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): **March 3, 2020**

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	VVUS	The Nasdaq Global Select Market
Preferred Share Purchase Rights		

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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 March 3, 2020, VIVUS, Inc. (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, 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 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 Ended December 31, 2019 Earnings Conference Call on March 3, 2020, 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 6, 2020

Exhibit 99.1

VIVUS Q4 2019 Earnings Conference Call

March 3, 2020 – 4:30 PM ET

Operator

Good afternoon and welcome to the VIVUS fourth quarter and full year 2019 financial results conference call. At this time, all participant lines are in listen-only mode. After the speakers' presentation, there will be a question and answer session.

[*Operator Instructions*]

Today's call is being recorded. An accompanying slide desk is available on today's webcast and also available on the presentation page of the VIVUS Investor Relations website.

For introductions and opening remarks, I'd like to turn the call over to Mr. David Carey with Lazar FINN 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, 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. As noted on Slide 2, 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, 2019, which was filed earlier today, March 30th, 2020[1], 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'll now turn the call over to John Amos.

John Amos – VIVUS, Inc. – Chief Executive Officer

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

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[1] Speaker intended to say March 3rd, 2020

We have spent the past 18-plus months focused on turning VIVUS into a specialty pharmaceutical company with a leading digital health platform. As you can see on Slide 3, 2019 was the first full year under our 10-quarter turnaround strategy, and we've ended the year with real traction to meet our turnaround objectives as planned. Shortly, I will review the performance of our commercial products in detail.

There are multiple key takeaways from today's call.

1. We have turned the tide on Qsymia®. The team has delivered four consecutive quarters of growth in both the percent of total market share and the percent of new prescriptions for anti-obesity medications.

2. We have also stopped the year-over-year slide in the number of PANCREAZE® scripts and sales, which had been the trend for this product before we acquired it in 2018. We have had three consecutive quarters of script stability. This turnaround has been tougher than anticipated, but we believe we have stabilized the product.

3. One challenge that companies typically have while executing a turnaround plan is making decisions on how to invest for the future while making sure you can meet the needs of the company currently. We've made investments in research and development to support the Qsymia safety and efficacy study in adolescents; we have made investments to improve product lifecycle management for PANCREAZE; and finally we have continued to focus on the opportunity VI-0106 holds for patients and VIVUS shareholders.

We believe that these results clearly demonstrate our ability to create value from our commercial portfolio, and we are confident that the innovative sales and marketing strategies that we have implemented will support continued prescribing and revenue growth going forward.

Now I'll dive into some of the more detailed information that provides the foundation for our confidence, beginning with the several notable developments within the company and our key markets as shown on Slide 5.

First, with respect to our company, the FDA approved the supplemental New Drug Application for the improved formulation of PANCREAZE with a 36-month shelf life. We expect that this formulation will limit the amount of product returned to us, reducing our costs as well as potentially reducing the out-of-pocket expenses for patients.

We also reported that the new data from a real-world study of Qsymia showed that patients who selected Qsymia compared with other weight loss management tools achieved at least a 5% weight loss. This data adds to the robust and growing body of clinical evidence supporting the safety and clinical efficacy of Qsymia, and we believe that they will help to drive increased prescribing of Qsymia.

Consistent with our strategy of capturing an increasing share of the global market for anti-obesity medications, our partner Alvogen officially launched Qsymia in South Korea. This is an important milestone in accessing the Asian anti-obesity therapy market and will also provide us with a new source of royalty revenues.

We made progress in our pipeline and expect to have additional news related to the timing of the filing of our IND and the initiation of a clinical trial for VI-0106, our pulmonary arterial hypertension, or PAH, development candidate in the weeks ahead.

Turning to notable market developments, the U.S. Food and Drug Administration, or FDA, requested the withdrawal of Belviq, an anti-obesity medication, from the market in February of 2020 based on new data demonstrating the potential for an increased risk of developing cancer. Eiasi voluntarily recalled Belviq the same day as the FDA requested the withdrawal. We believe that this situation creates an opportunity for Qsymia, both with respect to gaining new scripts from patients who had been taking Belviq and are now seeking an alternative anti-obesity medication, as well as reducing competition for Qsymia among patients initiating anti-obesity medication.

