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Teligent, Inc. NasdaqGS:TLGT

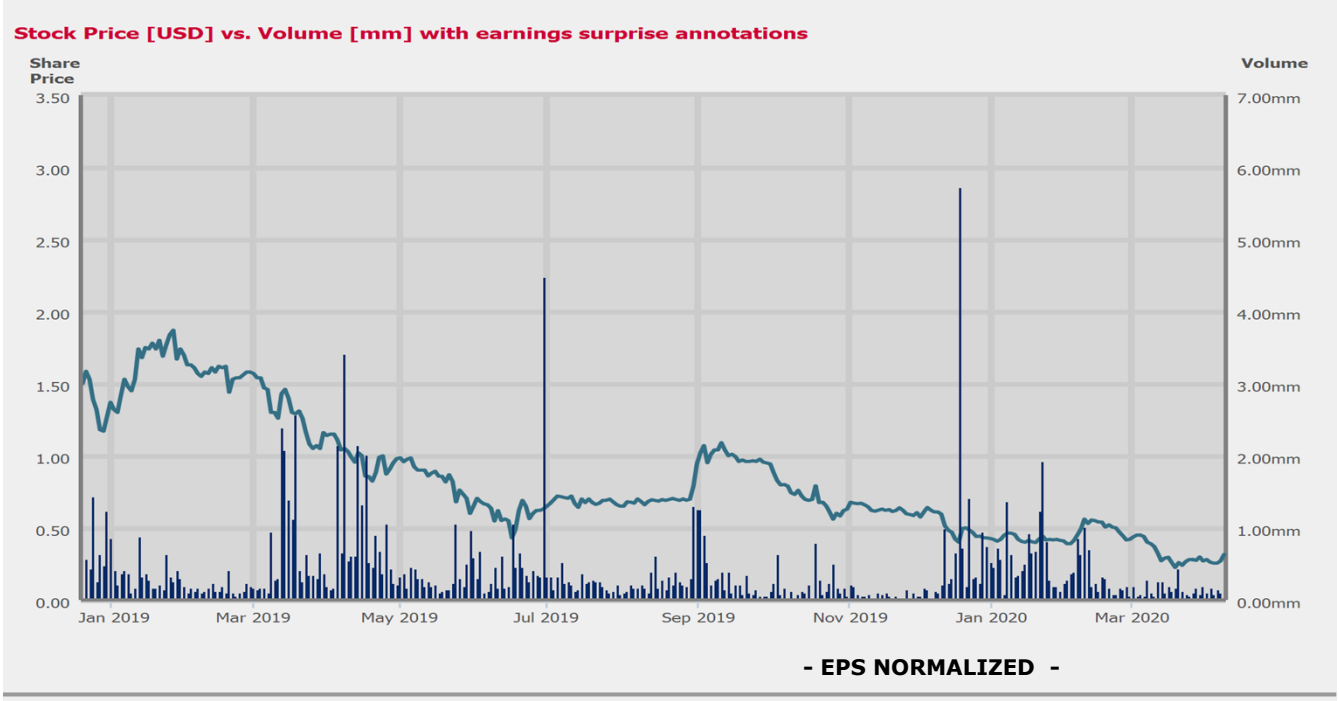
FQ4 2019 Earnings Call Transcripts

Wednesday, April 08, 2020 12:00 PM GMT

S&P Global Market Intelligence Estimates

	-FQ3 2019-			-FQ4 2019-		-FY 2019-	-FY 2020-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	SURPRISE	CONSENSUS	CONSENSUS
EPS Normalized	(0.02)	(0.04)	NM	(0.02)	NM	(0.20)	(0.01)
Revenue (mm)	19.37	18.47	▼(4.65 %)	19.51	▼(18.14 %)	69.39	87.85

Currency: USD
Consensus as of Feb-18-2020 5:03 AM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ4 2018	(0.02)	(0.18)	NM
FQ1 2019	(0.07)	(0.09)	NM
FQ2 2019	(0.04)	(0.04)	NM
FQ3 2019	(0.02)	(0.04)	NM

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Call Participants

EXECUTIVES

Damian Finio
Corporate Secretary & CFO

Timothy B. Sawyer
President & CEO

ANALYSTS

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

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Presentation

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Teligent, Inc. Fourth Quarter and Full Year 2019 Results Conference Call. [Operator Instructions] Please be advised that today's conference is being recorded.

