

**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): **August 6, 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 2.02. Results of Operations and Financial Condition

On August 6, 2019, VIVUS, Inc. (the “Company”) issued a press release regarding its financial results for the second quarter ended June 30, 2019, a business update and certain other information. The full text of the press release concerning the foregoing is furnished herewith as Exhibit 99.1.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release issued by VIVUS, Inc. dated August 6, 2019.</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: August 6, 2019



VIVUS Reports Second Quarter 2019 Financial Results

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

CAMPBELL, CA., August 6, 2019 - VIVUS, Inc. (NASDAQ: VVUS) (the “Company”), a specialty pharmaceutical company committed to the development and commercialization of innovative therapies focusing on treatments for patients with serious unmet medical needs, today reported financial results for the quarter ended June 30, 2019 and provided a business update.

“We recently initiated a variety of programs designed to improve patient access to Qsymia and PANCREAZE. The initial response to the Qsymia Advantage Program, while early, has been positive, accounting for 8% of second quarter prescriptions after just 4 months of this platform’s launch,” said John Amos, VIVUS’ Chief Executive Officer. “We believe that this platform is an important component of our strategy to realize the full potential of Qsymia, as our data show that patients actually fill 92% of Qsymia Advantage Program prescriptions compared with 65% of prescriptions issued through retail pharmacies. Our PANCREAZE sales force has been fully implemented with a revised compensation program that we believe will help support our dedicated sales representatives. We remain focused on expanding the market for both Qsymia and PANCREAZE by optimizing both traditional and innovative sales strategies that leverage our field force capabilities as well as online and social media opportunities. In addition, we are pleased to announce that we have reduced the cost to patients to provide greater access to these products that we believe have significant potential to provide meaningful lifestyle improvements.”

Recent Business Highlights

- ***Announced Approval of Qsymia® in the Republic of Korea***

In August 2019, VIVUS announced that its Korean marketing partner, Alvogen Malta Operations (ROW) Ltd, has obtained marketing approval for Qsymia (phentermine and topiramate extended-release) from the South Korea Ministry of Food and Drug Safety (MFDS). VIVUS will receive a milestone payment associated with the approval and remain eligible for future commercial milestones and royalties on net revenues.

- ***Launch of Online Platform to Improve Patient Access to Qsymia***

In June 2019, VIVUS launched an e-medicine platform that enables patients with a prescription for Qsymia to purchase the medication online and have their orders delivered directly to their homes. The online ordering platform is another component of the Qsymia Advantage Program, which is designed to improve patient access to Qsymia.

- ***Initiated Phase Four Safety and Efficacy Study of Qsymia in Obese Adolescents***

In May 2019, the first patient was enrolled in VIVUS’ Phase four 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. The Centers for Disease Control and Prevention estimates that nearly 21 percent of adolescents ages 12 to 19 years are obese. A study conducted by the World Health Organization found that obesity in children ages five to 19 years has risen ten-fold in the past four decades and estimates that more children globally will be overweight rather than underweight by 2022.



· ***Amended its Contract Manufacturing Agreement to Supply Current and Future Demand for PANCREAZE***

In June 2019, VIVUS amended its manufacturing and supply agreement with Nordmark Arzneimittel GmbH & Co. KG for PANCREAZE. The amended agreement covers a ten-year initial term and may be renewed for additional five-year periods, the first at VIVUS' option and by mutual agreement thereafter.

· ***Launched the PANCREAZE® Patient Assistance Program***

In May 2019, VIVUS announced a partnership to facilitate access to PANCREAZE (pancrelipase) Delayed Release Capsules for uninsured or underinsured patients with exocrine pancreatic insufficiency (EPI) that meet applicable eligibility criteria. PANCREAZE is available to eligible patients through the VIVUS Health Platform and the PANCREAZE Advantage Program integrated with HarborPath Direct's SuccorRx™ Patient Assistance Program (PAP) platform.

