Synthetic Biologics, Inc.
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August 09, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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SCHEDULE 14A

(RULE 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the

Securities Exchange Act of 1934

(Amendment No.)

Filed by the Registrant ¨

Filed by a Party other than the Registrant ¨

Check the appropriate box:

¨Preliminary Proxy Statement

¨ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

¨Definitive Proxy Statement

¨Definitive Additional Materials

xSoliciting Material under §240.14a-12

SYNTHETIC BIOLOGICS, INC.

(Name of Registrant as Specified in Its Charter)

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(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

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On August 8, 2018, Synthetic Biologics, Inc. (the "Company") held a conference call to discuss the Company's financial results for the second fiscal quarter ended June 30, 2018. A transcript of the call is furnished below.

Important Additional Information and Where to Find It; Participants in the Solicitation

Synthetic Biologics, Inc., its directors and certain of its executive officers are deemed to be participants in the solicitation of proxies from Synthetic Biologics, Inc.'s stockholders in connection with the matters to be considered at Synthetic Biologics, Inc.'s 2018 Annual Meeting of Stockholders. Information regarding the names of Synthetic Biologics, Inc.'s directors and executive officers and their respective interests in Synthetic Biologics, Inc. by security holdings or otherwise can be found in Synthetic Biologics, Inc.'s preliminary proxy statement for its 2018 Annual Meeting of Stockholders, filed with the Securities and Exchange Commission (the "SEC") on August 1, 2018. The preliminary proxy statement is available free of charge at the SEC's website at *www.sec.gov*. Synthetic Biologics, Inc. intends to file a definitive proxy statement and accompanying proxy card with the SEC in connection with the solicitation of proxies from Synthetic Biologics, Inc. stockholders in connection with the matters to be considered at Synthetic Biologics, Inc.'s 2018 Annual Meeting of Stockholders. Additional information regarding the identity of participants, and their direct or indirect interests, by security holdings or otherwise, will be set forth in Synthetic Biologics, Inc.'s definitive proxy statement for its 2018 Annual Meeting, including the appendices thereto. **INVESTORS AND STOCKHOLDERS ARE STRONGLY ENCOURAGED TO READ ANY SUCH DEFINITIVE PROXY STATEMENT AND THE ACCOMPANYING PROXY CARD AND ANY AMENDMENTS AND SUPPLEMENTS THERETO AS WELL AS ANY OTHER DOCUMENTS FILED BY SYNTHETIC BIOLOGICS, INC. WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION.** Stockholders will be able to obtain copies of the definitive proxy statement, any amendments or supplements to the proxy statement, the accompanying proxy card, and other documents filed by Synthetic Biologics, Inc. with the SEC for no charge at the SEC's website at *www.sec.gov*. Copies of the definitive proxy statement will also be available at no charge by visiting the Synthetic Biologics, Inc. website at *www.syntheticbiologics.com* and clicking on "Investors," then on "Annual Meeting Materials" or by contacting the Synthetic Biologics, Inc. Corporate Secretary at Synthetic Biologics, Inc., 9605 Medical Center Drive, Suite 270, Rockville, Maryland 20850.

Forward Looking Statements

The attached script contains forward-looking statements, including those related to certain proposals to be voted on at the Synthetic Biologics, Inc. 2018 Annual Meeting of Stockholders. These statements are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements, including, but not limited to, satisfaction of conditions to closing of the transactions, including the ability to secure the required stockholder approvals and other risks described in the Company's. All forward-looking statements are based on management's estimates, projections and assumptions as of the date hereof, and the Company undertakes no obligation to update any forward-looking statements.

