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): **November 5, 2019**

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

Delaware	**001-33389**	**94-3136179**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

900 E. Hamilton Avenue, Suite 550
Campbell, CA 95008
(Address of Principal Executive Offices, and Zip Code)

(650) 934-5200
Registrant's Telephone Number, Including Area Code

N/A
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock Preferred Share Purchase Rights	VVUS	The Nasdaq Global Select Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

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

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

☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

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 November 5, 2019, VIVUS, Inc. (the "Company") conducted a conference call during which members of its senior management team discussed financial results for the third quarter ended September 30, 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. Third Quarter Ended September 30, 2019 Earnings Conference Call on November 5, 2019, at 4:30 p.m. ET.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VIVUS, INC.

/s/ John L. Slebir
John L. Slebir
Senior Vice President, Business Development and General Counsel

Date: November 8, 2019

Exhibit 99.1

VIVUS, Inc. Q3 2019 Earnings Conference Call
November 5, 2019 - 4:30 PM ET

Operator

Good afternoon and welcome to the VIVUS Third Quarter 2019 Financial Results conference call. Today's call is being recorded. For introductions and opening remarks, I'd like to turn the call over to Mr. David Carey with Lazar 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 are John Amos, VIVUS' Chief Executive Officer, Mark Oki, Chief Financial Officer, and Dr. Santosh Varghese, Chief Medical Officer.

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

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

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.

Fiscal Q3 2019 represents the completion of quarter five of our 10-quarter turnaround. This was a busy quarter for the VIVUS team and one of tremendous progress made toward achieving our key objectives of growing the markets for Qsymia and PANCREAZE and reducing our debt overhang. For the first time in the history of VIVUS, we had two commercially available pharmaceuticals, Qsymia and PANCREAZE, obtain quarter over quarter prescription growth. We have been telling shareholders that we would grow both products in Q3 2019 and, in all transparency, while we are pleased with the performance of Qsymia, we expected to grow PANCREAZE a bit faster than we have to date.

I'd like to begin with a review of Qsymia, emphasizing that in the third quarter of 2019, we grew scripts slightly for the product compared with the second quarter of 2019. By comparison, from Q2 2018 to Q3 2018, Qsymia scripts declined by 8%. This change from negative to positive script growth is an indication that our new Qsymia sales and marketing strategies are gaining traction and driving increased adoption trends. Moreover, Qsymia has now grown quarter over quarter for the past three quarters delivering sustained growth that has not been achieved since 2014.

Our Qsymia Advantage Program has been a significant contributor to this turnaround. Taking advantage of the increasing market shift from retail pharmacy to online ordering, we launched the Qsymia Advantage Program in Q1 2019, and we processed 1,800 scripts in that quarter. In the second quarter, we processed 6,800 scripts and now, in Q3 2019, we processed nearly 19,000 scripts or more than a 170% increase quarter over quarter. The Qsymia Advantage Program has corrected several issues that patients had with accessing the product. We lowered the out-of-pocket cost by approximately 30%, flattened pricing across all strengths and made significant strides in moving new patients from the 14-day free trial offer to a six-week titration and initial therapeutic dose.

Going forward, we expect to see some fluctuation in our script volumes, which is partially attributable to the seasonal patterns in dieting habits around the holidays. Also, additional variation is expected to arise from both the elimination of the free trial offer and because we do not report our Qsymia Advantage scripts, which should comprise a greater portion of our scripts, through the normal data services. While the company had historically seen some fluctuations in quarterly volume, the occasional positive changes were for the most part not driven by active commercial efforts. While Qsymia has not yet reached what we believe is its full potential, we are happy to see this improved commercial performance.

We are also excited to begin piloting a telemedicine program in Q4 2019, with our first four physicians going live on the VIVUS Health Platform focused on BMI management as part of our Alpha Program. We expect another 11 physicians to migrate onto the platform in Q1 2020 as part of our Beta Program, with the full rollout taking place in the middle of 2020. This program would achieve a major milestone in our efforts to fully implement the VIVUS Health Platform for Qsymia.

We have also restarted long dormant conversations about reimbursing Qsymia in the payor landscape. Payors are showing an increased interest in how Qsymia as a BMI management therapy may provide them with improved healthcare economics, which we believe is partially driven by the desire to delay the onset of diabetes and improve clinical outcomes for patients who have undergone bariatric surgery. Payors, employers, and government payors are starting to realize that the obesity epidemic is not going to be solved with just diet and exercise. It is worth noting that in the last 150 years, there hasn't been a significant population health matter that has not been addressed without pharmaceutical intervention. Obesity is no different, and we believe that Qsymia has a critical role to play in addressing the growing health and economic challenges that obesity presents.