2019 Second Quarter vs 2019 First Quarter Financial Results

Revenue consisted of the following:

	(In thousands)	
	Three Months Ended	
	June 30, 2019	March 31, 2019
Qsymia net product revenue	\$ 9,994	\$ 8,423
PANCREAZE net product revenue	5,110	5,074
Supply revenue	1,780	1,604
Royalty revenue	1,506	1,045
Total revenue	\$ 18,390	\$ 16,146

Total revenue for the second and first quarters of 2019 was \$18.4 million and 16.1 million, an increase of 14%.

Qsymia net product revenue was \$10.0 million and \$8.4 million in the second and first quarters of 2019, respectively. Shipments were approximately 87,000 and 75,000 units in the second and first quarters of 2019, respectively. The Company made a number of changes to the Qsymia business in an effort to improve commercial performance, primarily allowing patients to migrate from a traditional retail pharmacy model to the Qsymia Advantage Program that is expected to improve access to Qsymia through, among other things, direct-to-patient distribution and improved pricing. The Company anticipates that this transfer, which started in February of 2019 with the re-launch, will be one of the key drivers of brand performance in the second half of 2019 and full year 2020. In the second quarter of 2019, approximately 86,000 prescriptions were dispensed as compared to 82,000 in the first quarter of 2019. During the second quarter, 8% of these scripts were dispensed through the Qsymia Advantage Program's Direct-to-Patient model, up from 2% in the first quarter of 2019.



PANCREAZE net product revenue was \$5.1 million in both the second and first quarters of 2019. During the second and first quarters of 2019, the Company shipped approximately 27,000 and 26,000 units of PANCREAZE, respectively. VIVUS now has a dedicated 10-person sales force, sampling program, full patient support program, a plan for investigator-sponsored trials in oncology, a digital marketing campaign strategy, along with a number of other enhancements.

Total cost of goods sold excluding amortization was \$4.4 million and \$4.3 million in the second and first quarters of 2019, respectively. The growth was primarily due to the growth in revenue.

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

Selling, general and administrative expense was \$10.1 million and \$9.8 million for the second and first quarters of 2019, respectively and included selling and marketing expense of \$4.6 million and \$4.5 million, respectively. VIVUS expects selling, general and administrative expenses to fluctuate with business development activities.

Research and development expense was \$2.4 million and \$2.5 million in the second and first quarters of 2019, respectively. In 2019, 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 ongoing PANCREAZE product improvement initiatives.

Total interest and other expense was \$3.9 million in both the second and first quarters of 2019, respectively. On an annual basis, VIVUS will make cash interest payments of approximately \$19.6 million on its convertible and senior secured notes.

Net loss for the second and first quarters of 2019 was \$5.9 million and \$7.9 million, respectively. Cash, cash equivalents and available-for-sale securities were \$94.4 million at June 30, 2019.

Recurring non-GAAP EBITDA for the second and first quarters of 2019 was \$2.1 million and \$0.1 million, respectively.

Conference Call Details

VIVUS will hold a conference call and an audio webcast to provide a business update and to discuss second quarter 2019 financial results today, August 6, 2019, beginning at 4:30 PM Eastern Time. Investors may listen to this call by dialing toll-free 1-877-359-2916 in the U.S. and 1-224-357-2386 from outside the U.S. The audience passcode is 5386769. A webcast replay will be available for 30 days and may be accessed at <http://ir.vivus.com/events-and-presentations>.



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 subsidiary Berlin-Chemie AG 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; risks and uncertainties related to



our expected future revenues, operations and expenditures; risks and uncertainties related to our ability to identify and acquire cash flow generating assets and opportunities; 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 commercialization of PANCREAZE as a new product and our recently changed management team initiating the commercialization of 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 the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods; 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 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 MTPC in which we do not have a commercial collaboration; 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 ("CVOT"); risks and uncertainties related to our dialog with the European Medicines Agency ("EMA") or certain member states on a decentralized basis relating to the resubmission of an application for the grant of a marketing authorization, the timing and scope of such resubmission, the assessment by European health authorities of the application for marketing authorization, and ultimately the decision of such European health authorities whether to grant marketing authorization for Qsymia in the EU; risks and uncertainties related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; and risks and uncertainties related to our ability to successfully integrate 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, 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.

