Jaguar Health, Inc. NasdaqCM:JAGX FQ4 2019 Earnings Call Transcripts

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S&P Global Market Intelligence Estimates

	-FQ4 2019-			-FQ1 2020-	-FY 2019-			-FY 2020-	
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	
EPS (GAAP)	(0.67)	(0.68)	NM	(0.49)	(5.96)	(9.01)	NM	(2.08)	
Revenue (mm)	2.95	1.51	▼ (48.81 %)	1.25	7.12	5.78	▼ (18.82 %)	7.91	

Currency: USD

Consensus as of Mar-24-2020 10:34 AM GMT



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Call Participants

EXECUTIVES

Carol R. Lizak Senior VP of Finance & Chief Accounting Officer

Ian Wendt Vice President Commercial Strategy

Lisa A. Conte Founder, CEO, President & Director

Pravin R. Chaturvedi Chair of Scientific Advisory Board & Acting Chief Scientific Officer

Steven R. King Chief Sustainable Supply, Ethnobotanical Research & Intellectual Property and Secretary

Presentation

Operator

Good day, and welcome to the Jaguar Health Investor Call. Today's conference is being recorded.

Before I turn the call over to management, I'd like to remind you that management may make forward-looking statements relating to such matters as continued growth prospects for the company, uncertainties regarding market acceptance of products, the impact of competitive products and pricing, industry trends and product and technology initiatives, including products in the development stage, which may not achieve scientific objectives or meet stringent regulatory requirements. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. These statements are based on currently available information and management's current assumptions, expectations and projections about future events. While management believes that its assumptions, expectations and projections are reasonable in view of currently available information, you are cautioned not to place undue reliance on these forward-looking statements.

The company's actual results may differ materially from those discussed in this call for a variety of reasons, including those described in the forward-looking statements and Risk Factor sections of the company's Form 10-K for the year ending December 31, 2019, which was filed on April 3, 2020, and its other filings with the SEC, which are available on the Investor Relations section of Jaguar's website. Except as required by law, Jaguar Health undertakes no obligation to update or revise any forward-looking statements contained in this presentation to reflect new information, future events or otherwise.

Additionally, please note that the company supplements its condensed consolidated financial statements presented on a GAAP basis by providing gross sales, non-GAAP EBITDA and non-GAAP recurring EBITDA. Jaguar believes that the disclosure items of these non-GAAP measures provide investors with additional information that reflects the basis upon which company management assesses and operates the business. These non-GAAP financial measures should not be viewed in isolation or as substitutes for GAAP net sales and GAAP net loss and are not substitutes for or superior to measures of financial performance in conformity with GAAP.

At this time, it's my pleasure to turn the call over to Lisa Conte, Jaguar Health's President and Chief Executive Officer. Lisa, the floor is yours.

Lisa A. Conte

Founder, CEO, President & Director

Thank you -- thank you very much. We thank you all, who are on the phone, very much for joining our call today. My name is Lisa Conte. I am the founder and CEO of Jaguar Health and our wholly owned subsidiary, Napo Pharmaceuticals. I may use the name, Napo and Jaguar interchangeably throughout this call.

First, I, of course, want to send my warmest wishes to everyone as we all navigate through these unprecedented times. We feel grateful to report that everyone at Jaguar and Napo are fine. We are all stuck at home, doing this call remotely. And as such, we will not be taking Q&A today.

1/3 of company has been together for over 10 to 25 years, 3 of us have been working together for over 30 years. That trusted familiarity and continuity allow us to work well together even when working remotely. Now we literally finish each other during sentences.

Thirty years ago, we were in the middle of another pandemic, HIV/AIDS. And for Napo, we were on a mission to find naturally sourced plant-based medicines to meet urgent global health needs. We successfully brought Mytesi from a tree that we would possibly harvest from the Amazon rainforest to the first and only oral plant-based prescription medicine approved under botanical guidance by the FDA. Today, we find ourselves in the middle of the COVID-19 pandemic, working with the FDA to determine if

Mytesi may be appropriate for emergency use authorization for symptomatic relief of diarrhea in patients with COVID-19.