Except for historical facts, the statements in this presentation as well as oral statements or other written statements made or to be made by Teligent Inc. are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve risks and uncertainties. For example, without limitation, statements about the company's anticipated growth and future operations, the current or expected market size for its products, the success of our current or future product offerings and the research and development efforts and the company's ability to file for and obtain U.S. Food and Drug Administration approvals for future products are forward-looking statements.

Forward-looking statements are merely the company's current predictions of future events. The statements are inherently uncertain, and actual results could differ materially from the statements made herein. There is no assurance that the company will achieve the sales levels that will make its operations profitable, or that FDA filings and approvals will be completed and obtained as anticipated.

For a description of additional risks and uncertainties, please refer to the company's filings with the Securities and Exchange Commission, including its latest annual report on Form 10-K and its latest quarterly report on Form 10-Q. The company assumes no obligation to update its forward-looking statements to reflect new information and developments.

[Operator Instructions] I would now like to hand the conference over to your speaker today, Mr. Damian Finio, Teligent Corporate's Chief Financial Officer. Thank you. Please go ahead, sir.

Damian Finio
Corporate Secretary & CFO

Thank you, Daniel, and good morning, everyone. I am Damian Finio, the Chief Financial Officer of Teligent. I am joined on this morning's call by our new President and CEO, Tim Sawyer. Before introducing you to Tim, on behalf of all employees of Teligent, I wanted to take a moment to thank our former President and CEO, Jason Grenfell-Gardner, for his vision and significant contributions made to this organization.

Now this morning, I'm excited to introduce you to our new President and CEO, Tim Sawyer. He brings over 26 years of experience in the pharmaceutical industry, having held a variety of senior executive positions in general management, marketing and sales. Prior to joining Teligent, Tim spent 16 years at Barr Laboratories, eventually serving as Executive Vice President, Global Generic Sales and Marketing, where he led a team of nearly 2,000 employees in 25 countries. Subsequently, Tim held positions such as Senior Vice President, Corporate Strategic Development at Mylan and President Retail Medicine at 1-800-Doctors, Inc. Most recently, Tim served as Chief Executive Officer of Geritrex, a manufacturer and marketer of generic over the counter pharmaceuticals.

Since Tim joined on February 5, his leadership style has been consistent, and it's no surprise he's had success in this industry. He's a great listener, adept at building relationships quickly, crystal clear with his expectations and does not hesitate in holding individuals accountable. We are confident in his ability to lead this organization through the next phase of our evolution.

And with that introduction, I will hand the mic over to Tim. Tim?

Timothy B. Sawyer
President & CEO

Thanks, Damian. Good morning, and thanks for that kind introduction. I truly appreciate the time you've spent helping me get up to speed quickly, thank you. I'm Tim Sawyer, the new President and CEO of

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Teligent. I'm delighted to be here with you this morning to discuss the Q4 and full year 2019 results for Teligent. It's been 5 months since Teligent's last call with investors, so needless to say, Damian and I have a lot of topics to cover this morning. I'd like to start by thanking the Teligent employees, Board of Directors and the many stakeholders, including shareholders, creditors, customers and vendors for their warm welcome, thank you. I look forward to working with you as we drive Teligent's business forward.

During my first 8 weeks with Teligent, I've been very clear with all of these stakeholders about my top 3 priorities. First, resolving the Warning Letter issued by the FDA in November of 2019. Second, passing the pre-approval inspection of our new injectable manufacturing facility in Buena, New Jersey. And third, managing cash flow.

Before walking you through these priorities in more detail, I'd also like to highlight that I believe in the company's TICO, topicals, injectables, complex and ophthalmic strategy, my plan is grounded on efficiently executing this strategy, not fundamentally changing it. I've worked in the pharmaceutical industry for nearly 30 years. I've seen strategies, companies, people and products come and go. But regardless of the ever-shifting headwinds this industry has faced for decades, the companies that succeed know how to execute. And to execute, you need to build an organization, hyper-focused on delivering an uninterrupted supply of high-quality, low-cost pharmaceutical products to its customers. My plan is to execute the TICO strategy, not change it.

Let's talk about our first priority, resolving the FDA Warning Letter. There are 2 phases to the Warning Letter remediation. Phase 1 is a physical audit of our facility conducted by a third-party auditor. This phase is intended to show that the current processes, procedures and policies of the company are compliant for pharmaceutical products. This phase has been completed, and the report was submitted to the FDA. Phase II is the documentation audit and review. This ensures that all products on the market that are within expiry are verified as safe, effective and fit for use. This phase is nearly complete, and we expect to file our final response to the agency in the coming days. Although ultimately, only the FDA can decide to lift a Warning Letter, I feel confident in the company's remediation efforts led by our enhanced quality team.