VIVUS, Inc.
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VIVUS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	June 30, 2019 Unaudited	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 25,022	\$ 30,411
Available-for-sale securities	69,344	80,838
Accounts receivable, net	24,568	25,608
Inventories	30,111	23,132
Prepaid expenses and other current assets	6,970	7,538
Total current assets	156,015	167,527
Property and equipment, net	306	341
Right-of-use assets	1,323	—
Intangible and other non-current assets	127,003	134,279
Total assets	<u>\$ 284,647</u>	<u>\$ 302,147</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 3,800	\$ 8,921
Accrued and other liabilities	34,384	33,044
Deferred revenue	1,205	1,235
Current portion of lease liability	710	—
Current portion of long-term debt	185,384	—
Total current liabilities	225,483	43,200
Long-term debt, net of current portion	107,007	294,446
Deferred revenue, net of current portion	3,738	4,290
Lease liability, net of current portion	894	—
Non-current accrued and other liabilities	—	234
Total liabilities	337,122	342,170
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; \$.001 par value; 5,000 shares authorized; no shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock; \$.001 par value; 200,000 shares authorized; 10,643 and 10,636 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	11	11
Additional paid-in capital	841,702	840,751
Accumulated other comprehensive loss	201	(270)
Accumulated deficit	(894,389)	(880,515)
Total stockholders' deficit	(52,475)	(40,023)
Total liabilities and stockholders' deficit	<u>\$ 284,647</u>	<u>\$ 302,147</u>



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

	Three Months Ended	
	June 30, 2019	March 31, 2019
Revenue:		
Net product revenue	\$ 15,104	\$ 13,497
Supply revenue	1,780	1,604
Royalty revenue	1,506	1,045
Total revenue	<u>18,390</u>	<u>16,146</u>
Operating expenses:		
Cost of goods sold (excluding amortization)	4,377	4,308
Amortization of intangible assets	3,638	3,638
Selling, general and administrative	10,070	9,818
Research and development	2,352	2,469
Total operating expenses	<u>20,437</u>	<u>20,233</u>
Loss from operations	(2,047)	(4,087)
Interest expense and other expense, net	3,880	3,870
Loss before income taxes	(5,927)	(7,957)
Provision for income taxes	8	(8)
Net loss	<u>\$ (5,935)</u>	<u>\$ (7,949)</u>
Basic and diluted net loss per share:	<u>\$ (0.56)</u>	<u>\$ (0.75)</u>
Shares used in per share computation:		
Basic and diluted	<u>10,640</u>	<u>10,637</u>



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

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

	Three Months Ended	
	June 30, 2019	March 31, 2019
Net loss	\$ (5,935)	\$ (7,949)
Adjustments:		
Interest expense and other expense, net	3,880	3,870
Depreciation of fixed assets	37	37
Amortization of intangible assets	3,638	3,638
Share-based compensation expense	467	468
Provision for income taxes	8	(8)
Non-GAAP EBITDA and Non-GAAP recurring EBITDA	<u>\$ 2,095</u>	<u>\$ 56</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 EBITDA as net loss before interest expense and other expense, depreciation of fixed assets, amortization of intangible assets, share-based compensation expense and provision for or benefit from income taxes. We define non-GAAP Recurring EBITDA as non-GAAP EBITDA adjusted for certain non-recurring revenues and expenses, such as non-recurring milestone revenues, non-recurring restructuring and transaction costs and the one-time impact of changes in accounting estimates or the impact of new accounting standards. Management believes that non-GAAP EBITDA is a meaningful indicator of our performance and provides useful information to investors regarding our results of operations and financial condition.