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)
August 7, 2018

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

900 E. HAMILTON AVENUE, SUITE 550
CAMPBELL, CA 95008
(Address of principal executive offices, including zip code)

(650) 934-5200
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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

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

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

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

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

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

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition

On August 7, 2018, VIVUS, Inc., or the Company, conducted a conference call during which members of its senior management team discussed financial results for the second quarter ended June 30, 2018, a business update and certain other information. A copy of the transcript of the conference call is furnished herewith as Exhibit 99.1.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. Second Quarter Ended June 30, 2018 Earnings Conference Call on August 7, 2018, at 1:30 p.m. PT.

EXHIBIT INDEX

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SIGNATURES

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

VIVUS, INC.

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

Date: August 10, 2018

Exhibit 99.1

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

Operator

Good afternoon and welcome to the VIVUS second quarter 2018 financial results conference call. Today's call is being recorded. For introductions and opening remarks, I'd like to turn the call over to Mr. Mark Oki, VIVUS' Chief Financial Officer. Please go ahead.

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

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

Before we get started, I would like to remind everyone that during this conference call, we will make certain statements that are considered forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as anticipate, believe, estimate, expect, forecast, intend, likely, may, opportunity, plan, potential, predict and should, among others. These forward-looking statements are based on VIVUS' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. Investors are advised to read the risk factors set forth in the VIVUS Form 10-K for the year ended December 31, 2017, as filed on March 14, 2018 and as amended by Form 10-K/A filed on April 26, 2018, as well as periodic reports filed with the Securities and Exchange Commission such as our Form 10-Q filed earlier today. VIVUS does not undertake an obligation to update or revise any forward-looking statements made on this call.

I will now review the second quarter financial results for 2018 and then turn the call over to John, who will provide a business update and discuss his vision for VIVUS going forward.

Qsymia net product revenue increased to $11.1 million in the first quarter [*sic*][1] of 2018, as compared to $8.5 million in the second quarter of 2017. The increase was primarily driven by the increase in shipments to 94,000 units in the second quarter of 2018, as compared to 83,000 units in the same period in 2017. Approximately 96,000 and 105,000 Qsymia prescriptions were dispensed in the second quarters of 2018 and 2017, respectively.

PANCREAZE net product revenue was $2.1 million in the second quarter and consisted of shipments made from the date of our acquisition of PANCREAZE on June 8, 2018 through June 30, 2018. During this period, we shipped approximately 7,100 units of PANCREAZE.

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[1] Speaker intended to say "… in the second quarter"

Total cost of goods sold excluding amortization was $3.3 million and $3.4 million in the second quarters of 2018 and 2017, respectively. The decrease was primarily a result of lower shipments of STENDRA and SPEDRA partially offset by higher shipments of Qsymia and the addition of PANCREAZE product revenue during the quarter.

Amortization of intangible assets was $1.3 million and $181,000 in the second quarters of 2018 and 2017, respectively. In 2018, the increase was due to the amortization of costs capitalized associated with the acquisition of PANCREAZE.

Research and development — Research and development expense was $2.0 million and $1.0 million in the second quarters of 2018 and 2017, respectively. Research and development expenses were impacted by increased development efforts of tacrolimus for the treatment of pulmonary arterial hypertension, specifically the Phase 1 pharmacokinetic study and the continued formulation efforts.

General and administrative expense was $8.2 million and $6.2 million for the second quarters of 2018 and 2017, respectively. The increase in general and administrative expenses was primarily due to one-time expenses of approximately $2.0 million related to advisory services and expenses related to the acquisition of PANCREAZE and the restructuring of our debt, in addition to the expense related to the new — in addition to expenses related to the new members of our senior leadership team.

Selling and marketing expense for the commercialization of Qsymia totaled $3.5 million and $5.4 million in the second quarters of 2018 and 2017, respectively. The decrease was due to the continued cost control initiative, the results of the realignment of our sales force, and the refinement of our marketing and promotional programs.

Total interest expense for the second quarter of 2018 was $8.7 million, as compared to $8.5 million in the second quarter of 2017. The increase was primarily due to the additional debt issued during the second quarter of 2018.

Net loss for the second quarter of 2018 was $12.6 million, as compared to $13.4 million in the second quarter of 2017. Cash, cash equivalents and available-for-sale securities was $123.5 million at June 30, 2018.