Regarding the second priority, passing the pre-approval inspection, we engaged the third-party auditor previously mentioned to conduct a mock audit of our prior approval supplement application and the Buena facility, which included the new sterile facility. At the conclusion of the audit, we reviewed the findings, and our quality and operational teams have worked diligently to address their observations. We believe we are prepared for the FDA inspection. Our original intent was to use our ranitidine product to trigger this PAI. However, in light of the FDA action on ranitidine last week, including requesting the market withdrawal of all ranitidine products, this is unlikely, and we will shift to our next injectable product to trigger the PAI. This product is expected to be filed shortly after the Warning Letter is submitted in the coming days.

Again, although it's ultimately up to the agency to decide, our preference and intent is to work with the FDA to perform a combined inspection in Buena that covers both what's necessary to lift the Warning Letter and approve our sterile facility for commercial production.

Managing cash flows has been and will continue to be a priority under my leadership. The organization was successful in reducing discretionary spending and redeploying the savings to fund more investment in our quality department previously. Cost savings, however, are an integral part of a generic company, and we will continue to focus on savings that impact our cost of goods to enable Teligent to remain cost competitive in the marketplace.

Another area of focus has been on the company's capital structure. As you'll hear from Damian, he has led the team in retiring, issuing and swapping convertible bonds in addition to executing amendments on our revolving credit facility and term loan with Ares Capital. Efforts to reduce costs will continue, and the capital structure will continue to evolve.

We also continue to work with our development partner and the FDA to address the second complete response letter received on our complex drug application.

And finally, we continue to work with Leerink on the noncore asset divestiture process initiated in October of 2019. We are progressing, and we'll provide updates as appropriate.

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At this point, let me turn the call over to Damian, so he can provide more insight to our actual and projected financial performance and a few other important topics. At the conclusion of Damian's remarks, I'll share some final thoughts before opening it up to your questions. Damian?

Damian Finio
Corporate Secretary & CFO

Thanks, Tim. Our last earnings call was in November of 2019. So I would like to spend a few more minutes than usual in order to provide you with a full update on 4 important topics. Number one, actual and projected financial performance; number two, key highlights to the Ares loan amendments announced earlier today; three, liquidity; and finally four, our listing status with NASDAQ.

So let's start with the first topic, actual and projected financial performance. Consolidated net revenues for the fourth quarter of 2019 were $16.7 million, bringing full year 2019 revenues to $65.9 million or 4% short of our last full year guidance. Fourth quarter revenues were dampened by failure to supply fees of $0.8 million, $0.4 million of which were incurred in Canada. And although difficult to quantify, it's reasonable to assume that past supply disruptions coupled with the noncore asset divestiture process initiated on October 1 and the Warning Letter issued by the FDA in late November 2019, combined to dampen demand for our products. As we work through these challenges, efforts to smooth the ongoing process of balancing supply and demand will be further emphasized. And with Tim's experience and leadership in this area, I remain confident that we will get there, absent any COVID-19-related business interruptions.

Gross margin for the fourth quarter was 12%, a 3,100 basis point decline from the 43% realized as of year-to-date September 30, 2019. Unfavorable customer and product mix accounted for 1,700 of those 3,100 basis points decline in the fourth quarter. Price erosion accounted for another 1,000 basis points, while incremental inventory reserves accounted for the remaining portion of the quarter-on-quarter decline.

Fourth quarter total operating expenses were consistent with previously reported September 30 year-to-date results. Specific to product development and research expenses, the incremental expense realized in the fourth quarter was driven by a $0.9 million noncash write-off of a prepaid asset relating to a delayed TEP transfer between 2 of our injectable contract manufacturers.

Specific to selling, general and administrative expenses, we continue to incur legal fees as we vigorously defend our position in ongoing litigation. However, for a company of our size, legal fees of $1 million in the fourth quarter and $3.7 million for full year 2019 are material. As reported in today's press release, adjusted EBITDA for the fourth quarter was a loss of $4.3 million. That said, consistent with what I described earlier, this loss includes the $0.8 million of failure to supply penalties recorded as an offset to revenue, the $0.9 million write-off recorded in product development and research expenses and the continuing legal defense costs.

In terms of full year performance, the company posted $65.9 million of revenue, which is consistent with 2018. Despite the less than expected performance in the fourth quarter of 2019, year-on-year gross profit improved by $0.7 million or 3%, while gross margin improved 200 basis points from 34% to 36%.

