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PRESENTATION

Operator

Good afternoon and welcome to the Synthetic Biologics' 2019 Year-End Investor Conference Call. (Operator Instructions) Please note, this event is being recorded. At this time, I would like to turn the call over to Vincent Perrone, Director, Corporate Communication at Synthetic Biologics. Vincent?

Vincent I. Perrone - *Synthetic Biologics, Inc. - Director of Corporate Communication*

Thank you, Carrie, and good afternoon, everyone. Welcome to Synthetic Biologics' 2019 Year-End Investor Conference Call. Today, I'm joined by our Chief Executive and Financial Officer, Steven Shallcross; Dr. Michael Kaleko, Senior Vice President, Research and Development; and Dr. Vince Wacher, Head of Product and Corporate Development.

Synthetic Biologics issued a press release this afternoon, which provided operational highlights and reported our financial results for the year ending December 31, 2019. The release can be found in the Investors section of our website.

During our call today, we'll provide an operational update on our GI and microbiome-focused clinical programs, and we'll summarize our financial results. We'll take questions after our prepared remarks. In addition to the phone line, this call is being streamed live via webcast, which will be archived on our website, www.syntheticbiologics.com, for 90 days.

During this call, we will be making forward-looking statements regarding Synthetic Biologics' current expectations and projections about future events. Generally, the forward-looking statements can be identified by terminology such as may, should, expects, anticipates, intends, plans, believes, estimates and similar expressions. These statements are based upon current beliefs, expectations and assumptions and are subject to a number of risks and uncertainties, including those set forth in Synthetic Biologics' filings with the SEC, many of which are difficult to predict. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements.

The information on this call is provided only as of the date of this call, and Synthetic Biologics undertakes no obligation to update any forward-looking statements contained on this conference call on account of new information, future events or otherwise, except as required by law.

With that, I'd like to turn the call over to Steve. Steve?

Steven A. Shallcross - *Synthetic Biologics, Inc. - CEO, CFO, Treasurer, Corporate Secretary & Director*

Thanks, Vincent. Good afternoon, everyone, and thank you for joining our 2019 year-end investor conference call. I'm happy to be with you all this evening and look forward to sharing important and exciting updates on our strategy and progress for advancing our late-stage and emerging clinical programs during today's call.

2019 was a year of considerable progress for the company, marked by several key advancements for our portfolio of GI and microbiome-focused clinical programs targeting critical unmet needs in the prevention of life-threatening gut microbiome infections and GI disorders. As a matter of fact, I can't remember any time when I've been more excited about our company, especially when thinking about what potentially lays ahead for us in 2020.

Our hard work and determination in and out of the clinic are beginning to align with the tangible results and goals we set out to achieve just over 18 months ago. Of particular note, we continue to make advancements in our ongoing Phase IIb clinical trial of SYN-010, which is being conducted as an investigator-sponsored clinical trial out of Cedars-Sinai Medical Center. We announced the clinical trial agreement with Washington University and subsequently held a Type C meeting with the FDA to solidify the clinical program parameters for a Phase Ib/IIa clinical trial of SYN-004 in allogeneic hematopoietic transplant patients, which is expected to begin in the second quarter.

We advanced product manufacturing, completed toxicology work and held successful pre-IND meeting with the FDA in December for our SYN-020 program in advance of our planned IND submission in early April. And we're also very active in securing additional protections to further bolster the intellectual property estate for our lead programs, which we believe are instrumental components in our discussions with prospective partners, including several important patents and claims related to the diagnosis and treatment of diseases and conditions caused by or associated with methanogens, including M. smithii, with anti-methanogenic compounds, including SYN-010, and significantly strengthened our international IP portfolio for SYN-010 by adding protection in several key foreign markets. Importantly, these initiatives and other activities were conducted under our continued sharp focus on prudent cash management and financial stewardship, allowing us to maintain a cash runway through at least the end of 2020.

With that backdrop, I'd like to share more detailed updates on our product portfolio, starting with our SYN-010 program. Currently approved in marketed therapies for IBS-C are typically nonspecific laxatives, which provide temporary relief to patients by facilitating movement of stool mass often at the cost of significant adverse side effects. SYN-010 is designed to target an underlying cause of constipation in IBS-C patients with the goal of normalizing bowel habits without diarrhea and nausea, which are often associated with over-the-counter and prescription therapies.

