
**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)
May 8, 2018

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 May 8, 2018, VIVUS, Inc., or the Company, conducted a conference call during which members of its senior management team discussed financial results for the first quarter ended March 31, 2018, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of VIVUS, Inc. First Quarter Ended March 31, 2018 Earnings Conference Call on May 8, 2018, at 1:30 p.m. PT.

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EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
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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 14, 2018

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VIVUS, Inc.
2018 First Quarter Financial Results and Business Update Teleconference
08-May-2018, 04:30ET/01:30 PT

Operator

Good afternoon and welcome to the VIVUS First Quarter 2018 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. Mark Oki, VIVUS' Chief Financial Officer. Please go ahead.

Mark K. Oki - VIVUS, Inc. — Chief Financial Officer

Thank you, operator. Good afternoon everyone, and welcome to today's teleconference. With me on the call today is John Amos, VIVUS' new Chief Executive Officer.

Before we get started, I would like to remind everyone that during this conference call we 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, 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 the VIVUS Form 10-K for the year ended December 31, 2017, as filed on March 14, 2018 and as amended by Form 10-K/A filed on April 26, 2018, 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 review the 2018 first quarter financial results and then turn the call over to John, who will provide a business update and discuss his vision for VIVUS going forward.

Total net revenue, excluding non-recurring items, for the first quarters of 2018 and 2017, was \$11.9 million and \$14.7 million, respectively. In the first quarter of 2017, VIVUS incurred two non-recurring items. First was a \$7.3 million adjustment to Qsymia net revenue due to the Company's adoption of the "sell-in" revenue recognition methodology. Second, the Company recognized \$5.0 million in license revenue for the license of certain clinical data, which we do not expect to re-occur.

Qsymia net revenue decreased to \$9.6 million in the first quarter of 2018, as compared to \$10.3 million in the first quarter of 2017, net of the one-time accounting adjustment. In the first quarters of 2018 and 2017, VIVUS shipped approximately 83,000 and 89,000 units of Qsymia to wholesalers, respectively. Approximately 92,000 and 102,000 Qsymia prescriptions were dispensed in the first quarters of 2018 and 2017, respectively.

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STENDRA and SPEDRA supply revenue was \$1.7 million in the first quarter of 2018, compared with \$3.8 million for the same period in 2017. The variations in supply revenue are a result of the timing of orders placed by our partners and may or may not reflect end-user demand for STENDRA and SPEDRA.

SPEDRA royalty revenue was \$585,000 for the first quarter of 2018, consistent with the \$580,000 in the first quarter of 2017.

Cost of goods sold was \$2.7 million and \$6.2 million in the first quarters of 2018 and 2017, respectively. The decrease was primarily a result of inventory buy-in and higher product revenues in 2017.

Research and development expense was \$1.4 million and \$2.2 million in the first quarters of 2018 and 2017, respectively. Research and development expenses were impacted by the payment of license fees of \$1.1 million to Selten in 2017. Excluding these fees, development costs increased as a result of expenses related to ongoing development of tacrolimus for the treatment of pulmonary arterial hypertension.

General and administrative expenses was \$5.8 million and \$6.0 million for the first quarters of 2018 and 2017, respectively, while selling and marketing expense for the commercialization of Qsymia totaled \$4.3 million and \$5.5 million in the first quarters of 2018 and 2017, respectively. Sales and marketing expenses in 2017 included a \$700,000 adjustment related to the one-time accounting adjustment for the change in revenue recognition methodology.

Operating loss excluding the one-time accounting adjustment and non-recurring licensing revenue was \$2.3 million and \$3.8 million in the first quarters of 2018 and 2017, respectively.

Cash, cash equivalents and securities available-for-sale totaled \$201 — \$209.1 million at the end of March 31, 2018.

I will now turn the call over to John to provide a business update and discuss his vision for VIVUS going forward.

John Amos — VIVUS, Inc. — Chief Executive Officer

Great, thank you, Mark, and thanks to all of you who are participating on today's call. It is my pleasure to have the opportunity to speak with you today about recent activities that VIVUS has undertaken to set our company on the road to commercial growth and profitability.

Before I do that, however, I'd like to take a few minutes to share with you what attracted me to VIVUS and why I am proud and excited to be leading the company at this pivotal time in our corporate development.

For the past 24 plus years as a general manager, CEO, Board member and investor in healthcare and pharmaceutical companies, I have had the tremendous opportunity to work with and build teams of talented individuals that have helped create growth, sometimes significant, in enterprise value.