Additionally, Allergan sold ZenPep, the second largest product in the Pancreatic Enzyme Replacement Therapy, or PERT, market and competitor to PANCREAZE, to Nestlé. Now, we believe that the product will continue to be a tough competitor in the marketplace, and as of right now, we don't anticipate a material change in our PANCREAZE strategy.

We believe that each of these market events will benefit our products and are confident that we are positioned to capture increasing shares of these markets as their respective landscapes evolve.

I will now provide additional detail on Qsymia.

Key fourth quarter 2019 takeaways for Qsymia are summarized on Slide 6.

Revenue was up slightly in the fourth quarter compared with the third quarter of 2019, and Mark will provide more detailed financial information later in the call.

Script volume in the fourth quarter of 2019 increased compared with the prior year period, and while down slightly compared with the third quarter of 2019, this slight decrease is actually an improvement in the trend of decreasing fourth quarter scripts, which occurs every year as people change their eating and dieting habits around the holidays. This decrease from the third to fourth quarter of 2019 was 3%, which was an improvement compared to a decrease of 7% in the year – in the prior period year.

We continue to gain significant traction in our direct-to-patient Qsymia Advantage program, with 31% of all Qsymia scripts coming from this program in the fourth quarter, compared with 22% in the third quarter of 2019. We also continue to see traction driven by our sales representatives as they make progress in portions of the market which we previously weren't engaged. During 2019, we started a pilot program to utilize inside sales reps coupled with our digital program and continue to be encouraged by the team's progress.

The Qsymia sales performance over the past eight quarters is shown on Slide 7.

As noted, the blue portions of the bars represent sales through the traditional retail pharmacy and the yellow portion represent sales through our direct-to-patient Qsymia Advantage program. There are a few things I'd like to highlight here.

The total number of scripts grew in the third and fourth quarters of 2019, compared with these periods in 2018. This is the first time in five years that we have grown fourth quarter scripts year-over-year. Scripts from our dedicated or our direct-to-patient Qsymia Advantage program has grown steadily over the past four quarters but appears to be normalizing.

There a few other points I'd like to make about the Qsymia Advantage program.

First, patients filling a prescription through the program appear to be more durable compared with patients filling their scripts at a retail pharmacy, based on 90-day scripts. Additionally, 94% of the online Qsymia scripts are filled, compared with only 65% of scripts that need to be filled at a retail pharmacy. More male patients are using Qsymia Advantage to fill their scripts, which may reflect the ability of the program to eliminate the discomfort that many men have discussing their weight. This is an important aspect of the program – for both men and women – which may help to remove barriers to care and enable more patients to take positive steps toward achieving and maintaining a healthy BMI. We have been told consistently that both men and women feel some level of shame when utilizing pharmaceuticals for weight loss.

Slide 8 shows the Qsymia market share in orange as a percent of the total market for branded obesity therapies. As shown, Qsymia has experienced growth over 2019, especially following the full launch of the Qsymia Advantage program in May, while Contrave and Belviq, two of the product's main competitors, had some substantial headwinds. As I noted at the start of the call, Belviq was withdrawn from the market last month, which may help to further drive increases in Qsymia scripts.

Slide 9 shows total new Qsymia scripts in orange and the Qsymia market share of all new scripts in blue. As shown, there has been an increasing trend in new Qsymia scripts since 2017, and in 2019 the share of new scripts has increased quarter-over-quarter.

As I noted at the start of the call, we believe the growth in Qsymia scripts and the percent of market share are strong evidence of our ability to drive additional value from this product, and we expect to see continued growth in both these metrics over the next few years.

Now let me turn to PANCREAZE.

Key Q4 2019 PANCREAZE highlights are shown on Slide 10.

Total PANCREAZE sales were up slightly in the fourth quarter compared with the third quarter of 2019, with a significant increase in topline Canadian sales. As noted, we have also achieved three consecutive quarters of script stability in the United States, which we believe indicates a reversing of the declining trend that had been in process when we acquired the product in 2018.

