ceocfointerviews.com

Issue: December 21, 2020

Intec Pharma: Making the Drugs You Take Better

Jeffrey A. Meckler
Vice Chair & Chief Executive Officer

Intec Pharma Inc.
(NASDAQ: NTEC)
https://www.intecpharma.com/

Contact:
Will O'Connor
212-362-1200
will.oconnor@sternir.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: ***Mr. Meckler, what is the focus today at Intec Pharma Inc? What is the status on your Accordion Pill®?***

Mr. Meckler: Thank you, Lynn. Our mission at Intec is to create value by leveraging the potential of our Accordion Pill® (AP) platform. Our growth strategy is to advance a mix of internally-led drug development programs and proprietary partnered programs. We believe this approach provides a variety of "shots on goal" that will provide Intec with a growing pipeline and long-term royalty stream with the potential to create significant value over time.

Despite not meeting the primary endpoint in our Phase 3 ACCORDANCE study of AP-Carbidopa/Levodopa (AP-CD/LD) last year in Parkinson's disease patients, we gained important information and knowledge from the ACCORDANCE study and, importantly, demonstrated that the AP performs with an acceptable level of safety.

We continue to advance our collaboration with Merck and were particularly pleased with the recent decision by Merck to proceed into a new research collaboration program with us. In addition, we also recently announced a new cannabinoid research collaboration with GW Pharma.

We also continue to make progress on our internally-driven cannabinoid program, where we are developing an AP to deliver either or both of the primary cannabinoids contained in Cannabis sativa, cannabidiol (CBD) and tetrahydrocannabinol (THC) for a variety of pain indications. We recently completed a reformulation of the AP design for the AP-THC program and we are on track to initiate the clinical trial by year-end.

There are also additional discussions with other potential pharmaceutical partners for the development of new custom-designed APs. We believe this is the most efficient strategy for building our pipeline and for creating value from our platform. These are the primary objectives the company will focus on throughout the balance of this year and into 2021.

CEOCFO: ***How do you go further into the results to see what you need to do next?***

Mr. Meckler: The clinical trial data readout was in late July 2019. We spent the latter part of the summer going through the data, gaining an understanding of what the data demonstrated and where we could optimize performance. The key

learnings from the trial are that our technology was safe and we delivered the drug with a steadier pharmacokinetic (PK) profile than the immediate release formulations on the market today. Safety data from both the Data Monitoring Committee and the Phase 3 open label extension study provided us with the first validation of the long-term safety of the Accordion Pill on a large scale. This is a really important learning from this trial.

What we believe we did not do is use a trial design that allowed for the delivery of enough drug to the patients in the higher dosage cohort of the immediate release arm of the study. Patients who were in the higher end of the dosing regimen were not getting enough drug in the AP arm, given that the AP arm was limited to 1500 mg of levodopa. Some of this is attributable to the novelty of the AP and FDA's inexperience with the safety profile of the long-lasting gastroretentive platform that resulted in a maximal dose limit of 1500 mg. We believe the safety data we have today would alleviate this concern in any future study. Trial design impacted our ability to demonstrate superiority over standard therapy in the trial and skewed the results. One of the real key lessons, not just for Intec, but for a lot of small companies, is that small companies who have to make tough decisions about resource allocation often do not do as much Phase 2 work as a large pharma company would before entering Phase 3. Much of that information guides the development of the pivotal program and can impact the success of a Phase 3 trial. Looking back, if we had more information coming out of Phase 2, we likely could have achieved a trial design that would have had a better probability of success.

"Between our cash and our equity line, we have runway through 2021 which allows us to focus on advancing our pipeline, expanding our partnerships, and creating value through these new opportunities." Jeffrey A. Meckler

CEOCFO: ***How are you looking to branch out today? Would you give us some specifics?***

Mr. Meckler: Our research and manufacturing teams continue to drive innovation as we expand our capabilities and build out our portfolio of potential applications. In addition to the variety of film technologies and release mechanisms we have developed to date, including those we created for partners, we continue to innovate and are working on next generation AP technologies that will increase gastric retention time (i.e., a 24-hour Accordion Pill). We have also enhanced our delivery profile capabilities, which provide us with greater options for designing and constructing new APs that can include films for immediate release, delayed immediate release, extended release, delayed extended release, etc. This optionality allows us to develop custom-designed APs that meet specific PK parameters. We are also working on including larger molecules in the platform such as peptides, which opens up a multitude of opportunities for enhanced delivery of these important therapeutic compounds that are now largely delivered intravenously or via subcutaneous injection.