This growth has been achieved through the disciplined approach of deploying capital for acquiring cash-flow positive assets, managing expenses and buying assets at the right price. That collection of experiences inspired me to work with Ken Suh and help Ken build Willow Biopharma. We collectively believed we could build a significant ethical pharmaceutical company through disciplined deal-making and building a portfolio of pharmaceutical brands and products to meet patients' needs. Consistent with that strategy, in the fourth quarter of 2017 we began to evaluate acquiring PANCREAZE, a cash-flow positive product we believed had unrealized value.

It was during this evaluation that Athyrium Capital introduced us to the VIVUS leadership team. VIVUS shared a similar viewpoint on the healthcare and pharmaceutical industry. We began to explore a number of potential deal constructs. As those talks progressed, collectively the team of Willow and VIVUS came to the realization that we had a shared vision for how our respective companies could create value for patients and stakeholders. Ultimately, we all concluded that VIVUS' exciting and under-levered portfolio of specialty pharmaceutical products along with VIVUS' significant development, regulatory and commercialization expertise could serve as a foundation platform for executing our value-creating strategy. Rather than executing a licensing agreement for PANCREAZE, we decided to unify our shared vision by having VIVUS acquire Willow and having the Willow management team assume significant and strategic roles at the helm at VIVUS. On a combined basis, VIVUS now has the talent, three commercial products, one development product and a decently constructed balance sheet to build value from in the future. As a management team, we firmly believe we can create that long-term value.

Before I turn to the rationale for acquiring PANCREAZE, let me provide some framework we use in acquiring assets. I will break it down into five key points:

Point 1: The price of the target asset has to be defined early on in the process. We might not have the exact number, but we have to be in a ballpark range that will generate acceptable returns on invested capital. We tend to stay away from big banker processes and we utilize our relationships in industry to obtain proprietary or semi-proprietary looks at assets and companies.

Point 2: While we utilize leverage, we will not financially engineer returns.

Point 3: We need to see that the product has some market barriers to entry for at least a defined period of time or that the market has flushed through a number of competitors.

Point 4: We tend to look for products with a significant clinical following and are important in the treatment of the medical indication for the product.

And point 5: We look for assets that don't require heroic or a large number of strategies to achieve performance. We don't mind turnaround assets, but there are limits to what can be done, realistically performed in the creation of value.

Let me now turn to our rationale for acquiring PANCREAZE, which is the first of what we hope will be a series of product acquisitions designed to generate revenue and strengthen our financial position.

As we announced last week, VIVUS has entered into a definitive agreement to acquire all product rights for PANCREAZE Delayed-Release Capsules in the United States and Canada held by Janssen Pharmaceuticals, Inc. for \$135 million US. PANCREAZE is specifically indicated for the treatment of exocrine pancreatic insufficiency, or EPI, due to cystic fibrosis or other conditions. EPI is a condition that results from a deficiency in the production and/or secretion of pancreatic enzymes. It is associated with cystic fibrosis and chronic pancreatitis and affects approximately 85% of cystic fibrosis patients. There is no cure for EPI and pancreatic enzyme replacement therapy is the main treatment for the condition.

Approved in 2010, PANCREAZE is a pancreatic enzyme preparation consisting of pancrelipase, an extract derived from porcine pancreatic glands, as well as other enzyme classes, including porcine-derived lipases, proteases and amylases. The pancreatic enzymes in PANCREAZE act like digestive enzymes physiologically secreted by the pancreas. We intend to leverage VIVUS' existing operating infrastructure, including supply chain, regulatory, finance among others to efficiently and commercialize — and effectively commercialize PANCREAZE. The PANCREAZE asset was a semi proprietary deal, involved what we consider a reasonable amount of leverage, an important product, does not require a herculean effort to hopefully improve performance, and we paid an acceptable price based on a historical performance.

This product will allow us to enter the global gastrointestinal marketplace, which is predicted to reach \$48 billion in 2022 according to GBI Research. PANCREAZE exemplifies the type of cash flow-positive specialty pharmaceutical products that we will pursue as we work to build a profitable company and address the amount and structure of our debt, which is key — which is a key corporate priority.

Consistent with that priority, we have entered into an agreement to restructure a portion of VIVUS' corporate debt while raising new funds through the issuance of debt securities to investment funds managed by Athyrium Capital. As announced last week, VIVUS has entered into a \$120 million Senior Secured Note Purchase Agreement with investment funds managed by Athyrium. The agreement provides for \$110 million of notes to be issued by VIVUS concurrent with the closing of the PANCREAZE acquisition and subject to the satisfaction of other customary closing conditions, with the remaining \$10 million available for issuance upon meeting certain financial thresholds or repurchasing the Company's Convertible Notes at certain prices. The Senior Secured Notes due 2024 will bear interest at 10.375% and will be interest-only for the first three years. Concurrently with the Senior Secured Notes issuance, VIVUS will repurchase \$60 million of Convertible Notes held by funds managed by Athyrium at a discount to par.

