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)
November 1, 2018

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

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

o 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 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 November 1, 2018, VIVUS, Inc., or the Company, conducted a conference call during which members of its senior management team discussed financial results for the third quarter ended September 30, 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.

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. Third Quarter Ended September 30, 2018 Earnings Conference Call on November 1, 2018, at 1:30 p.m. PT.

EXHIBIT INDEX

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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: November 6, 2018

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

Operator

Good afternoon and welcome to the VIVUS Third Quarter 2018 Financial Results conference call. Today's call is being recorded. For instructions 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 is John Amos, VIVUS' 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 VIVUS' Form 10-K for the year ended December 31, 2017, that was 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 third quarter financial results for 2018 and then turn the call over to John, who will provide a business update and discuss several key initiatives that will be a focus as we finish 2018 and move into and through 2019.

Qsymia net product revenue was $9.7 million in the third quarter of 2018, as compared to $9.9 million in the third quarter of 2017. The slight decrease was primarily driven by the decrease in shipments to 86,000 units in the third quarter of 2018, as compared to 92,000 units in the same period in 2017. Approximately 89,000 and 97,000 Qsymia prescriptions were dispensed in the third quarters of 2018 and 2017, respectively.

PANCREAZE net product revenue in the U.S. was $6.7 million in the third quarter of 2018 and represents the Company's first full quarter of PANCREAZE revenue. During this period, we shipped approximately 34,000 units of PANCREAZE. We anticipate that future PANCREAZE net product revenues will be negatively impacted by higher fees as VIVUS takes over supply chain management and implements certain promotional strategies.

We recognized $0.6 million of royalty revenue from Canadian PANCREASE sales during the third quarter of 2018 and $500,000 of royalties from Menarini for net sales of SPEDRA.

Supply revenue to our licensees, Menarini and Metuchen, for SPEDRA and STENDRA were $0.5 million and $2.1 million in the third quarters of 2018 and 2017, respectively. Both Menarini and Metuchen have minimum order requirements and their orders do not necessarily reflect end-user demand.

In the third quarter of 2017, we recognized $2.5 million of revenue related to the licensing of commercial and development rights for Qsymia to Alvogen for South Korea.

Total cost of goods sold, excluding amortization, was $3.5 million and $3.4 million in the third quarters of 2018 and 2017, respectively. The increase was primarily a result of the addition of PANCREAZE product revenue during the quarter partially offset by the decrease in supply revenue.

Amortization of intangible assets was $3.6 million and $91,000 in the third 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 $2.1 million and $0.9 million in the third 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, specifically the Phase I pharmacokinetic study as well as continued formulation efforts. We also assumed certain post-marketing requirements from Janssen as part of the PANCREAZE acquisition.

General and administrative expenses was $5.4 million and $5.6 million for the third quarters of 2018 and 2017, respectively. The decrease was primarily due to control of expenses and financial discipline. As the Company continues the integration of PANCREAZE activities, there may be increases to general and administrative expenses.

Selling and marketing expense totaled $3.1 million and $2.8 million in the third quarters of 2018 and 2017, respectively. The slight increase was due to marketing expenses associated with PANCREAZE. We expect our sales and marketing expense to increase over the next several quarters as we plan to launch PANCREAZE in the first quarter of 2019. Additional expenses will include growth in our field force and potential administrative, partnering and/or promotional activities.

Total interest expense was $9.6 million and $8.4 million for the third quarters of 2018 and 2017, respectively. After our October $8.574 million convertible note repurchase, we will pay approximately $19.6 million a year in annual interest on our outstanding convertible and secured notes.

Net loss for the third quarter of 2018 was $9.2 million, as compared to $6.0 million in the third quarter of 2017. Cash, cash equivalents and available-for-sale securities were $115.1 million at September 30, 2018.

Non-GAAP EBITDA for the third quarter of 2018 was $4.8 million, as compared to $0.8 million, excluding one-time license revenue, in the third quarter of 2017.