Dr. Varghese will provide an update on our clinical activities and development priorities later in the call.

Let me turn now to a review of PANCREAZE. In the third quarter of 2019, we successfully grew the brand from Q2 2019 levels. This quarter over quarter growth represents the first sequential growth in the brand in the last 14 quarters, which includes the periods prior to our ownership of the product. It is important to note that the PANCREAZE market was on a downward trend prior to VIVUS' acquisition of the product due to lack of sales and marketing support. We purchased the brand because we believe it has unrealized clinical and commercial value that VIVUS could unlock and, while we are making progress towards that goal, PANCREAZE growth is moving slower than we expected. While we are starting to see some modest improvement in script volume, we are currently about two quarters behind expectations due to challenges with transitioning the product from JNJ and our re-launch activities. We have a plan to mediate these issues with an initial focus on stabilizing the PANCREAZE market and then seeking to expand it through renewed and innovative marketing efforts.

Let me provide some context about our PANCREAZE strategy, keeping in mind that a prescriber typically needs to be visited seven times to change prescribing behavior. Prior to VIVUS relaunching the brand, there had been no commercial efforts supporting PANCREAZE since 2012. We re-launched this product in Q1 of 2019 with 10 representatives covering healthcare providers and on average we have since seen our targeted physicians seven to eight times through the end of Q3. We have also initiated our efforts to contract with PBMs to expand payor coverage. Additionally, we have a few digitally focused programs that are additions to the PANCREAZE Advantage Program, and now have a dosing calculator, the PANCREAZE Dosing Assistant app, in various app stores. Moreover, we recently launched a website designed to help educate healthcare providers on whom our sales force does not call about the benefits that PANCREAZE — and the benefits that PANCREAZE may provide to their patients. Based on initial feedback from physicians, it appears the physician community is pleased that the product is available again. Our goal moving forward is to build and grow support for PANCREAZE among targeted physicians through focused marketing efforts directed toward prescribers at leading cystic fibrosis treatment centers. We are also planning to launch some additional programs focused on the underinsured market as well as cash-paying patients.

Our development program VI-0106 for PAH is still in stability testing in an effort to resolve a stability issue that forced us to make a change to the underlying chemistry of the development product formulation. This change to date has been promising, but there is still more work to do and will need to be resolved before we can submit an Investigational New Drug Application to the FDA.

The STENDRA/SPEDRA product is either partnered out or licensed in various global territories. We continue to collect royalties and manage the manufacturing process for our marketing and license partners. We are working with these various partners in this program to reduce our working capital exposure 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.

A key part of our strategy has been focused on acquiring or partnering of additional EBITDA generating products. To date, we have reviewed several multiple potential deals but have not found a transaction that met the criteria we have previously laid out. We will continue such efforts and remain opportunistic on appropriate asset acquisitions going forward.

Turning to the discussion of our capital structure. We paid down a significant portion of our most expensive debt this quarter that will result in savings of $10.5 million due to a reduction in interest payments over the remaining term of the loan. We believe that we solved core issues related to the historical performance of the company, built a pipeline of high value opportunities and we want to make sure that we drive long-term value for the shareholders of VIVUS. We are pleased to have taken this important step toward improving our long-term financial health. We recently engaged a financial advisor to help us through the right sizing process of our capital structure and to aid the board and management in ensuring the best outcome for shareholders and the corporation.

We have announced some departures at both the senior manager level as well as the board level. In the case of our board members, they are both pursuing additional outside activities not related to VIVUS, which are going to dramatically reduce the amount of time that they can focus on VIVUS. With respect to the two senior managers who left the company, we had asked them to move to different roles within the business. They both declined to take these new roles, and we honored our commitments to them related to their employment severance agreements.

We thank both the board members and the senior managers for their time and effort in support of VIVUS, and we wish them well in their new endeavors. At this time, we will not be making any replacement appointments or hires and believe that we have the right people in place to drive the future success of VIVUS.

As we have stated numerous times, we expect that turning VIVUS around will take 10 quarters. We have completed 50% of this turnaround and based on the metrics we have seen to date, we believe that we are on schedule to achieve our goals.