A growing body of evidence continues to demonstrate that excess methane production by the microbe M. smithii is a primary causative factor of constipation and associated symptoms in IBS-C. Dr. Mark Pimentel, who is chair of our IBS-C Clinical Advisory Board and a recognized and revered KOL in the GI field, recently published 2 papers which outline his work studying how changes to the gut microbiome can lead to the development of both IBS-C and IBS-D.

In a paper published with his colleague, Dr. Anthony Lembo, who is also a member of our IBS-C Clinical Advisory Board, Mark and Anthony provide further support that microbial factors play key roles in both functional categories of IBS pathophysiology. They go on to discuss how elucidating the specific mechanisms by which gut microbes exert effects on their host may allow for targeted treatments such as SYN-010 in order to successfully treat the underlying causes of IBS-C.

In a separate clinical guideline statement published in the American Journal of Gastroenterology, Dr. Pimentel and his colleagues further elaborate the correlation between elevated levels of breath methane and symptoms associated with IBS-C. They go on to propose a new term, intestinal methanogen overgrowth, or IMO, for patients who score higher than 10 parts per million at any point during breath methane testing.

The abstracts for both publications are available on our website and are of particular importance to our SYN-010 program as they represent an ongoing shift in the current IBS paradigm away from temporary therapies that focus on short-term symptom relief towards a reality of understanding and treating the mechanism of these disease states while providing patients with long-term chronic relief.

We believe SYN-010 exemplifies this paradigm shift. Its unique mechanism of action is intended to act in the intestinal track to reduce methane production by the organism M. smithii without causing detrimental disruption to the gut microbiome. It is designed to be a chronic daily treatment suppressing methane production and potentially providing sustained relief from constipation, pain and bloating.

Last year, we began enrollment in a Phase IIb investigator-sponsored clinical trial in collaboration with our research partner, Cedars-Sinai Medical Center, to further evaluate the efficacy and safety of SYN-010. This study is being led and conducted by the distinguished team of the Medically

Associated Science and Technology, MAST, program at Cedars-Sinai. It is a 12-week randomized, placebo-controlled trial evaluating 2 dose strengths of SYN-010 in patients diagnosed with IBS-C. Enrollment of the study commenced in 2019 and remains ongoing. A data readout is anticipated during the first half of 2020.

The clinical data we expect to generate from this targeted patient population is important for several reasons. First, this trial is designed to address specific queries about dose response and length of treatment that led to the design of the Phase IIb/III adaptive design clinical program previously agreed to with the FDA. Second, by partnering with Cedars-Sinai, we are generating this data at a significantly lower cost than if we were to run this trial on our own. And lastly, positive results from this trial may allow us to reengage with prospective partners who found the Phase IIa data compelling but not conclusive enough to justify the significant capital investment required to complete the clinical trials necessary for product registrations.

We previously discussed that generating such a data set requires rigorous screening criteria in order to obtain reliable baseline parameters. For IBS-C patients, this includes foregoing their current constipation interventions for a period of time prior to breath methane screening. This has proven to be a challenging proposition for some patients, leading to higher-than-anticipated inadvertent patient-related screen fail rates for patients who presented at screening with breath methane levels below the protocol required, 10 parts per million.

We recently met with the investigators at Cedars-Sinai for an update. And following some discussion, we collectively agreed that generating a meaningful data set may be possible with a smaller study population than previously anticipated. However, in order to ensure the possibility of generating a data set of the highest quality with a smaller patient population, Cedars-Sinai may elect to conduct a blinded interim or futility analysis in the second quarter in advance of top line data readout. This may be necessary to determine whether the study should continue beyond the previously anticipated deadline or is adequately powered and ready for analysis based on the number of patients who are enrolled and have completed the study.

I want to reiterate, that is our absolute main objective for this -- I want to reiterate that our absolute main objective for this trial remains to generate a comprehensive and meaningful data set from a very high quality and clinically representative group of patients, which we hope will provide clearer evidence of SYN-010's safety and efficacy in what we believe is a very underserved IBS-C patient population. The investigators at Cedars-Sinai share this objective. And together, we will determine the best course of action as it relates to this clinical trial.

