

Meaningful advances showing the Intec Pharma Inc. Accordion Pill® Carbidopa/Levodopa Phase 3 Clinical Development Program is providing a better Baseline Levodopa to Reduce the Motor Fluctuations Associated with Advanced Parkinson's Disease



Nir Sassi
Chief Financial Officer

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

Interview conducted by:
Lynn Fosse, Senior Editor
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CEOCFO: *Mr. Sassi, it has been about 6 months since we spoke with your CEO, Jeffrey Meckler. Would you bring us up-to-date? Where is Intec Pharma Inc. today?*

Mr. Sassi: Since your discussions with our CEO in October 2018, we have made significant progress across a number of important clinical and corporate strategic initiatives.

Most notably, we made meaningful advances to our Phase 3 clinical development program for the Accordion Pill® Carbidopa/Levodopa (AP-CD/LD) to treat advanced Parkinson's disease (PD) patients. We recently announced that the last patient completed the last visit in this pivotal clinical trial and we are now awaiting the top-line results from this study in the July/August time frame. In addition, in February we were delighted to report positive data from a pharmacokinetic (PK) study of AP-CD/LD 50/500 mg in PD patients, demonstrating that AP-CD/LD when dosed three times per day (TID) showed a statistically significant reduction in plasma levodopa variability when compared to standard oral CD/LD dosed five times per day. This is especially encouraging because many Parkinson's disease experts believe a reduction in levodopa fluctuation is a proxy for efficacy. Moreover, we continue to be pleased that greater than 90% of the patients who complete the Phase 3 clinical trial have opted to enter the open-label extension study.

Beyond the progress with the clinical developments for the AP-CD/LD, we continue to invest in pre-commercial activities, which coupled with what we hope will be positive data, should enhance the partnership opportunities for this late-stage asset. Our ongoing payor research confirms the need for better baseline levodopa treatment and concluded that peak U.S. base case annual gross revenues in excess of \$300 million are possible for AP-CD/LD with appropriate pricing and access. We also made significant progress with our partner, LTS LohmanTherapie-Systeme (LTS), on building out the commercial scale manufacturing for the AP-CD/LD. At the end of 2018, we delivered the large commercial scale production line and have been working on installing and connecting it with all the ancillary machines and systems. In the coming months, we intend to begin the validation, bioequivalency and stability studies that are designed to position us to file for regulatory submission and to support a commercial launch. As a result, we remain confident we are on track to submit a New Drug Application for approval of AP-CD/LD in mid- to late-2020, assuming positive topline data.

We also made important strides with our program with Novartis. Last December we reported that our team successfully created a customized AP for Novartis' proprietary compound that met the required *in vitro* specifications set forth in our feasibility agreement. Recently, we were very excited to initiate the human PK study of this new Accordion Pill. Assuming this *in vivo* study is positive, we hope to take the next step with Novartis to negotiate a commercial license agreement for this product. This partnership holds significant promise as the market opportunity for this proprietary compound is in excess of \$1 billion and a commercial agreement would likely include a multi-million dollar upfront payment along with single digit royalty payments.

In addition, just last week we were delighted to announce a research collaboration with Merck. This collaboration is similar in structure to the Novartis partnership and we are excited to begin work on the development of a custom-designed Accordion Pill for Merck's proprietary compound.

CEOCFO: *What is the financing strategy? What has it been and what will it be as you move forward?*

Mr. Sassi: From the beginning, we have funded our operations through public and private financings, grants from the Israeli Office of the Chief Scientist and from organizations such as the Michael J. Fox Foundation, as well as from payments received from the agreements with big pharma that provide full coverage of our development costs for those programs. In the past two years, we have successfully raised nearly \$100 million through equity offerings. These financings have helped support the Phase 3 development program in PD and are expected to be sufficient to bring us to the top-line data readout from this pivotal trial and into 2020. Moving forward, we expect to satisfy our future cash needs through the same vehicles and will also seek to monetize our platform assets with agreements with third parties, such as Novartis or Merck. For example, we plan to license or partner our Parkinson's disease asset and expect to receive a substantial multimillion-dollar upfront payment along with double digit royalties. As we continue to add programs to our pipeline and to partner them, you can see how we will build a revenue stream from such milestone and royalty payments.