Fourth quarter financial performance led to a shortfall in our goal of forging the path to profitability in 2019, as we posted adjusted EBITDA equivalent to a $0.2 million loss for the full year.

We filed for a 10-K extension on Monday, March 30. The extension provides us with an incremental 15 days. Additional time was needed to execute the loan amendments with Ares and as a resulting and required subsequent event disclosures to Form 10-K. We intend to file by the end of this week, but certainly before the extended deadline of April 14.

Lastly, in terms of projected financial performance, we will not be providing 2020 financial guidance on today's call. There are several major variables weighing on our ability to accurately project and deliver our 2020 financial targets. Aside from the impact COVID-19 might have on our manufacturing capability and/or patient demand for our products, Teligent is also operating under a Warning Letter. As a consequence of that Warning Letter, our filed topical ANDAs will not be approved, and the injectable pre-approval

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inspection will happen either in parallel or after Warning Letter resolution. Variables such as COVID-19, a Warning Letter, pre-approval inspection, complex drug application and the noncore asset divestiture process are material and not entirely within our control. For all of these reasons, we will not be providing 2020 guidance today. However, we do anticipate reporting an approximate 50% decline in first quarter 2020 revenues.

Looking beyond the first quarter of 2020, assuming successful resolution of the material events mentioned, we would expect to see financial performance improvement over the remainder of the calendar year.

This leads me to the second of the 4 topics I'd like to cover, and that is providing key highlights to the loan amendments announced earlier today. Both our actual 2019 financial performance and medium-term projections were reviewed and discussed in detail with our secured creditor, Ares Capital. As an outcome of those collaborative discussions, we executed amendments to both our first lien revolver and second lien term loan agreements on April 6, 2020. These amendments serve to eliminate the original fourth quarter 2019 financial covenants, while significantly reducing the financial performance required to meet financial covenants going forward. For the 4 quarters of 2020, the company must record trailing 12-month net revenues of $59 million, $55 million, $54 million and $57 million, respectively. Beginning with the quarter ended March 31, 2021, the company must report trailing 12-month adjusted EBITDA performance in excess of a range beginning with $10 million, increasing to $14.5 million for the last quarter, just prior to loan maturity.

Also, the calculation of adjusted EBITDA per the amendment now includes certain add-backs, including, but not limited to legal expenses within certain limitations. In addition, the amendments provide the company with the option to continue picking or deferring cash interest paid on the term loan for an additional year, if the company is successful in resolving the Warning Letter and passing the injectable pre-approval inspection by December 2020. If only one of those items occurs by this time, then the company may still elect to pay interest in kind during 2021, but only from the time the second condition has been satisfied. Beyond December 2021, a portion of interest on the loans accruing at a rate of 4.25% per annum may continue to be paid in kind.

Although our preference is to generate the operating cash flow needed to service our debt to avoid the compounding effect of picking interest, this provision improves the company's ability to maintain the liquidity needed to execute our strategy. In consideration of the relaxed covenants and potential to extend the pick option, the cost of capital increased. The amended interest rate on the first lien revolving credit facility is LIBOR plus 5.5% with a 1.5% LIBOR floor. The new rate is about 100 basis points more than at loan inception in December 2018 or 225 basis points more than the rate just prior to executing the amendment. The difference between the increment at loan inception versus today relates to the 15-month decline in the LIBOR. The amended interest rate on the second lien term loan is LIBOR plus 13%, also with the 1.5% LIBOR floor. The new rate is about 350 basis points more than at loan inception or 475 basis points more than the rate just prior to executing the amendment. Again, the difference between the incremental loan inception versus today relates to the 15-month decline in LIBOR.

Lastly, Ares was granted approximately 5.4 million warrants at the cost of $0.01 per warrant, equivalent to just under 10% of the outstanding shares of the company at December 31, 2019. More detail on these loan amendments will be made available to the public when we file Form 8-K after market close today.

Going forward, by resolving the Warning Letter, passing the pre-approval inspection and consistently achieving positive financial results, COVID-19 aside, our credit profile should improve, and we will be in a better position to work with Ares Capital, our existing bondholders and potentially new creditors to address our capital structure and thus reduce our cost of capital.

