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 26, 2019

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 February 26, 2019, VIVUS, Inc., or the Company, conducted a conference call during which members of its senior management team discussed financial results for the fourth quarter and year ended December 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.

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. Fourth Quarter and Year Ended December 31, 2018 Earnings Conference Call on February 26, 2019, at 1:30 p.m. PT.

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: March 1, 2019

Exhibit 99.1

VIVUS, Inc. Q4 2018 Earnings Conference Call
February 26, 2019 - 4:30 PM ET

Operator

Good afternoon and welcome to the VIVUS fourth quarter and full-year 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, Sir.

Mark K. Oki — VIVUS, Inc. — SVP, Chief Financial Officer & Chief Accounting 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, 2018 that was filed earlier today, February 26, 2019, as well as periodic reports filed with the Securities and Exchange Commission.

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

I will now review the fourth 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 through 2019.

Qsymia net product revenue was $10.1 million in the fourth quarter of 2018, as compared to $8.9 million in the fourth quarter of 2017. The increase was primarily due to improvements in Qsymia's gross to net deductions, including sales returns and discounts. Shipments were approximately 87,000 units in the fourth quarter of 2018, as compared to 88,000 units in the same period in 2017. Approximately 83,000 and 91,000 Qsymia prescriptions were dispensed in the fourth quarters of 2018 and 2017, respectively.

PANCREAZE net product revenue in the U.S. was $7.4 million in the fourth quarter of 2018, up sequentially from $6.7 million in the third quarter of 2018 and represents the Company's second full quarter of PANCREAZE revenue. During this period, we shipped approximately 32,000 units of PANCREAZE. Beginning in the first quarter of 2019, we anticipate that future PANCREAZE net revenue — net product revenue will be impacted by higher wholesaler fees as VIVUS takes over supply chain management and implements certain promotional strategies, including the issuance of discount coupons.

During the fourth quarter of 2018, we recognized $0.5 million of royalty revenue from Canadian PANCREASE MT sales and $0.5 million of royalties from Menarini for net sales of SPEDRA.

Supply revenue to our licensees, Menarini and Metuchen, for SPEDRA and STENDRA were $1.7 million and $2.3 million in the fourth quarters of 2018 and 2017, respectively. Both Menarini and Metuchen have minimum order requirements and their orders do not necessarily reflect end-user demand.

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 increase was primarily a result of the addition of PANCREAZE product revenue during the quarter.

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 the assumption of certain post-marketing requirements (PMRs) from Janssen as part of the PANCREAZE acquisition and the initiation of the Qsymia PMR of an adolescent safety and efficacy study.

General and administrative expense was $4.6 million and $5.7 million for the fourth quarters of 2018 and 2017, respectively. The decreases were primarily due to cost control initiatives during the year. In 2019, we expect a slight increase in general and administrative costs as we continue the integration of PANCREAZE activities. In addition, G&A expenses may vary materially based on business development activities.

Selling and marketing expense totaled $3.1 million and $3.0 million in the fourth quarters of 2018 and 2017, respectively. The slight increase was due to marketing expenses associated with PANCREAZE. We expect our sales and marketing expenses to increase from fourth quarter levels with the launch of PANCREAZE in the first quarter of 2019, which John will describe in greater detail shortly. Additional expenses will include growth in our field force and potential administrative, partnering and/or promotional activities.

Total interest and other expense, net 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 $8.574 million of convertible notes. On an annual basis, we will pay approximately $19.6 million in annual interest payments on our outstanding 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.

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. It is great to have a chance to discuss VIVUS with you. 2018 was a year of transformation for the company. We started the year with a board member, Tom King, serving in the role of Interim CEO with the daunting task of executing on a strategy to transform VIVUS into a fully integrated biopharmaceutical company that generated positive EBITDA. Tom did a great job and we thank him dearly.

The strategy began to take further shape with the addition of management with significant commercial and M&A experience in myself, Ken Suh, and Scott Oehrlein, and at the same time acquiring PANCREAZE.

Starting July 1, 2018, we effectively re-booted the company. In the second half of 2018, we generated $10.9 million of recurring EBITDA, a major improvement compared with the loss of $7 million in fiscal year 2017.