I will now turn the call over to Mark Oki to review the financials of Q3 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 John discussed, we completed the fifth quarter of a 10-quarter turnaround, which included relaunching both PANCREAZE and Qsymia in the first quarter of 2019. As a result, we believe that comparing the third quarter of 2019 with the second quarter of 2019 will provide you with a better indication of how our turnaround efforts are progressing.

Qsymia net product revenue was $9.6 million and $10 million in the third and second quarters of 2019, respectively. As John mentioned, we saw an increase in the number of scripts filled during the quarter. The decrease in net revenue is attributable to the timing of orders placed by our wholesalers, which we believe was impacted by seasonal purchasing trends and the shift of our business to the Qsymia Advantage Program, resulting in lower purchases by the retail channel.

In the third quarter, 22% of scripts were dispensed through the Qsymia Advantage Program's Direct-to-Patient model, up from 8% in the second quarter of 2019.

PANCREAZE net product revenue in the U.S. was $5.3 million in the third quarter of 2019, compared to $5.1 million in the second quarter of 2019. In the third quarter, we assumed commercial responsibility for Canadian PANCREASE MT sales and as a result recognized $0.1 million of Canadian revenue. We anticipate that future PANCREAZE product revenue will increase as a result of our U.S. re-launch efforts in the first quarter of this year and from recognizing a full quarter of Canadian sales going forward.

We did not generate any supply revenue to our licensees, Menarini and Metuchen, for SPEDRA and STENDRA in the third quarter. Second quarter supply revenue was $1.8 million. We remind you that both Menarini and Metuchen have minimum order requirements. These minimum order requirements do not reflect end user demand, nor do we consider this revenue a driver of economic performance for VIVUS.

In the third quarter of 2019, revenue related to royalties earned from Menarini sales of SPEDRA, which has typically run from $500,000 to $600,000 per quarter, was approximately $600,000 in the third quarter. From our acquisition of PANCREAZE in June 2018 through the second quarter of 2019, we also recognized royalty revenue on Canadian sales of PANCREASE. As a reminder, royalty revenue from Canadian sales was approximately $500K higher in the second quarter as additional product was shipped into the channel to avoid any potential supply chain disruptions with the changeover to VIVUS assuming commercial responsibility.

During the third quarter, we recognized $2.5 million of milestone revenue earned under our agreement with Alvogen for the commercial approval of Qsymia in South Korea.

Total cost of goods sold, excluding amortization, was $3.0 million and $4.4 million in the third and second quarters of 2019, respectively. The decrease was primarily due to the lack of STENDRA or SPEDRA supply revenue in the third quarter.

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

Research and development expense was $3.3 million and $2.4 million in the third and second 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 ongoing PANCREAZE product improvement initiatives.

Selling, general and administrative expense was $9.2 million and $10.1 million for the third and second quarters of 2019, respectively, and included selling and marketing expense of $4.5 million and $4.6 million, respectively. During the quarter, we incurred professional fees of

approximately $0.7 million related to the repurchase of $48.6 million of our outstanding senior secured debt. VIVUS expects selling, general and administrative expenses to fluctuate with business development activities.

Total interest expense, net, was $9.9 million and $3.9 million in the third and second quarters of 2019, respectively. In the third quarter, we recognized $6.4 million of additional interest expense related to the repurchase of our senior secured notes. The reduction of the outstanding notes will result in an annual $5 million dollar reduction in cash interest expense.

Net loss for the third and second quarters of 2019 was $11.1 million and $5.9 million, respectively. Cash, cash equivalents and available-for-sale securities were $40.1 million at September 30, 2019.

Non-GAAP EBITDA for the third and second quarters of 2019 was $3.0 million and $2.1 million, respectively. Excluding the Qsymia milestone revenue and certain professional fees related to our debt buyback, recurring non-GAAP EBITDA was $1.2 million for the third quarter of 2019. 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 lifecycle update.

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

Thanks Mark. I will review the clinical and regulatory aspects of Qsymia, PANCREAZE, and VI-0106 as we have made significant progress in advancing clinical programs and projects for new data.

With respect to Qsymia, we continue to enroll 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 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.