Having reviewed the key highlights of the loan amendments, let's move to topics 3 and 4, our liquidity. As you heard Tim mention in his opening remarks, one of our top priorities is to manage cash flows, and I will add, particularly in the second quarter of 2020. Given the impact COVID-19 might have on our business and less anticipated cash collections from customers as a consequence of the decline in first quarter 2020 revenues, available cash balances will decline over the course of this quarter. We issued Series B Bank 2023 convertible bonds in the fourth quarter of 2019. We used $29.3 million of gross proceeds from those

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bonds, plus a final $10 million draw from our term loan with Ares to cover fees associated with the capital raise, pay down current liabilities, retire $13.1 million of December 2019 convertible bonds and provide the company with further liquidity. With the increase in current assets and decline in current liabilities associated with this bond issuance and term loan draw, working capital at December 31, 2019, increased to $45 million. This represents a $28.4 million improvement in working capital from what we reported at September 30, 2019. More specifically, we ended the year with $15.5 million of cash on the balance sheet.

In order to preserve cash, we will continue to pick or defer cash interest payments on our Series B May 2023 convertible bonds and the term loan with Ares. Keeping in mind, the company now has the potential to extend this option for another year, if we are able to resolve the Warning Letter and pass pre-approval inspection by December 2020. We continue to pay regular interest on our Ares revolving credit facility as well as our Series A May 2023 convertible bonds. With the loan amendments announced today, Teligent's quarterly 2020 cash interest payable to Ares will increase by about $150,000. This increase relates solely to the estimated 225 basis point increase on the revolving credit facility. And our next semiannual interest payment to bondholders is $1.6 million and is payable in May 2020.

Lastly, we, like many other companies with less than 500 employees, are exploring and have applied for COVID-19 relief made available by recently passed state and federal legislation in the form of payroll-related reimbursements and low-cost small business association loans.

Allow me to switch gears to the last topic, our NASDAQ listing status and potential for a reverse split of our common stock. In June 2019, we received a delisting notice from NASDAQ due to our share price trading below $1 for 30 consecutive trading days. The notice specified that our share price must trade above $1 per share for 10 consecutive trading days prior to December 2, 2019, in order to prevent our common stock from being delisted. On December 2, 2019, we had yet to regain compliance. We requested a second 100-day -- 180-day extension, NASDAQ denied our request, and the company chose to file for an appeal. The company was granted a hearing date for the end of January 2020. Subsequent to the appeal hearing, shareholders approved a reverse stock split in the range of any whole number ranging from 5 and 10 to 1 and soon after, we were informed by NASDAQ that our appeal was denied. In light of the COVID-19 impact on the markets, NASDAQ set a deadline to regain compliance of June 1, 2020. Although possible, it is not probable that business performance alone, particularly as we navigate through COVID-19 related challenges, will be the catalyst to increase the share price above $1. If our shares are delisted from the NASDAQ, we would be in default of the nonfinancial covenant required by our senior credit facilities and convertible bonds, and we would need to seek a waiver or seek new capital, thus leaving a reverse stock split as the only remaining option to prevent this occurrence. While we believe that the reverse stock split will ultimately increase our share price above $1 for the required 10 consecutive trading days, we can provide no assurances this will be the case.

With that, let me now turn the call back over to Tim for his final remarks before we move to the question-and-answer portion of today's call. Tim?

Timothy B. Sawyer
President & CEO

Thanks, Damian. I can confirm my first 2 months here at Teligent have been exciting. As Damian and I highlighted, the company has some headwinds. However, the untapped potential of this company is evident, and I'm thrilled to be here and confident that I have the management team and employee base needed to execute efficiently to achieve our objectives.

We hope that you and your families are safe and in good health. Our teams here at Teligent, particularly those on-site working in Buena, inspire me every day. Their dedication, commitment and loyalty to both this company and our customers and patients is admirable. During this pandemic, we have taken many extra steps to protect our employees, and I'm glad to report that no Teligent employee has tested positive for COVID-19.

Manufacturing in Buena and distribution from our third-party logistics provider has been thankfully uninterrupted. We are recognized as an essential business in each municipality and country where we are located. And as such, we are operating as normal. We continue to closely monitor our supply chain to

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ensure we have the materials necessary to produce our products. To date, we have not experienced any significant delays in production, thanks to the commitment of our operators.

We're proud to have a U.S. manufacturing facility for our products. We look forward to utilizing its expanded capacity upon approval from the FDA.
With that, I will now ask Daniel to open up the call to questions. Thank you.

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Question and Answer

Operator

[Operator Instructions] Our first question comes from Matt Hewitt with Craig-Hallum Capital Group.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Tim, welcome. Nice to hear from you this morning. I've got a few questions. Maybe the first that you could start with is, what attracted you to this opportunity? Where do you see the near-term low-hanging fruit? And how quickly do you think you can capitalize on that?