Before moving on, I want to take a moment to briefly share some interesting findings from a commercial assessment study of the IBS-C and CIC landscape we currently have underway. This project is being conducted by a well known and highly regarded consultancy group and will serve to better inform strategic decision-making as it relates to potential partnering and future commercialization opportunities.

Interestingly, we learned that while GI physicians and KOLs view IBS-C and CIC as similar but separate disease states, they often treat both conditions utilizing similar therapeutic interventions. That is the treatment paradigm for treating IBS-C and CIC is nearly indistinguishable. This represents an interesting opportunity to potentially expand the SYN-010 addressable market, as we believe SYN-010 can provide a potential therapeutic benefit for CIC patients who test positive for elevated breath methane. These findings may also have implications for our future Phase III clinical development plans as the inclusion of methane-positive CIC patients in future registration studies may allow for less expensive and accelerated clinical trials.

Next, I'd like to provide an update on our SYN-004 or ribaxamase program. SYN-004 is our first-in-class therapeutic intervention designed to protect the gut microbiome from antibiotic-mediated dysbiosis. SYN-004 is administered orally in conjunction with certain IV beta-lactam antibiotics, and its novel mechanism of action is designed to degrade residual antibiotic excreted into the GI tract before it can disrupt the natural balance of the gut microbiome.

It has been well established that the prolonged use of antibiotics significantly increases the risk of developing gastrointestinal infections like CDI as well as the emergence and spread of antimicrobial-resistant genes. Protection of the gut microbiome may also play a pivotal role in improving health outcomes for patients who are administered long courses of IV antibiotics as part of their treatment plan for bone marrow and solid organ transplantations.

Specifically, we believe SYN-004 may provide a significant benefit to allogeneic hematopoietic cell transplant, or HCT, recipients. Allogeneic HCT patients have a very high risk of CDI, VRE colonization and potentially fatal bacteremia and acute graft-versus-host disease, or aGVHD, following long courses of IV beta-lactam antibiotics used to treat fever after conditioning therapy.

First-line therapies such as penicillins and cephalosporins in the U.S. and Europe and carbapenems in China are used to treat neutropenic fever, which occurs in 80% to 90% of allogeneic HCT patients. Damage to the gut microbiome caused by these antibiotics is also strongly associated with a number of potentially fatal adverse outcomes in allogeneic HCT recipients, most notably AGVHD, again, VRE colonization, bacteremia and CDI. The high incidence and severe outcomes of aGVHD, VRE and CDI brings into sharp focus the futility and toll of waiting to treat these problems until they arise.

In a previously completed 4- and 12-patient clinical trial evaluating CDI prevention in pneumonia patients, SYN-004 was shown to protect the gut microbiome of treated patients compared to placebo, significantly reducing the incident rate of CDI and importantly, VRE colonization. The message is very clear and obvious: prevention is absolutely critical.

Last year, we entered into a clinical trial agreement with the Washington University School of Medicine in St. Louis to conduct a Phase Ib/IIa clinical trial. Following this announcement, we held a Type C meeting with the FDA to solidify the clinical program requirements needed to conduct this study. In accordance with guidance we received from the FDA, the Phase Ib/IIa clinical trial will comprise a single-center, randomized, double-blinded, placebo-controlled clinical trial of oral SYN-004 in up to 36 available adult allogeneic HCT recipients.

The goal of this study is to evaluate the safety, tolerability and potential absorption into the systemic circulation, if any, of 150 milligrams of oral SYN-004 administered to allogeneic HCT recipients who receive an IV beta-lactam antibiotic to treat fever. Study participants will be enrolled into 3 sequential cohorts and will be administered a different study-assigned IV antibiotic. Eight participants in each cohort will receive SYN-004 and 4 will receive placebo. We expect data readouts throughout the study following the completion of each cohort.

Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV antibiotic. The proposed study will also evaluate potential protective effects of SYN-004 on the gut microbiome as well as generate preliminary information on the potential therapeutic benefits and patient outcomes of SYN-004 in allogeneic HCT recipients. Enrollment is expected to commence next quarter contingent upon approval of the final clinical trial protocol by the Washington University Institutional Review Board and the FDA.