We intend to continue to execute on this strategy by acquiring new products and re-energizing our existing products, PANCREAZE and Qsymia. In addition to delivering on the goal of generating positive recurring EBITDA, we have corrected or made significant progress on 14 identified issues with the business. We concluded executing a reverse stock split, buying down and restructuring the portion of our debt, improving analytics, improving profitability on Qsymia, integrating PANCREAZE, improving the financial discipline of VIVUS, and developing a go-forward plan for VI-0106.

We know from our experience that turnaround companies like VIVUS typically takes about 10 financial quarters. July 1, 2018 through December 2018 represents the completion of the first two of these 10 quarters, so in other words, we're about 20% of the way to our turnaround. We are very pleased with our progress, and we believe there is still so much more stockholder value that can be created with VIVUS in the next 24 months and beyond.

So, let's talk about the next 24 months, the other 80% of the turnaround. We are focused on the following core activities: one, growing PANCREAZE profitably; two, growing Qsymia profitability: three, continuing to license STENDRA/SPEDRA; four, continuing development of VI-0106; five, managing and preparing to pay down our May 2020 convertible notes of $181.4 million; and continuing our business development activities to acquire assets and find licensing deals

First, we will discuss PANCREAZE.

On February 19th, 2019, last week, following an efficient and smooth transition of the product from Janssen to VIVUS ownership, we relaunched PANCREAZE. In combination with our leadership, we have secured a tremendous brand leader along with an incredibly experienced sales force of 10 that will focus on GI and Cystic Fibrosis health care providers. The sales force has an average of 10-and-a-half — 10 to 15 plus years of pharmaceutical experience, primarily in the fields of gastroenterology and pulmonology. We are targeting approximately the top 40% of U.S. physicians who prescribe treatment for exocrine pancreatic insufficiency, or EPI, with our sales effort.

In addition to establishing a robust sales force, we have created the PANCREAZE Advantage Program, part of the evolving VIVUS Health Platform. Our pharmaceutical Advantage programs encompass our physician sampling program, patient access programs, co-pay cards, vitamins and nutritional supplements. We believe our program will be recognized as the easiest to use and most efficient patient support program in the US Pharmaceutical industry. We built the program using a handful of HIPAA compliant cloud technologies coupled with the VIVUS Amazon store front, demonstrating our ability to leverage technology to advance the marketing and adoption of our products.

We are hopeful and believe that the combination of our sales force, the pharmaceutical quality and efficacy of PANCREAZE and the PANCREAZE Advantage Program will enable VIVUS to generate above-market growth for the brand.

We believe that we will be able to generate six to nine percentage points of EPI market share in the next 24 to 36 months. As a reminder, each point of market share is worth approximately $1.1M of net revenue.

To provide us with an additional dose for adult pancreatitis patients, we are working closely with our manufacturing partner, Nordmark, to develop our high-dose unit of measure PANCREAZE pill, with the goal of launching this dose in the first half of 2021.

Typically, with a relaunch of a legacy branded product it takes between two and three quarters to see meaningful sales growth. We believe that in the third quarter of 2019, we will see meaningful sales growth for the PANCREAZE brand. We are optimistic that our new initiatives will lead to a faster uptick in sales, and we will have greater insight into our market position as we move forward with PANCREAZE as a VIVUS product over the next several quarters. As Mark noted, however, the launch of PANCREAZE in the first quarter of 2019 may put pressure on our operating results for the next few quarters due to the increased investment in sales, marketing and distribution.

Let’s move on to Qsymia.

First and foremost, we were pleased with how Qsymia performed in the fourth quarter, but we believe there is additional growth for this important product. There are approximately 90 million Americans with a BMI greater than 30, which may make them eligible to take Qsymia. Given the safety and efficacy of Qsymia and the well-known health benefits of losing weight, Qsymia is a drug that eligible Americans and their physicians should seriously consider as part of their treatment for high BMI. The VIVUS team has been working hard to make sure that more and more Americans and healthcare professionals have the required knowledge of and access to Qsymia, which should expand the use of Qsymia in patients who can benefit from weight loss.

Given the safety and pharmaceutical efficacy of Qsymia, we are often asked why the product has been challenged to deliver on the expectations initially laid out for it in 2012.