Nearly 38 million people with HIV globally and nearly 25 million people use antiretroviral therapy based on data from UNAIDS at the end of June 2019. As a reminder, Mytesi is a first-in-class antisecretory agent, currently FDA-approved for the indication of symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.

We have an essential product with Mytesi, we're in essential business, and we'd anticipate stocked up and taking steps to ensure that patients living with HIV, who rely on Mytesi, have uninterrupted access to this first of its kind oral plant-based prescription medicine.

Mytesi, as we said before, is a product in the pipeline. We're actively developing multiple potential followon pipeline indications focused on GI indication, the most advanced being cancer therapy-related diarrhea, which we refer to as CTD. Other potential GI indications include irritable bowel syndrome, inflammatory bowel disease and Crohn's supportive care, functional diarrhea and pediatric rare gastrointestinal disease indications.

There are 5 primary topics we'll be covering for today's call with 5 participating speakers from the company, the same speakers.

I'll begin with a status update regarding our ongoing business development efforts and provide an update on COVID-19-related activities. Next, I'll turn the discussion over to our Senior VP of Finance and Chief Accounting Officer, Carol Lizak, who will recap financials for 2019 and provide a comparison to 2018. After Carol, we'll introduce Ian Wendt, our Vice President of Commercial Strategy. Ian will discuss the multiple facets of Napo's enhanced market access strategy for Mytesi for the currently approved indication of HIV-related diarrhea, which is an initiative we're quite excited about and occurring real time.

Dr. Steven King, our Chief of Ethnobotanical Science and also the project leader of our cholera development program, will provide information regarding recently approved funding support from the National Institute of Allergy and Infectious Diseases in support of the cholera program moving forward. Steve will also discuss the role that traditional medicine has played and potentially is currently playing in the fight against global pathogen scourges.

And finally, Dr. Pravin Chaturvedi, our Scientific Officer, will speak to the regulatory developments related to crofelemer for the potential CTD indication and potential pediatric rare disease indication for congenital diarrheal disorder and short bowel syndrome.

Let's jump right in. Looking forward, we believe 2020 has the potential to be a transformative year for Jaguar and Napo. Our core goals for 2020 include initiating the pivotal trial in the second half of this year for Mytesi for CTD, cancer therapy-related diarrhea, and completing the rollout of our enhanced market access strategy, which is part of the company's larger strategy to support the health of HIV patients, especially during this time of global crisis.

The majority of people living with HIV/AIDS in the United States are older. As Tez Anderson, the founder of the nonprofit organization, Let's Kick ASS - AIDS Survivor Syndrome, pointed out to me recently, it's not our first pandemic, Lisa. The community is resilient as is Napo, and we believe our enhanced patient access plan will help expand Mytesi access among HIV patients, which you'll hear more about from Ian.

Key to our business model, this sustainable-based commercial business efforts supports the company's strategy to become a stable, cash flow positive business, supported primarily by growth in Mytesi sales. Simultaneously, and as I stated before, we are confident that by mid-2020, we'll forge a regional ex U.S. business development deal, possibly more than 1, to bring in nondilutive dollars to support the pivotal trial initiation and/or key clinical development activities for pipeline follow-on indications for Mytesi.

Our mantra at Napo is pipeline, pipeline, pipeline driven by business development, business development for that pipeline mobilization. We have a remarkable risk-mitigated product pipeline, a pipeline within a product, I can't say that enough, which contains multiple, novel and important follow-on indications for Mytesi. Let me remind you, it's a drug product that is already approved by

the FDA for chronic indication and, therefore, supported by chronic safety package, GMP, commercial manufacturing is in place for Mytesi and several of the follow-on indications for Mytesi are backed by strong Phase II and/or proof-of-concept data.

The depth of our pipeline provides potential supportive care solutions for a large patient population across multiple disease indications around the globe. And we believe this pipeline will fuel long-term value creation for investors and provide nondiluted funding opportunities for partner collaborations around the world.

Diarrhea related to cancer therapy continues to be the core focus of our pipeline development efforts. A significant portion of patients undergoing cancer treatment experience diarrhea. Novel targeted cancer therapy agents, such as epidermal growth factor receptor antibodies, Herceptin, for example, and tyrosine kinase inhibitors, Herceptin, for -- I am sorry, anyways, tyrosine kinase inhibitors with or without standard chemotherapy agents may activate natural chloride secretion pathways in the gastrointestinal mucosa, potentially leading to secretory diarrhea.