Synthetic Biologics will serve as the sponsor of this study and will supply SYN-004 to Washington University. Dr. Erik Dubberke, Professor of Medicine and Clinical Director of Transplant Infectious Diseases at Washington University and a member of our SYN-004 steering committee, will serve as the principal investigator of this study in collaboration with this Washington University colleague, Dr. Mark Schroeder, Associate Professor of Medicine of the Division of Oncology, Bone Marrow Transplantation and Leukemia. We are very excited about this collaboration with Washington University and look forward to updating you on our progress.

Before I review our financials for 2019, I'd like to share a brief update on one of our more promising early-stage assets, SYN-020. SYN-020 is an oral form of intestinal alkaline phosphatase, or IAP. IAP is an endogenous enzyme expressed in the upper small intestine that plays an important role in reducing GI inflammation, tightening the gut barrier and promoting a healthy gut microbiome. Through these activities, oral delivery of IAP has the potential to treat both GI and systemic disorders.

Despite its broad therapeutic potential, industry development of IAP as an oral drug had been hindered by manufacturing hurdles, which has led to currently commercially available IAP costs of up to $10,000 a gram. We believe we have overcome these hurdles and now have the ability to produce more than 3 grams per liter of IAP for roughly a few hundred dollars a gram and incorporates SYN-020 into an oral dosage formulation, an achievement that we believe makes SYN-020 a commercially attractive compound.

We've reviewed a number of potential clinical indications for SYN-020 and are currently pursuing the treatment and prevention of radiation enteropathy, secondary to cancer therapy, as the first indication with a large unmet medical need. During the fourth quarter, we made additional progress towards the completion of IND-enabling toxicology study and assay development that are expected to support our IND filing for this

program toward the end of the first quarter or shortly thereafter. We remain encouraged and excited about this program and its potential to be a value-added catalyst for the company.

As you've heard today, we remain steadfast and focused on the execution of the clear and viable strategies we've shared. We believe these actions will allow us to creatively and aggressively advance our development pipeline in ways that have the potential to drive significant value for our investors.

With that backdrop, I'll review our financial results for the year ended December 31, 2019. During 2019, we continue to reduce operating expenses while remaining focused on the execution of our development strategies to further advance our clinical pipeline. Our balance sheet remains well capitalized as we reported cash and cash equivalents of $15 million at the end of the year.

We believe this cash balance is enough to maintain our projected operating runway through at least the end of 2020. This is particularly important as it should allow us to report on several important clinical milestones, including a data readout from the ongoing Phase IIb study of SYN-010. We will continue to operate in an efficient manner and seek to identify additional areas where we can further reduce our cash burn while remaining focused on execution.

Now I'll turn to the results for 2019. General and administrative expenses decreased to $4.6 million for the year ended December 31, 2019, from $5.7 million for the year ended December 31, 2018. This decrease of 19% is due to decreased stock-based compensation expense related to forfeitures and decreased option grants, along with the reduction of investor relations, consulting, registration and legal fees. The charge related to stock-based compensation expense was $265,000 for 2019 compared to $1 million for 2018.

Research and development expenses decreased to $11.1 million for the year ended December 31, 2019, from $11.8 million for the year ended December 31, 2018. This decrease of 6% is primarily the result of lower SYN-004 indirect program costs for the year ended December 31, 2019, including salary and related expense reductions resulting from the 2018 restructuring and the fact that no clinical activity for SYN-004 was ongoing during the year ended December 31, 2019. And this was offset by an increase in manufacturing and pre IND-enabling toxicology study costs for our SYN-020 program. Research and development expenses also included a charge related to noncash stock-based compensation expense of $75,000 for 2019 compared to $1.1 million for 2018.

Other income was $283,000 for the year ended December 31, 2019, compared to other income of $4.1 million -- $4.2 million for the year ended December 31, 2018. Other income for 2019 is primarily comprised of interest income, while total other income for 2018 is comprised of noncash income of $4.1 million from the change in the fair value on warrants. The decrease in the fair value of warrants was due to a decrease in our stock price during 2018. Cash and cash equivalents on December 31, 2019, were $15 million, a decrease of $13.9 million from 2018.