On August 20th, we announced the results of a pilot clinical study conducted at Wake Forest School of Medicine demonstrating that patients receiving Qsymia before and after laparoscopic sleeve gastrectomy surgery lost more weight and had a greater probability of achieving a body mass index of less than 40 compared with patients undergoing surgery alone. We believe the use of Qsymia with a low-calorie diet prior to laparoscopic sleeve gastrectomy surgery has the potential to decrease weight and reduce surgical risk, while post-laparoscopic sleeve gastrectomy surgery Qsymia use could increase and maintain the total amount of weight lost with the potential to eliminate the need for a second surgical procedure. Further studies would be beneficial to validate these results.

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 trial, which was required as part of the initial approval of Qsymia. We have incorporated the FDA's recent feedback into a revised protocol and hope to have a final protocol agreed upon over the next two quarters.

We continue to explore regions and markets in which Qsymia could benefit patients on their weight-loss journey. Toward that end, on October 7th, we announced that the European regulatory agencies in Sweden, Denmark, Finland, Iceland, Norway, and Poland had accepted the Marketing Authorization Application for Qsymia on a decentralized basis, with Sweden acting as the lead Concerned Member State. The target for a decision will be some time in the second half of 2020.

Finally, we are continuing 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.

Regarding PANCREAZE, we continue to evaluate additional pancreatic studies including those in pancreatic oncology. We are working with Cedars Sinai Hospital in Los Angeles, CA to start a study to look at the treatment of exocrine pancreatic insufficiency in patients with pancreatic cancer.

With respect to our VI-0106 program for pulmonary arterial hypertension, or PAH, we anticipate filing the IND and initiating the planned Phase 2 clinical study once the stability issues with our unique proprietary once-daily extended-release formulation have been resolved. We continue to believe our proprietary formulation will facilitate therapeutic drug levels while minimizing immunosuppressive effects for patients with PAH.

The stability test is ongoing, and the results will dictate the timing of our IND filing.

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

Operator

Thank you. [*Operator instructions*]

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

John Vandermosten — Zacks Small Capital Research

Good afternoon, guys. I wanted to start out with a question on the VIVUS Health platform. We here at Zacks think that's a pretty innovative way to approach distribution and wanted to hear about some of the details on that beyond what you stated in the intro, John, especially where you see the telehealth program may be in a year or two. I think you said you added about four individuals, four doctors, to that so far. Can you expand on that a bit?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes, sure, thanks for the question John, and thanks for your time. So we're testing the technology in an alpha and beta program, so for the next six months — we've got four doctors going on this quarter, 11 doctors going on next quarter. We just want to make sure that we understand the physician on-boarding process, the patient on-boarding process, and make sure that we understand how it interacts with the patient's own technology. So the patient has to either have an Android phone or an iOS phone. And then what the patient receives is at minimum a Bluetooth-enabled scale. And what this does for the physicians and the healthcare providers is it allows them to have a passively active — passively collected datapoint each week from the patient, or even daily if the patient wants to weigh themselves that often, and based on resting metabolic rate and activity rates that we capture through the phone and Apple watches and such, we're able to really understand how diet, exercise and Qsymia relate and can treat a patient from a weight loss perspective. One of the first physicians that we have going on the platform is a member of the American Obesity Group of Physicians and Doctors, and he believes that this is a relatively significant step forward in the treatment of obesity because diet and exercise just really hasn't worked. And so the next six months are focused on getting doctors on the platform, getting patients on the platform. And in terms of where we see this a year from now, our hope is to have about 3,000 physicians in total on the platform who are focused on obesity management and endocrinology issues, and we think that that physician and healthcare provider population will be able to really bend the healthcare cost curve as it relates to obesity and all of the downstream costs that obesity drives. But we're going to take this next six months to be careful and methodical about what we're doing, and as long as it responds to how we think it should, then we will continue to roll out and plan on accelerating that in the coming quarters.

John Vandermosten — Zacks Small Capital Research

And in our estimates, we have some pretty strong estimates for PANCREAZE growth over the next several quarters. What are some of the more aggressive moves that you guys can make specifically on PANCREAZE to get that moving on a little faster?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes. It's a good question. So there's a couple of things that we're doing. One, just starting to treat the underserved market that pays cash for this segment of pharmaceuticals. We think that that's going to be relatively beneficial, and we're going to roll that out this quarter.