Key to advancing these innovations and attracting new partners is our ongoing work on commercial scale manufacturing with our partner LTS. Together, we built a commercial scale manufacturing facility and conducted preliminary validation work using our AOP CD/LD platform. This manufacturing facility stands at the ready for the Parkinson's program and conceivably, for other programs that may advance to a commercial scale.

CEOCFO: ***Why the choice of LTS Lohmann Therapy-System AG in Germany?***

Mr. Meckler: That is great question! There are a variety of parameters that led us to LTS Lohmann. First and foremost is their position as one of the world's leading manufacturers of transdermal drug delivery products. They have a large business in drug-on-film manufacturing, consisting of oral thin films, from transdermal patches to micro-needle patches. There are only a handful of third-party contract manufacturers out there that have this expertise, and LTS is the clear global leader in terms of this specialized technology. Both their approach and facilities are world class. This is a company that does not cut corners, that provides excellent quality product across everything they do, and that aligns very well with our commercial approach.

Another reason we selected LTS was its proximity to Israel. Being in Germany, LTS is only one-hour time zone difference from Jerusalem, which makes the collaboration that much more viable. Also, the company that actually manufactures and

assembles our AP machine is in Germany as well. Therefore, the ability to have all the parties working together, both in proximity and approach, on a commercial scale operation really makes a difference.

CEOCFO: ***What did you learn from the Novartis partnership?***

Mr. Meckler: A lot! With big pharma companies, we learned that decision processes are not always linear. What I mean by that is going from point A to point B is not always a straight line. Novartis gave us a very difficult assignment, probably one of the most technically difficult the company has had. We successfully achieved their stringent PK parameters, both *in vitro* and in humans. Our team was very excited to advance the program as we saw a real opportunity to improve the therapeutic benefit of the compound. We delivered them the data in mid-2019. It was not until the end of the year that they completed their commercial assessment and determined not to move forward with the program. It was a disappointment for our team and a lesson on how decision by committee can really slow the process.

Another lesson for us is that we need to adapt our business model for their processes and take a broader shots-on-goal approach to how we collaborate with large pharmaceutical companies, so that we develop partnerships that can adjust to those timelines. We need to be better equipped as a business to interact with external parties while managing our own timelines and portfolio growth.

"We do not make the drugs you take; we make the drugs you take better." Jeffrey A. Meckler

CEOCFO: ***Would you tell us a bit more about your programs regarding cannabinoid? What is your idea and thinking in this area?***

Mr. Meckler: First of all, we are not a pot stock company or medical marijuana company. There are many cannabinoid companies taking semi-recreational approaches to both product development and distribution. We are not that. We are looking to fill the void in the development of medical uses of the cannabinoid, particularly THC and CBD, through adequate and well-controlled trials as a regulated therapeutic. We look for indications that are difficult to address because of the challenges with oral delivery of these compounds. We use synthetic material, not a botanical, because we want to ensure our approach aligns with the FDA and will be viewed as a meaningful therapeutic option.

Cannabinoids are very oily and are poorly soluble in the human body. The combination of the slower rate of rise with sustained and consistent plasma levels is expected to lead to an improved therapeutic effect and reduce the adverse events that are correlated with rate of rise and peak THC plasma levels. Also, given the known analgesic properties of cannabinoids, we are enthusiastic about the potential for these programs and believe our AP-cannabinoids will be applicable to a variety of pain indications, such as post-operative, opioid-sparing pain management, fibromyalgia and/or for breakthrough cancer pain management.

We completed an initial PK study with AP-THC in 2019. As with most any iterative process, the initial results showed that the delivery of THC did not fully meet our expectations for this program. As said earlier, we were delighted to report the completion of a new AP design for our AP-THC program that we expect will meet our stringent PK specifications and are awaiting receipt of the active pharmaceutical ingredients so we can initiate clinical material production and advance this program into the clinic later this year.

On positive data from this program, we would look for a partner to license the asset and advance the development and commercialization of our AP cannabinoids. Here, we look to work with a partner who is aligned with our goals to pursue legitimate medical indications through the FDA regulatory process. We believe the work we are doing now is forming the foundation for success with this type of collaboration.