I’d like to take a moment now to review some of the historical challenges with Qsymia that have been barriers to realizing its full clinical and commercial potential.

There are a number of misunderstandings of the anti-obesity market. First, the assumption that the BMI therapeutics would be reimbursed like typical branded pharmaceuticals turned out to be incorrect. BMI therapeutics have little to no payor reimbursement, thus exposing the brand to more consumer-like price elasticity shaping and effectively shrinking the market based on actual price.

Second, Wall Street over-estimated the number of people with a desire to take a “pill” to aid weight loss. The reality is only about 10% to 15% of the eligible high BMI patients are willing to take a pill to aid in weight loss, and among these patients, a “pill” could be an over-the-counter weight loss supplement or a prescribed therapeutic.

Three — finally, the company and the analyst community over-estimated the duration that these patients would want to be on a BMI pharmaceutical. While the initial expectation was that these therapies would be used chronically, the reality is that they are more typically used for just three to six months.

We believe that these three factors created a shrinking effect on the market acceptance of Qsymia.

In addition to these three factors, VIVUS has been running a 15-day free trial offer in some form or another since launch with the goal of providing patients free access to the initial titration dose. The program has garnered a lot of new therapeutic starts, however, because patients haven't been on the product long enough or at higher dosages to experience weight loss, about 50% of the patients don't continue with therapy beyond the free trial. Many of these patients are led to believe the product doesn't work for them, which probably isn't the case. We are in the process of replacing the 15-day free trial offer program with an initial prescription of 45 days at $98 that allows the patient to titrate onto Qsymia, plus, for responders, experience weight loss. VIVUS generates $98 of revenue versus $50 straight loss per free trial offer script. The physician and patient feedback to date has been very positive. Due to this change, we will anticipate experiencing a decline in the number of Qsymia starter dose prescriptions, but overall, we believe the change will have a positive effect on patient new starts, profitability and revenue.

In addition to the free offer trial change, our outstanding sales and marketing team have kicked off the relaunch of Qsymia as of yesterday, February 25, 2019. As part of the relaunch, we are doing the following.

One, we are moving the market from the traditional retail channel to direct to patient home channel. This change does several things, most importantly lowering the out of pocket cost to the patient by 40% with minimal change in net revenue to VIVUS on a per script basis. We are enabling patients to order the product from home via the web once a prescription has been filed. We intend to launch a telemedicine experience for the patient, along with nutritional products and weight loss focused vitamins as part of the evolving VIVUS Health Platform and the Qsymia Advantage Program. We are creating a managed care program focused on self-insured employers and Medicare Advantage members. We don't expect this program to be live until 2020, but the initial discussions in the market have been extremely positive. We have increased the size of our Qsymia sales team from 18 to 21, utilizing three inside sales reps to contact healthcare professionals that we would not be able to address efficiently through our existing field-based sales force.

Qsymia has been used to treat over 600,000 Americans to date, and we believe that based on the changes that we are making to our Qsymia sales and marketing strategies, we will be able to expand the market size in the range of six to 11 million individuals in the United States alone. The very high price point for Qsymia to date has severely constrained the size of the market. We think that these changes would translate into meaningfully increased annual U.S. revenues.

Last month, we announced that the data supporting the cardiovascular safety of Qsymia had been published in *The Journal of Clinical Endocrinology & Metabolism.* In concert with this announcement, we also summarized key findings from multiple clinical trials and peer-reviewed publications that all support the cardiovascular safety of Qsymia. We believe that this robust body of safety data will afford patients and physicians useful information that the use of Qsymia does not increase the risk of major adverse cardiovascular events. We intend to include these findings from the retrospective observational study of claims databases in our ongoing discussions with the U.S. Food and Drug Administration related to our requested label modification for Qsymia. The requested modification will allow for the safe and effective short-term use of Qsymia and could potentially reduce or modify the need for a cardiovascular outcomes study.

As for the EU, we are planning for a decentralized submission in certain EU countries in the second half of 2019. We previously underwent a centralized Qsymia MAA submission but were denied approval. We believe that a decentralized approach will increase our opportunities to gain approval and marketing experience in certain EU countries. In addition, we expect our first ex-U.S. approval of Qsymia in 2019.