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 John for a business update and discussion of our goals and strategy going forward.

John Amos — VIVUS, Inc. — Chief Executive Officer

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

The third quarter of 2018 is the first full quarter under our newly integrated management team, and I'm pleased with the progress that we have made towards improving our financial performance and growing our commercial opportunities. As I stated during our last quarterly call, the theme for 2018 and beyond is progress.

Each member of the management team joined VIVUS because we believe in its people, products and potential. When the management team was recast on April 30th, 2018, we collectively identified 15 to 20 key aspects of the business that required significant attention in order to ensure that we have the runway and long-term resources to build a best-in-class biopharmaceutical and healthcare company. I'm pleased to report that we've either fully addressed or made definitive progress on approximately two-thirds of the items that were on that initial to-do list, and we have plans in place to address the remaining items over the next several quarters. Let me provide a few tangible examples of the progress that we have achieved in the third quarter and lay out the next set of milestones against which you can measure our ability to execute on our strategic plans.

Let's discuss the balance sheet and our liquidity. At the end of the second quarter of 2018, we had approximately $176 million of net debt with $1 million of EBITDA, excluding non-recurring expenses. By contrast, at the end of the third quarter of 2018, we had $185 million of net debt with $4.8 million of EBITDA. Obviously, we still have a lot of work to grow the business into the proper leverage ratio, but we are proud of this progress we are making toward this important objective.

The execution of a 1-for-10 reverse stock split enabled us to regain compliance with the Nasdaq listing requirements and VIVUS shares began trading on a split-adjusted basis on September 11, 2018. Following the reverse split, Nasdaq notified us that we had achieved compliance with the applicable requirements required for continued listing. Our Nasdaq listing provides us with important liquidity that we believe is essential for transforming VIVUS into a sustainable and profitable business.

In October, we repurchased $8.574 million of our convertible notes due May 2020 at a discount to par. The repurchase of the notes is expected to save the Company approximately $2 million in principal and interest. We will continue to evaluate opportunities to further deleverage our financial structure, which is essential for improving our credit risk profile and allowing us access additional financial resources. We are committed to fiscal responsibility, discipline and intend to pursue a variety of strategies that allow us to improve the amount and the structure of our debt. Improving our capital structure and financial resources goes beyond specific financial transactions. A healthier capital structure provides us greater flexibility to expand our commercial opportunities and to leverage our expertise into additional product opportunities.

We have made important additions to our Board. Earlier this week, we announced the additions of Karen Ferrell and Ed Kangas. We expect that each of them will provide invaluable input and perspective that will help us identify and execute on new ways to build value for patients and stockholders. Karen's expertise in the managed care markets will be beneficial as we explore new ways to market our existing commercial products, while Ed's extensive experience as a director at multiple commercial and not-for-profit organizations will provide new perspectives on diverse aspects of our business and markets.

Now, while the accomplishments I just described will certainly contribute to our success, driving sustainable increases in our product revenues and recurring EBITDA will be the key determinant of our ability to create value for stockholders over the long-term. In order to achieve this goal, we are pursuing a number of initiatives to maximize the market potential for our current commercial products as we continue evaluating additional in-licensing and acquisition candidates.

Let me spend a few minutes discussing our current product portfolio.

As I discussed on last quarter's call, we've developed a more comprehensive understanding of the market for Qsymia and we have several ongoing and planned initiatives that we believe have the potential to increase the utilization of this very important product in the U.S. healthcare system. We have been running two pilot programs in the states of Georgia and Texas. These programs streamline and improve access to Qsymia. The results have been promising and we are planning to roll out an enhanced version of the same program in a few additional states over the next few months.

We have spent time with physicians and other healthcare providers to understand how they utilize Qsymia. One example is worth mentioning. Certain bariatric surgeons utilize Qsymia in a post-operative setting to help manage cravings and move the patient to a healthier level of caloric intake. The results appear to be helpful for these patients, and we will continue to learn more about this application of Qsymia.