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THIS PRESENTATION IS FOR INFORMATIONAL PURPOSES ONLY AND SHALL NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY ANY SECURITIES, NOR SHALL THERE BE ANY SALE OF SECURITIES IN ANY JURISDICTION IN WHICH THE OFFER, SOLICITATION OR SALE WOULD BE UNLAWFUL PRIOR TO THE REGISTRATION OR QUALIFICATION UNDER THE SECURITIES LAWS OF ANY SUCH JURISDICTION. THIS ANNOUNCEMENT IS NEITHER AN OFFER TO SELL NOR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES AND SHALL NOT CONSTITUTE AN OFFER, SOLICITATION OR SALE IN ANY JURISDICTION IN WHICH SUCH OFFER, SOLICITATION OR SALE IS UNLAWFUL.

Conference Call Transcript

Synthetic Biologics 2018 Second Quarter Investor Conference Call

Thursday, August 8, 2018 at 4:30pm (EDT)

Event ID:

Event Name: SYN – Synthetic Biologics, Inc. 2018 Second Quarter Investor Conference Call

Event Date: 2018-08-08

Officers and Speakers

Vincent Perrone; Synthetic Biologics, Inc.; Manager, Corporate Communications

Steven Shallcross; Synthetic Biologics, Inc.; Acting CEO and CFO

Analysts

Katherine Xu, William Blair & Co.

Presentation

Operator: Good afternoon, everyone, and welcome to the Synthetic Biologics 2018 First Quarter Investor Conference Call -- Second Quarter Investor Conference Call.

(Operator Instructions)

Please note today's event is also being recorded.

At this time, I'd like to turn the call over to Mr. Vincent Perrone, Director of Corporate Communication at Synthetic Biologics. Vincent, you may begin.

Vincent Perrone: Thanks, Jamie, and good afternoon, everyone. Welcome to Synthetic Biologics' 2018 Second Quarter Investor Conference Call. Today I'm joined by our Acting CEO and CFO, Steven Shallcross, and our Chief Medical Officer, Dr. Joseph Sliman.

Synthetic Biologics issued a press release this afternoon which provided operational highlights and reported our financial results for the period ending June 30, 2018. The release can be found on the Investor Relations section of our website.

During our call today, we will provide an operational update on our microbiome-focused clinical programs and summarize our financial results. We'll take questions after our prepared remarks.

In addition to the phone line, this call can being streamed live on the internet, which will be archived on our website at www.syntheticbiologics.com for 90 days.

During this call, we'll 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 our 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 the 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 Shallcross: Thank you, Vincent. Good afternoon everyone, and thanks for joining our call. Before I dive into our clinical and operational update, I want to start by stating very clearly that I and the Synthetic Biologics team are more dedicated and determined than ever to continue our work of advancing our portfolio of cutting-edge microbiome-focused therapies. Our objective is incredibly clear: Unlock the value of our great and vast portfolio of products for patients they aim to serve and for our dedicated shareholders.

During today's call, I'll share important and exciting updates on our clinical programs.

First, we've made considerable progress with ribaxamase, which is our oral enzyme designed to degrade certain IV-beta-lactam antibiotics within the GI tract to protect and preserve the natural balance of the gut microbiome from antibiotic-mediated dysbiosis and CDI. I'm pleased to report that we remain on track to hold our end-of-Phase 2 meeting with the FDA towards the end of the third quarter.

In the past three months we have made excellent progress in our partnering efforts, both domestically and especially in China. Following my recent trip to China, I believe the company is well positioned to continue to pursue our core objective of completing a licensing and/or co-development deal in the region.

We also completed a health economics study which provided key insights on the positive benefit ribaxamase may have on the healthcare system. In addition to ribaxamase, we are developing an emerging and promising portfolio of microbiome-focused drugs, including SYN-010, with the potential to treat significant unmet market needs.

And lastly, we've taken important measures to solidify the financial stability of our company.

On the clinical front, I'm pleased to report we continue to have strong momentum with ribaxamase, our first-in-class therapeutic intervention designed to prevent the onset of primary C. difficile infection by protecting the gut microbiome from antibiotic-mediated dysbiosis. Ribaxamase holds the potential to be a disruptive yet simple approach to more effective antibiotic therapies.

