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NanOlogy –Advancing their PURCISION™ Technology using Intratumoral Therapy to Solve the Toxicity Problem when Treating Cancer



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CEOCFO: Mr. Arthur, what is the concept behind NanOlogy, and what attracted you to take on the role of CEO?

Mr. Arthur: NanOlogy is a clinical-stage oncology company advancing a technology platform aimed at improving the treatment of cancer without increasing toxicity. The technology, called PURCISION™, forms particles of pure cancer drugs optimized for intratumoral (IT) delivery. These particles are delivered directly to the site of the tumor, where they continuously deliver high local concentration of drug to the tumor over time, with minimal systemic toxicity. NanOlogy has established feasibility of the PURCISION™ technology in many small molecules and has studied three intratumorally delivered investigational drugs preclinically or clinically in several solid tumors. The technology, supporting data, and team all attracted me to take on the role of CEO as I believe my background and experience can help position the company to benefit cancer patients and create long term value to shareholders. I think NanOlogy has got to be one of the more attractive companies out there right now.

CEOCFO: What can you tell us about the technology?

Mr. Arthur: A significant unmet need in oncology is to improve the treatment of solid tumors. Solid tumors are very hard to treat and rational combinations including chemotherapies, and newer agents like targeted therapies and immunotherapies, will remain standard of care (SOC) for the foreseeable future. Research has shown that chemo and targeted therapies help kill the tumor and elicit an immune response, called "immune priming", to help improve solid tumor response to immunotherapy.

Over the years, researchers have been working on many methods to target the delivery of cancer drugs to help improve solid tumor response. Targeted therapies given systemically are an example but have not lived up to their promise because of off-target toxicities and other limitations.

Instead of systemic administration, the PURCISION™ technology is designed to be given locally to directly kill the primary tumor or tumors and prime the immune system to increase solid tumor response to newer SOC therapies. Our proprietary

technology uniquely uses supercritical fluid carbon dioxide as an antisolvent to form what we have come to characterize as large surface area microparticles, or "LSAMs", of pure drug optimized for intratumoral delivery. The microparticles retain a particle size that is sufficient for tumor retention but with a huge increase in surface area that allows for high local drug release over time. LSAMs are covered by a composition of matter patent forming the foundation of more than 100 issued patents filed globally protecting composition, use, formulation, and technology.

Our research as well as independent research indicates that high sustained concentration of chemotoxic agents in solid tumors kills them in such a way as to prime the immune system. Our goal is to further validate this in late-phase clinical research.

CEO/COO: *How did the technology come about?*

Mr. Arthur: As with many advances in technology, the PURCISION™ technology was years in the making and originally developed at the University of Kansas in Lawrence, Kansas. The promising technology was spun out of Kansas about 15 years ago to a newly formed company called Critech Particle Engineering Solutions, now a Nanology partner, to develop better ways of delivering multiple kinds of drugs, not just for cancer, in pure drug format.

The obvious uses are for the highly toxic cancer fighting drugs, and many of them now can be delivered in pure drug form directly to the site of the tumor without the terrible consequences of systemic toxicity. In other therapeutic areas, the delivery of pure drug through inhalation or pulmonary devices, can deliver drugs directly into the lungs, and, beyond that, the technology can serve as a better way of directly delivering drugs to other areas of the body as well.

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CEO/COO: *Where are you in the development process?*

Mr. Arthur: There are many different types of solid tumors, and most are now accessible because of advancements in imaging and advancements in interventional procedures over the last decade. One of the things that excited me about Nanology when I came onboard was the breadth of clinical experience that they have already achieved with their LSAM investigational drugs. On two LSAM assets, Nanology has run seven clinical trials across six different solid tumors including bladder, lung, pancreas, prostate, ovarian, and peritoneal cancers. We are now talking with Strategic Pharma and other groups to advance those assets further in clinical development in prioritized indications.