We have also received FDA approval for the advanced formulation of PANCREAZE with a 36-month shelf life and expect to launch that product in the U.S. in the fourth quarter of 2020.

In November of 2019, we submitted a pediatric investigation plan to the Canadian regulatory authority in anticipation – and anticipate approval of the plan in August 2020.

Slide 11 shows the quarterly performance of PANCREAZE from the first quarter of 2016 through the fourth quarter of 2019, with new scripts shown in blue and total scripts shown in orange. As shown, total and new PANCREAZE scripts had been declining for 13 consecutive quarters. Beginning in the second quarter of 2019, we have now seen three consecutive quarters of script stability and are investing in new sales personnel and implementing programs, such as making PANCREAZE available through the VIVUS Health Platform and the PANCREAZE Advantage program in order to begin growing the market share for this product.

We have recently entered into a contract with a large national PBM, which will go live in July of 2020 and is designed to afford PANCREAZE better formulary placement. We also believe that the 36-month shelf life will allow us to capture more sales while lowering our overall supply chain costs.

Slide 12 shows PANCREAZE script trends since VIVUS re-launched the product in February 2019, with total scripts shown in green and market share shown in purple from 2018 to February 2019, and in blue from 2019 through the end of the year. These trends demonstrate that our promotion efforts to date have reversed the decline in PANCREAZE scripts and the market share and have produced modest growth, with a 2% increase on a daily script basis in the fourth quarter of 2019 compared with the third quarter of 2019, and a 1% working day script growth since its launch in February 2019.

Slide 13 summarizes the status of STENDRA®/SPEDRA™. This product that has been partnered out or licensed in various global territories. We continue to collect royalties and manage the manufacturing processes for our marketing and license partners. We are working with these various partners in this program to reduce our working capital exposure for the program – for the product and to improve our return on invested capital. We are also continuing our efforts to find commercial partners in key open territories, including the Middle East, Mexico and Russia.

Turning to Slide 14, I’m pleased to report that we have made additional progress in our VI-0106 program, our investigational therapy for pulmonary arterial hypertension, or PAH. We noted in our last quarterly call that we had adjusted the chemistry of the product formulation in order to address a stability issue. The results of the stability testing of the new formulation are preliminary but look promising, and we hope to provide an update on the resolution of the stability and timing of the filing of an IND and starting a clinical trial in the second half of 2020. We are hopeful that following validation of our data we can provide a further update in the weeks ahead.

Slide 16 – we engaged Piper Sandler in Q4 of 2019 as the advisor for VIVUS to work through the complex details of our refinancing effort. We are focused on obtaining a capital structure that allows us to grow the company while still investing in VI-0106. We are engaged with multiple capital providers regarding a complete refinancing of the capital structure of VIVUS to fund our operations and repay our debt as it matures. We are focused on both the immediate date of the refinancing and also working hard to ensure that the company is properly financed to leverage the opportunities that are before it in its business.

Slide 17 summarizes our key growth drivers for 2020. We are very pleased with our achievements in 2019 and believe that we have generated significant momentum in increasing total scripts and market share for Qsymia and PANCREAZE. We intend to carry out that momentum into 2020 as we continue executing on our 10-quarter turn around.

For Qsymia, we continue to expand the Qsymia Advantage program, the VIVUS Heath Platform and are in the process of launching our program combining Qsymia, telemedicine and technology.

We will also be focusing on self-insured employers, Medicare Part D patients and other managed care customers.

With respect to PANCREAZE, we will continue to build on our sales team's progress in engaging with key prescribers and will be highly proactive in building visibility and awareness for the brand at multiple medical conferences throughout the year.

I will now turn the call over to Mark Oki to review the financials of Q4 2019 in more detail, after which Dr. Varghese, who will provide an update on our clinical programs.

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

Thank you, John.

As we just completed the sixth quarter of our 10-quarter turnaround, as a result, we believe that comparing the fourth quarter of 2019 with the third quarter of 2019 will provide you with a better indication of how our turnaround efforts are progressing as shown on Slide 18.