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. Ribaxamase is designed to be taken in conjunction with certain IV beta-lactam antibiotics. Its novel mechanism of action acts to prevent opportunistic GI infections such as CDI before they occur by degrading residual antibiotics that may disrupt the natural balance of the gut microbiome.

As we have previously shared, we have reached preliminary agreement with the FDA on key elements of our planned Phase 3 clinical program for ribaxamase. We are continuing to prepare for our end-of-Phase 2 meeting with the FDA, which I'm happy to say remains on track for the end of the third quarter.

Within 30 days of the conclusion of this meeting we expect the FDA will provide us with the final meeting minutes, which we have every expectation will confirm and solidify the remaining elements of the planned Phase 3 ribaxamase clinical program. We believe the information provided in the meeting minutes will also help us to establish with greater accuracy the estimated world-wide costs of the Phase 3 trial. Importantly, being armed with firm details on trial endpoints, patient enrollment size, and costs will be highly beneficial in our ongoing partnership discussions.

When I took over earlier this year, I made a commitment that we would recruit the best advisors and experts to help guide us with advancing our clinical development programs. As such, I'm also excited to report that our clinical team has created a ribaxamase Phase 3 steering committee, which has been working with the company in establishing an optimal clinical trial design to maximize the likelihood of a successful trial.

This committee is chaired by Dr. Milton Packer out of Baylor University, who has over three decades of FDA advisory panel experience and is a leading expert in the design of clinical trial programs. The committee is also comprised of a recognized leader in clinical trial development as well as experts in infectious disease and CDI with deep experience working with the FDA. We expect to share additional information on this steering committee and its members on our website shortly.

We have been highly encouraged by the FDA's recognition of the unmet need for novel interventions to combat and prevent the proliferation of CDI. If approved, ribaxamase will be the first intervention specifically designed to prevent CDI associated with the most commonly used IV antibiotics, and I and the entire Synthetic Biologics organization are motivated every day to bring a new, efficacious therapeutic intervention to the more than 450,000 new patients who contract and suffer from CDI each year.

Our team also recently completed a Health Economics Outcomes Research study, which was conducted to generate key insights on how we can expect healthcare practitioners to evaluate patient access for ribaxamase while also providing a framework for reimbursement strategies.

Findings from this study reinforced our belief that hospital CMOs and IDC Directors find ribaxamase's value proposition very compelling,

We also confirmed that the healthcare system as a whole stands to benefit by including ribaxamase on the hospital formulary. The study also validated our earlier beliefs that healthcare practitioners are willing to pay for ribaxamase.

And, finally, we answered several key questions for prospective partners surrounding reimbursement strategies.

On the partnering front we are continuing to engage in business development discussions to explore and evaluate potential opportunities in North America, Europe and especially China. China represents a very interesting partnering opportunity for both SYN-010, and especially for ribaxamase.

Since the beginning of the year, I've spent a lot of time in China discussing both our lead programs, which I can assure you is something I would not be doing if there weren't -- if I weren't extremely encouraged by our prospects of solidifying a path that may ultimately lead to the completion of a licensing or co-development deal in the region.

Having recently returned from my third trip, I can say confidently that the progress we are making in China is the best I've seen at the company to date. We continue to engage at the most senior levels, and have met with several dozen strategics, including pharmaceutical companies, distributors, investors and CROs.

These efforts have been critical to building the relationships needed in the region in order to move our discussions forward. It has become abundantly clear that there is an emerging recognition by both industry and government to act against the various threat of antibiotic-mediated CDI and antimicrobial resistance.

Moving on to SYN-010, our proprietary modified release formulation of lovastatin lactone, SYN-010 remains an integral component of our portfolio of best-in-class microbiome-focused programs. SYN-010 is designed to reduce methane production in the GI tract to treat the underlying cause of the symptoms often experienced with irritable bowel syndrome with constipation.