Another asset we are excited about is the development of cisplatin into LSAM-Cisplatin. Cisplatin is a chemotherapy that has been around for a while with many uses but has terrible side effects when given systemically. We have developed a clinical formulation of LSAM-Cisplatin and are nearing completion of preclinical studies with our lead indication for a rare devastating pediatric brainstem tumor called diffuse intrinsic pontine glioma (DIPG). This is a devastating, highly lethal cancer in children, with typical onset between the ages of two and ten. There is no treatment other than radiation. Unfortunately, the median survival for these children after diagnosis is only 10 months.

A key problem is that DIPG is deep in the brain. It is very difficult to get systemically administered drugs through the blood brain barrier to the tumor, and these tumors are inoperable because of their location. But recent advances have allowed us to use a highly precise MRI guided targeting system, to inject LSAM-Cisplatin directly into the tumor. We are hopeful that delivery LSAM-Cisplatin directly to the tumor will offer hope for children and families facing this horrible disease and that LSAM-Cisplatin could become one of the first approved medicines with significant benefit for the treatment of DIPG.

CEO/COO: *Do you think parents of children with this devastating illness would be willing to take a chance on something so new or choose to stay with the conventional just enjoy the time they have with their child?*

Mr. Arthur: I can't imagine what it would be like to have your child diagnosed with DIPG, knowing that there is no real treatment option other than radiation, which only provides minimal clinical benefit. Unfortunately, current choices are to

try experimental treatments, more radiation, or make your child's final months as comfortable as possible. It is an awful decision to have to make. I think many parents will be very interested in this new option that has the potential to increase the quality and duration of life.

There are several companies out there working on other type of drugs and treatments for DIPG, and I believe at least a handful of these will be approved, and may have potential to work in combination together. I believe that parents are going to want to utilize all available treatments.

We believe based on the work we have done leading us up into the clinic, that we can be a medicine with potential to effectively treat this disease and do no harm. So, I think the answer to your question is yes, parents will want to try LSAM-Cisplatin as a potential treatment for DIPG.

CEOFCO: *What does the timetable look like?*

Mr. Arthur: We have announced that the next step is to submit an Investigational New Drug (IND) application to FDA. An IND includes information on whether the drug is safe, whether it works, and whether you can manufacture it and deliver it to the patient safely. Once our IND has been reviewed and accepted by FDA, that will allow us to initiate a first-in-pediatric clinical trial in DIPG.

We plan to submit our IND application mid-year. We are hopeful we might be able to treat our first patient before the end of the year or early 2027 at the latest. From that point on, we will enroll and evaluate patients as rapidly as possible. Given the aggressive nature of DIPG, we should be able to evaluate preliminary results pretty quickly on whether LSAM-Cisplatin is providing therapeutic benefit.

CEOFCO: *What has been the interest from the medical community?*

Mr. Arthur: The interest among the pediatric oncologists and the pediatric neurosurgeons has been very high. The reason we are developing LSAM-Cisplatin for this illness is because we were approached by a leading pediatric institution. We were asked to develop this drug because in one of their internal processes, they identified this illness as one of the most devastating and one of the least researched illnesses, with the least number of treatment options. Doctors on the front lines who are interacting with the families and children with DIPG are desperate for new treatment options and they are familiar with cisplatin because it is already used systemically for the treatment of certain pediatric cancers. Therefore, the interest level is very, very high.

CEOFCO: *I am sure before you took on the role, like most CEOs, you did a tremendous amount of due diligence. But what surprised you when you actually took over NanoOlogy?*

Mr. Arthur: Right off the bat, I was very impressed with the science and the technology that underlies Large Surface Area Microparticles because LSAMs overcome toxicity, a key limitation of many of the drugs in development or on the market.

For example, when we hear about a friend who has cancer, the first thing they say is they are going to undergo chemo and/or radiation. We all know what then comes to mind: nausea, vomiting, fatigue, loss of hair, etc. That is a huge limitation to those treatments. Well guess what? This technology may solve that problem. You asked me what I was excited about after my due diligence, and potentially solving the systemic toxicity problem for drugs that we know work is at the top of the list.