In closing, I'd like to thank each of you for joining the call today. As I hope I have conveyed clearly in my remarks, we are continuing to successfully deliver on our strategy by advancing our portfolio of early and late-stage clinical programs. I'm proud of the partnerships that we've cultivated with several of the most recognized and accomplished organizations in the country, and I'm incredibly excited and encouraged by the confidence and enthusiasm they continue to demonstrate in our clinical assets.

I and the entire team at Synthetic Biologics are focused on executing on clear and achievable milestones and value drivers as we've established for our clinical vision. We look forward to continuing to update you on our progress in the weeks and months ahead.

Now I'll turn the call back over to Vincent.

Vincent I. Perrone - *Synthetic Biologics, Inc. - Director of Corporate Communication*

Thank you, Steve. Carrie, we'd like to open the phone line to questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) The first question will come from Jason McCarthy of Maxim Group.

Michael Okunewitch - *Maxim Group LLC, Research Division - Equity Research Associate*

This is Michael Okunewitch on the line for Jason. So with the Phase IIb data readout coming up for SYN-010, I'd like to see if you could help us frame the possible results. So like what sort of rates would you consider to make 010 a competitive entry in the IBS space, considering that from the other drugs out there, we've seen pivotal overall response rates at around 30%?

Steven A. Shallcross - *Synthetic Biologics, Inc. - CEO, CFO, Treasurer, Corporate Secretary & Director*

I'll let Vince Wacher take that question, and I think there's 2 parts. There's the initial answer for your question, and I think there are some ideas that we may have on how we may approach our discussions with the FDA as we think about a Phase III clinical design program. Vince, do you want to take that?

Vince Wacher - *Synthetic Biologics, Inc. - Head of Product and Corporate Development*

Yes. I think the short answer is that the -- on average, there's about -- as you indicated, about a 30% response rate across the board in the general IBS population. We are still working on how to effectively evaluate our response rate because our data, and the further we go mechanistically with our program, indicates that we should be considering methane-positive patients as our population, so not everybody necessarily in the entire IBS or CIC landscape. But based on our mechanism of action, we should be focusing on methane-positive patients.

We know from our Phase IIa studies that we can knock down methane. What we don't know in a large clinical trial is the overall effect of knocking methane down in a broader population of patients, and that's something we will need to look forward to as we see the results from this study and evaluate how to move forward into Phase III. So I realized that's kind of nebulous. But I mean as a baseline, 30% is the industry standard. But we would look to be better in patients that had a methane problem that was causative of their constipation.

Michael Okunewitch - *Maxim Group LLC, Research Division - Equity Research Associate*

Actually, I wanted to talk about the mechanism of action a little bit, considering how unique SYN-010's mechanism is and especially given the really impressive bloating reduction rate of 70%. And I want to see -- is there an opportunity to use this as a combination therapy in those groups where they're responding on one of the particular metrics but maybe not an overall responder?

Vince Wacher - *Synthetic Biologics, Inc. - Head of Product and Corporate Development*

You're quite right. I mean we are certainly not bloody minded about, "You must use our drug versus the other drugs there." So I think there's room for combination therapy in this space. And any IBS or CIC patient, just through the lifetime of their disease, has used combinations. But things that are over-the-counter, it would certainly make sense that if there's something additional or different like SYN-010 to go with something like a linaclotide or any of other agents to draw water into the intestine, there is an opportunity potentially to use them either in sequence or in combination to optimize therapy. So yes, we do think that, that's a possibility in the population.

Michael Okunewitch - *Maxim Group LLC, Research Division - Equity Research Associate*

And then the last one, I'd like to switch gears a bit over to graft-versus-host disease actually. So I'd like to see if you could give us a bit more color on the addressable market for ribaxamase in GVHD. How many of these patients are actually receiving beta-lactam excluding carbapenems? And then how would moving into GVHD position you to expand into the broader organ transplant and infection control markets?

Vince Wacher - *Synthetic Biologics, Inc. - Head of Product and Corporate Development*

The first answer is 80% to 90% of patients will end up developing a fever, and they'll get an IV beta-lactam antibiotic at some stage. So a very large portion of the patients would get -- end up potentially being candidates for SYN-004. And as a preventative, they don't even have to have signs of developing GVHD. We want to prevent all of that. So anybody -- any patient that's got an IV beta-lactam antibiotic is a candidate for our drug. So it's not a fraction of 80% to 90% or 80% to 95% of those patients. It's potentially all of them.

