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Goodwin Biotechnology, Inc. Uniquely Meets the Contract Development and Manufacturing Needs for Today's Complex, Targeted Biopharmaceuticals

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CEOCFO: ***Mr. Pinto, what is happening today at Goodwin Biotechnology Inc? You are in a growth mode; would you give us some of the basics?***
Mr. Pinto: Goodwin has been evolving for many years as a company. We started way back in 1992 and, depending on how you look at it, even earlier than that, so that makes us about twenty seven years old. That is quite a pedigree right there. We have been evolving those years. The evolution that has happened in the last year and a half has been probably the biggest step that we have taken. We are actually right in that process right now. Therefore, it is really a very pertinent question.

In a nutshell, Goodwin has set a certain set of foundations in place at the company to scale our operation to the next level over the next year, or so. We are already probably six months into this process. When I say scale our operation, we are, as you said, in growth mode; yes we certainly are growing in terms of our size, our capability sets, our compliance levels, the kind of people that we have and everything that's required to support these aspects of growth.

CEOCFO: ***Why now?***
Mr. Pinto: Multiple things are actually happening in our industry. On one level, there is a huge level of consolidation that is going on in the CDMO space, the Contract Development and Manufacturing space, where we help our clients develop and manufacture their new cutting edge products, often before they even are available in the market. This is a large and growing industry (outsourcing makes business sense!) and one of the huge trends within this industry, especially in the last four to five years, has been a humongous level of consolidation among the various players.

Companies have been acquiring others; have been merging with others and some of the smaller ones no longer exist. Now we have far fewer, but much larger sized companies out there in the marketplace. Goodwin continues to be one of the smaller, more specialized CDMOs. It continues to remain independent as a CDMO, unaligned to any of the larger companies. We see our relative smallness and our independence to actually be a "strength" within the industry and we are priming ourselves to take advantage of this strength, in order to provide certain unique benefits to our clients.

CEOCFO: ***Would you walk us through what you do at Goodwin and a somewhat typical and a somewhat atypical engagement.***
Mr. Pinto: As I alluded to in my earlier response, we are what is called a CDMO, a Contract Development and Manufacturing Organization. As the name suggests, we work on contract with our clients. Our clients are typically companies that develop their own products; they have often invented their own products. These are therapeutic drug

products. We work with biologics, or biotech drugs, which is a very specialized category of drugs, and different from typical pharmaceuticals (which are generally chemical-based). Therefore, companies like Goodwin serve a very important purpose within the industry in that we work as a service provider, as a development and manufacturing partner, to our clients.

Our clients are the ones that have the invention, that have done the initial research and that are running clinical trials, for example. Goodwin is the company that actually takes their technology, industrializes and scales up the manufacturing process for that particular technology or product and we have the capability, expertise, and the special facility to actually manufacture the products for our clients as per cGMP (current Good Manufacturing Practices), and according to FDA regulations.

CEOCFO: ***Do many companies take advantage of that? Are they coming to you because you can be a "soup to nuts" provider?***
Mr. Pinto: Yes. As I mentioned, a growing trend in our industry is the increase in outsourcing. One of the reasons is that the best technologies and inventions often lie within smaller companies. Those companies prefer to put their often limited financial resources into actually doing the research rather than building expensive, highly regulated, brick and mortar manufacturing facilities. That is where companies like Goodwin are engaged to do the manufacturing for them. Another reason is that we have a set of expertise's to make these things that would typically take years and years to develop in a new facility, because these are highly complicated and complex processes and infrastructures that we have put together over the last many years. Therefore yes, increasingly more and more companies are using the outsourced manufacturing model, particularly during their clinical phases as well as when they first come out into the market.

"We are the unique CDMO platform within the industry which is efficiently built to handle small-to-medium volume, highly complex biologic products with the quality, infrastructure and experience required to take these products from the start, right up to commercial production in very short periods of time."- Karl Pinto

CEOCFO: ***How do you stay on top of the changes and innovations in the industry? What is the key to really knowing what is going on?***
Mr. Pinto: Actually, I could give you a standard answer like you have got to attend lots of conferences and read lots of trade journals and meet lots of people. There is that, yes. However, the main learning that we get and the main channel of learning that we get is through our clients themselves. By virtue of doing what we do, we have direct access into some of the most cutting edge technologies that one could ever imagine. Scientifically speaking, mankind is literally pushing the boundaries of understanding disease better and understanding how we, as a species, need to combat that disease. To say that we have come a long way, particularly over the last decade or so, is understating it! We know a lot more about a disease like cancer, say, today than we did even ten years ago.

