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): **April 30, 2019**

VIVUS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-33389**	**94-3136179**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 Preferred Share Purchase Rights	VVUS	The Nasdaq Global Select Market

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):

o 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)

o Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

Item 2.02. Results of Operations and Financial Condition

On April 30, 2019, VIVUS, Inc. (the "Company") conducted a conference call during which members of its senior management team discussed financial results for the first quarter ended March 31, 2019, a business update and certain other information. A copy of the transcript of the conference call 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 otherwise subject to the liabilities of that Section, 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.

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. First Quarter Ended March 31, 2019 Earnings Conference Call on April 30, 2019, at 4:30 p.m. ET.

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: May 3, 2019

VIVUS, Inc. Q1 2019 Earnings Conference Call
April 30, 2019 - 4:30 PM ET

Operator

Good afternoon and welcome to the VIVUS first quarter 2019 financial results conference call. Today's call is being recorded. For introductions and opening remarks, I'd like to turn the call over to Mr. David Carey with Lazar Partners. Please go ahead.

David Carey — Lazar Partners

Thank you, operator. Good afternoon everyone and welcome to today's teleconference. With me on the call is John Amos, VIVUS' Chief Executive Officer, Mark Oki, VIVUS' Chief Financial Officer, and Dr. Santosh Varghese, VIVUS' Chief Medical Officer.

Before we get started, I would like to remind everyone that during this conference call, VIVUS will make certain statements that are considered forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as anticipate, believe, estimate, expect, forecast, intend, hope, likely, may, opportunity, plan, potential, predict and should, among others. These forward-looking statements are based on VIVUS' current expectations and actual results could differ materially.

There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. Investors are advised to read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2018, which was filed on February 26, 2019, as well as periodic reports filed with the Securities and Exchange Commission, such as our Form 10-Q filed earlier today.

VIVUS does not undertake an obligation to update or revise any forward-looking statements made on this call.

I will now turn the call over to John for a business update.

John Amos — VIVUS, Inc. — Chief Executive Officer

Thanks, David, and thanks to everyone on the call for your time this afternoon.

Fiscal Q1 2019 represents the completion of quarter three of our 10-quarter turnaround.

To review, Q3 and Q4 of 2018 were designated for stabilizing the business. During this time, we worked hard to put in place a cost structure, commercial set of capabilities and a go-forward commercial plan that would allow us to transition the company into a cash flow generating pharmaceutical company as part of the 10-quarter turnaround. In order to effectuate these changes, during the last three quarters we have incurred north of $6M of one-time expenses, with the heaviest expense load in Q1 of 2019. We still have some

additional one-time expenses to incur however, we expect these to tail off in Q2 of 2019. These one-time expenses include new sales and marketing capabilities for both Qsymia and PANCREAZE; product life cycle management activities, including market research, for Qsymia, PANCREAZE and STENDRA; additional technologies for sales force management; and investment into the VIVUS Health Platform. Many of these investments were focused on the Q1 2019 relaunches of PANCREAZE and Qsymia.

We are happy to report that both relaunches took place in the latter part of February 2019.

Let's discuss Qsymia and the relaunch.

In the last week of February 2019, our sales leadership brought the 18 sales professionals together for a week-long meeting focused on training, clinical messaging, general review of the brand, and the launch of the Qsymia Advantage Program, our direct-to-patient sales channel. The Qsymia Advantage Program was a direct offshoot of two successful pilot programs that we ran in Q3 and Q4 of last year.

To review, we sell Qsymia through two distinct channels. One is the typical wholesale-to-retail pharmacy channel, and our new channel, Qsymia Advantage, which leverages e-prescribing and direct-to-patient mail delivery.

There are a number of challenges with Qsymia in the traditional legacy retail model. The first challenge is the low conversion rate for a provided prescription. When a physician wrote a prescription for Qsymia, the prescription was picked up at the pharmacy by the patient approximately 65% of the time.

The second challenge was that approximately 10-12% of our prescriptions in the legacy model were driven by our free trial offer. Patients were provided with 14 days of our titration dose to determine their tolerance to the product. We provided this free pharmaceutical with the hopes that we could convert them into a paying customer. On the surface, the program made a lot of commercial sense, but in reality, patient conversion was well below expectations given the expense of the program. The primary driver of the lack of performance was patients' expectations of weight loss in the first 14 to 15 days. However, patients need to move to a therapeutic dose for the next 30 days to truly experience the clinical performance of Qsymia.

Another challenge was the high out-of-pocket price compared to other BMI therapeutics.

These challenges resulted in declining prescriptions filled over the past three years.