Finally, we want to update you on our ongoing dialogue with the FDA regarding our cardiovascular outcomes trial, or CVOT, post-marketing requirements. By way of background, the approval of Qsymia included a number of post-marketing requirements, including a CVOT. To date, VIVUS has satisfied or advanced each of the post-marketing requirements with the exception of the CVOT, which we are seeking to either significantly reduce or eliminate. As we mentioned earlier on the call, Qsymia is not used chronically despite this indication in its label. The vast majority of patients take Qsymia for three to six months. We have generated a significant amount of usage data supporting the CV safety profile of Qsymia. The short-term use of Qsymia coupled with the real-world safety data, in our opinion, supports the reduction or elimination of the CVOT requirement. As I mentioned previously, we have submitted an sNDA seeking a label modification from chronic to short-term usage, which we believe would justify the reduction or elimination of the CVOT. The sNDA is pending with no anticipated timeframe for a response from FDA.

In addition, we continue to respectfully engage with the FDA to identify alternative studies to the CVOT that would provide FDA with additional Qsymia CV safety data. It is our hope that such alternative studies would significantly reduce or eliminate the need for the CVOT, but to date we have not reached final agreement with the FDA on the design of any such study or the impact any such study would potentially have on the CVOT post-marketing requirement.

To conclude on Qsymia, we have learned a lot about the product and the market since approval and especially in the last eight months. It is a safe and efficacious product that delivers the positive outcome of weight loss. We have tested a couple of programs to drive sales, and they have worked. We are rolling these programs out to a larger portion of the US population. We believe that we can grow the revenue and the profitability of Qsymia. You should expect some negative impact on the script numbers as we change the sales models, but be assured, we intend to keep working to grow this product.

Let me now turn to Avanafil, which is marketed as STENDRA in the United States and SPEDRA in Europe.

As we have previously discussed, 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 2018, we received notifications of approvals to commercialize SPEDRA from Jordan, Saudi Arabia, and Turkey, and just recently received regulatory approval in the United Arab Emirates. We are expecting the completion of regulatory review in Russia in 2019. Although we will continue to drive licensing opportunities for Avanafil and manage our partnerships, we only see it as a royalty-like contributor to VIVUS' long-term financial performance.

Our product portfolio also includes a development asset, VI-0106. This development asset is a proprietary lipid-based soft capsule formulation of tacrolimus that is being developed for the treatment of pulmonary arterial hypertension, or PAH, a serious, rare and progressive 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. As a potentially class/disease-modifying medicine that could extend survival for PAH patients, we believe there is an opportunity for VI-0106 to receive fast track and/or clinical breakthrough designation from the FDA.

Tacrolimus has been approved in multiple organ transplant settings, atopic dermatitis and ulcerative colitis. The robust body of safety data for tacrolimus should help streamline the regulatory pathway for VI-0106, as should preliminary data we have related to the use of the approved tacrolimus formulation in patients with PAH. If VI-0106 receives breakthrough designation therapy, we believe there is a clinical and regulatory pathway that could lead to approval in late 2021 or 2022.

We believe that the compassionate use data, our UK based phase 1 trial data, the investigator-led phase 2 trial data, the longstanding use of tacrolimus in humans for other indications, and the dosing required for the PAH indication being less than required for immunosuppression will lend significant support to our ongoing effort to obtain approval for the treatment of PAH.

We are frequently asked about the timing of partnering this asset. While we have had preliminary conversations with interested parties around partnering, we believe that more value can be realized by moving the product further through the development process for a relatively nominal investment, while still constantly evaluating our partnering options. Partnering at this moment in time would result in our missing out on much of the upside of the asset if VI-0106 ultimately gains approval. Additionally, some of the strategic partners we have spoken with have financial capabilities that we don't have, but VIVUS' pharmaceutical approval track record is better. Some of the partners have broader commercial capabilities, but VI-0106 doesn't require an extensive sales force, only probably about 10 people, with a single dedicated medical director. Plus, VIVUS' financial position has significantly improved from mid-2018. As it stands right now, we are planning to file an Investigation New Drug application with the FDA in 2019. We will continue to explore our options with respect to raising capital specifically for VI-0106, but we are just unwilling to do something prematurely that would likely not retain value for VIVUS shareholders.