Non-GAAP EBITDA for the second quarter of 2018 was ($1.0) million, as compared to ($4.0) in the second quarter of 2017. Excluding the one-time expenses discussed above, VIVUS generated EBITDA of approximately $1.0 million during the second quarter of 2018.

Reconciliation of these non-GAAP measures can be found in the press release filed earlier today with the Securities and Exchange Commission.

Before I turn the call over to John for the business update, I would like to provide some guidance on how we will be reporting financial results going forward. While our quarterly filings with the Securities and Exchange Commission on Form 10-Q will continue to provide complete financial data, our quarterly press release and conference calls will focus on our run rate rather than one-time expenses, as run rate is a more accurate reflection of our ongoing business activities. Examples of one-time expenses are costs associated with specific transactions, such as the acquisition of PANCREAZE and Willow Biopharma. Our goal with this approach is to make it easier for our investors to compare our financial results quarter over quarter, and we expect that we will demonstrate continued improvement in quarterly financial results as we continue to build a portfolio of cash flow positive assets.

With that I will now turn the call over to John for a business update and discussion of our goals and strategies going forward.

John Amos - - VIVUS, Inc. — Chief Executive Officer

Thanks, Mark, and thanks to everyone on the call for your time this afternoon. VIVUS had several notable accomplishments in the second quarter of 2018 that put us on a path toward building a sustainable and profitable specialty pharmaceutical company. As announced in April, we welcomed three new members to the VIVUS management team, and we now have a leadership team that is focused on building a portfolio of cash flow-positive assets.

The theme of the second quarter of 2018, and really for the rest of 2018, is progress. We believe we have made progress in the company in the following areas: management team, financial progress, commercial products, corporate development, pipeline development.

Management Team

In addition to myself, we have also welcomed Ken Suh, President of VIVUS, and Scott Oehrlein, Chief Operations Officer. Among the three of us, we have added over 70 years of healthcare and pharmaceutical operating and investing experience to the existing team of Mark Oki, Chief Financial Officer; John Slebir, Senior Vice President, Business Development and General Counsel; Deb Larsen, Chief Strategy Officer; Santosh Varghese, Chief Medical Officer; and Steve Feller, Head of Human Resources. In total, the eight senior managers of our company have over 150 collective years of pharmaceutical and healthcare operating experience that we intend to deploy to create value for patients and stockholders.

Consistent with our new leadership and focus on building a sustainable and profitable business, we have streamlined our key business objectives into three overarching goals:

1) Build pharmaceuticals and healthcare solutions that address patients' unmet medical needs and improve their overall wellbeing while generating profits;

2) Acquire a collection of businesses and assets that will generate operating cash flows and grow book value, with a goal of having the intrinsic value of VIVUS shares outperform the S&P 500;

3) Build a culture that retains as well as attracts tremendously talented individuals.

In order to achieve these goals, we are focusing on the data-driven decision-making processes based on determining and researching a comprehensive fact set and making decisions that are grounded in current realities and supported by rigorous predictive models. If course corrections are needed, we will utilize this same approach to adjust our activities quickly and ensure that we continue moving toward our goals.

Finance

Critical to our strategy of building sustainable and profitable businesses is addressing the amount and structure of our corporate debt. We took a significant step towards achieving this objective with the closing of an agreement to restructure a portion of our corporate debt while raising new funds through the issuance of debt securities to investment funds managed by Athyrium Capital Management. Concurrent with the closing of the PANCREAZE acquisition, we issued $110 million of notes, with an additional $10 million available for issuance upon meeting certain financial thresholds or repurchasing the Convertible Notes at certain prices. Concurrent with the Senior Secured Notes issuance, we repurchased $60 million of Convertible Notes held by funds managed by Athyrium at a discount to par. In addition to addressing a portion of our debt, this transaction also provides us with flexible access to new funding that we can use to pursue additional cash flow-positive assets that meet our investment criteria.

Commercial Products

I'd like to provide some perspective on how we plan to manage and grow revenue of our current product portfolio — PANCREAZE, Qsymia, and STENDRA/SPEDRA — in a more profitable manner. Our acquisition of rights to PANCREAZE in the United States and Canada, which closed in June, is an example of the types of assets that we will look to acquire going forward. PANCREAZE was approved in 2010 for the treatment of exocrine pancreatic insufficiency, or EPI, a condition that results from the deficiency in the production and/or secretion of pancreatic enzymes. It is associated with cystic fibrosis and chronic pancreatitis and affects approximately 85 percent of cystic fibrosis patients. There is no cure for EPI and pancreatic enzyme replacement therapy is the main treatment for the condition. PANCREAZE, which is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions, is a pancreatic enzyme preparation that acts like digestive enzymes physiologically secreted by the pancreas.

