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TRACON leverages its innovative product development platform that includes US commercializing expertise to license potential best-in-class checkpoint inhibitor, with a proven mechanism of action, to address an unmet need in patients with advanced sarcoma



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CEOCFO: *Dr. Theuer, on your website one of the first things you see is that Tracon Pharmaceuticals Inc. is focused on being a leader in the development of targeted therapies for patients with cancer, ophthalmology and fibrotic diseases. Why is this such an important area that offers so much hope?*

Dr. Theuer: Our goal is to advance the current standard of care by identifying unmet needs in the care of patients, with our main focus being in oncology. While most patients with advanced or metastatic disease will succumb to their disease, there are clearly new therapies, especially targeted therapies, that have made a huge impact on cancer care. Our goal is to participate in this revolution of cancer care through the concept of precision medicine whereby certain aspects of a tumor dictate that a certain therapy should be effective. Our lead asset, which I will talk about later, is an example of a precision medicine approach that we expect to develop to improve the care for sarcoma patients with advanced or metastatic disease.

We also have an important program in wet age-related macular degeneration or AMD. While not a fatal disease, wet AMD is a very debilitating disease that is the most common cause of blindness in the Western world. It is another disease in need of new treatments.

CEOCFO: *You were Director of Clinical Oncology at Pfizer, Inc., and had a great deal of other experience before joining Tracon in July of 2006. How did your prior experiences prepare you for your challenges at Tracon and what are some of the things you can point to that show your imprint as CEO of Tracon?*

Dr. Theuer: Pfizer was a really defining moment for me and for many of our team members here at Tracon who were also part of teams that developed life changing therapies while at Pfizer. One drug that we were intimately involved with while we were part of the clinical oncology group at Pfizer is called Sutent, which is still a commonly used drug for the treatment of kidney cancer more than ten years after its approval in 2006. Prior to the approval of Sutent, the standard of care treatment for kidney cancer patients was a drug called interferon alpha that was associated with numerous and sometimes severe side effects, including severe flu-like symptoms, and had a very low response rate. That resulted in a

very poor risk/benefit ratio for the patient. However, interferon alpha was the most commonly used therapy in kidney cancer prior to 2006. Fortunately, we were able to develop Sutent, a therapy that targets the tumor vessels in kidney cancer to produce a ~30% response rate in patients compared to the less than 5% response rate seen with interferon alpha. That was a dramatic improvement in the standard of care, and developing Sutent was incredibly satisfying, as I was part of a team that revolutionized the standard of care and provided hope for a great number of patients. That feeling of giving hope to patients and improving the standard of care is what we are trying to recreate with a new class of therapies at Tracon.

“The most important partnership we have done is the most recent one with 3D Medicines and Alphamab Oncology, because it solves for our quest to license a product that has near-term commercial potential. With Envafolelimab, a subcutaneous PD-L1 checkpoint inhibitor, our goal is to start a potential pivotal trial in sarcoma this year. Our goal is to have interim data next year, to have final data in 2022 and then to commercially launch envafolelimab in the US in 2023.”- Charles P. Theuer, M.D., Ph.D.

CEOFCO: *Your approach to doing clinical trials is unique in this industry. Would you tell us about that?*

Dr. Theuer: One thing we are proud of at Tracon, beyond our goal of bringing new drugs to patients that we hope will change the standard of care, is our way in developing drugs that we feel is faster, generates higher quality data and it is less costly than the typical model of drug development. We have developed what we call our product development platform of drug development which is a CRO independent drug development platform. The way drugs are typically developed by most companies is they have a plan and they have a drug, but in order to implement the actual clinical trial to prove activity of the drug, they outsource the conduct of clinical trials to a contract research organization, or CRO. The problem with that is that CROs generally operate on a fee-for-service model. All of us have experienced the detriments of fee-for-service businesses: a bad car mechanic is a fee-for-service business that I think all of us have been frustrated with at times; a bad law firm is a fee-for-service business that many of us in biotech have also been frustrated with at times. Unfortunately, because of the fee-for-service model, many CROs are not necessarily aligned with the biotech company who want the trial done quickly, at high quality and at low cost. Sometimes bad behavior is rewarded, as a CRO may make more money if the trial takes longer to enroll or if additional services are required to correct a mistake they made! We realized that CRO beholden development was not an ideal model for us, so in 2011 we developed a product development platform whereby we internalized clinical trial operations. The result is that, instead of paying internal staff to monitor a CRO to make sure they do their job, we pay our staff to actually implement the trial. We feel our platform enhances quality because we directly interact with the sites who enroll the patients, we feel it is faster because if there is a problem we are highly incentivized to correct the problem right away, and we feel it is less expensive because don't pay a team to oversee the CRO and then also pay the CRO and we don't make more money the longer the trial takes to enroll.