The other thing that we're doing too is that if you look at the previous owner's history in terms of managing PBM contracts, we're either on tier 3, or in one particularly large PBM we're excluded. And so PBMs — you typically contract out a minimum of six months up to 18 months out, and so we're now actively going out and working on PBM contracts. So, all of those things kind of create a little bit of chunky revenue for you. So you'll see growth in blocks. You get the PBM contract, then you go out with your sales force to create pull-through through the retail pharmacy channels, and so that's — Like I said, we're a couple of quarters behind and part of that, being a couple of quarters behind, is related to how we didn't get the PBM contracts in the place that we wanted to a year ago.

John Vandermosten — Zacks Small Capital Research

Okay. And gross margin looks to be a bright spot and I want to see if I can get some commentary on how we can break that down. And then also does that indicate where we might be in the next few quarters on gross margin?

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

Yes. Gross margins should stay relatively consistent. We do have a relatively fixed cost base in our agreement with our provider, but yes, we should see relatively consistent margins.

John Vandermosten — Zacks Small Capital Research

Okay. Consistent with I guess the first three quarters, because it looked like it improved, strengthened in the third quarter. Actually it seems like improved a bit over the last two quarters.

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

Yes. It should start flattening off.

John Vandermosten — Zacks Small Capital Research

So we should probably take an average I guess of the first three quarters of the year and look at that going forward?

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

Yes. That would be a good approach.

John Vandermosten — Zacks Small Capital Research

Okay. And the last question just on Korea. That was announced a while back and I just was wondering if we had seen or anticipate seeing sales in the very near term, first sales in Korea? Is there any timing update on when we might see that?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes. It looks like Q1 of 2020.

John Vandermosten — Zacks Small Capital Research

OK, great. Thank you, guys. Appreciate it.

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes. Thank you, John.

Operator

Thank you. [*Operator Instructions*].

And our next question comes from Robert Mendralla, a private investor. Your line is open.

Robert Mendralla, Private Investor

Good afternoon, gentlemen. Thank you for the update today. Just a few questions for you.

With respect to PAH, do we have a little more color on the timeline for the investigational new drug application? I know in the last call, we were thinking the fourth quarter of this year, but it looks like there has been some slippage there. Could you give us a little better outlook on what you think the timeline would be for that IND?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes. So the issue that we are dealing with right now is related to the stability of the product. So the product in our opinion scientifically works. We de-risked all the biology, but we have to have a product with one year of shelf life from a stability perspective. And as this particular tacrolimus, the underlying molecule, is a very, very difficult molecule to work with and it requires containment facilities. It requires specialized care and handling. And so as we deal with this molecule, trying to get it to the proper formulation that delivers therapeutic benefit while not triggering immunosuppression, we need to do still a little bit more work. We've made a change to the underlying chemistry, which has been plaguing us in creating this stability issue. So that change in the underlying chemistry to date looks pretty good, but we've only been testing stability for about a month. So we need to see stability data for three to six months before we can really feel comfortable that we can put the drug into clinic. The last thing we want to do is start an IND, put patients on therapy, and then not have a stable product. It's just a horrific mistake to make and we refuse to do that. So we would love to have this problem solved, but unfortunately chemistry and science are sometimes hard, and I think we thought we had a pretty good solution a couple of quarters ago, but the product degraded a little bit. So we had to go back and make some changes. So I wish — nobody...

Robert Mendralla, Private Investor

So we'll look probably, John, Q2 or Q3 in 2020 at the earliest.

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes. We will keep you updated. It won't be Q2. We still probably need at least another three months of stability work under our belt.

Robert Mendralla, Private Investor

Okay. My next question goes back to the cash on hand. If I'm correct, it's at $40.1 million?

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

Correct.

Robert Mendralla, Private Investor

Okay, thanks, Mark. And John, going back to the last quarter, we talked about debt restructuring in 2020 and the long-term debt and I know primarily, I think the biggest holder is still Icahn Enterprises. Any thoughts on going forward into next year, because I think that's coming due in May of 2020. Is that correct?

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes, May 1, 2020. It's a day near and dear to everybody's heart here at VIVUS. Ultimately — a couple of things. We've gone and hired an outside advisor. So there are a number of ways for us to solve this. What we're trying to do is make sure that we solve it in a way that's most beneficial for the corporation and shareholders of the company. And so we've made a number of underlying improvements to the business. We've managed our expenses. And as I said earlier in the call, we've actually started to see growth in both of our commercial products that we own the sales and marketing here in the United States and Canada. So ultimately, we've created all the right — we've done all the right things other than grow PANCREAZE a little bit faster. That's in terms of how we've managed the company over the last year-and-a-half, or over the last five quarters. So while we don't have a finalized solution for our payoff on May 1st of next year, we didn't expect to have that solved at this point in time. We are expecting to solve it in late Q4 or Q1 next year, and we're still working towards that goal.