According to data appearing in treatment guidelines for CID, which stands for chemotherapy-induced diarrhea, a component of CTD, and this was in the April 2004 issue of Gastroenterology & Endoscopy News, diarrhea is the most common adverse event reported in chemotherapy patients. Diarrhea in this patient population has a potential to cause dehydration. OTC, antimotility agents, such as the opioids, Imodium or loperamide, cause constipation and lethargy. And many cancer patients with diarrhea require drug holidays or dose reductions in their life-saving cancer therapy.

Better management of diarrhea allows for better -- potentially allows for better compliance with the therapeutic dosing of targeted treatments for cancer. And as we've shown in relevant animal models, potentially leading to better clinical outcomes for cancer patients, and in particular, for cancer patients on long-term adjuvant therapy.

To continue, I want to mention our efforts to make Mytesi available for supportive care related to COVID-19. We submitted an emergency release authorization request on March 21, 2020. The request was based on and accompanied by a letter of endorsement submitted to Dr. Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, and CC to FDA Commissioner, Dr. Stephen Hahn, from a world leader in the field of infectious diseases and epidemiology.

The letter of endorsement is based on information and publications with key opinion leaders has been reviewing real time, which indicates that there is adequate information to document that diarrhea and other gastrointestinal symptoms are early symptoms of COVID-19 prior to the pulmonary symptoms. His review of data also supports the tenets that the virus can be shed from the dress and is thus potentially transmissible via the fecal-oral route. Decreasing fecal volume by changing the stool consistency from watery to formed stool is key to the mechanism of action and the results of Mytesi would not only support patient's care, but could thus also reduce the contagion risk to health care providers.

As we've heard from the FDA, they expect to get back to us in days with respect to this potential off-label use of Mytesi. We're so pleased to have the FDA's attention for a request to provide possible support to COVID-19 patients and potentially reduce contagion among patients and health care workers. And we're grateful to and proud of the many Napo stakeholders that have taken the initiatives and perseverance in the time to chaos to play a meaningful role in seeking to address the weak during this pandemic.

Back to our major core business. We'll now move along to the 2019 financial results. The company filed its 2019 10-K on Friday, April 3, with the SEC. The 10-K can, of course, be viewed on the SEC's website and on the Investor Relations section of the Jaguar website.

I'll now turn the call over to Carol Lizak, Jaguar's Senior Vice President and Chief Accounting Officer, to review top line financial results for the year ended December 31, 2019. Carol?

Carol R. Lizak

Senior VP of Finance & Chief Accounting Officer

Thank you, Lisa, and thank you all for joining our call today.

Key financial highlights for the year ended December 31, 2019, are as follows: 2019 Mytesi net sales were approximately \$5.7 million, an increase of 36% in year-over-year. The Mytesi total prescription volume increased to 62% in the year 2019 over the year 2018. The total operating expenses for the year 2019 was \$34.7 million as compared to \$35.2 million for the year 2018, a 1% or \$500,000 decrease year-over-year. The decrease in total operating expenses was primarily due to the write-off of goodwill of \$5.2 million in the year 2018, offset by an impairment of long-lived intangible assets of \$4 million and \$600,000 in the settlement of the royalty license agreement.

That concludes my recap of high-level financials for 2019. I'll now hand the discussion over to our next speaker, Ian Wendt.

Ian Wendt

Vice President Commercial Strategy

Good morning, all. As Lisa stated in her opening comments and as the company announced last week, Napo is expanding NapoCares, our patient support program for Mytesi, the company's FDA-approved plant-based prescription drug indicated for the symptomatic relief of noninfectious diarrhea in adult patients living with HIV on any retroviral therapy.

The changes to the NapoCares program are intended to increase Mytesi patient access, uptake and persistency. HIV enteropathy, which is chronic diarrhea due to the direct or indirect effects of HIV on the GI tract is a problem for many HIV positive patients.

Unlike certain antidiarrheal products that are only approved for acute use, Mytesi is a nonopioid derivative and has a very low-risk of causing constipation. Mytesi is approved for chronic use and its unique mechanism of action helps ensure that diarrhea does not have to become the new normal for adult patients living with HIV on any retroviral therapy.