CEOFCO: *How does that affect the cost of bringing a drug through clinical trials?*

Dr. Theuer: One important part of our product development platform is the cost, as we do trials at less than half the cost of companies that are beholden to CROs. That is an important aspect of the Tracon business model that reflects our innovative culture. While we instituted the product development platform to lower the cost and speed the development of our own drugs, we realized our platform that also includes US commercialization expertise, was not just a great business model for developing our own assets, but could benefit companies in need of the advantage of our unique capabilities. As a result, our product development platform has been the basis for collaborative partnerships with multiple companies, whereby these companies trust us to manage the regulatory and clinical development aspects of development and commercialization in the US, in return for which where we share the risk, we share the cost and then we share the potential profits, knowing that we are able to do trials that at a much lower cost than they would pay a CRO, and knowing that we provide much better economics than a typical royalty from a pharma company. Thus, our product development platform helps us develop our own molecules and also helps us to secure partnerships to new potential first-or best-in-class assets from partners that want to take advantage of our speed, quality and cost-effectiveness.

CEOFCO: *Dr. Theuer, would you tell us about one or two of the deals that you have?*

Dr. Theuer: We are really excited about our most recent deal. That deal came about when we reviewed data at the ASCO 2019 Cancer Conference showing the class of therapies called checkpoint inhibitors that have revolutionized cancer

care across multiple tumor types, are active in refractory sarcoma, which is a rare tumor of connective tissue that has limited treatment options that are associated with low response rates. Importantly, sarcoma consists of many different subtypes; there are over seventy subtypes of sarcoma. Of those subtypes, checkpoint inhibitors, which reactivate the immune system to attack the tumor, are active in certain common subtypes, including undifferentiated pleomorphic sarcoma, or UPS, but not every single one. Notably, the ASCO data showed a checkpoint inhibitor produced a response rate in UPS patients of 23%. That's impressive, because patients with refractory UPS treated with standard of care treatment have about a 4% response rate!

We therefore embarked on worldwide search for a potential best-in-class checkpoint inhibitor and we were very pleased on December 20th to announce a collaboration with two companies in China, 3-D Medicines and Alphamab Oncology, that not only had a checkpoint inhibitor but had a checkpoint inhibitor that is given by subcutaneous administration. In contrast, all checkpoint inhibitors currently approved are given by intravenous administration requiring an IV, time in an Infusion Center and a much longer time at the hospital. One thing a cancer patient doesn't want to do is waste time at a hospital in an Infusion Center. We are planning to develop Envafolelimab using a precision medicine approach. That is, we plan to target UPS and other select subtypes of types of sarcoma that are responsive to checkpoint inhibition: we are going to focus on the subtypes that actually respond to activating the immune system. However, we also will assess biomarkers, like PD-L1 expression, that may identify patients with other sarcoma subtypes that also may respond to treatment with Envafolelimab. We feel Envafolelimab can satisfy the unmet need for checkpoint inhibitor therapy in patients with sarcoma. We want to prove the activity and make the drug available to patients as an approved therapy. Another advantage is the subcutaneous administration that I think will be much more convenient for patients.

CEOCFO: *What led you into the area of Wet AMD? Would you tell us about macular degeneration and why DE-122 is an important development in this indication?*

Dr. Theuer: We have a drug in our pipeline called DE-122 that is an antibody that inhibits new blood vessel growth. Wet AMD is a disease where patients develop abnormal blood vessels in the back of the eye that occlude vision, especially central vision. Thus patients are unable to see when looking straight ahead. Unfortunately, wet AMD is the most common cause of blindness in the Western world. There is one class of therapies that is very effective for many patients: drugs like Lucentis and Eylea, which target a pathway called the VEGF pathway. They are highly effective for about a third of the patients with wet AMD. Unfortunately, a large segment of patients don't experience the optimal treatment effect and it is clear that a second drug that could be combined with either Lucentis or Eylea could provide benefit for patients who do not derive great benefit from single agent treatment with Lucentis or Eylea.

We developed DE-122 to satisfy that need and we partnered with a company that has a great deal of ophthalmic experience, Santen Pharmaceutical Co., Ltd., which is the largest ophthalmic products company in Japan that markets drugs globally. In 2014, we partnered with Santen and granted them rights to develop DE-122 globally. Santen have completed Phase 1 testing and presented positive data from that Phase 1 trial in 2018. Recently they completed Phase 2 enrollment in a trial where they compare Lucentis as a single agent to the combination of Lucentis and DE-122, with the goal being to show improved visual acuity with the combination. We expect that Santen will disclose the data from the Phase 2 trial in the first half of this year and we look forward to those data.