PANCREAZE is an exciting addition to our portfolio and we expect to complete the process transferring the management of this product to VIVUS in the U.S. by the end of 2018. Based on our evaluation of the facts around the PANCREAZE patient demographic and market opportunity, we believe that we can grow the utilization of this important therapy in the U.S. marketplace and effectively differentiate it from competing products in the eyes of patients and physicians.

I'd like to note that the second quarter revenue that we reported for this product today reflects baseline sales in the absence of significant marketing initiatives. We expect to launch PANCREAZE as a VIVUS product in October or November of 2018, and we believe that there is significant growth opportunity for the product in a highly defined market with an identified base of high prescribers.

We have been spending a lot of time thinking about Qsymia. We have effectively reworked the Company's previous market analysis and market understanding. We now believe that we can improve the profitability and market share of Qsymia in the U.S. marketplace, and we expect to launch new and innovative marketing initiatives in the third quarter that are based on the facts, patient dynamics and marketplace in which Qsymia is focused. We believe that we can increase the utilization of this very important product in the U.S. healthcare system. During the second quarter of 2018, we have actually seen modest territory growth in seven of our 18 territories versus the first quarter of 2018. While we are not — while we are encouraged by these numbers, one quarter does not a business make. Yet these small improvements serve as encouragement to our team that we can improve Qsymia utilization.

We are also exploring approvals in geographies outside of the United States in order to expand the Qsymia revenue opportunity.

Let me turn now to avanafil, which is marketed as STENDRA in the United States and SPEDRA in Europe. Both products are largely managed as a licensing opportunity, and as they are approved in additional territories around the globe, we will have additional licensing opportunities. For example, in July of 2018, we received approval to commercialize SPEDRA from the Turkish Government.

Corporate Development

As a core VIVUS activity, we are evaluating additional in-licensing and acquisition candidates that would meet our goals of working toward profitability and creating stockholder value. Our approach to evaluating these opportunities:

1) The price of the target asset has to be defined early on the process as being in the range that would generate acceptable returns on invested capital;

2) While we utilize financial leverage, we will not financially engineer returns;

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

4) Identify products that have significant clinical following and are important in the treatment of the medical conditions for which the product is indicated;

5) Acquire assets that don't require heroic or large number of strategies to achieve our performance targets. Turnaround assets can become cash flow positive, but there are limits to the activities and initiatives we will undertake in the pursuit of value creation around an acquired product.

We evaluated several opportunities and are continuing discussions on a couple of these programs. We are too early to provide any details, but these discussions are constant and on-going.

We reported positive data from a Phase 1 pharmacokinetic study of VI-0106, a proprietary soft capsule formulation of tacrolimus that is being developed for the treatment of pulmonary arterial hypertension, which we will refer to as "PAH," a serious disease with significant unmet need and no curative therapies. We are developing VI-0106 under the U.S. Food and Drug Administration's 505(B)(2) pathway, which will allow us to leverage the FDA's finding of safety and effectiveness for tacrolimus in other indications as well as a significant body of previously published tacrolimus safety and efficacy data in other conditions as well as in PAH. Consequently, use of the 505(B)(2) pathway could potentially shorten our development timeline and costs. We intend to seek both Fast Track and Breakthrough Therapy Designation for VI-0106, either of which would further accelerate the development timeline.

The U.S. Food and Drug Administration (FDA) approved tacrolimus in 1994 for use in lowering the risk of organ rejection in patients undergoing kidney transplant, and the drug is currently indicated for use in additional organ transplant settings and to treat atopic dermatitis. As a result, there is a significant body of safety and efficacy data in this indication.

Importantly, data published in 2013 in the *Journal of Clinical Investigation* demonstrated that low doses of the existing tacrolimus formulation reversed dysfunctional signaling through the bone morphogenetic protein receptor 2, or BMPR2, pathway, which is down-regulated in PAH patients. These results suggested that tacrolimus could be useful in the treatment of PAH.

Positive results from a Phase 2a study of tacrolimus conducted by academic investigators in PAH patients were published in the *European Respiratory Journal* in 2017.