The human genome project was probably one of the big step function progressions that we had, that has enabled us to understand these conditions a lot better and enables us to design better products. As a service provider, for Goodwin, the very fact that we are approached by and work with some of these companies which have the greatest innovations that you could ever think of, that in itself is where the majority portion of our learning as a team, as a company, lies. That is because we take those technologies into our facility and we develop off of them, we develop over them, we insure that we scale them up to industrial size, consistent processes within FDA regulations, to manufacture the particular therapeutic. Therefore, the answer is that we keep up to speed on the technology mainly through our clients. They are the ones who are the real innovators and we basically learn from them.

Additionally, we have our own capability sets including our expertise in mammalian cell culture and the other development and manufacturing technologies that we have as core competencies. There are great technology advances going on there as well, which we make it our business to continuously imbibe and use within the services that we provide to our clients.

CEOCFO: ***Would you tell us the steps you have taken in the growth process and what is left to do?***
Mr. Pinto: Traditionally, Goodwin has been a company that has manufactured these highly complicated and complex products for our clients, mainly focusing on clinical (trials) stage cGMP manufacturing. Increasingly, we have been taking on more and more late-stage or Phase-III trial manufacturing projects. When you start doing late stage manufacturing for your clients, it is inevitable that one or more of them starts planning on the manufacture of their product after approval by the FDA. One such client of ours approached us a couple of years ago, in 2017, and asked us whether we would be willing to support them through, what is called, their BLA process. BLA stands for Biological License Application and is

filed with the FDA after a successful Ph-III clinical trial. If all of your data (clinical and manufacturing) that you submit to them is strong enough, the FDA approves your product. Your BLA is approved.

So when our client came to us, it was sort of an inflection point for Goodwin. Do we want to continue to play within the clinical trial space or do we want to extend our capabilities, enhance our compliance levels and enable us to support clients with their commercial manufacturing as well? We took a Board level decision in 2017 to support this client (and others in the future) to take their product into commercial manufacturing. Therefore, we started the process of figuring out what we needed to do in order to be able to support commercial manufacturing. That process actually had two main components to it. One was a technical/regulatory component to it, or upgrading our capabilities. The second was the finance component to be able to invest in and fund the building of what we needed to.

So we hired a bunch of consultants and advisors to advise us on what we needed to do as a company both from the technical as well as the financing perspectives. We went through that process in 2018. It was highly involved on multiple fronts, and the middle of last year (2018) was when we got a very strong plan of action that we put in place on the technical side of things in terms of what we needed to do. That was also when we pretty much kicked off the endeavor of attracting outside capital into the company to fund this new expansion.

Fast forward to 2019. We have done a couple of things this year. Number one was that we expanded our space by acquiring the campus which we previously leased, within which we have operated all these years here in Plantation, Florida, close to Fort Lauderdale. This gave us about forty percent more space than we were currently occupying. Then in April of this year we announced that we had taken on a new investor into the company. Signet Healthcare Partners, a very smart, successful New York-based private equity firm specializing in providing growth capital to firms within our space, were invited to infuse a new round of funding into our company, new funds. We were fortunate to have attracted great interest from lots of companies, larger companies, financial institutions and so forth, to invest in our little company and we finally selected Signet.

Now, flush with this new funding and new space, we are in the process of kicking off our planned expansion, extending our current capacity into new capacity. We are in the process of hiring a few very key senior executives for the company to help us and support us in this next phase of our growth. We will also soon start aggressively marketing these new capabilities into the marketplace.

CEOCFO: ***Do you do much outreach for new clients or are you known in the industry and people are turning to you at this point?***
Mr. Pinto: That is a very important aspect of the focus that we currently have, Lynn. Are we known in the industry? Yes we are, because we have been in the industry probably longer than most other CDMOs out there. Even though most of them are many, many times larger than us, few if any of them, have been in existence longer than Goodwin has. Therefore yes, we are reasonably known in the industry. However, we are known in the industry as a small company that operates in the early stage clinical trial portion of the industry, of the spectrum of the business.

One of the focus areas that we are undertaking right now is to build a go-to-market strategy, a very, very aggressive go to market strategy, to announce to the world, to go out and announce to potential clients and potential partners that this is going to be the new Goodwin. We are putting in a lot of investments towards increasing our scale and towards increasing our compliance levels and frankly, towards increasing the breadth of what we have to offer to the market. That is something that is an area of great impetus for the company over the next couple of quarters.