Qsymia net product revenue was $9.8 million and $9.6 million in the fourth and third quarters of 2019, respectively. As John mentioned, we continue to see an increase in the number of scripts filled as we transition from the traditional retail pharmacy model to the Qsymia Advantage program. In the fourth quarter, 31% of Qsymia scripts were dispensed through the Qsymia Advantage program's direct-to-patient model, up from 22% in the third quarter and 8% in the second quarter.

While we experienced a 3% seasonal drop in Qsymia scripts compared to the third quarter of 2019, this is significantly less than the 7% decrease between the same periods in 2018.

PANCREAZE net product revenue was $5.8 million in the fourth quarter of 2019 compared to $5.3 million in the third quarter of 2019. In the third quarter, we assumed commercial responsibility for Canadian PANCREASE MT sales, and as a result recognized Canadian revenues of $0.9 million in the fourth quarter as compared to $0.1 million in the third quarter of 2019.

Fourth quarter supply revenue was $1.2 million, which consists of sales of Qsymia to Alvogen to support the recent launch of Qsymia in South Korea. We remind you that supply revenue is impacted by minimum order requirements and supply chain management by our partners and may not reflect end-user demand, nor do we consider this revenue a driver of economic performance of VIVUS.

In the fourth quarter of 2019, revenue related to royalties earned from Menarini SPEDRA sales, which has typically run from $500,000 to $600,000 per quarter, was approximately $500,000 in the fourth quarter.

While we did not record any milestone revenue in the 2019 fourth quarter, we will receive $2 million from Alovgen's launch of Qsymia in South Korea that was announced last month. Milestone revenue in the third quarter of 2019 represents the payment received related to Alvogen obtaining marketing approval for Qsymia from the South Korea Ministry of Food and Drug Safety.

Total cost of goods sold, excluding amortization, was $4.0 million and $3.0 million in the fourth and third quarters of 2019, respectively. The increase was primarily due to the increase in Qsymia and PANCREAZE product sales as well as the increase in supply revenue over the third quarter.

Amortization of intangible assets was $3.6 million in both the fourth and third quarters of 2019. This amount was primarily the amortization of costs capitalized related to the acquisition of PANCREAZE.

Research and development expense was $2.4 million and $3.3 million in the fourth and third quarters of 2019, respectively. Research and development expenses were primarily related to the Qsymia adolescent safety and efficacy study, PANCREAZE post-marketing requirements assumed from Janssen, and PANCREAZE product improvement initiatives.

Selling, general and administrative expense was $10.9 million and $9.2 million for the fourth and third quarters of 2019, respectively, and included selling and marketing expense of $4.3 million and $4.5 million, respectively. During the quarter, we incurred approximately $1.9 million of severance costs.

Total interest expense, net, was $2.9 million and $9.9 million in the fourth and third quarters of 2019, respectively. The decrease in interest expense in the fourth quarter was primarily a result of prepayment premiums related to the reduction in debt balances incurred in the third quarter.

Net loss for the fourth and third quarters of 2019 was $6.5 million and $11.1 million, respectively. Cash and cash equivalents were $32.6 million at December 31, 2019.

Recurring non-GAAP EBITDA for the fourth and third quarters of 2019 was $2.3 million and $1.2 million, respectively.

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. Varghese for a clinical and product life cycle update.

Dr. Santosh Varghese – Senior Vice President, Chief Medical Officer

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

With respect to Qsymia, as per our announcement on Monday and as shown on Slide 17, we have completed enrollment of subjects in our Phase 4 study designed to evaluate the safety and efficacy of Qsymia in obese adolescents between the ages of 12 and 17 years. We expect the last subject to be completing treatment by the end of Q1 2021. We believe that Qsymia could be an important part of integrated strategies to address adolescent obesity, and this study is designed to provide clinical data to support a potential label expansion for this indication.

We have also reported results from two studies that further support the efficacy of Qsymia. In November 2019, the results of a clinical study were published demonstrating that patients with binge-eating disorder or bulimia nervosa receiving Qsymia had a significant reduction in binge day frequency compared with placebo over four weeks and was well tolerated in these patient populations. The study results appear online in the *International Journal of Eating Disorders*.