We believe our Qsymia Advantage Program addresses these core challenges plus the added benefit of creating a model that allows patients to become more durable on therapy. We have only rolled the program out to approximately 450 healthcare professionals, but the response has been incredibly positive and early program data metrics support that physician and customer reaction. Growth in the program has been strong, and we have grown from nine prescriptions per day in May 2019 — or excuse me, per day in January 2019 to 30 per day in March 2019, to 45 per day in April 2019. While this program is still new, the growth nonetheless has been encouraging.

As I mentioned earlier, the conversion from a written prescription to an actual purchased prescription is 65% in legacy retail. In Qsymia Advantage, that conversion rate is now at 88% for the month of March and 89% for the month of April. We have also made a significant change in the free trial offer. Instead of providing 15 days of therapy to the patient for free, we provide 45 days of therapy for the price of $98 plus shipping and handling. Patients are likely to experience weight loss in this period of time, and we expect their durability to therapy to be much higher.

Finally, we have normalized our pricing across all strengths. In the retail model, patients face significant increases in their Qsymia out-of-pocket expenses as their dose increases along the course of their weight loss journey. These increases have forced a number of patients off of Qsymia therapy. We are hopeful that our flat pricing structure will keep patients on therapy significantly longer and, thus, experience the weight loss that has been experienced by other Qsymia patients.

While we are pleased with the performance of the Qsymia Advantage Program, we expect to see some turbulence in our Qsymia revenue through Q2 of this year as we convert the market out of the retail model to the Qsymia Advantage model. We now expect to have the — We now expect to have the online payment system up and running by June of 2019. We believe — which we believe will accelerate the utilization of the Qsymia Advantage Program.

Additionally, we are now spending time with self-insured employers discussing how the VIVUS Health Platform can be customized to help them manage their healthcare costs related to obesity and high BMI employees. We expect to see revenue generated from these programs in 2020.

Let’s shift gear to PANCREAZE.

We closed the transaction to acquire PANCREAZE on June 8th, 2018. However, we continued to rely on the previous owner for a wide variety of services. In January of 2019, we started to sell the product under our own label. In February of 2019, we launched our own sales force of 10 representatives, a full-fledged sampling program, co-pay assistance, a vitamin and nutritional supplements program, all marketed under the VIVUS PANCREAZE Advantage program. We view the Q1 2019 revenue performance as a modest baseline from which we believe we can grow to six to nine points of market share in the next 24-36 months. Each point of market share is worth approximately $11M per annum. As we mentioned earlier, we will see some additional expense in Q2 of 2019 related to PANCREAZE, but our marketing efforts should show improved brand performance in Q3 and Q4 of 2019. The market response has been better than expected related to the relaunch of this product. The early returns on new patient starts have been positive. New patient starts for the four weeks post launch were 13.4% higher than the previous period. Additionally, our Cystic Fibrosis patients starts have been strong. These are two encouraging data points.

In the second quarter, we will also be launching several programs designed to expand access to PANCREAZE, and we expect that these programs will further drive revenue growth for the product while also removing barriers to care for patients who may benefit from PANCREAZE therapy. We will provide updates on these programs and our Canadian launch activities as they are rolled out during 2019.

We continue to receive inbound interest on our VI-0106 program, but to date we have been unwilling to partner the asset. Dr. Varghese will review the latest development status of the program in his update.

We continue to pursue regulatory approvals for STENDRA/SPEDRA and then subsequently seek commercial licensing partners for the open territories.

I will now turn the call over to Dr. Varghese, or excuse me, to Mark for discussion of the Q1 financials.

Mark K. Oki — VIVUS, Inc. — SVP, Chief Financial Officer & Chief Accounting Officer

Thank you, John. I will now review the first quarter 2019 financial results and then turn the call over to Dr. Varghese, who will provide an update on our clinical programs.

Qsymia net product revenue was $8.4 million in the first quarter of 2019, as compared to $9.6 million in the first quarter of 2018.

Shipments were approximately 75,000 units in the first quarter of 2019, as compared to 83,000 units in the same period in 2018. Approximately 82,000 and 92,000 Qsymia prescriptions were dispensed in the first quarters of 2019 and 2018, respectively.

As John discussed, we expect continued turbulence in the market in our sales as we move from the traditional retail distribution model to the Qsymia Advantage Program.

PANCREAZE net product revenue in the U.S. was $5.1 million in the first quarter of 2019. During this period, we shipped approximately 26,000 units of PANCREAZE. We now view the U.S. PANCREAZE business as a fully operated business by VIVUS and that this is the true starting point for a baseline for PANCREAZE revenue. We will absorb additional one-time expenses in the second quarter as we continue the launch activities, but we should see the benefits of these efforts beginning in the third quarter.