In short, we are more optimistic that there are multiple tactical opportunities to grow Qsymia as a stand-alone pharmaceutical for weight management.

That said, we believe the greater opportunity for this undervalued product is in the context of a comprehensive platform for achieving and maintaining a healthy body mass index, or BMI. The number of individuals in the United States who have an unhealthy high BMI continues to grow, leading directly to substantial rates of morbidity and mortality and dramatically increasing the risk of developing other serious health conditions, including cardiovascular disease and diabetes. New approaches to addressing this crisis are urgently needed, and we believe that a holistic approach may succeed where other endeavors have performed below expectations. We are focused on building a platform that integrates nutritional, information-based and pharmaceutical technologies to help patients reach and maintain a healthy BMI. We expect to have more detailed information on this platform to share with you in the first half of 2019.

In addition, we are exploring regulatory and commercial strategies in geographies outside of the United States in order to expand the Qsymia revenue opportunity to include Europe, South America and Asia.

Let’s shift now to PANCREAZE.

A key factor in the significant growth of our product revenues in the third quarter of 2018 compared with the same period in 2017 is the addition of PANCREAZE to our product portfolio. PANCREAZE net revenue in the third quarter of 2018 was $6.7 million, representing more than a third of the quarter’s total revenue. While we are still in the process of fully transferring this product to VIVUS, we have made progress in positioning PANCREAZE within the managed care markets as a cost-effective, clinically beneficial treatment for exocrine pancreatic insufficiency, or EPI.

As a reminder, EPI results from a deficiency in the production and/or secretion of pancreatic enzymes, making it difficult or impossible for these individuals to digest nutrients, such as fats, proteins and carbohydrates. It is associated with cystic fibrosis, chronic pancreatitis and pancreatic cancer. Approximately 85% of patients with cystic fibrosis also suffer from EPI. There is no cure for EPI. Pancreatic enzyme replacement therapy is the main treatment for the condition. PANCREAZE, which is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions, is a pancreatic enzyme preparation that acts like digestive enzymes physiologically secreted by the pancreas.

We expect to complete the transfer of PANCREAZE in the United States to VIVUS by the end of 2018, with Canada transferring in 2019.

As we gear up for the full U.S. product launch in the first quarter of 2019, we are engaged in productive discussions with leading gastroenterologists, pulmonologists and cystic fibrosis specialists to understand their needs and to develop an effective strategy for marketing directly to the healthcare providers who treat the majority of EPI patients.

Let’s now discuss Avanafil, which is marketed as STENDRA in the United States and SPEDRA in Europe.

Avanafil is largely managed as a licensing opportunity and as it is approved in additional territories around the globe, we will have additional licensing opportunities. In this regard, in 2018 we have received notifications of approvals to commercialize SPEDRA from Jordan, Saudi Arabia, and Turkey.

Shifting to our development stage product, VI-0106, which is a proprietary soft capsule formulation of tacrolimus that is being developed for the treatment of pulmonary arterial hypertension, or PAH, a serious disease with significant unmet medical need and no curative therapies. New therapies that address the underlying cause of the disease are urgently needed, and available data suggests that VI-0106 may fill this need. We’re exploring a variety of strategies for advancing this very promising program consistent with our goals of working towards profitability and reducing our corporate debt. Potential approaches could include partnering the program with another pharmaceutical, securing direct funding for the development of VI-0106, or a potential sale of the asset. We are in active discussions with several entities and are optimistic that we will identify a path for the further development of VI-0106.

Our corporate development activities continue to move forward. We have and are constantly evaluating new product and corporate acquisitions. We tend to look for opportunities that are generating positive cash flow, fit with our business capabilities, and are opportunities that we can grow post-acquisition.