Robert Mendralla, Private Investor

OK, great. And my final question, we're half way through the turnaround here. This is kind of tricky for you, John, so just answer as you will. But how do you feel about the turnaround so far? I think there has been a big change certainly and maybe you can add a little color on what you did very well and maybe where you — where maybe a little bit more help is needed. So I'll keep it — put that out. It's a tough one.

John Amos — VIVUS, Inc. — Chief Executive Officer

Yes, no, no, look this is really — VIVUS is a really, really great little company. It's got a great research and development team, great folks who work here. The big concern that a lot of people advise me about when I — before I came into the company was you'll never get Qsymia turned around, just give up on it. And we have — it's a great product. It was improperly positioned in the U.S. healthcare system and we've been able to do some pretty good things about that product. And the point that I made earlier in the call about for the last 150 years, no large population health issue hasn't been addressed without utilizing the advent of pharmaceuticals. That's a really important factor. This country is going to go broke because of obesity and that's — we have an outstanding pharmaceutical solution to help patients understand that, and to treat patients. So we're really, really happy about what we've done with Qsymia.

We did a great job on acquiring PANCREAZE and bringing that product in. There were a couple of things that we needed to do better, and those were a couple of the mistakes that we made. We're going through a process to mitigate those and to get that product turned around and perform the way that we expect it to perform. And that's been a bit of a drag on our financial performance. We've managed our expenses appropriately. We've made proper investments in R&D. We would love to make more investments in R&D. We have some interesting things that we can do with Qsymia and PANCREAZE, and obviously we need to solve this issue with VI-0106. I've been doing science programs for a long time and they're hard and they're difficult sometimes.

And the other thing that we're disappointed in is we haven't been able to find something that we can acquire. Now that we have both of our products growing, we're in a good position to go buy another asset, but we've been just looking at a lot of not very good programs — I was going to use other language. But at the end of the day, we're trying to buy stuff that we find really interesting. And the STENDRA asset, it's a great program, and we have a lot of licensing opportunities, and so we're trying to do those and create opportunities around that licensing to drive value for shareholders as well. But I think overall what we've done really well is we've done a great job with Qsymia. We've gotten the license in other territories and approved in other territories and it looks like we're going to continue that role. We've got a great plan around PANCREAZE. We've got to execute on that a little bit more effectively, and we've done a good job managing our capital and expenses. So, more to come. We've got another five quarters to go.

Robert Mendralla, Private Investor

Sure. And I'll take that offline with you John on the product end, but I look forward to when the company is profitable. I think it's done a pretty good job in the turnaround so far. And it's never a straight line. So, thank you, gentlemen.

John Amos — VIVUS, Inc. — Chief Executive Officer

No, it never is. Thanks for the call.

Operator

Thank you. And I am showing no further questions from our phone lines. And I'd now like to turn the conference back over to John Amos for any closing remarks.

John Amos — VIVUS, Inc. — Chief Executive Officer

Okay. Thanks to all of you for your time today and your continued interest in VIVUS. Last month, I participated in a panel discussion at the Cleveland Clinical 2019 Medical Innovation Summit that was focused on the treating of obesity. At the summit I had the opportunity to showcase VIVUS' unique and innovative approach to addressing the obesity epidemic. We believe that VIVUS is uniquely positioned to play a critical role in providing integrated solutions that utilize both BMI therapeutics as well as information solutions.

Qsymia is clinically proven to help patients achieve and maintain a healthy Body Mass Index, and our innovative VIVUS Health platform is enabling more patients to access and adhere to effective treatment.

Before closing the call, I would like to re-emphasize that we believe that there is a massive demand for a comprehensive solution around weight loss. With a growing body of evidence supporting the safety and efficacy of Qsymia, we are focused on realizing the clinical and commercial value of the VIVUS health platform and our Qsymia Advantage programs

Additionally, we are exploring additional opportunities at expanding awareness of PANCREAZE through improved marketing efforts and rightsizing our supply chain.

I look forward to updating you on that progress in the months ahead. I'll turn it back over the Operator.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program. You may all disconnect. Everyone have a wonderful day.