Now I would like to address the topic of our debt. We currently have a net debt position of $182 million as of December 31, 2018. If we take our fourth quarter 2018 EBITDA and annualize it, we are running at approximately 7.45 turns of net debt to EBITDA versus what we consider an acceptable standard of 5X net debt to EBITDA. While we recognize the company is still modestly over levered, we believe we have greatly improved the quality of the balance sheet of the company. Our continued focus on improving the operations and profitability should continue to further mitigate this risk. We have been in the market discussing our credit needs for the first half of next year due to the fact that we will need to refinance a portion of our debt. Given our significant improvement in performance in the second half of 2018 and the plans that we have in place for 2019 and the first quarter of 2020, our collective anxiety has significantly subsided. We now believe there are multiple paths to solve this issue once and for all. Now this doesn't mean our debt still isn't a challenge, but we believe this risk has significantly been reduced.

As we work to maximize the value of our current product portfolio and advance VI-0106, we are also seeking new cash flow-positive product and corporate acquisition opportunities. We have evaluated 24 plus deals and have submitted a number of letters of intent. We have lost a couple of deals because of price, we offered lower than owner wanted and in one case were outbid by 50 plus percent. Some of the other deals are still under consideration.

We are evaluating candidates that would meet our goals and fit our criteria of meeting patients' needs while working toward profitability and building stockholder value.

Bottom line is we want to and can acquire assets but will only do so if they meet our criteria.

We are also evaluating co-promotion deals as well. We have expanded commercial capabilities, our Advantage programs along with the ever expanding VIVUS Health Platform make us a very attractive co-promotion partner.

In conclusion, I believe that 2018 was a truly transformative year for VIVUS. Our newly combined management team has developed and is successfully executing an array of strategies designed to position us for long-term, sustainable profitability and success. As I mentioned, we are just about 20% of the way through our turnaround. We believe that the changes and progress we have already achieved in reducing our debt, increasing our EBITDA, developing and implementing new sales and marketing strategies and identifying multiple opportunities to grow revenues from our current commercial portfolio, should provide clear evidence that we have what it takes to reach our goals.

We have already made significant progress on our key portfolio objectives for 2019 by re-launching PANCREAZE under the VIVUS brand and the deployment of our sales force team. Our expanded sales force with multiple new capabilities around Qsymia are very exciting. We are also focused on implementing the Advantage model for Qsymia and PANCREAZE. As I have indicated each quarter since becoming CEO last spring, reducing our debt, increasing EBITDA, acquiring EBITDA-positive assets and achieving an appropriate leverage ratio will continue to be our overarching priorities in 2019 and 2020.

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*]

We'll take our first question from Jim Birchenough with Wells Fargo Securities. You may begin.

Chuck Whitesell — Wells Fargo Securities

Hi. Congratulations on all the progress. This is Chuck Whitesell for Jim. I know you talked about your plans for refinancing debt and making progress on that front. Can you speak at all, give any insight to cash runway at this point?

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

Sorry, we had a hard time hearing you. Can you repeat that?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah.

Chuck Whitesell — Wells Fargo Securities

Yeah, thanks for the update on the plans to refinance debt through 2020. Can you speak to the cash runway position, how that looks?

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

Yeah, I mean, our biggest factor is the convertible notes that are due in May of 2020. We have more than sufficient cash to get us to that point, but we have to do some refinancing or raising capital some way prior to actually paying off that debt.

Chuck Whitesell — Wells Fargo Securities

Okay, all right, thank you.

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

Thanks.

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah, let me just further to add on that, we're effectively not burning cash anymore — maybe a little bit because our expenses are going to go up in Q1, Q2, just because of the re-launch of PANCREAZE. But overall, we've made tremendous progress in eliminating the cash burn that company has had for the last few years.

Chuck Whitesell — Wells Fargo Securities

Okay, good. Thank you very much.

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah.

Operator

[*Operator Instructions*]

And our next question comes from John Vandermosten. You may proceed.