This technology also solves a major issue of limited bioavailability of tumor-killing drugs to the site of the tumor, which impacts many drugs leading to suboptimal clinical outcomes. Once I understood our technology solves that, I could see that potential not only for our LSAM investigational drugs, but the huge potential for working with pharmaceutical companies, and identifying drugs they have in development that show promise but have been put on a shelf because of systemic toxicity or lack of bioavailability. We can rapidly evaluate the potential of our technology to solve those problems.

CEOFCO: *I bet there are tons of those!*

Mr. Arthur: I spent 22 years in big pharma, and I can validate your comment. There are a lot of drugs out there that can be improved by reducing systemic toxicity and increasing bioavailability.

CEO CFO: *What else is going on at NanOlogy?*

Mr. Arthur: I will answer that in two parts. Part one is the program we have been discussing. We plan to be in the clinic treating children with DIPG hopefully by the end of the year. Shortly thereafter, we intend to initiate a randomized clinical trial of IT LSAM-Cisplatin in a large adult indication and have already begun work to identify the best initial indication to pursue. It is not a question of whether LSAM-Cisplatin will work, we all know cisplatin works, but it is a question of picking the right solid tumor type outside of the brain that has a significant unmet medical need and a meaningful early surrogate endpoint that allows for read out and potential partnering interest as soon as possible.

The second part of the story is what is going on today, which is we are actively discussing our two clinical assets, LSAM-PTX (paclitaxel) and LSAM-DTX (docetaxel), with strategic partners. Based on the clinical data we have generated to date, we are well underway on discussions with partners to help take these drugs further into clinical drug development with lung, bladder, and pancreas cancers our current priorities.

CEO CFO: *Are you seeking funding, investment, or more partnerships?*

Mr. Arthur: We are incredibly fortunate that, to this point, we have been funded through family offices and a leading pediatric institution. I am one of the few CEOs out there that is going to answer your question by saying that at this moment I am not raising money.

However, once we get into the second half of the year, we will better understand what types of strategic partnerships we may be entering into and what our next clinical trial outside of DIPG with LSAM-Cisplatin will look like. I then plan to go back to our current investors and ask them if this is a good time to begin looking at new investors or whether they want to continue to fund the company on their own.

We are rapidly approaching significant near-term milestones that will position us well for an external capital raise in early 2027 to advance clinical research with LSAM-Cisplatin if we decide to pursue this option. We are also advancing promising opportunities for clinical collaboration on late-phase clinical research on our clinical-stage assets. Both will seek to further validate our technology and programs for a liquidity event in the next several years.

CEO CFO: *What should people know about NanOlogy that we have not discussed?*

Mr. Arthur: Intratumoral therapy is rapidly gaining momentum as a potential important part of the treatment of solid tumors – in early disease to prevent or delay progression and in late disease, combined with newer systemic agents, to improve response without the severe stacked toxicities associated with systemic combinations. We are beginning to see the proverbial hockey stick in interest emerge – whereas only a few clinical trials involving IT modalities were underway a few years ago, almost 200 clinical trials are currently underway. Large pharma is beginning to take note, too, with companies like J&J already significantly investing in the space. NanOlogy is a leader in IT therapy aimed at improving solid tumor response without increasing toxicity with growing evidence in support of this aim.

CEO CFO: *Finally, put it all together for readers-why pay attention to NanOlogy?*

Mr. Arthur: NanOlogy is an exciting company. We currently have three assets and two have already completed seven clinical trials across six solid tumor types. By the end of this year, we expect to have these assets positioned for late-phase clinical research and our third asset treating a rare pediatric brain cancer and ready for clinical research in a large market solid tumor indication. As I mentioned previously, I think NanOlogy has got to be one of the more attractive companies out there right now.