In January 2020, the University of Colorado announced the publication of new results from its Toolbox Trial, a real-world clinical trial conducted in urban safety-net primary care clinics offering patients a “toolbox” of cost-effective weight management tools. The study, published in the Journal of General Internal Medicine, found that a higher proportion of subjects who initially selected Qsymia from the toolbox or added it to their weight management plans during the study period achieved at least a 5% weight loss compared with subjects who never used Qsymia.

We continue to have productive discussions with the FDA regarding a study designed to evaluate the effect of Qsymia on ambulatory blood pressure. We believe this study could provide us with new data to further inform our dialogue with the FDA regarding our post-marketing cardiovascular outcomes trials, which was required as part of the initial approval of Qsymia. We hope to have a final protocol agreed upon in the next quarter.

We also continue to work with researchers at major institutions to develop clinical protocols and initiate the related clinical trials to evaluate health technology platforms to augment and track patients’ efforts in weight management. We hope to have more information in the coming months regarding the results of these efforts.

Finally, we expect that the European Medicines Agency will respond to the decentralized Qsymia Marketing Authorization Application in the second quarter of 2020.

Turning to PANCREAZE, the FDA approved the sNDA for the 36-month shelf life formulation in February of 2020, and we continue to evaluate additional pancreatic studies, including those in pancreatic oncology. We are currently working to start a study with Cedars Sinai Hospital in Los Angeles, California to look at the treatment of exocrine pancreatic insufficiency in patients with pancreatic cancer.

Finally, as John also discussed earlier, we anticipate filing the IND for VI-0106 and initiating the planned Phase 2 clinical study in patients with PAH after finalizing our unique proprietary once-daily extended-release formulation. We believe this formulation will facilitate therapeutic drug levels while minimizing immunosuppressive effects for patients with PAH.

This concludes our opening remarks. Operator, you may now open the line for the question and answer period.

Operator

[*Operator instructions*]

Please stand by while we compile the Q&A roster.

Our first question comes from John Vandermosten with Zacks. Your line is open.

John Vandermosten – Zacks Investment Research

Good afternoon, John, Mark and Santosh. Hope you're having a nice day. I wanted to start out with a question just on the capital structure and how it may change or how the balance of it may change after refinancing. I mean, obviously, you're -- most likely you're in negotiations right now, but I was just wondering what you can tell us about that.

John Amos – VIVUS, Inc. – Chief Executive Officer

Yes. I think, what we're trying to do, John, is find -- unfortunately, we can't give you a concrete answer right now. What we are working to try and do is make sure that we focus on current shareholders of VIVUS, we make sure that the company is set up so we can actually grow the business, long-term, and make sure that we can really take advantage of the VI-0106 opportunity. We are pleased with our chemistry performance and the modification that we made. And we still have a fair amount of work to do to validate it, but so far, it's interesting to us. So, we're really trying to come out of this 10-quarter turnaround plan of which quarter seven is really -- was deemed and tasked as the time to get our capital structure properly structured. So, then those last three quarters we can really just focus on growth and continued R&D development. We're going to make announcements over the next six to eight weeks, we believe, as these discussions mature.

John Vandermosten – Zacks Investment Research

Okay, thank you for that clarification. And then, there's been a lot of good news out there for Qsymia, some of the research that's been done, some of the studies have been fairly positive. And I'm wondering if you can modify your platform to take advantage of these new -- some of these new benefits, you know, adolescence -- I'm not sure if it's able to be used off-label or it is used off-label, but is there a way to leverage your platform to take advantage of some of the new populations that are shown to have benefit?