Supply revenue to our licensees, Menarini and Metuchen, for SPEDRA and STENDRA were $1.6 million and $1.7 million in the first quarters of 2019 and 2018, respectively. We remind you that both Menarini and Metuchen have minimum order requirements and their orders do not necessarily reflect end-user demand. The slight decrease in revenue was due to timing of orders from these commercialization partners.

During the first quarter of 2019, we recognized $0.6 million of royalty revenue from Canadian PANCREAZE MT sales and $0.5 million of royalty revenue from Menarini for net sales of SPEDRA, both consistent with prior periods.

We expect to assume responsibility for Canadian PANCREAZE MT sales in mid-2019, at which time we will report net product revenue and associated expenses of Canadian sales rather than as a royalty revenue.

Total cost of goods sold, excluding amortization, was $4.3 million and $2.6 million in the first quarters of 2019 and 2018, respectively. The increase was primarily the result of the addition of PANCREAZE product revenue during the quarter.

Amortization of intangible assets was $3.6 million and $91,000 in the first quarters of 2019 and 2018, respectively. The increase was due to the amortization of costs capitalized with the acquisition of PANCREAZE.

Research and development expense was $2.5 million and $1.4 million in the first quarters of 2019 and 2018, respectively. Research and development expenses were impacted by the assumption of certain post-marketing requirements, or PMRs, from Janssen as part of the PANCREAZE acquisition, the preparation for the Qsymia adolescent safety and efficacy study, also a PMR, and development efforts to improve the PANCREAZE formulation.

General and administrative expense was $5.3 million and $5.8 million for the first quarters of 2019 and 2018, respectively. The decrease was primarily due to lower business development spend in 2019 compared to 2018. VIVUS expects general and administrative expenses to fluctuate with business development activities.

Selling and marketing expense totaled $4.5 million and $4.3 million in the first quarters of 2019 and 2018, respectively. The increase was due to commercial efforts associated with PANCREAZE including additions to its field force that supported the relaunch in the first quarter of 2019. We expect our sales and marketing expenses to remain stable in future quarters.

Total interest expense, net, was $3.9 million and $8.3 million for the first quarters of 2019 and 2018, respectively. On an annual basis, we pay approximately $19.6 million in annual cash interest payments on our outstanding convertible and senior secured notes.

Net loss for the first quarter of 2019 was $7.9 million, as compared to $10.7 million in the first quarter of 2018. Cash, cash equivalents and available-for-sale securities was $104.7 million at March 31, 2019.

Non-GAAP EBITDA for the first quarter of 2019 was $0.1 million, as compared to a negative non-GAAP EBITDA of $1.2 million in the first quarter of 2018.

Reconciliation of these non-GAAP measures can be found in the press release filed earlier today with the Securities and Exchange Commission.

With that, I will now turn the call over to Dr. Santosh Varghese for a clinical and product life cycle update.

Dr. Santosh Varghese — VIVUS, Inc. — Chief Medical Officer

Thanks, Mark. I will review the clinical and regulatory aspects of our pharmaceutical programs VI-0106, PANCREAZE, and Qsymia.

Our VI-0106 program for pulmonary arterial hypertension, PAH, is moving forward with an intended IND filing in the second half of this year. We intend to open the IND with a Phase 2 study. This IND is expected to include pending stability data on our unique proprietary once-daily extended-release formulation. We believe our formulation will facilitate therapeutic drug levels while minimizing immunosuppressive effects for patients with PAH.

It is important to note that stability testing is ongoing, and the results will dictate the timing of our IND filing.

Now moving to Qsymia, we expect to submit our Market Authorization Application, MAA, on a decentralized basis in six EU countries in the second half of 2019.

We also expect our first ex-U.S. approval for Qsymia in the second half of 2019 with our partner Alvogen in South Korea.

We have submitted an ambulatory blood pressure protocol for consideration to the U.S. FDA at their request in conjunct — I'm sorry, in connection with our ongoing dialogue related to the Qsymia CVOT requirement. We believe this study would provide important additional safety data. The FDA did note that our Phase 3 trial data did not report an adverse effect of Qsymia on blood pressure.

In our pivotal studies, participants with a history of hypertension at baseline who were treated with Qsymia reduced their systolic blood pressure by 6.9 mmHg on the recommended dose and by 9.1 mmHg on the high dose. In all patients, regardless of their blood pressure status, who were treated with Qsymia reduced their systolic blood pressure by 4.5 mmHg on the recommended dose and by 5.6 mmHg on the high dose. All these results were statistically significant. Further details can be found in an article published in the *Lancet* by Gadde et al., back in April of 2011.