Our field team's efforts remain focused primarily on physicians who are already writing Mytesi prescriptions, on alleviating access issues faced by patients and on increasing the duration of Mytesi therapy in HIV patients is clinically appropriate, while also reducing Mytesi-related cost burdens in non-government supported payer channels.

The expansion to the NapoCares program raises income limits on patients eligible for Napo's uninsured free drug program, significantly increases co-pay support for commercially insured patients and allows the co-pay amount to remain the same whether a patient fills a 30-day or 90-day prescription of Mytesi. These changes became effective on April 1.

A key component of the NapoCares market access program involves offering significantly expanded support for eligible patients to reduce out-of-pocket cost as a barrier to obtaining Mytesi in the U.S. The income limit for the patient assistance program, which offers free drug for uninsured patients, had increased from 2x the federal poverty limit to 5x the federal poverty limit, a 150% increase, and the Mytesi co-pay benefit for commercially insured patients has been increased from an annual maximum of \$1,200 to \$6,000, which is a 400% increase. Most eligible patients will now pay no more than \$25 for their Mytesi prescription. Additionally, patients can now use their co-pay cards if they refill Mytesi prescriptions earlier and every 30 days. Fast-start prescriptions will soon be available to provide immediate access to Mytesi for patients facing reimbursement challenges, and a bridge drug program will soon be available for patients who have a lapse in insurance coverage.

To support providers, patients with access services from reimbursement and prior authorization support to appeals and patient assistance dispensing for Mytesi, Napo is working with Florida-based AssistRx to design and implement a comprehensive patient support services program. AssistRx has extensive experience supporting HIV patients and has developed an industry-leading technology platform called iAssist to streamline therapy initiation.

Our new market action strategy is also designed to significantly increase the number of specialty pharmacies involved in Mytesi's distribution. Specialty pharmacies offer a high-touch patient engagement model to help ensure appropriate use of drugs like Mytesi and optimal patient outcomes. The fact that our

expanded patient support program is launching during the COVID-19 pandemic should especially benefit Mytesi patients who may have lost jobs or health insurance during the crisis.

We are removing barriers for patients to access Mytesi, and the changes we've instituted should help ensure patients can employ good social distancing practices while still obtaining their medication.

Diarrhea is a chronic life-altering condition in HIV patients on ART, and it's our goal to remove Mytesi access hurdles for all patients in need, regardless of their income level as well as for their providers, especially during this national crisis.

That concludes my comments for today. Steve, I will now turn the discussion over to you.

Steven R. King

Chief Sustainable Supply, Ethnobotanical Research & Intellectual Property and Secretary

Thank you, Ian. And thanks for those of you on the phone to make time to join us this morning. My name is Steven King. I'm the Chief Sustainable Supply, Ethnobotanical Research & Intellectual Property Officer for Jaguar and Napo.

To begin, I'm happy to report that Napo was informed last week, on April 1 that it received additional preclinical services from the National Institute of Allergy and Infectious Diseases to support the development of lechlemer, Napo's growth product candidate for cholera indication.

Under NIAID's suite of preclinical services, NIAID-funded contractors will conduct toxicology testing for a 28-day rat study. NIAID is part of the National Institute of Health.

As previously announced under NIAID's suite of preclinical services, these NIAID-funded contractors conducted toxicology testing for a 7-day rat and dog study.

Cholera is an acute diarrheal illness caused by the infection of the intestine with the bacterium Vibrio cholerae. According to the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services, an estimated 3 million to 5 million cholera cases and more than 100,000 cholera-related deaths occur each year around the world. The deaths are due to dehydration, not the cholera infection itself. It simply occurs in the first 2 to 18 hours after the infection.

Lechlemer, which we also refer to as SB-300, has the same mechanism of action as crofelemer and is significantly less costly to produce. We have previously presented Phase II data on crofelemer for the treatment of the devastating diarrhea in cholera patients from the renowned International Center for Diarrhoeal Disease Research in Dhaka, Bangladesh.