John Vandermosten — Zacks Small-Cap Research

Good afternoon, John and Mark. I wanted to ask just about additional geographic opportunities for licensing Avanafil. And I'm especially thinking about the former Sanofi territories. What opportunities are ahead in that area?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah, so definitely the Middle East is a big opportunity for us there. So we're looking at a comprehensive set of — there's probably three or four folks that we're having conversations with right now around continuing to extend our market penetration, particularly in the Middle East. As we see Russia and Central America and Mexico, those are additional opportunities as well for us. So probably see seven or eight territories, probably encompassing, call it a half billion people from a population perspective — well, call it 250 million people from a population perspective.

John Vandermosten — Zacks Small-Cap Research

Okay, thank you.

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah. Thanks for the question, John.

Operator

[*Operator Instructions*]

If there are no further questions, I will turn the line back over to John Amos for closing remarks. Sir, you may proceed.

John Amos — VIVUS, Inc. — Chief Executive Officer

Oh, Operator, it appears that we have one more question from Steve Slavin.

Operator

Mr. Slavin, you may please go ahead.

Steve Chlavin — Investor

Yeah, hi. Congratulations on the nice turnaround, it looks very impressive.

John Amos — VIVUS, Inc. — Chief Executive Officer

Thank you.

Steve Chlavin - Investor

I had a question about your new marketing for Qsymia and I was wondering if you're going to do some — any type of television advertising or going directly to people that might not think about going through a doctor, but aren't aware of the product, because you have such a great story and a great track record. I would think that TV ads, sending them to a website would possibly help. What are your thoughts on that?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yeah, no, it's a great question, Steve, and I appreciate it. I think what we did do as one of the initiatives, we changed the way that we're managing our digital campaign. And what we found is that the return on investment for focused digital campaigns are a much better return on investment than television advertising. It allows us to do a much more finite and targeted messaging, and we're able to — through our digital ad campaigns, we're able to more quickly and rapidly identify patients that will benefit from our therapy.

I think the — if you look at some of the other competitors in the product, they did focus and utilize television ad campaigns to drive their volumes. And while they were initially successful, ultimately it led to basically a bankrupt financial model. They just ended up not working properly. And so, what we're further doing is really improving access around the program as well too. So, with the introduction of telemedicine, we're effectively eliminating the number of the barriers. Right now, a patient has to go into the physician's office, actually has to interact with the physician. What we're really trying to do is make this a process that is very — something that you can do from the comfort of your own home. This is also — weight loss is very similar to ED in terms of it's what is referred to as a "door-handle" conversation. So right before the patient leaves a physician's office, as they're holding the door handle, they turn around and they say, hey, what about weight loss products. And by moving to telemedicine and utilizing advanced digital metrics for patient identification, we believe that we'll be able to track some growth there. So, we're going to stay off of traditional television. It just burns a lot of cash, hard to measure ROI, and we're going to stick with programs that are more effective in terms of driving shareholder volume. Does that answer your question?

Steve Chlavin - Investor

Okay, another question — yes, thank you. And also, what are the possibilities of this product before the patent expires or your exclusivity about getting an over-the-counter type of approval? Is that any — any possibility?

John Amos — VIVUS, Inc. — Chief Executive Officer

No, that's — I would never say never, but I'd say pretty close to never. It has phentermine in it, and phentermine is a controlled substance. It's called a C4 class drug. And for vast majority of — well, all C4, C3, C2 drugs are all managed and monitored pretty heavily by the DEA. So I think the probability of us moving to that over-the-counter is severely — very, very extraordinarily low profitability — probability and it's not something that we're pursing with the FDA.

Steve Chlavin - Investor

All right, well, thank you very much. And I really do notice the way you guys are turning the company around and turning it into an actual business, where you're running it kind of like a business model instead of just throwing products around. I really see you doing a great job. Thank you.

John Amos — VIVUS, Inc. — Chief Executive Officer

Thank you very much. Appreciate your time.

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

Thank you.

Operator

Thank you. If there are no further questions, I will now turn the call back over to John Amos for closing remarks.

John Amos — VIVUS, Inc. — Chief Executive Officer

All right, thank you everybody for your time today. We're excited for 2019 to be our first full year under new management team and believe that the accomplishments we made just the few months in 2018 and beginning of 2019 are important evidence of what we will achieve in the year ahead.

Mark and I look forward to sharing our progress with you. And, operator, we'll hand it back over to you.

Operator

And that concludes today's call. All parties may now disconnect. Have a great day.