively.

Net loss was \$5.2 million for the first quarter of 2020 and \$6.5 million for the fourth quarter of 2019. Cash, cash equivalents and available-for-sale securities were \$32.9 million at March 31, 2020.

Non-GAAP EBITDAR (Earnings Before Interest, Taxes Depreciation, Amortization and discretionary Research) was \$3.2 million for the first quarter of 2020 and \$1.9 million for the fourth quarter of 2019.

Conference Call Details

VIVUS will hold a conference call and an audio webcast to provide a business update and to discuss first quarter 2020 financial results today, May 6, 2020, beginning at 4:30 PM Eastern Time.

To listen via webcast, please visit <http://ir.vivus.com/>, or by [clicking here](#).

To listen via phone, please use the dial in information provided below.

Dial in Details:

Toll-Free: (877) 359-2916

International: (224) 357-2386

Passcode: 6939389

The webcast replay and slide presentation will be available in the Events and Presentations section on the VIVUS website for 30 days.

About Qsymia

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

The effect of Qsymia on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established.

For more information about Qsymia, please visit www.Qsymia.com.

Important Safety Information for 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.

About PANCREAZE

PANCREAZE is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis or other conditions. PANCREAZE may help your body use fats, proteins, and sugars from food. PANCREAZE contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas. PANCREAZE is safe and effective in children when taken as prescribed by your doctor.

Important Safety Information for 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.pancreaze.com.

About STENDRA/SPEDRA (Avanafil)

STENDRA® (avanafil) is approved in the U.S. by the FDA for the treatment of erectile dysfunction. Metuchen Pharmaceuticals LLC has exclusive marketing rights to STENDRA in the U.S., Canada, South America and India.

STENDRA is available through retail and mail order pharmacies.

SPEDRA™, the trade name for avanafil in the EU, is approved by the EMA for the treatment of erectile dysfunction in the EU. VIVUS has granted an exclusive license to the Menarini Group through its subsidiaries to commercialize and promote SPEDRA for the treatment of erectile dysfunction in over 40 European countries plus Australia and New Zealand. Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation (MTPC). VIVUS owns worldwide development and commercial rights to avanafil for the treatment of sexual dysfunction, with the exception of certain Asian-Pacific Rim countries. VIVUS is in discussions with other parties for the commercialization rights to its remaining territories.

For more information about STENDRA, please visit www.STENDRA.com.

Important Safety Information for 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.

About VIVUS

VIVUS is a specialty pharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs. For more information about the Company, please visit www.vivus.com.

Forward-Looking Statements

Certain statements in this press release 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 reach agreement with IEH Biopharma LLC to restructure the outstanding principal amount of the convertible notes and any resulting need of the Company to seek relief under the U.S. Bankruptcy Code; risk and uncertainties related to the timing, strategy, structure and implementation of any restructuring transaction with IEH Biopharma LLC; 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 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 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 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 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 MTPC in which we do not have a commercial collaboration; and risks and uncertainties related to the market and other conditions. 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 by the Form 10-K/A filed 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.

VIVUS, Inc.	Investor Relations: Lazar
	FINN Partners
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VIVUS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	March 31, 2020	December 31, 2019
	Unaudite d	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,854	\$ 32,649
Accounts receivable, net	24,724	22,338
Inventories	33,936	33,679
Prepaid expenses and other current assets	6,340	8,134
Total current assets	97,854	96,800
Property and equipment, net	201	233
Right-of-use assets	930	1,135
Intangible and other non-current assets	116,923	120,140
Total assets	<u>\$ 215,908</u>	<u>\$ 218,308</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 11,015	\$ 7,726
Accrued and other liabilities	32,912	32,398
Deferred revenue	1,296	1,249
Current portion of lease liability	741	767
Current portion of long-term debt	181,822	183,006
Total current liabilities	227,786	225,146
Long-term debt, net of current portion	58,910	58,721
Deferred revenue, net of current portion	2,769	3,063
Lease liability, net of current portion	399	602
Total liabilities	<u>289,864</u>	<u>287,532</u>
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; \$.001 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock; \$.001 par value; 200,000 shares authorized; 10,649 and 10,649	11	11

shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively

Additional paid-in capital	843,146	842,808
Accumulated other comprehensive loss	108	(35)
Accumulated deficit	(917,221)	(912,008)
Total stockholders' deficit	(73,956)	(69,224)
Total liabilities and stockholders' deficit	<u>\$ 215,908</u>	<u>\$ 218,308</u>

VIVUS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)
(Unaudited)

	<u>Three Months Ended</u>	
	<u>March</u>	<u>December</u>
	<u>31,</u>	<u>31,</u>
	<u>2020</u>	<u>2019</u>
Revenue:		
Net product revenue	\$ 14,697	\$ 15,599
Milestone revenue	2,000	-
Supply revenue	1,823	1,186
Royalty revenue	1,111	469
Total revenue	<u>19,631</u>	<u>17,254</u>
Operating expenses:		
Cost of goods sold (excluding amortization)	4,627	3,970
Amortization of intangible assets	3,638	3,638
Selling, general and administrative	10,960	10,944
Research and development	2,445	2,380
Total operating expenses	<u>21,670</u>	<u>20,932</u>
Loss from operations	(2,039)	(3,678)
Interest expense and other expense, net	3,219	2,852
Loss before income taxes	(5,258)	(6,530)
Provision for income taxes	(45)	17
Net loss	<u>\$ (5,213)</u>	<u>\$ (6,547)</u>
Basic and diluted net loss per share:	<u>\$ (0.49)</u>	<u>\$ (0.61)</u>

Shares used in per share computation:

Basic and diluted

10,649

10,646

VIVUS, INC.
GAAP to NON-GAAP RECONCILIATION
NET LOSS to EBITDAR
(In thousands)
(Unaudited)

A reconciliation between net loss on a GAAP basis and non-GAAP EBITDAR is as follows:

	Three Months Ended	
	March 31,	December
	2020	31,
		2019
Net loss	\$ (5,213)	\$ (6,547)
Adjustments:		
Interest expense and other expense, net (excluding amortization)	3,219	2,852
Depreciation of fixed assets	32	40
Amortization of intangible assets	3,638	3,638
Share-based compensation expense	338	608
Provision for (benefit from) income taxes	(45)	17
Non-GAAP EBITDA	<u>\$ 1,969</u>	<u>\$ 608</u>
Research Spending	1,226	1,279
Non-GAAP EBITDAR	<u>\$ 3,195</u>	<u>\$ 1,887</u>

Use of Non-GAAP Financial Measures

We supplement our condensed consolidated financial statements presented on a GAAP basis by providing an additional measure which is considered non-GAAP under applicable SEC rules. We believe that the disclosure of this non-GAAP measure 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.

We define non-GAAP EBITDAR as net loss before interest expense and other expense, depreciation of fixed assets, amortization of intangible assets, share-based

compensation expense, provision for or benefit from income taxes and discretionary research expenses. Management believes that non-GAAP EBITDAR is a meaningful indicator of the performance of our commercial business, providing useful information to investors.