In May we were granted a U.S. patent that includes claims related to the composition of matter of our SYN-010 formulation for the use of anti-methanogenic compositions to treat IBS-C. This adds to the already-comprehensive patent portfolio that we have around this asset, enabling us to include it in our discussions with potential partners. Fortifying our patent portfolio is a priority for us, and we now have more than 60 granted U.S. and international patents for SYN-010.

We are also continuing to focus on identifying a strategic partner or partners, both domestically and internationally, to advance SYN-010 in a manner that recognizes the capital investments needed to move this program forward. In parallel to these partnering efforts, we are also considering potential opportunities to expand on the established clinical dataset for SYN-010 without a significant capital investment.

We are already in a favorable position of having an approved Phase 2b/3 clinical trial protocol from the FDA, but we will continue to explore near-term clinical opportunities to further demonstrate the potential clinical and commercial value of SYN-010 to partners and to potentially accelerate its future clinical advancement.

While we are sharply focused on advancing and pursuing our partnering strategies for our later stage assets ribaxamase and SYN-010, we are also continually working on delivering new value from our diverse

microbiome-focused R&D engine. Two of the most promising of these pre-clinical assets are SYN-007 and SYN-020.

SYN-007 is our reformulation of ribaxamase designed to be used with orally administered beta-lactam antibiotics, such as amoxicillin, to protect the gut microbiome from antibiotic damage. During the second quarter, we completed a second canine animal study in which oral SYN-007 was co-administered with oral amoxicillin and oral Augmentin.

The results from this second canine study were similar to those from our first study and demonstrated that oral SYN-007 did not interfere with blood levels of either antibiotic but did diminish the microbiome damage associated with these antibiotics.

These results are an important next step in the evolution of our franchise of gut microbiome protection. The data underscore our formulation expertise and, most importantly, dramatically expand the potential utility of ribaxamase from use with IV antibiotics to also include the use with oral antibiotics.

During the second quarter we generated some very encouraging data for our SYN-020 program. SYN-020 is our 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 maintaining GI homeostasis and promoting a healthy gut microbiome. IAP has several key functions, two of which are to detoxify GI inflammatory mediators and to diminish so-called "leaky gut." Through these activities, oral delivery of IAP has the potential to treat both local and GI systemic disorders.

Despite its broad therapeutic potential, the development of IAP as an oral drug has been hindered by manufacturing hurdles which would result in an untenable high cost of goods. We have overcome these hurdles with dramatically improved manufacturing processes and tablet formulation that should provide recombinant IAP at a suitable cost for commercialization.

We recently completed several preclinical animal studies that support the clinical utility of SYN-020 for multiple gastrointestinal disorders. We are highly encouraged by these promising initial findings. The team is currently establishing strategies to advance IAP to and through clinical trials for up to three novel indications, which have unmet medical needs and span a range of market sizes. Importantly, we believe that with a small capital commitment, we can begin moving SYN-020 towards an IND.

We are excited at the breadth of our early-stage and late-stage clinical assets and their potential to offer new treatment paradigms for many challenging and burdensome healthcare conditions. We look forward to continuing to update you on our progress.

Now I'd like to shift gears and discuss the recent steps we have taken to ensure we have a fortified financial and organizational foundation in place to continue on our path forward of advancing our highly valuable, best-in-class microbiome-focused products.

Last week we announced that we'll be executing a 1 for 35 reverse stock split that will become effective on August 10. I can assure you that I, along with our board of directors, determined that this is an essential step necessary to strengthen the long-term financial position of our company. Our decision to execute on a reverse stock split, specifically at a ratio of 1 for 35 was done with careful consideration and chosen for a number of key reasons.

First and most importantly, to maintain our listing on the NYSE American Exchange.

Maintaining our listing is of the utmost importance, and it is critical to advancing our world-class programs. Remaining listed on a national exchange helps to ensure the stock remains tradeable, liquid, and that we continue to have the ability to access the equity capital markets as necessary. Additionally, a reverse split ratio of this nature should ensure that our continued listing on the NYSE American is not jeopardized again following the split.