Athyrium is a long-term investor in companies with clinically meaningful products, and they understand the value that flexible financing provides in the pursuit of compelling new business development opportunities. Athyrium has been a strong partner in helping us develop and execute a strategy to address the amount and structure of our debt, and we appreciate their support of our long-term objectives. The availability of the new debt capital from Athyrium provides us with financial flexibility as we continue to seek cash-flow positive assets and products that enhance our financial strength while providing clinical benefit to patients.

As we evaluate additional value-creating assets with which to expand our portfolio of commercial products, we are also pursuing opportunities to grow VIVUS organically.

Qsymia is a very interesting product. Qsymia offers an opportunity for organic growth and is a very attractive asset that we believe can be prescribed and promoted more effectively. As you may be aware, the product is sold and marketed utilizing a REMS program. The REMS program has provided VIVUS with excellent visibility to how the drug is utilized by patients and prescribed by physicians. We continue to believe that Qsymia provides patients with significant benefits as a platform for managing body mass index, or BMI, which is used as an indicator of obesity status. We believe that real world learnings related to Qsymia as a chronic therapy do not accurately reflect its potential as an integral part of BMI management. In this regard, and in connection with our ongoing dialogue with the US FDA, we have respectfully submitted options to the Agency, including a label modification, to allow for the safe and effective short-term utilization of Qsymia while significantly reducing or eliminating the cardiovascular outcomes study.

Additionally, we are also evaluating, utilizing and using Qsymia in combination with diet, exercise and with digital tools to comprehensively address the lifestyle issues that can give rise to increased BMI. We believe Qsymia is really part of the overall process of BMI management.

We are exploring a number of changes to our sales models for Qsymia. We believe the changes to the current model would bring VIVUS closer to physicians and patients who wish to use Qsymia for BMI management, which could increase brand recognition and brand loyalty, both of which are important for growing Qsymia utilization. We expect that our current sales force will have the capacity to continue promoting Qsymia even as it takes on PANCREAZE.

In terms of new product development, VIVUS is developing a 505(b)2 opportunity utilizing tacrolimus for the treatment of pulmonary arterial hypertension, or PAH, a degenerative and life-threatening disease that makes it difficult for the heart to pump blood to the lungs to be oxygenated and may ultimately lead to heart failure. Current PAH treatment options only address symptoms, slowing but not preventing the disease. In January 2017, we acquired exclusive, worldwide rights to develop and commercialize tacrolimus for the treatment of PAH and related vascular diseases.

VIVUS has made important progress in moving a proprietary formulation of tacrolimus toward the clinic, and believe that tacrolimus has significant clinical potential in a disease for which new therapies are urgently needed. We are currently evaluating a variety of strategies for maximizing the value of this promising development candidate in a manner that is consistent with achieving our capital objectives.

We are also looking for additional potential licensing opportunities for STENDRA, our erectile dysfunction therapy, that would generate near-term capital to support our acquisition and debt reduction strategies.

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I believe these combined strategies will enable VIVUS to become a profitable, commercially-focused specialty pharmaceutical company that can create significant value for patients and investors.

Before I conclude my remarks, I would like to leave you with the following thoughts.

Post the close of the PANCREAZE deal, VIVUS will have two products in which we believe can build a cash flow positive and growing pharmaceutical company.

With the restructuring of a portion of our debt and the additions to the VIVUS management team, we believe we have the ability to acquire assets and then grow those assets intelligently and in a regulatory-complaint manner.

We believe that with our disciplined expense and financial management, coupled with our potential for organic and inorganic growth, we will hopefully be able to create retained earnings in the VIVUS platform

That concludes my remarks today. Operator, you may now open the line for the question and answer period.

Operator

Thank you. Ladies and gentlemen, if you would like to ask a question at this time, please press * and 1 on your touchtone telephone. If your question has been answered or you wish to remove yourself from the queue, please press the # key. Again, that is * then 1 to ask a question.

And if there are no questions at this time, I will turn the line back to John Amos for closing remarks.

John Amos- VIVUS, Inc. — Chief Executive Officer

Thank you, and thank you all again for your time today. Mark, the management team and I are pleased to have had the opportunity to share the vision for VIVUS with you. We believe that the tried and true strategy of building a portfolio of cash flow-positive products and addressing the size and structure of our debt will put us on a strong growth trajectory. I joined VIVUS because I truly believe the company has multiple compelling opportunities ahead of us and the team and talent to transform those opportunities into shareholder and patient value. We look forward to sharing our progress toward these goals with you in the months ahead.

Thank you to everyone on the call for participating.

Operator

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

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