Timothy B. Sawyer
President & CEO

Thanks. So I think a couple of things. First, what attracted me to the opportunity obviously, you heard a bunch about headwinds and things today, but what attracted me to the opportunity specifically, is the product portfolio and the injectables transition that the company had was under -- that was undergoing at the time that I joined. I think injectables are a critical component to the medical treatment protocol. I think that they are an area where there is lots of opportunity, particularly as you've seen in the marketplace with drug shortages, if you track that area. So I think that was very, very interesting to me. And I think that the ability of this company to launch into that market is really exciting. So that's the first part. The second part, what do I see as low-hanging fruit? I think the first thing that we did and are doing is improving our product supply. So one of the things that this company was burdened with previously was, they were unable to be a reliable supplier for customers. And customers demanded that in this marketplace, not being an intermittent supplier, and that causes lumps in your sales, lumps in your earnings. And so we've undertaken a comprehensive plan to overhaul our supply chain and our processes for how we work and forecast and predict our business going forward. So that's -- the first thing is to become a reliable supplier for our customers, and that will pay off in dividends when our customers see us as such and are able to rely on us day in and day out when we become their first tier call when they're looking for new products. So I think that's an area of low-hanging fruit for us. And I think I might have forgotten what your -- third part of your question was.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

No. That's perfect. You touched on one of the things. So as you look at getting the injectables facility up and approved by the FDA, one of the opportunities with the first drug that was submitted was that it was a drug that had a history of shortages, whatever. As you look at shifting to a second submission to garner the -- or to trigger the inspection, is that your plan with that second submission is to find an opportunity where it's a drug that either is currently on shortage or has the history of being on shortage? Or maybe even there's an opportunity within something within the coronavirus treatments where there's a need and a demand that would trigger the FDA to maybe come in sooner rather than later?

Timothy B. Sawyer
President & CEO

Yes. So good question. So what we're looking at, the second product, obviously, will be filed here shortly. It doesn't have a shortage currently. However, as a part of an NDA and it's a pre-approval supplement, as I mentioned, what's going -- what will happen is there's a statutory time line that the FDA has to come in and inspect for, so -- because they have to respond to the agent, to the supplement within certain number of months. So number one, this product allows us to push a faster track on that. Number two, we are always -- and what you mentioned is important, we are always looking for opportunities to accelerate the time line. And if there are COVID-19 related ways to do that, we will pursue them rigorously to work with the agency to get -- to accelerate that approval for the facility.

Matthew Gregory Hewitt

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Craig-Hallum Capital Group LLC, Research Division

Okay. And then -- and I don't know if you know the answer to this, but I thought I'd ask it anyway. Given the situation with the country right now, are there -- are you hearing anecdotally any issues with the FDA conducting inspections? I know that they're considered obviously an essential business, and they're still going to work. But is that slowing down the inspection process in any way that you've heard?

Timothy B. Sawyer
President & CEO

They have made a couple of announcements at the agency about delaying inspections of certain particular types. We believe that -- quite frankly, we believe that with what's going on with this pandemic, the fact that we are a U.S. manufacturing facility located in New Jersey, as we talked about on the call, that we would want to -- that there is an incentive for them to approve domestic manufacturing capacity. And so we believe that they will want to do that with us, and we'll give them every reason to approve us. So we're going to move forward quickly, but we think that there's an incentive for them to do that.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Understood. And then you actually just touched on another question I had, maybe just elaborate a little bit further. Given what's happened regarding the coronavirus, COVID-19, and what appears to be at least the initial stages of a desire to bring more manufacturing back into the country versus China, India, whatnot, how does that set you up? Let's assume we get through the headwinds over the next year, get through these inspections and what not, but how does that set you up going forward given your domestic capacity?

Timothy B. Sawyer
President & CEO

I think it sets us up well. Obviously, we are right in the wheelhouse there, being a domestic manufacturer. I think it sets us up for the potential for success. And while we don't know exactly what -- it's awful hard to predict exactly what the FDA or what, quite frankly, the government will do, but we feel good about being a domestic manufacturer, and we feel good about the opportunities that, that's going to present for us in the future.

Operator

Ladies and gentlemen, this concludes our question-and-answer session. I would now like to turn the call back over to Tim Sawyer, President and CEO, for any closing remarks.

Timothy B. Sawyer
President & CEO

All right. Thank you all for your time and attention this morning. That concludes our call. Have a great day.

Operator
Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.

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