CEOCFO: ***What are your challenges or what concerns you, or is it just a matter of doing it?***
Mr. Pinto: When you run a business there are lots of things that concern you; from things that are core to your own environment to things that are happening outside of your environment that you cannot control. From our perspective, what we do; biotechnology in and of itself, is a highly complex art, if you may. When you are dealing with living organisms, there are factors that we do not always understand, but they are there at play. That is always a concern, each of our projects comes with its own sort of peculiarities and challenges. Now, it is our job to overcome these and we have become really, really good since we have been doing it for so many years. While we believe that we provide a very, very consistent and easy to understand sort of methodology to our clients, there are fundamental uncertainties there sometimes.

Another uncertainty relates to the strategy that we are following itself, even though it is well thought out and seems to be right in line with what the market needs. Is this the right strategy, or not? At some level, we are one of the few companies

that is embarking on such a strategy. Let me explain. I mentioned to you earlier that there is a huge trend of consolidation within our industry. This means that our competitors have become larger and larger in size. When they become larger, they very often loose inherent advantages that they had when they were smaller. For one thing, it is systems, processes and bureaucracies. Let us say I am a small CDMO that becomes part of a larger CDMO. Suddenly, the way I did things needs to change, because they need to be harmonized with how the head office wants me to do them. Therefore, you lose your inherent ability to be flexible, to do things the way you used to before. There is that, that comes with increased size. With increased size also comes increased costs. Your fixed costs suddenly become much larger, because now you have got huge, facilities that you need do run & maintain, armies of people that you need to manage and hence, what that does is it forces you to raise your prices on your clients, because you have got to be profitable. That is the trend of what is going on in the industry, and clients, particularly smaller ones, are feeling the reduced flexibility in engagement and higher costs.. Goodwin fills in this void which is being created by industry consolidation.

The next part of our strategy has to do with helping alleviate the problem of complicated supply chains. Therapeutic products, particularly those that fight diseases such as cancer today are becoming more and more complex. We call them the complex biologics, or the new biologics. These are often multiple products combined with each other, like ADCs, or Antibody Drug Conjugates. In order to successfully bring them to a point of administration to a patient, there is a humongous amount of supply-chain related activity that needs to go on at the back end. Sometimes, one product component is made in Ireland, another one is made in Puerto Rico, these two products need to be sent to California so that they are conjugated to each other, then this whole thing needs to be sent to Canada to be tested and released to be sent to the various hospitals that are going to administer the product. I am just giving you a simplistic example of a pretty complicated supply chain. Clients often deal with different CDMOs for different aspects of this supply chain. This often turns out to be very challenging since there is inherent risk in each of these steps which is multiplied across the chain and eventually you are only as strong as your weakest link. If there is failure or deficiency at any one of these points, basically the whole product fails. This is true particularly for these more complex, new biologicswhich are really becoming more the norm than they ever used to be.

CEOCFO: ***Would the market benefit by having all of these services under one roof?***
Mr. Pinto: Our belief is that if you have a CDMO site that has a breadth of services and capabilities all under the same roof, it is a solution that the market would really do very well with, instead of having to move in-process product to different places and sites. Granted, when you follow an approach like this it is challenging to build it out at a very large scale, since these varied capabilities all need to reside under the same roof, within the same quality system. But therein also lies the advantages of this model – being able to do multiple things consistently, efficiently, with much lower costs and importantly, risks, associated with it. And for the client, working with one CDMO partner is a lot easier than working with multiple sites.

As a complement to this next-generation, “small” CDMO site that I described, we are seeing that the way scientists are inventing these new products, new biologics, is also interesting. They are very targeted towards particular diseases or patients and are becoming more and more personalized. You’ve probably come across these terminologies; personalized medicine, targeted therapies and immunotherapies. In fact, sometimes products only work for a few hundred patients, so they have got to be very specifically designed for those particular patients. Due to these facts, the amount of physical product needed to be made is actually quite small. This “small” CDMO site suddenly becomes a very attractive platform to make such medicines.

CEOCFO: ***This is where Goodwin Biotechnologies comes in?***
Mr. Pinto: This is where Goodwin comes in. We pride ourselves on being small, but being able to handle these very complex next generation biologics. We have been doing this for quite a few years, but are only now in the process of effectively “coming out”. As part of our new financing and expansion, we are further cementing our position as the unique CDMO platform within the industry which is efficiently built to handle small-to-medium volume, highly complex biologic products with the quality, infrastructure and experience required to take these products from the start, right up to commercial production in very short periods of time. So our target client is one which has a complex biologic product, which may not need very large volumes, and needs to develop and get their product approved within a very quick turnaround time.