Second, our post-reverse split share price is expected to allow for potential investment by new fundamental investors who have price minimum requirements significantly higher than our current share price.

We continue to meet regularly with notable, fundamentally-focused institutional investors whose names you would all be very familiar with. The feedback we continue to receive has been consistent. They like our story, they think we have great assets, but they're unable to seriously consider an investment in our company because of our current share price.

The reverse stock split should go a long way in strengthening our image on the Street, particularly in the event we need to raise capital, as a higher share price resulting from our chosen ratio should improve access to fundamental investors. Am I happy with the need to effect a reverse split of the stock at a ratio of 1 for 35? No, absolutely not. But I assure you that it was necessary. And, just like my colleagues, my stock options are completely underwater.

But, you know, I'm not concerned about that now because I truly believe and our team believes that we have a pipeline of phenomenal assets along with a clear and viable regulatory path towards marketing approval for our long-term programs that, over time, will allow us to unlock the true value of these assets, which is certainly not reflected in our current share price.

The reverse stock split is only one component of our broader efforts to strengthen and solidify our financial footing. We recently filed a preliminary proxy to be voted on during our Annual Shareholder meeting on September 24.

We included a proposal which would increase the number of authorized shares post-reverse split from 10 million to 200 million shares. We believe approval of this proposal will ensure the company is well positioned and can maintain maximum flexibility as we continue to explore various funding, partnering and licensing opportunities in the near and long term.

With that said, our approach to financing has not and will not waver. We continue to prioritize the pursuit of nondilutive forms of capital, specifically partnering of our unique and highly valuable assets SYN-004 and SYN-010, which I am personally involved with and have committed a significant portion of my time to.

However, should alternative forms of funding become required, we believe the steps we have taken and have announced will allow us to do so in a manner that affords us optimal flexibility and negotiating strength. In this regard, we are constantly evaluating options, and we will always consider their impact on our shareholders and the long-term viability of our company.

With that backdrop I'll review our financial results for the period ending June 30, 2018.

Financial stewardship and cash management remain a top priority for us. While I understand and fully appreciate that cash considerations and capital formation are top of mind, our primary goal remains to obtain a partnering or licensing deal, which we believe will alleviate some of the financial risks associated with our company.

General and administrative expenses decreased 13% to $1.4 million for the three months ended June 30, 2018, compared to $1.6 million for the same period in 2017. This decrease is primarily the result of lower salary expense, stock compensation, and related benefit costs incurred in 2018 due to the resignation of the previous CEO, along with the reduction of travel and consulting expense, offset by higher registration, investor relations and legal costs.

The charge related to stock-based compensation expense was $264,000 for the three months ended June 30, 2018, compared to $539,000 for the same period in 2017.

Research and development expenses decreased 25% to $3.6 million for the three months ended June 30, 2018, compared to $4.8 million for the same period in 2017. This decrease was primarily the result of lower ribaxamase and SYN-010 program costs for 2018, since no clinical trials were ongoing during the quarter.

The research and development costs incurred during the quarter were primarily related to planning for future ribaxamase Phase 3 and SYN-010 Phase 2b/3 clinical trial programs as we seek to secure the financial resources necessary for the completion of these clinical trials.

The charge related to noncash stock-based compensation expense was $293,000 for the three months ended June 30, 2018, compared to $331,000 for the same period in 2017.

We recorded other income of $789,000 for the three months ended June 30, 2018, compared to other income of $2.2 million for the same period in 2017. Other income for the three months ended March 31, 2018 is primarily comprised of noncash income of $783,000 from the change in fair value of warrants. The decrease in the fair value of the warrants was due to the decrease in our stock price from the prior quarter.

Cash and cash equivalents as of June 30, 2018 was $7.1 million.