John Amos – VIVUS, Inc. – Chief Executive Officer

Yes. So, we can't comment obviously on off-label usage of the drug. So, in terms of what we're focusing on, in terms of on-label utilization of the drug, we are expanding our conversation with bariatric surgeons. We are expanding our conversation with GIs. One of the things that we found in the GI space is that patients who have gone through bariatric surgery, a surgical event maybe two three years prior are starting to have some weight issues coupled with GI issues. And so, we're starting to see GIs actually start to prescribe Qsymia. We just kind of really figured it out probably over the last six to nine months. So, that's one area. With the binge eating disorder data, obviously going and having conversations with binge eating or specialists is on the platform.

I'll turn it over to Dr. Varghese if he has any additional comments.

Dr. Santosh Varghese – Senior Vice President, Chief Medical Officer

Yes. I think the -- those that are within our indications, such as what John mentioned, the bariatric surgeons and those treating those types of patients, those are on-label discussions because they are patients who qualify as obese or overweight, and they may or may not have co-morbidities in that case if they're obese. But those are well within the patients that we already can treat on label, and we are exploring other avenues based on this information that we've been getting from individual researchers who have conducted various investigator initiated studies on other areas for further investigation and data collection to see what may warrant the discussions with the FDA for label expansion.

John Amos – VIVUS, Inc. – Chief Executive Officer

And I think one final point there too is the Qsymia label is excellent. There's a very, very large number of patients that are eligible for therapy. And one of the challenges for Qsymia is really just letting people know about the product and the efficacy associated with the product. And so, there are a couple of initiatives that we're rolling out throughout the course of 2020 to really try to raise brand awareness around the product and coupled with some additional scientific information around evolutionary biology and why we eat. And I think we're hopeful that those will be promising, and we'll talk about those over the next couple of calls.

John Vandermosten – Zacks Investment Research

Okay. And any sense of the size of the market that the withdrawal of Belviq opens up to you?

John Amos – VIVUS, Inc. – Chief Executive Officer

You know, it's still early, John. It's a great question, it's one that we're definitely trying to figure out. We've had a number of clinics that we've reached out to and that have reached out to us, which I would call – some of the weight loss clinics across the United States, the anti-obesity clinics across the United States, they tend to anchor on a therapy. So, there'll be -- they write a lot of Belviq or they write a lot of Qsymia or they're Saxenda shops. And a number of Belviq shops, because it's an oral solid, have been reaching out to us, and so we're starting to have those conversations.

We know that our drug as well as Saxenda are both efficacious pharmaceuticals. We believe our safety profile is better. Sorry, I had to look at Dr. Varghese to make sure I was allowed to say that. But, ultimately, we believe that we have a better safety profile, and our efficacy has been demonstrated through real world data that we've collected, tremendous efficacy within the label of the product. So, it's really early, the product just came off the market mid last month, but hopefully, obviously, there's a lot of other things going on in the world right now related to health, but we're hopeful over the next two or three quarters to see some demonstration there and have further conversations with these clinics as we try to move them onto their Qsymia Advantage Platform.

John Vandermosten – Zacks Investment Research

Okay. And last question is just on the telemedicine. That seemed to have started off pretty nicely, and I was wondering if there's any update there on how that's progressing.

John Amos – VIVUS, Inc. – Chief Executive Officer

Yes. So, the software, it took us a tiny bit longer to get through the software contracts. So, we are utilizing a third party. We'll make some announcements about that here in the next couple of weeks. Overall, we're -- we believe that we're really well positioned. We've got a couple of doctors on the platform. We are I'd call it six weeks behind on that, but we expect to rapidly catch up. Doctors are really interested in this program, and we just needed to make sure that we had kind of all of our I's dotted and T's crossed. There's a HIPAA component to it, there's a utilization component to it, there's a billing component to it. And so, it just took us a tiny bit longer to get through that, but we've gotten through the software contract, we're developing training materials, we've got a couple of clients on the platforms and we're going from there.

John Vandermosten – Zacks Investment Research

Thanks for taking my questions.

John Amos – VIVUS, Inc. – Chief Executive Officer

Yes, no thank you, John. We appreciate the interest in the company.

Operator

Our next question comes from line of Jim Birchenough with Wells Fargo Securities.