Finally, regarding PANCREAZE, we are in the process of exploring possible additional pancreatic studies, including those in pancreatic oncology.

Operator, you may now open the line for the question and answer period.

Operator

Thank you. Today's question and answer session will be conducted electronically.

[*Operator* instructions]

Our first question comes from John Vandermosten of Zacks Small Capital Research. Your line is open.

John Vandermosten — Zacks Small Capital Research

Thank you and good afternoon, everyone. I wanted to ask just first on I guess the proportion of sales of Qsymia that's gone from I guess the traditional model to the direct model. It sounds like you've made really great progress with some of those stats that you put out there, but, you know, just in terms of numbers of prescriptions that are in one versus the other category.

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah. John, we've run about 1,800 to 2,000 scripts through the new model. The online payment processing has slowed us down a little bit, just getting through that technology. We expect to open up the online payment system in the month of May, early June and then we'll be able to accelerate that. But so far, the results have been very encourage — or encouraging for that program.

John Vandermosten — Zacks Small Capital Research

Okay. Yeah. It sounds like you really picked up in April versus March based on that stat you provided.

And then just in terms of I guess the revenue levels for PANCREAZE and Qsymia. Obviously, there were a lot of changes that happened with the relaunch and everything for both of these products. Should we look at Q1 as kind of the baseline going forward and then kind of build off that base? Or is there still some more work that's got to get done to kind of get these things settled in with the new way that they're going?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah. I think the way that I would approach it is on PANCREAZE, it's certainly a baseline. And we're now — we now run and manage that program and product and brand as a fully owned VIVUS brand. It was still under Janssen's control. While they weren't providing any marketing services, they have different wholesale costs than we do and that actually affects our gross-to-net adjustment.
On Qsymia, it's still going to be a little bit choppy for a little bit through Q2. Our digital campaign is also kicking-off for Qsymia in Q2 and so we'll see market improvement on that. And that free trial offer from a scripts basis, we're really trying to move from that

old free trial offer, which has been one, extraordinarily expensive, and two, hasn't delivered the patient either results or revenue that we anticipated. So as we get through that through Q2, there's still going to be a little bit of choppiness there.

John Vandermosten — Zacks Small Capital Research

Okay. And looking at that $6 million that was cited in the release, that is all related I think right to Qsymia and PANCREAZE efforts right? On the sales side pretty much is that correct?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah. There is a block of expense that was related to the expansion of unit of measure on PANCREAZE. And so as we go through and we're building out a high dose on PANCREAZE, part of that expense was incurred to further that development.

John Vandermosten — Zacks Small Capital Research

Okay. And then, I guess that was probably mostly in the SG&A line over the last three quarters, that $6 million?

Mark K. Oki — VIVUS, Inc. — SVP, Chief Financial Officer & Chief Accounting Officer

SG&A and then again, it's associated with the development of the product of PANCREAZE —

John Vandermosten — Zacks Small Capital Research

Okay, very good. And just so I understand that number and to help me kind of think forward where to take that out of, you know, I think I heard you guys say that we're going to probably have a little bit more expenses like that in the second quarter, but after that they're going to — then the majority of them are going to roll off. Is that correct?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah. It's certainly flat now and we'll end up with a baseline expense. It should come down a little bit, but our digital spend will increase a little bit. So you'll see a little bit of offset there, a little bit of improvement, but it's not going to come completely up.

John Vandermosten — Zacks Small Capital Research

Okay. Thank you for the answers to my questions. Appreciate it.

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah. And I appreciate the questions, John.

Operator

[*Operator Instructions*]

There are no further questions. I'd like to turn the call back over to John Amos for any further remarks.

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah. Thanks, Operator.

Thanks again for your time today. Of course, we strive to have positive financial results, but as part of our 10-quarter plan, we made important decisions to strategically invest in our business at critical points in the turnaround. The relaunch of Qsymia and PANCREAZE warranted these investments.

Since we joined VIVUS on April 30, 2018, we have invested north of $6 million into VIVUS to focus on product lifecycle management of PANCREAZE, to build out the VIVUS Health Platform, the addition of 10 new sales reps for the relaunch of PANCREAZE, and the creation of the Qsymia Advantage Program.

I believe that these first-year achievements should provide our stockholders and the investor community at large with confidence in our ability to establish VIVUS as a cash flow positive specialty pharmaceutical company capable of delivering long-term clinical and commercial value.

We will share our progress with you as we reach additional milestones towards this goal.

Thank you, Operator.

Operator

And that concludes today's call. All parties may now disconnect.