“Our ongoing payor research confirms the need for better baseline levodopa treatment and concluded that peak U.S. base case annual gross revenues in excess of \$300 million are possible for AP-CD/LD with appropriate pricing and access.”- Nir Sassi

CEOCFO: *Do you plan to build a sales force of your own as you move towards commercialization or does that depend on the end result of the trial?*

Mr. Sassi: As I mentioned earlier, we have been conducting a variety of pre-commercial activities that we believe position the AP-CD/LD for commercial partnership. We have invested in the commercial scale manufacturing, regulatory, market assessment and payor access work that will make this product an attractive candidate to license. Currently, there are a number of companies with either Movement Disorder or Neurology specialty sales forces that could add AP-CD/LD to their portfolio to leverage their investment in commercial infrastructure with a product that has a U.S. base case market opportunity of \$300 million. It doesn't make sense for Intec to invest \$200 million in building another such sales force. Looking ahead, our goal is to focus on building our Accordion Pill drug delivery platform with the addition of both partner-sponsored R&D programs and internally-led drug reformulation programs where we would conduct the clinical studies through proof-of-concept and then would partner them for their continued development and commercialization.

CEOCFO: *Intec Pharma has been presenting at a number of conferences. What are you telling potential investors? What do they want to know about Intec that they do not recognize now?*

Mr. Sassi: We have been telling potential investors that this is a great opportunity to invest in a company that has both a late-stage pivotal data readout in the near-term, as well as the potential for significant commercial agreements with big pharma via Novartis and/or Merck. We are focusing investors on the value of the platform, which we believe is not getting credit at this time as many investors are solely looking to the Phase 3 data inflection point in PD this summer. With the recent addition of the Merck collaboration, we hope investors are starting to recognize the substantial value that can be built on this AP platform both in the near- and long-term.

With regard to our PD program, we are highlighting the potential for AP-CD/LD to provide a better baseline levodopa treatment than what is currently available. We consider this program de-risked in that levodopa is well-characterized, we have supportive Phase 2 data showing the reduction in OFF time and our recently reported TID PK data demonstrated a significant reduction in plasma levodopa variability. We believe that at every effect size there is a substantial market opportunity and the market and payor research we conducted supports this. In addition, we have done the pre-commercial work that will make this asset attractive to potential partners.

CEOCFO: *Are the people with Parkinson's in your trials excited as well?*

Mr. Sassi: Oh yes! We receive many stories from and about patients with Parkinson's disease who are very excited about the potential of the AP-CD/LD to provide a better baseline levodopa to reduce the motor fluctuations associated with the disease. We also maintain a close working relationship with the Michael J. Fox Foundation, where we have participated on their Industry Research Consortium to enhance the communications between patients, their physicians and caregivers. Here, nearly everyone we interface with is very excited at the prospect of bringing a better baseline levodopa to PD patients. In addition, more than 90% of the patients coming out of our randomized Phase 3 trial have opted into the open-label extension study. That's a high percentage wanting to maintain access to the drug. We are also hearing anecdotally

that patients completing the open-label study are requesting to continue on drug after the 12-month study is finished. This kind of excitement and enthusiasm for the Accordion Pill is very encouraging.

CEOCFO: *How else are you using your resources, other than clinical development of the Accordion Pill?*

Mr. Sassi: While the bulk of our resources have been on the clinical trials of the AP-CD/LD, as I mentioned earlier, we are resourcing a variety of pre-commercial activities that will enhance this program's potential for partnership. One area where we have invested a lot of time and money is on the commercial scale manufacturing of the product. Last year, we announced a manufacturing partnership with German-based, LTS, for the commercial production of AP-CD/LD. LTS is one of the world's premier drug-on-film manufacturers and is used by a host of global pharmaceutical companies. This is a particularly good partnership for us because LTS has the experience and the state-of-the-art the infrastructure to scale production of the Accordion Pill in their cGMP facilities. We have also invested in market assessment and payor access work to support our assumptions about the substantial market opportunity. In addition, we have added headcount in key areas such as regulatory, clinical operations, R&D and business development.