Chuck Whitesell – Wells Fargo Securities

Hi, it's Chuck Whitesell in for Jim Birchenough. Congratulations on all the progress. Just kind of a follow-up to John's question. In terms of the capital structure and your discussions there, and then the Belviq opportunity possibly opening up, those could be parallel tracks, but is there some consideration to maybe having that as an all-encompassing new vision for the company or restructuring, if you will, keeping in mind the opportunity that may now be possible with Belviq? Thank you.

John Amos – VIVUS, Inc. – Chief Executive Officer

Yes, that's a great question. So, a couple of things there. So, there's a little bit to unpack here. So one of the things we're trying to do, we've been burning $20 million a year of cash in interest expense. And so, you're sitting here faced with this growth opportunity, potentially with Belviq. Dr. Varghese and the clinical team have done a fantastic job, in my opinion, of expanding the clinical data around Qsymia. And so, we believe that we're very well positioned to go out and compete more effectively in the marketplace. The sales and marketing programs that we put in place where Qsymia Advantage have shown growth, and we think some of the things that we're going to do around raising brand awareness are really innovative, really interesting, and really kind of get through the shame issue of obesity and high BMI patients. And so, that's this opportunity that sits in front of us. And so, the conversation that we're having around with the engaged capital partners is making sure that we're not putting the company in such a position where we have these kind of overhang EBITDA requirements that prevent us from making good decisions about driving investment to grow the overall equity value. So, that's the balancing act that we're in. Belviq coming off the market, it was obviously -- that's a pretty interesting opportunity. But, as I answered for John, we don't -- we're still early in that process. We can speculate and we believe that yes, we're -- Belviq is gone, we competed against that therapy very well. We've had pretty nice inbound interest from folks. So, in terms of revisioning the company overall, this is -- was always our plan as part of the 10-quarter turnaround.

So, obviously, our maturity occurs on May 1st. And so, we've obviously got to get all of that solved, but we've been working with Piper Sandler since Q4, early Q4 of last year. So, we're well down the process of getting this done.

Chuck Whitesell – Wells Fargo Securities

Okay, thank you very much for taking the question.

John Amos – VIVUS, Inc. – Chief Executive Officer

No, thank you. We appreciate it.

Operator

[*Operator Instructions*]

Our next question comes from the line of Robert Mendrala, a private investor. Your line is now open.

Robert Mendrala, Private Investor

Good afternoon, gentlemen. Thank you for the update. Really appreciate it. A lot of color there. Just a thought going back to Belviq, John. Orexigen was a competitor in the past. They went out of business. I believe Pernix Therapeutics bought them. I believe the name of the drug was Contrave, and they bought it out for $75 million, and Pernix is not doing too well. I think they're out of business. Were there any learning lessons that happened from that event a few years ago that could be applied to what's going on with Belviq and Eisai?

John Amos – VIVUS, Inc. – Chief Executive Officer

Yes. No, I think, the two situations are very, very different. So, the issue with Contrave and Orexigen – I think the lesson -- there is the lesson there. Don't spend $60 million to $75 million on a direct-to-consumer advertising campaign. I think that was probably the driving force behind their exit from the marketplace. The product -- Contrave is actually a decent product. We have respect for that product, but it works for a smaller segment, based on real world data that we've seen. It works for a smaller segment of the population. Belviq, we felt, we've always felt that we competed extremely well against that product from a head-to-head perspective, from an efficacy perspective. And so, if you look at Eisai's decision and how they made that decision, we had heard that their -- how would you say, their emphasis on that product and continuing marketing efforts around the Belviq product in the marketplace, all the rumors that you hear were waning. And so, we're not surprised that once the FDA came out with this conclusion based on their data, that Eisai agreed very rapidly with the FDA to pull the product from the marketplace. So, I think, the learning there is, okay, how do we go – or the opportunity for us there is to those previous, John and Chuck asked, how do we go capture some of that market share, build brand awareness. VIVUS for a long time, for the previous few years, as you can see it in the performance figures, really didn't build brand awareness around Qsymia and didn't really contribute in a meaningful way to the data profile of the product, and that's something that we've been very focused on. We've been very focused on getting back on the podium, engaging with physicians in a more meaningful way, engaging with obesity societies in a more meaningful way, talking to payers. So, those are the things that we're really trying to execute on.