This Phase 2a study was a randomized, placebo-controlled, single-center clinical study that evaluated low, middle and high target levels of tacrolimus in 23 PAH — PAH patients with New York Heart Association functional class II-III symptoms. Patients in the tacrolimus arms of the study were started on 1.5 mg of oral tacrolimus and then had their doses adjusted to achieve one of the tacrolimus target blood levels. Investigators noted that even the high level of tacrolimus in this study is not typically targeted for immunosuppression as it only has mild immunosuppressive effects. The primary objective of the study was to demonstrate the safety and tolerability of tacrolimus and to demonstrate the feasibility of targeting different low-dose tacrolimus ranges. Adverse events, vital signs, serum creatine [*sic*][2], hemoglobin and white blood cell counts were used to assess safety and tolerability.

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[2] Speaker intended to say creatinine.

Key findings from the study:

- Approximately 50% of the patients in the study were on triple PAH therapy, 25% were on dual therapy, and 25% were on monotherapy.
- Blood draw results suggested a favorable and narrow range of bioavailability with low-level tacrolimus in PAH patients.
- All doses of tacrolimus were well tolerated. Nausea/diarrhea was the most common side effect occurring in 11 patients, most of which were in the medium or high-dose tacrolimus arms.
- Four patients experienced fluid retention/edema, which is mild — which was mild to moderate in intensity and transient in duration, resolving without initiation or changes to diuretic regimens.
- One patient experienced hemoptysis as a serious adverse event that was determined to be most likely not related to tacrolimus.
- No side effects associated with the immunosuppressive doses of tacrolimus were observed during the study period, nor were cardiovascular events, worsening of PAH symptoms or hospitalization for PAH.
- Dose-dependent increases in BMPR2 were observed, although these changes did not reach statistical significance in this small sample population.
- Investigators concluded that these results support the evaluation of tacrolimus in a Phase 2b efficacy study in PAH patients.

The currently approved formulation of tacrolimus was also provided for compassionate use in three class 3 or 4 patients. The compassionate use demonstrated dramatically reduced rates of hospitalizations, and functional class improvements were observed. The results of these compassionate use cases were published in 2015 in the *American Journal of Respiratory and Critical Care Medicine*.

Taken together, these data provide a compelling rationale for evaluating tacrolimus in the treatment of PAH. We believe that a proprietary formulation that optimizes dosing in this indication would provide significant and commercial value. This was the rationale for conducting the recently reported Phase 1 PK study. The single-center, Phase 1 PK study was conducted in two parts. Sixteen healthy volunteers were enrolled in Part 1, and each patient sequentially received single doses of three different tacrolimus prototype regimens administered at least 10 days apart. An interim analysis was conducted following the third dosing period to select a formulation prototype with the most desirable PK profile. Three subsequent periods assessed the selected formulation at different doses or under different fed/fasted conditions. The second part of the study evaluated steady-state PK parameters in 12 healthy volunteers receiving seven daily doses of the selected prototype formulation.

The key findings from the Phase 1 PK study show that prototype formulations had PK profiles consistent with earlier in-vitro evaluations, namely an extended Tmax, a lowered Cmax, and an increased Area Under the Curve, or AUC, compared with available immediate release tacrolimus. Moreover, data from this study demonstrate that once-daily dosing of VI-0106 may facilitate maintenance of the low tacrolimus concentrations required for the treatment of PAH with minimal monitoring of drug levels.

The ongoing COMPERA registry study demonstrates that the five-year survival rate for the high-risk PAH patients is only 22.8%. New therapies that address the underlying cause of disease are urgently needed, and we are hopeful that VI-0106 can fill this need. We are exploring a variety of strategies for leveraging this collection of data to advance this program consistent with our goals of working towards profitability and reducing our corporate debt.

We recognize that driving profitability and creating value for patients and stockholders requires more than products. It also requires an employee base that is committed to our company and our vision for making a positive impact on the lives of patients with serious medical conditions. Building a vibrant and collaborative culture is essential for our long-term success, and we are pursuing multiple initiatives to ensure that we can re-train — retain and attract passionate, dedicated employees who bring relevant and necessary skill sets and experiences. These include a new program to support individual learning and professional development as well as a more streamlined employee measurement and engagement process.

Taken together, I believe our activities in the second quarter of 2018 have advanced our capital structure, financial strength, product portfolio, development pipeline and corporate culture. I believe we have the resources we need to succeed in building a sustainable and profitable specialty pharmaceutical company, and I am excited to move forward with realizing that vision.