And then the mechanism of action is the same for multiple indications. So preventing GVHD, preventing Clostridium difficile infection, preventing opportunistic infection by vancomycin-resistant enterococci, they are all a function of protecting the microbiome from the antibiotic damage and that's something we need to emphasize. We don't have a biological target in the patient. We -- our target is the "toxin," which is the -- any of the antibiotic that's excreted in the intestine.

So by doing that, by protecting the microbiome, the microbiome prevents the VRE. The microbiome prevents the Clostridium difficile infection. And so by pursuing these end points in a study of allogeneic HCT patients, we have an opportunity to see multiple potential effects in aGVHD preventing CDI, and the CDI rate in that population is as high as 30%, and VRE colonization and infection.

Those outcomes, even if they are secondary end points in a clinical trial, are things that could help guide the utility and expanded evaluation post-market and to expand into other broader indications. Clearly, we -- that will take more clinical experience. That will take additional clinical trials or clinical use, but that could be investigator-driven that could be done at the hospital level once the product is available through its initial approval.

Michael Okunewitch - *Maxim Group LLC, Research Division - Equity Research Associate*

Congratulations on the progress. Looking forward to future releases.

Operator

I would now like to turn the conference back over to Steve Shallcross for any closing remarks.

Steven A. Shallcross - *Synthetic Biologics, Inc. - CEO, CFO, Treasurer, Corporate Secretary & Director*

Thank you. Just a couple of comments here in closing. As I stated at the beginning of our call today, we really believe we're very, very close to realizing the benefits from over 18 months of some really, really hard work.

More specifically, we've developed what I think is an exciting path forward for ribaxamase that is not only realistic from a funding perspective but clinically relevant in terms of addressing a significant unmet need in the marketplace. More importantly, our strategy is simple in that we're initially targeting a small segment of the market, namely the acute graft-versus-host disease and bone marrow transplant patient market where the incident rate of VRE colonization, bacteremia and CDI are just incredibly high.

So if we're successful, we plan to expand that label, as we just talked, into the potentially lucrative market which would include solid organ transplant. And ultimately, we believe we can end up in the broader indication for the prevention of C. difficile infection and antimicrobial resistance.

Our key achievements for ribaxamase just in this last 12 to 18 months include our collaboration with Washington University, who, by the way, is a leading bone marrow transplant center in the world; agreement with the FDA on a path forward with a Phase Ib/IIa clinical trial design; and very shortly, we'll be in a position where we initiate that trial.

Second, we strengthened our partnership with Cedars-Sinai and initiated a Phase IIb investigator-sponsored study that is primarily funded by the Cedars team. And as you know, it's ongoing and being conducted by their highly acclaimed MAST organization. When this study is finished, we really believe we'll have identified the ideal dose to advance this program into Phase III clinical trials ultimately with the goal of generating the efficacy and safety data that will be exciting to potential partners.

As I also said earlier in the call, we're investigating opportunities to further expand SYN-010 for chronic constipation patients who test positive for breath methane. This is an incredibly exciting opportunity to ultimately have a product like SYN-010 be used more broadly in patients that just simply don't have a solution today. I promise we'll keep you informed on our commercial assessment work, and we'll have more to talk about in the near future.

Finally, we've advanced our internally developed SYN-020 IAP program. With a significant cost-of-goods advantage for this product, we really believe we have a number of possible clinical and commercial opportunities for this incredibly important compound. Having said that, as I said earlier, we're going to be filing the IND for this program by the end of the first quarter or sometime shortly after that. And we're working diligently to prepare to move this into human clinical trials in a Phase I study, and that could happen as soon as the end of the year.

So when all is said and done, we've accomplished a lot of work with a small group of dedicated folks on our team. With the support of the experts that we have and developed relationships with, namely the Cedars team, the Washington University folks and the folks from Mass General, we've moved much, much closer to realizing our vision. I honestly believe 2020 is going to be the year that we break out and we deliver on the number of commitments and milestones that we all said and laid out and put a plan together in what we were going to do. I'm looking forward to reporting on these events and further advancing these programs. Once again, thank you for your support.

Operator

Thank you. The conference has now concluded. Thank you all for attending today's presentation. You may now disconnect your lines. Have a great day.