CEOCFO: *What are some of the other indications and clinical trial you have ongoing today?*

Dr. Theuer: Beyond Envafolelimab and DE-122, we have three other clinical stage assets, and two of them were licensed through partnerships so our partners could utilize the benefits of our product development platform. One is with Johnson & Johnson, with whom we are collaborating on the development of a drug to treat patients with prostate cancer, including patients that fail currently approved therapies Xtandi and Erleada. That drug is called TRC253 and is in a Phase 2 trial. We expect to present a Phase 1/2 data package to Johnson & Johnson later this year, which will trigger a 90 day period whereby they will have the opportunity to reacquire the drug for a significant cash payment to Tracon. If they do not opt-in and reacquire the drug, we will have global rights to develop TRC253. Another deal we did, that leveraged our product development platform of CRO independent research, was a partnership with the Chinese company I-Mab, that is developing the antibody TJ4309 targeting a second generation immune oncology target called CD73. We are responsible for the development of TJ4309 in the US and are currently studying TJ4309 in a Phase 1 trial as a single agent and in combination with approved checkpoint inhibitor TECENTRIQ, which is a standard of care therapy for multiple tumor types.

One additional asset in our pipeline is TRC102, which is a small molecule designed to reverse resistance to chemotherapy. We have a cooperative research and development agreement with the National Cancer Institute, such that the NCI funds the four ongoing clinical trials of TRC102. We expect updated clinical trial data will be presented at the ASCO 2020 Cancer Conference.

CEOCFO: *You have partnerships with 3D Medicines and Alphamab Oncology, Santen Pharmaceutical Co., Ltd., Janssen Pharmaceuticals, and I-Mab Biopharma. What do these partnerships mean for Tracon?*

Dr. Theuer: The most important partnership we have done is the most recent one with 3D Medicines and Alphamab Oncology, because it solves for our quest to license a product that has near-term commercial potential. With Envafolelimab, a subcutaneous PD-L1 checkpoint inhibitor, our goal is to start a potential pivotal trial in sarcoma this year. Our goal is to have interim data next year, to have final data in 2022 and then to commercially launch envafolelimab in the US in 2023.

By commercializing in the US, we would satisfy our vision to becoming a fully integrated company. By fully integrated company what I mean is we have a powerful developmental engine, our product development platform that we feel is second to none. We have access to a broad pipeline of assets that we have discussed, but what we did not have until the December Envafolelimab deal was a near-term opportunity for US commercialization. The Envafolelimab license, in our view, has solved for that problem and provides us with the opportunity to become a fully integrated company potentially by 2023. That is an exciting transformational event for Tracon.

CEOCFO: *Would you tell us about the potential markets for the therapies you have in development? What are some of the current treatments and how will for example Envafolelimab be different?*

Dr. Theuer: In sarcoma today, the standard of care first line agent is a drug that was literally approved more than forty years ago, called doxorubicin chemotherapy. That gives you an idea of the progress that still needs to be made in the treatment of patients with sarcoma. There have been some more recent approvals in sarcoma that includes the tumor type of sarcoma we are most interested in, called UPS: Votrient is approved for patients who fail doxorubicin chemotherapy, but the response rate is 4%, so clearly there is room for improvement. No drug approved in sarcoma actually releases the immune system to attack the tumor. That is the unmet need we want to meet with Envafolelimab. We feel the market size for Envafolelimab in UPS and select other sarcoma subtypes would be about \$200 million. Our eventual goal is to expand beyond the initial proposed study of UPS patients into broader sarcoma subtypes which could substantially increase that market.

CEOCFO: *Is reaching out to the investment community an important part of your role as CEO? Do you attend much conferences and if so, what has been their response to your targeted therapies?*

Dr. Theuer: We are constantly reaching out to investors and we fortunately have relationships with some great bank analysts at Wells Fargo, Jefferies, BTIG, and H.C. Wainwright. I think the analysts and investors have been very excited by our most recent deal with 3D Medicines and Alphamab Oncology, as a way to realize our vision of being a company with the near-term commercial potential. I think the investors now are looking for Tracon to execute on its plan. We have completed a license and have Envifolmab as a product for development in sarcoma. The next key is to meet with the FDA to vet our pivotal trial plan and then to initiate dosing, and then to report interim and final data. I believe investors are now looking for us to execute on our plan.

CEOCFO: *You recently announced a change to Nasdaq Capital Market. Why is that important?*

Dr. Theuer: Our listing on the Nasdaq capital markets is critical to our success to continue to attract investors including retail investors as well as institutional investors that will support Tracon and our story. We have an ATM facility and equity line of credit that require we be a publicly listed company.

CEOCFO: *In closing, do you have the funds in place to continue growth and development?*

Dr. Theuer: One unique thing about Tracon, is that because we have our product development platform, our capital requirements are much lower than companies that are beholden to CROs. For the next year our capital requirements are about \$4M per quarter. Thus, our current cash provides capital into 2021 and have an equity credit line for \$15M as well as an ATM facility that we can utilize to further extend the runway. Beyond that, we also have the opportunity to receive success based milestones from our partners. For example, if J&J opts-in to reacquire TRC253, they would need to pay Tracon \$45M. If Santen begins a Phase 3 trial they would be obligated to pay Tracon \$10M. There are further success based milestones due us as part of our partnership with I-Mab.