Before we get to questions, I want to make it perfectly clear that we are more focused than ever on getting the job done. The objective is crystal clear for us: Unlock the value of our great and vast portfolio of products.

During the last eight months I have deeply examined every aspect of our company's operations to fully understand our strengths and weaknesses. Here are a few of the things that I've learned.

We have assets with the potential to create enormous value. I am not at all happy with the disconnect between our market cap and the potential NPV of our assets. However, I can tell you that I am fully committed to fixing this problem, and I think we're well on our way to doing that.

We have products that can address large global markets with significant unmet needs. We just need to match our products with the right value proposition. In other words, we need to be prudent with defining how much clinical investment is needed to develop our products and to develop them for the right indications while at the same time mitigating our investment, clinical, regulatory, and commercial risks.

We have an incredible -- we have incredible support from the clinicians and KOLs that we consistently talk with and are in contact with. We are told by them that time and time again that our products are needed and that they will be used.

We have an incredible core competency in manufacturing that has resulted in innovative formulation approaches that have demonstrated already that we have ability to significantly reduce production costs. This is absolutely critical in a price-sensitive marketplace.

And finally, with our vast portfolio of products, we have multiple shots on goal to achieve success. We are a multiproduct company with multiple ways to succeed. As we move forward, we will continue to prioritize our development activities so they are fully aligned with our ability to finance them while delivering shareholder value.

Once again, I want you to know that the team and I are committed to getting the job done and that we are privileged to be a part of the development of an exciting and potentially game-changing portfolio of products. Now I'd like to turn the call back over to Vincent so that we can get into the Q&A session.

Vincent Perrone: Thank you, Steve. Jamie, we'd like to open the phone line to questions. Would you please describe the procedure to ask questions for our listeners?

Questions & Answers

Operator: (Operator Instructions)

And our first question comes from Katherine Xu, from William Blair. Please go ahead with your question.

Katherine Xu: Just wondering the kind of deal that you're looking at potentially. Do you think that deal would be able to fund the whole Phase 3 study for ribaxamase, and why the guidance of the start in second half of '19?

Steven Shallcross: So, the first part of your question is kind of tough to answer. I mean, clearly that would be optimal for us. As I stated previously, I'm not going to talk about the progress, where we're at, and when something may or may not happen, for that matter. The ideal situation for us is to seek a traditional type of transaction that I think most everybody is familiar with, some form of upfront, some form of reimbursement for development activities, and then on the back end additional milestones and royalties. But specifically I can't even comment at this point whether or not any of these potential partners are going to cover what percentage of any type of development deal.

And then your second part of the question, I'm sorry, was related to --

Katherine Xu: The timing of the start of the Phase 3, second half of '19?

Steven Shallcross: Yes, right now, with the end-of-Phase 2 meeting set for the end of the quarter coming up here, we've got some manufacturing issues that will coincide with what we learned from the FDA. And then we also have on the operations side the necessity to get a CRO onboard, identify the sites, which actually is in process, qualify them, go through the process of putting the contracts in place. And I think that's going to take about a year to do. So right now I would suggest that the second half of '19 is accurate at this point.

Katherine Xu: Thank you.

Operator: (Operator Instructions)

And, ladies and gentlemen, at this time I'm showing no additional questions. I'd like to turn the conference call back over to Steven Shallcross for any closing remarks.

Steven Shallcross: Thank you. In closing, I'd like to thank each and every one of you for joining our call today. As I hope I have conveyed with my remarks today, we are truly excited, and we're at an inflection point, and an important inflection point, in Synthetic Biologics' evolution. We enter this next phase with a crystal-clear picture of the vast opportunities we have and what we need to do to achieve our success going forward.

We have an exciting portfolio of products. We deeply appreciate the confidence and dedication you've all shown us, and we look forward to continuing to update you on our progress as we continue in the weeks and months ahead. Thank you, and have a good evening.

Operator: Ladies and gentlemen, that does conclude today's conference call. We do thank you for attending. You may now disconnect your telephone lines.