Until permitted, we plan to follow the same study design for lechlemer, following the same protocol, using the same principle investigators and using the same clinical trial sites in Bangladesh for the development of lechlemer. Additionally, we believe this drug candidate may support efforts to receive a priority review voucher from the FDA for cholera indication. Priority review vouchers are granted by the FDA to drug developers as an incentive to develop treatments for neglected diseases and rare pediatric diseases.

As many of you are no doubt aware, Napo's mission dating back to the company's founding is to discover and develop novel, safe and effective plant-based prescription medicines that can be responsibly harvested to meet urgent global health care needs.

Crofelemer, the active ingredient in Mytesi, our FDA-approved nonopioid prescription drug indicated for the symptomatic relief of noninfectious diarrhea in adult patients living with HIV on antiretroviral therapy is extracted and purified from the Amazon rainforest tree, Croton lechleri. The latex of the Croton lechleri tree has a rich history of medicinal use by indigenous people in South America.

At present, as a result of the COVID-19 pandemic, there is a great deal of information from global media related to another plant-based medicine, one that's changed the world a long time ago. The medicine I'm referring to is quinine, which was discovered originally by the Quechua people of Ecuador, Peru and Bolivia, who used the bark of the Amazonian tree, Cinchona officinalis, to treat fevers, inflammation and pain.

Other explorers from South America learned about quinine's additional properties in the beginning of the 17th century. Quinine remains an important anti-malarial drug almost 400 years after its effectiveness was first documented. Quinine and quinidine are still FDA-approved drugs used to treat cardiac disorders, digestive problems and muscle spasms. Quinine came to the world as malarial treatment that allowed European nations to develop and explore across the region that have been devastated by uncontrolled malaria.

The synthetic derivatives of quinine, Atabrine and chloroquine were developed between 1931 and 1934 to prevent and treat malaria before and after World War II. Chloroquine and another synthetic derivative, hydroxychloroquine are also used today to treat rheumatoid arthritis and lupus. There is now medical research focusing on the potential to use these 2 synthetic derivatives of quinine to combat COVID-19. It's not clear if these drugs will prove to be safe and/or effective for COVID-19, but I believe it's worth remembering that the medical practice in discovery of new therapeutics has used methods of medical knowledge in diseased people and the vast data used for centuries as part of their traditional medicine.

In fact, as an interesting historical footnote, Winston Churchill reportedly once have said that the gin and tonic saved more Englishmen's lives, and minds, than all the doctors in the Empire. The so-called tonic in the original gin and tonic was quinine.

I'm very proud of the fact that Mytesi also has its roots in traditional medicine, and I'm proud that Mytesi, as a pipeline in a product, a term frequently employed by Lisa, is being developed as multiple possible follow-on indications.

With Napo's daring commitment for development and commercializing traditional plant-based medicines, we expect that it won't be another 100 years before they're once again made aware of the reason of conserving and leveraging traditional medical knowledge. Pravin, onto you.

Pravin R. Chaturvedi

Chair of Scientific Advisory Board & Acting Chief Scientific Officer

Thank you, Steve. Good morning, everybody. Thanks for joining. And my name is Pravin Chaturvedi, and I'm the Chair of Napo Scientific Advisory Board and also serve as the Chief Scientific Officer of Napo Pharmaceuticals and Jaguar Health.

As Lisa mentioned earlier, Napo is planning the initiation of preclinical trials for crofelemer in the second half of 2020, a pivotal trial for the indication of prevention and treatment of cancer therapy-related diarrhea, called CTD, in adult cancer patients, a target indication we refer to as CTD and 2 pediatric studies for diarrheal disease, orphan gastrointestinal disorder such as short bowel syndrome, I'll refer to it as SBS, these are being planned.

For the adult CTD study, we have been in active discussions with the FDA and with key opinion leaders, and we have received their input on the clinical trial and statistical analysis plan. We are revising the clinical protocol to accommodate their input and are preparing the requisite documents, including the statistical analysis plan based on consent and other requirements to initiate the pivotal adult CTD trials under a new IND. The principal investigator for the CTD trial is at a major institution -- major cancer institution in the United States.

Our goal is to ensure that the protocol addresses the unmet medical need for the treatment of CTD combined with the practicality of patients enrollment and trial design. But we are also ensuring that statisticians from both Napo Pharmaceuticals and the FDA agree on the endpoint that are relevant to crofelemer's unique physiological mechanism of action.