I am well aware, as those of you on this call, that the financial results of a single quarter do not define a company's success or potential. While we are very pleased with the improvements in our third quarter financial results for 2018, we know that we must continue to execute on our strategies and demonstrate ongoing progress towards our goal of building a sustainable, profitable business in the quarters ahead. We are committed to making this progress and to providing current and future stockholders with clear-cut evidence that we have the products, management, employees and strategies to succeed over the long term and to be worthy of their support. We intend to build on the success of the third quarter by continuing to set and achieve objective metrics of our progress and by helping to improve the lives of patients who are our ultimate and most important focus. But as Mark mentioned, our operating results over the next couple of quarters will come under pressure from our launch of PANCREAZE in the first quarter of 2019.

Before I conclude my remarks today, we have had two questions that have consistently come in through our IR contact line that I would like to address.

Question 1: Shortly after the reverse split was completed VIVUS filed a shelf for an equity offering. What are the plans for the company to do an equity raise?

While we don't have any immediate capital needs, we wanted to have a shelf registration in place as part of an evolving capital toolset should we determine it appropriate to raise capital through registered debt and/or equity. We evaluate the weighted cost of capital on a regular basis and we believe that issuing stock at our current market capitalization and under current circumstances would not be appropriate. As a reminder, I purposefully aligned my interests with those of our stockholders by acquiring shares in the open market for a total of $1 million of my own money shortly after joining the Company.

Question 2: Why doesn't VIVUS use its cash for share buybacks?

Our Senior Secured Notes precludes us from buying back shares. Additionally, given our outstanding debt, we believe share buybacks would be an inappropriate use of cash.

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. To ask a question, press the * then the 1 key on your touchtone telephone. Again, that's * then 1.

We'll wait one moment for questions.

Once again ladies and gentlemen, that's * then 1.

We'll take our first question from the line of Robert Mendralla. Your line is now open.

Robert Mendralla, Investor

Yes, thank you, this is Robert, and I appreciate the update, John, on the report. I guess this is kind of a two-part question. One is, I know you brought on Mr. Suh as — into the organization of VIVUS. What is the status of Willow Biopharma? And the second part of my question is, there's a lot of moving parts here with the re-positioning of PANCREAZE, you gave us some color around tacrolimus, and STENDRA/SPEDRA, looks like there's, you know, it's been a good money maker, but how to grow that. Is it — Is it fair to say that in the future, I know future acquisitions might be on the horizon, but, you know, there's still some decision making with the current product mix. Could you provide a little bit more color on what your strategy or thoughts are around that?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes sure, so to answer the first question about Ken. So, Ken's now President of VIVUS. His primary focus is commercial operations as well as working with John Slebir, who's our General Counsel and SVP of BD, in finding opportunities for us to out-license products, in-license products and acquire other assets.

Willow Biopharmaceutical is effectively a shell operating company that's been folded under the VIVUS ownership. So that's I think — hopefully answers your first question.

The second question is obviously a little bit more complex. So, we're huge fans of QSYMIA and we're huge fans of PANCREAZE. So, we're a multi-product pharmaceutical company and we're going to continue to find ways to try to sell that product — both of those products — more effectively and efficiently, and the management team of this company, the eight or nine of us who are really involved in this company in terms of the day-to-day setting of commercial strategy — you know, 150 years of selling pharmaceuticals in the U.S. and abroad. So, I think we're really excited about those two products.

STENDRA/SPEDRA/AVANAFIL has been, as you aptly described, a money maker for us, and that product continues to get more and more approvals across the globe. It's a fantastic product. And so we are very excited about that product, but we really have partnered it out, so we're hopeful that our partners will be successful, and we've continued to have regular interactions with our partners to help them think about how to be more effective in that product. That marketplace has changed a lot because of generic Viagra coming in the marketplace.

