
**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)
February 21, 2019

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 2.02. Results of Operations and Financial Condition

On February 26, 2019, VIVUS, Inc., or the Company, issued a press release regarding its financial results for the fourth quarter and year ended December 31, 2018, 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 Item 2.02 of 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On February 21, 2019, the Board of Directors, or the Board, of the Company authorized and approved the promotion of Mark K. Oki from his role as Chief Financial Officer and Chief Accounting Officer to the role of Senior Vice President, Chief Financial Officer and Chief Accounting Officer. On the same date and in connection with this promotion, the Compensation Committee of the Board of the Company authorized and approved an increase to Mr. Oki’s annual base salary for 2019 from \$395,500 to \$411,000, retroactive to January 1, 2019, and an increase to Mr. Oki’s target bonus from 40% to 50% of his annual base salary.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by VIVUS, Inc. dated February 26, 2019.

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: February 26, 2019



VIVUS Reports Fourth Quarter 2018 Financial Results

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

CAMPBELL, CA., February 26, 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 December 31, 2018 and provided a business update.

“We are pleased to have recorded a third consecutive quarter of positive EBITDA, excluding one-time expenses associated with the PANCREAZE acquisition and debt restructuring, which demonstrates our ability to execute on our strategy of returning VIVUS to profitability,” said John Amos, Chief Executive Officer at VIVUS. “We intend to execute several new initiatives in 2019 that we believe will further grow revenues from our existing product portfolio, including launching PANCREAZE under the VIVUS brand in the first quarter and streamlining the Qsymia acquisition process for patients. The VIVUS Health Platform, a new integrated strategy through which we will partner with physicians, dieticians, nutritionists, self-insured employers, private and public insurers and, most importantly, patients, is expected to increase utilization of Qsymia and PANCREAZE as tools for patients to achieve their healthy weight goals. We also intend to continue evaluating additional in-licensing or acquisition opportunities that can accelerate our trajectory toward profitability.”

Recent Business Highlights

- ***Publishing of Data Supporting the Cardiovascular Safety of Qsymia***

In February 2019, results from a new retrospective study evaluating the cardiovascular safety of Qsymia® (phentermine and topiramate extended-release) capsules CIV were published in *The Journal of Clinical Endocrinology & Metabolism* and are currently available online. The new findings indicate that the combined risk of major adverse cardiovascular events (MACE) was not elevated in patients currently taking Qsymia, or concurrently taking both phentermine and topiramate, compared with former users of these medications. The number of MACE events (3 events during 3,245 person-years of follow-up) was too few to draw a definitive conclusion from the data.

- ***Addition of Two New Members to the Board of Directors***

In October 2018, VIVUS announced the appointments of Karen Ferrell and Edward A. Kangas to VIVUS’ board of directors. With these appointments, VIVUS’ board of directors expands to nine members in total.

- ***Retirement of \$8.574 Million of its Convertible Notes due 2020***

In October 2018, VIVUS repurchased \$8.574 million of its convertible notes due May 2020 at a discount to par plus accrued and unpaid interest. The repurchase of the notes is expected to save the Company approximately \$2 million in principal and interest between the transaction date and the due date.

Fourth Quarter Financial Results

Revenue consisted of the following:

	(In thousands) Three Months Ended December 31,	
	2018	2017
Qsymia net product revenue	\$ 10,055	\$ 8,934
PANCREAZE net product revenue	7,363	—
Supply revenue	1,660	2,343
Royalty revenue	1,036	664
Total revenue	\$ 20,114	\$ 11,941

Total revenue for the fourth quarter of 2018 was \$20.1 million, an increase of 68% compared to \$11.9 million during the same period in 2017.

Qsymia net product revenue was \$10.1 million and \$8.9 million in the fourth quarters of 2018 and 2017, respectively. The increase was primarily due to improvements in Qsymia's gross to net deductions, including sales returns and discounts. Shipments were approximately 87,000 and 88,000 units in the fourth quarters of 2018 and 2017, respectively. Approximately 83,000 and 91,000 Qsymia prescriptions were dispensed in the fourth quarters of 2018 and 2017, respectively. Sales of Qsymia tend to be significantly impacted by seasonality and future sales of Qsymia could differ materially from fourth quarter results.

PANCREAZE net product revenue was \$7.4 million in the fourth quarter of 2018. VIVUS acquired PANCREAZE in June 2018. During this period, the Company shipped approximately 32,000 units of PANCREAZE. Beginning in the first quarter of 2019, PANCREAZE net product revenues will be negatively impacted by higher wholesaler fees as VIVUS takes over supply chain management and potential promotional strategies, including the issuance of discount coupons.

Total cost of goods sold excluding amortization was \$5.2 million and \$3.8 million in the fourth quarters of 2018 and 2017, respectively. The growth was primarily due to the addition of PANCREAZE revenue in 2018.

Amortization of intangible assets was \$3.6 million and \$91,000 in the fourth quarters of 2018 and 2017, respectively. The increase was due to the amortization of costs capitalized with the acquisition of PANCREAZE.

Research and development expense was \$1.8 million and \$1.2 million in the fourth quarters of 2018 and 2017, respectively. Research and development expenses were impacted by increased development efforts of VI-0106 for the treatment of pulmonary arterial hypertension. VIVUS also assumed post marketing requirements from Janssen as part of the acquisition of PANCREAZE. VIVUS expects research and development expenses to increase in connection with initiation of enrollment in the Qsymia adolescent safety and efficacy study (OB-0403) beginning in the first quarter of 2019.