Our planned study for CTD is analogous to the successful pivotal trial for Mytesi's currently-approved HIV indication, and as a part of our risk mitigation strategy, we intend to use the same formulation and dosing as the currently commercialized Mytesi.

In addition to working with the key opinion leaders on clinical strategy and trial design, we've been coordinating with the Multinational Association of Supportive Care in Cancer, also referred to as MASCC. We are supporting their efforts to ascertain guidelines for the treatment and management of diarrhea in

cancer patients. We are a Gold Level sponsor for the MASCC Conference, which was to be held in Spain in June this year. However, it has been postponed for obvious reasons at this time. However, we'll continue to work with the leadership team of MASCC and provide them a good support, while we all work through the challenges of this global pandemic.

For the pediatric clinical study in the orphan indication of short bowl syndrome, we prepared a dossier to support the pre-IND discussion with the FDA. And we've submitted it, and we expect the FDA to revert to us in approximately 30 days with their input on the pre-IND package. This pre-IND releasing document from Napo outlines the plan for clinical trial in short bowl syndrome and potentially -- and congenital diarrheal disorders as well as provide the rationale for addressing diarrhea to reduce the nutritional requirements in children with either short bowel syndrome or congenital diarrheal disorders. SBS and CDD, short bowel syndrome and congenital diarrheal disorders are much more prevalent in regions such as the Middle East and North Africa region, the MENA region, where there are consanguineous marriages. And we are pleased to actually have the support of the key opinion leader in that region, Dr. Mohamad Migdady, from the Sheikh Khalifa Medical Center in Abu Dhabi, who's providing us with the leadership and guidance to conduct appropriate clinical studies in the MENA region.

As mentioned earlier, reduction of enteral and/or parenteral nutritional requirements in these children with SBS or congenital diarrheal disorders would improve both the quality of their lives as well as improve the odds of their survival. Hence, we are planning for potentially doing 2 pediatric clinical studies that will provide evidence of safety of Mytesi as well as proof of efficacy in SBS and/or CDD patients.

I will now pass the microphone back on to Lisa for her comments -- closing comments. Thank you. Over to you, Lisa.

Lisa A. Conte

Founder, CEO, President & Director

Thanks, Pravin. Thank you to all the speakers, and thank you to all the listeners.

In closing, I'm proud to announce this past February, the nonprofit American Botanical Council has given the 2019 Varro E. Tyler Commercial Investment in Phytomedicinal Research Award to Napo in recognition of Napo's ongoing commitment to the sustainable development and production of natural therapeutic preparation. We had to miss that award ceremony for obvious reasons as well. Specifically, this award acknowledges the successful development and approval of crofelemer, which is derived as Steve said, from the traditional Croton lechleri tree in the Amazon rainforest. The development of crofelemer has been the key mission of Napo's core team members for more than 30 years, and we remain fully committed to expanding crofelemer access to all patients in need throughout the world.

Previous recipients of this award include our partner, Italian-based Indena, one of the world's largest producers of clinically-tested botanical extracts for the pharmaceutical market.

As a reminder, Mytesi is the first and only oral plant-based prescription medicine drug approved under FDA's botanical guidance. And there's no pathway by which a generic product can be developed for a drug approved under botanical guidance.

I'm extremely pleased with our achievements in 2019 and continue to be grateful for the ongoing support and dedication of our employees, stockholders and all of our stakeholders as we continue efforts in 2020 to grow sales, bring on more partners across multiple possible follow-on indications to Mytesi and drive this company to a break-even cash flow positive situation.

I'm also very proud to be working with the team with such high integrity and value, which has been displayed probably during this time of global crisis. I'll repeat the words of Tez Anderson. This is not our first pandemic, Lisa. And we are grateful to be working together to make a difference in the lives of people living with chronic life-altering GI conditions.

As I said earlier, we believe 2020 has the potential to be a transformative year for Jaguar and Napo.

With that, we conclude our comments. Thank you all once again for joining today's call. Please be safe, be well and stay home. Thank you.

Operator

And that does conclude today's conference. Again, thank you for your participation.

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