With respect to VI-0106 tacrolimus, another product — Just to tell you personally, I was not super excited about that product when I joined the company, but John Slebir and Santosh really turned me around on that and once I was able to dig through, understand the product more effectively, how it worked, how we could identify patients, there's a diagnostic pathway, the fact that it wasn't a "me too" therapy, that it was curative, it was actually disease-modifying — All of those factors became very important, you know, in our decision to continue to move that product forward. I think, you know, unfortunately, tacrolimus comes — is sitting on the balance sheet as an asset where we need our cash to pay off our debt in May of 2020, and so we're in a little bit of a tricky situation where we're trying to finance that project to continue to move it forward because it's really, really important while being able to meet our financial goals in May of 2020. So, and then just on top of that, we are looking for — constantly looking for acquisitions, and Ken and John are doing a great job of finding opportunities for us, you know, to eventually fit in there. But you kiss a lot of frogs and you look at a lot of frogs in the M&A world, and you can make some really, really easy and bad mistakes if you don't do your diligence properly or you're overly aggressive, and that's just something that we won't do, so we're not going to do a deal for the deal's sake, we're going to do a deal when it's properly valued and it fits with what we're trying to do strategically. This is, you know, I think we've got a fantastic management team, and as you said, we have lots of moving pieces, but we're pretty good at managing those moving pieces even though we've only been together for six months. We're still, you know, we should get better at what we're doing over the next hopefully couple of years.

Robert Mendralla, Investor

OK, very good. Thank you.

John Amos — VIVUS, Inc. — Chief Executive Officer

You bet. Thanks for your question.

Operator

Thank you, and as a reminder, ladies and gentlemen, if you have a question at this time, please press the * then the 1 key on your touch tone telephone.

If there are no further questions, I will turn the line back to John Amos for closing — I'm sorry, we are showing — I am showing a follow-up question from Robert Mendralla. Your line is now open.

Robert Mendralla, Investor

Hello?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes?

Robert Mendralla, Investor

Yes, John, can you hear me?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah, sure can!

Robert Mendralla, Investor

OK, Robert Mendralla again. I see — is there currently more than one analyst that is following VIVUS or it's still at one? I was getting a little confused about some of the reports out in the general public.

John Amos — VIVUS, Inc. — Chief Executive Officer

Well, I think there's one human analyst that covers us, and then there's a number of what I would call artificial intelligence analysts that follow us.

Robert Mendralla, Investor

Sure. I think it's important. I think analyst coverage, if maybe another one or so could cover, I think that provides more transparency, visibility into VIVUS as it goes through its turnaround, and I realize that's a one to three-year plan, but I think that would certainly promote more interest in the markets because people are having questions on the stock. And so I think that might just be helpful for the overall mission of VIVUS moving forward.

John Amos — VIVUS, Inc. — Chief Executive Officer

Excellent point and it's something that we've gone out and met with over a hundred plus investors over the last six months. We've met with a number of analysts, but as you can imagine, given where VIVUS was and where we hope to bring VIVUS, we've got to — we've got to show some people that we can do what we're talking about.

Operator

If there are no further questions, I would like to turn the call back over to John Amos for closing remarks.

John Amos — VIVUS, Inc. — Chief Executive Officer

Thanks again for your time today. It's gratifying to have multiple positive achievements to share with you, and we are focused on continued attainment of our key objectives. As Mark noted during his review of the financial results, non-GAAP EBITDA for the third quarter of 2018 was $4.8 million, as compared to $0.8 million, excluding one-time license revenue, in the third quarter of 2017. We believe these results are evidence that we are making meaningful progress against our objectives and that our strategies are starting to achieve their desired effects.

Going forward, our primary areas of focus are relaunching PANCREAZE under the VIVUS brand, improving sales and marketing for QYSMIA, identifying partners for VI-0106 and continuing to address our financial structure.

I look forward to sharing our progress towards these goals with you in the months ahead.

Thank you to everyone on the call who participated. Operator, back to you.

Operator

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