Moving forward, we expect to reduce our clinical expenses while increasing our investment in R&D. Our R&D work is expanding as we build our clinical pipeline with the cannabinoid program, the Novartis program and the Merck collaboration. We also continue to test new compounds for the Accordion Pill and plan to increase those activities as we license out our Parkinson's disease program and, hopefully advance our work with Novartis to a commercial agreement. In addition, we are building R&D bandwidth in order to expand our work with potential new partners to develop custom-designed Accordion Pills.

CEOCFO: *Are there any other partnerships in the works that you can share?*

Mr. Sassi: As I said earlier, we have an active feasibility agreement with Novartis for the development of one of their proprietary compounds, which is now in a Phase 1 PK study. We also have the newly announced Merck research collaboration where we are developing a custom-designed Accordion Pill for one of their proprietary compounds. Our team continues to actively engage in dialogue with other potential partners to add new partnerships to our growing pipeline. Partnerships such as these will be an important component of the Company's growth as it allows us to focus our efforts on the early-stage development of new Accordion Pills and puts the later-stage clinical development and commercialization in the hands of big pharma who have the resources and capabilities to successfully execute those undertakings.

We believe these programs with Novartis and Merck pave the way for other new collaborations to further validate the AP platform and confirms our technical abilities to build custom APs. Importantly, these new programs offer the opportunity for us to pursue additional patents to further bolster our intellectual property portfolio.

CEOCFO: *Is it frustrating to have to wait, as things always take time to develop when it comes to drugs, when you have something that is potentially so helpful? How do you deal with that on a personal level?*

Mr. Sassi: I have been with Intec for more than nine years. When I started, the Company was in the very early stages of development for its two leading programs. One was in the middle of Phase 2 clinical development and the other had not entered the clinic. Everyone knew it was going to take time. Still, once you are in this type of venture it becomes a passion! It's what drives you to come to work every day. It is more than just filing financial reports. You are part of a big program that started small in the early days with a few people here in Jerusalem and has grown to where we now have a U.S office and global board members. It is very exciting—certainly not a boring 9 to 5 job! When you have successes from R&D, such as what we did in the lab for Novartis – it is gratifying and everyone feels a part of it. Now, we are just ahead of our data readout for our Phase 3 program in Parkinson's disease and, if successful, and we are able to bring a new drug to patients suffering from this debilitating disease – it will have been well worth the wait!

CEOCFO: *Would you tell us about your IP protection?*

Mr. Sassi: We have a broad-based patent estate that covers four layers of different protection – we refer to these as four families of patents. First, we have the platform IP that is focused on the gastric retentive oral drug delivery of drugs-on-films and includes protection for the unique way we load drug on the films, the shapes of the films, and even the way we fold the films. We also have a significant amount of IP around our manufacturing processes and this includes a lot of know-how and trade secrets. As I mentioned earlier, each AP is unique and uses different constructs. For example, some of the films have perforations, some have reservoirs and some use disc layers – we create IP around each of these. In addition, we are building a family of patent protection around the combination of the drug and the platform and have specific IP on AP-CD/LD, AP-THC and AP-CBD. Moreover, we have treatment IP for the AP-CD/LD in Parkinson's disease. We are very comfortable with our families of patents and are confident that collectively they provide protection for

would-be competitors in a number of important ways. At conferences, we have had other companies come up to us to tell us that they tried to do something like what we are doing, but they failed. This is not easy to replicate – it is difficult and expensive -- and we have solid IP protection.

CEOCFO: *Finally, has the investment community recognized the potential of Intec Pharma?*

Mr. Sassi: As we discussed earlier, I think the investment community sees the value in the Parkinson's disease program but hasn't given us the value for the potential of the platform to provide meaningful value over time. We have two value-creating assets: the PD program and the Accordion Pill platform. The PD program's inflection point is happening this summer and the platform has a couple of years to reach its value-creating inflection point.

We have a solid base of sector-specific institutional investors who are very supportive of the Company. Our largest shareholder is Dexcel, the second largest pharmaceutical company in Israel, who hold approximately 15.5% of Intec. We continue to appreciate our investors' support and encouragement as we advance our clinical programs and are working to add more to this list of outstanding investors.

As we continue to execute to plan and hit our clinical and corporate milestones, we believe we can meaningfully create value for shareholders and believe more investors will take notice.