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

Operator

[Operator instructions].

And our first question comes from David Falcone, a private investor. Your line is now open.

David Falcone, Private Investor

Oh, hi guys.

John Amos - - VIVUS, Inc. — Chief Executive Officer

Hello, how are you?

David Falcone, Private Investor

Oh good, good. As a private investor, I did as much research as I can on your company and, I don't know, I think what you guys got is like a home run, and I've been with you guys for a while, but I just like the new stuff that you're coming out with, and I've been telling my friends about you guys to invest, but there's one big problem, and I just think it's sales. And I think three conference calls ago, same thing came up. I mean, for the stuff you guys got out there, I think the sales, I mean just to be blunt, I think they stink. I mean, the sales just aren't good, and I'm glad that you said just now that you're coming up with different ways to sell your products now, because I think what you guys got out there, you should be able to be selling a lot better. Anything sort of to say about your sales, just to help me out here?

John Amos - - VIVUS, Inc. — Chief Executive Officer

So first off, David, I appreciate the question. I think we're focused certainly on — we have two excellent products that we actually commercialize. STENDRA and SPEDRA is commercialized by other organizations. Given — we've just taken on PANCREAZE, and so the team that we've brought together and the team that was here at VIVUS prior, I think — you know, we've got 150 years of collective experience in commercializing pharmaceuticals in the U.S. as well as abroad.

And so when we look at the PANCREAZE asset, we acquired that asset because we fundamentally believe that we can grow that asset in the marketplace, and we believe that our commercialization capabilities, knowledge and skills will help us grow that product. We have high expectations as well, but we hope to meet those.

With respect to Qsymia, Qsymia is a challenging product. It is released as a, and sold as a general medicine in the marketplace, though it has a REMS program against it, which forces it into more of a specialty pharmaceutical. And I think some of the decisions that were made previously inside of the company were all fine decisions based on their perception and the lens that they had on that market. Our new team, from a collective approach, we approach the market a little bit differently, and we believe that one, Qsymia is a drug that based on its label, it performs extraordinarily well against that label, and that our ability to commercialize that product given the marketplace that we're in, it's a challenging marketplace, I'm not going to lie to you, but it certainly is also a marketplace that needs this type of solution for body mass index management, and we believe that Qsymia, as long as it's promoted and performs against its label, which it does — we've dosed over 550,000 patients in the United States, we need to be better at telling that story and telling that message. And we also have to improve access to that pharmaceutical in that marketplace.

So those are things that we'll — initiatives that we're taking, and we'll continue to provide information and provide dialogue in the course of this call, the quarterly calls, as we move forward. But we appreciate the question. We agree that we need to be better at sales and marketing, and we're certainly focused on that, and the new team, it's a constant discussion internally.

Operator

[Operator Instructions]

And our next question comes from John Milan, private investor. Your line is now open.

John Milan, Private Investor

Hi. A while back I heard that you were doing a study for Qsymia for the treatment of sleep apnea and type 2 diabetes. How are those studies going?

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

We've put all development outside of obesity on hold. We are dealing with the FDA on the CVOT, so until we get that resolved, we don't believe it's a good use of our money to explore additional indications for Qsymia. So, they'll be put on hold until we resolve that with the FDA.

John Milan, Private Investor

You don't know how long that may take?

John Amos - - VIVUS, Inc. — Chief Executive Officer

The FDA is a fabulous organization. It does very, very important things, and we're certainly in the queue, but we really are limited to when the FDA can provide updates. So as soon as we know more, we'll certainly pass that along, but — So we'll leave it at that.

John Milan, Private Investor

Okay, thank you.

John Amos - - VIVUS, Inc. — Chief Executive Officer

Of course! Thank you for your interest.

Operator

There are no further questions, I will turn the line back to John Amos for closing remarks.

John Amos - - VIVUS, Inc. — Chief Executive Officer

Thanks again for your time today. As proud as we are of our achievements in the second quarter and the steps we have taken to put VIVUS on a path toward profitability and long-term value creation, we are even more excited about the road ahead. Key objectives for the rest of 2018 include launching PANCREAZE under the VIVUS brand, implementing new marketing initiatives for Qsymia in the United States and evaluating the potential submission of a regulatory application for Qsymia in the EU, exploring additional in-licensing and acquisition targets, and seeking additional opportunities to decrease our leverage.

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

Thank you to everyone on the call for participating.

Operator

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