Robert Mendrala – Private Investor

Okay. Thank you, John. And another question, STENDRA/SPEDRA, Menarini has bought out the rights and they are paying royalties to VIVUS. You mentioned about other markets to pursue.

I think it’s a great product. Could you add a little more color on what you’re pursuing, because it really is a product they need there?

John Amos – VIVUS, Inc. – Chief Executive Officer

Yes. We always joke it really would have been the one product in the marketplace had it been launched originally, or first to market, excuse me. So, I think what we’re trying to do is we spend a lot of time going through these marketing efforts on individual territories, and they require a fair amount of effort on each individual territory. And so, what we’re really looking for right now and then we’re having active discussions around trying to find somebody to take over the products on a global basis. And so, there is people who’ve expressed interest in that. And that’s really just been probably in the last four -- three, four months that we’ve made that decision strategically to look for a partner that can think about the product on a more global basis.

Robert Mendrala – Private Investor

Off the top there, my understanding was Menarini possibly might have tried to attempt an IPO attempt fourth quarter. I don’t know if they were successful or not, but it might be a player as well there, possibly. But anyway, both markets for Q and STENDRA/SPEDRA I think are -- it’s ripe, it’s a great marketplace on both ends.

So, with respect to the Nestlé ZenPep, that was a very interest – I never thought that Nestlé would get into the PANCREAZE marketplace. But would you agree, John, that lower cost for PANCREAZE as well as a longer shelf life are really good competing strengths for VIVUS against ZenPep?

John Amos – VIVUS, Inc. – Chief Executive Officer

Yes. I think, there’s obviously greater price sensitivity with payers in the marketplace around these products -- around every pharmaceutical product. When we acquired the product, we had -- we didn’t have any clinical deficiencies, but we had a unit of measure deficiency at the large unit measure side, which we’re working hard to address that as well. And then, we had this shelf life issue. So, we knew both of those things were problems. And on our commercial basis, we’ve been really transparent. Like hey, we stubbed our toe in February of last year. We think we’ve stabilized the product now, just given the last three quarters of performance. Sales and marketing team is doing the good job. We have good response from clinicians. We are having good, very, very productive conversations with the PBM and the payer market. We’ve secured and closed the contract that will be active in July of 2020 with a large PBM. And so, it’s I think the value of PANCREAZE we still absolutely, positively believe in. We continue to invest in the brand. We continue to sort through the previously aforementioned problems, and we’re improving the commercial platform on a quarter-by-quarter basis. And so, that’s a product that we believe in for the next 10 to 15 years. So, it’s going to take us a couple of quarters longer to get to where we wanted to go. But we’re chipping away at that. And that’s what it takes in this industry.

Operator

And that will conclude our question-and-answer session. I'd like to turn the call back to John Amos for closing remarks.

John Amos – VIVUS, Inc. – Chief Executive Officer

Yes. Thanks to all of you for your time today and your continued interest in VIVUS.

Before closing the call, I'd like to reiterate that we are successful -- successfully executing our 10-quarter turnaround strategy and we're pleased with our progress to achieving our goals. The significance of the positive changes in script and market share trends accounts for both Qsymia and PANCREAZE cannot be overstated and demonstrates that the VIVUS leadership team has the insight, expertise and ability to continue to unlock significant value from our commercial portfolio. It's especially true of our ability to stabilize the number of PANCREAZE scripts for three consecutive quarters, following years of decline. Particularly following with the withdrawal of Belviq from the market, we believe there's an opportunity for Qsymia to capture an even larger share of the anti-obesity medication market. Our fourth quarter financial results also demonstrate that our innovative sales and marketing programs are gaining traction, and we believe that removing barriers to access in Qsymia will both help to grow our share of the market and to address the obesity epidemic.

We still have work to do ahead of us to address our capital structure, but we remain confident that we have the company on the right track to create value for patients and our shareholders. And I look forward to updating you on our progress in the months ahead. Operator, I'll turn it back over to you.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.