General and administrative expense was \$4.6 million and \$5.7 million for the fourth quarters of 2018 and 2017, respectively. The decrease was primarily due to control of expenses and financial discipline. VIVUS expects general and administrative expenses to slightly increase as the Company continues the integration of PANCREAZE activities.

Selling and marketing expense totaled \$3.1 million and \$3.0 million in the fourth quarters of 2018 and 2017, respectively. VIVUS expects to increase commercialization efforts for PANCREAZE, including additions to its field force to support its re-launch in the first quarter of 2019, and potential administrative, partnering and promotional activities.

Total interest and other expense was \$6.3 million and \$8.2 million for the fourth quarters of 2018 and 2017, respectively. Fourth quarter 2018 results include a \$1.4 million gain on the repurchase of \$8.6 million of convertible notes. On an annual basis, VIVUS will make interest payments of approximately \$19.6 million on its convertible and senior secured notes.

Net loss for the fourth quarter of 2018 was \$4.5 million, as compared to \$10.1 million in the fourth quarter of 2017. Cash, cash equivalents and available-for-sale securities were \$111.2 million at December 31, 2018.

Non-GAAP EBITDA for the fourth quarter of 2018 was \$6.1 million, as compared to a negative EBITDA of \$1.0 million in the fourth quarter of 2017.

Conference Call Details

VIVUS will hold a conference call and an audio webcast to provide a business update and to discuss the 2018 fourth quarter financial results today, February 26, 2019, beginning at 4:30PM 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 7583536. 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 or potentially reduce our outstanding balance of the convertible notes due in 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; 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; 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 develop a proprietary formulation and to demonstrate through clinical testing the quality, safety, and efficacy of our current or future investigational drug candidates; 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”) relating to the U.S.-based CVOT for Qsymia, and the resubmission of an application for the grant of a marketing authorization to the EMA, the timing of such resubmission, if any, the results of any required CVOT, the assessment by the EMA of the application for marketing authorization, and their agreement with the data from any required CVOT; 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)
(Unaudited)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 30,411	\$ 66,392
Available-for-sale securities	80,838	159,943
Accounts receivable, net	25,608	12,187
Inventories	23,132	17,712
Prepaid expenses and other current assets	7,538	7,178
Total current assets	167,527	263,412
Property and equipment, net	341	542
Intangible and other non-current assets	134,279	1,014
Total assets	<u>\$ 302,147</u>	<u>\$ 264,968</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 8,921	\$ 10,072
Accrued and other liabilities	33,044	21,475
Deferred revenue	1,235	2,075
Current portion of long-term debt	—	5,147
Total current liabilities	43,200	38,769
Long-term debt, net of current portion	294,446	230,536
Deferred revenue, net of current portion	4,290	4,674
Non-current accrued and other liabilities	234	327
Total liabilities	342,170	274,306
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; \$.001 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2018 and 2017	—	—
Common stock; \$.001 par value; 200,000 shares authorized; 10,636 and 10,603 shares issued and outstanding at December 31, 2018 and 2017, respectively	11	11
Additional paid-in capital	840,751	834,824
Accumulated other comprehensive loss	(270)	(608)
Accumulated deficit	(880,515)	(843,565)
Total stockholders' deficit	(40,023)	(9,338)
Total liabilities and stockholders' deficit	<u>\$ 302,147</u>	<u>\$ 264,968</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenue:				
Net product revenue	\$ 17,418	\$ 8,934	\$ 56,784	\$ 44,983
License and milestone revenue	—	—	—	7,500
Supply revenue	1,660	2,343	4,863	10,407
Royalty revenue	1,036	664	3,415	2,483
Total revenue	20,114	11,941	65,062	65,373
Operating expenses:				
Cost of goods sold (excluding amortization)	5,213	3,845	14,613	16,643
Amortization of intangible assets	3,638	91	8,640	544
Selling, general and administrative	7,706	8,681	37,941	40,130
Research and development	1,800	1,204	7,347	5,263
Total operating expenses	18,357	13,821	68,541	62,580
Income (loss) from operations	1,757	(1,880)	(3,479)	2,793
Interest expense and other expense, net	6,257	8,190	33,419	33,302
Loss before income taxes	(4,500)	(10,070)	(36,898)	(30,509)
Provision for (benefit from) income taxes	—	5	52	2
Net loss	\$ (4,500)	\$ (10,075)	\$ (36,950)	\$ (30,511)
Basic and diluted net loss per share:	\$ (0.42)	\$ (0.95)	\$ (3.48)	\$ (2.89)
Shares used in per share computation:				
Basic and diluted	10,633	10,594	10,621	10,574

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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Net loss	\$ (4,500)	\$ (10,075)	\$ (36,950)	\$ (30,511)
Adjustments:				
Interest expense and other expense, net	6,257	8,190	33,419	33,302
Depreciation of fixed assets	40	64	235	267
Amortization of intangible assets	3,638	91	8,640	544
Share-based compensation expense	635	721	3,285	2,942
Provision for (benefit from) income taxes	—	5	52	2
Non-GAAP EBITDA	\$ 6,070	\$ (1,004)	\$ 8,681	\$ 6,546
Non-recurring revenue	—	—	—	(7,500)
Impact of change in accounting estimate	—	—	—	(6,037)
Non-recurring transaction costs	—	—	2,034	—
Non-GAAP Recurring EBITDA	<u>\$ 6,070</u>	<u>\$ (1,004)</u>	<u>\$ 10,715</u>	<u>\$ (6,991)</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 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.