CEOCFO: ***How do you continually innovate the technology?***

Mr. Meckler: This speaks to our roots of being a data driven company focused on improving human health. Our research and manufacturing teams continue to drive innovation as we expand our capabilities and build out our portfolio of potential applications. We have spent a lot of time analyzing the huge amount of data collected from our Phase 3 study,

literally gigabytes of data, and we've learned a ton about release times and gastric retention in the process. In addition, every time we development a new product, there is an opportunity for innovation, product development and creation of new intellectual property. Novartis, for example, approached us to create a mechanism we had not done before and we were able to build a customized Accordion Pill. As a result, we developed new films and will apply for new patents on that. So, as you can see, we are constantly reviewing our data, exploring new approaches and refining our technology.

This year, our main focus on innovating the technology is on the development of a 24-hour AP. Currently, the AP design is geared for eight to ten hours of gastric retention, with the capsule and the film staying in the stomach for that period. Given all we've learned in the last few years, we are looking at a 24-hour AP, meaning you will take one pill, once a day. In addition, we've developed new release mechanisms, so that from a PK profile, we can offer a variety of custom drug release mechanisms and combinations. This enables us to approach potential partners with different options for custom designing how to better deliver their drugs.

We are a drug delivery company not a drug discovery company. I often say, "We do not make the drugs you take; we make the drugs you take better." We do that by how we deliver the drug into the stomach. For us, innovating on the platform means constantly applying and learning and reviewing data to evaluate how we can advance the application, release and retention of already existing drugs and drugs in development.

CEOCFO: ***How are you handling the COVID environment? What advice would you give CEOs in these times, both during COVID and with moving forward from a failed Phase III trial?***

Mr. Meckler: It has certainly curtailed my travel, so I am home now all the time! Not sure how my wife feels about that! That said, our primary focus is to ensure that our employees are safe, motivated and engaged. Without question, the pandemic has definitely changed the way we are doing business. For starters, social distancing makes the collaborative R&D process more difficult. Whether it is with our internal R&D team, where we cannot bring everyone into the conference room due to social distancing rules, or with our partners and potential new partners, where we have to find new ways and formats to work together. The first challenge of dealing with the pandemic is learning how to be collaborative in a social distancing environment.

On a more macro view, I am proud to be part of an industry that is stepping up and innovating many ways to address the pandemic. This is not just in the realm of vaccines; it is across a large number of therapeutic approaches with literally hundreds of companies looking for ways to combat the disease. Some of these treatments we have had experience with and the level of effort is a testament to the capability of the industry to focus for the greater good of society.

As far as advice for other CEOs following on a failed Phase 3 trial, once again, I think it is all about being data driven. The real key is to look at the data and see what was learned. The pharmaceutical business is about learning and innovating from what is learned. This is a large part of why I love this business. I think you need to plan for failure and then celebrate success. All too often, we get so excited about the opportunities that maybe we lose sight of what can go wrong. It is important to keep positive but also to be realistic. I say this with regard to all constituents, whether it is your investors, your employees, your board of directors or your partners. Importantly, you need to be sure you have enough runway that if things go wrong, you have time to figure it out and adjust. Lastly, I would say, communicate, communicate, communicate. When you have a setback, people's emotions and fears can take over. It is the CEO's job to reassure them. "Here are the facts; here is what we are doing and why." For us, we had a really tough decision in the second half of last year that led to a restructure and a reduction in staff. These are not just employees. They are colleagues and friends. Throughout the process, we kept everyone informed on our decision process and about the consideration, and we did it with a good deal of respect. All in all, it is really about keeping positive, realistic and being data driven.

CEOCFO: ***Why is Intec Pharma and your Accordion Pill Technology so important? Why should people pay attention?***

Mr. Meckler: The Accordion Pill technology allows drugs to be delivered in a unique way that can improve the therapeutic benefit for patients in a variety of potential indications. It is this patient benefit that drives us to advance the AP platform. Driving Intec's innovation is our commitment to the patient and to demonstrating how our AP technology

can improve lives. At the end of the day, that's the core of what we do and we think it is important for the patient, the scientific community and for investors as well.

While we are not working on drugs that address the COVID-19 pandemic, we are doing work on programs that can make a huge difference in the lives of patients. Despite the setback with our Phase 3 program in Parkinson's disease, we continue working on it and are in discussions with potential partners. We are advancing the Merck collaboration from R&D into human clinical studies and we are preparing to move our AP-THC program into the clinic later this year

As I look back on the previous year, we took our losses. We analyzed the data and made decisions on how to move forward. Now, the company is in on solid footing. Between our cash and our equity line, we have runway through 2021 which allows us to focus on advancing our pipeline, expanding our partnerships, and creating value through these new opportunities.