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Delivering Integrated Manufacturing Solutions for Complex Biopharmaceuticals

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CEOCFO: ***Mr. Pinto, we spoke a little over a year ago and at that point Goodwin Biotechnology, Inc was in growth mode. How has that developed over this past year?***
Mr. Pinto: Yes Lynn, we have had a very, very interesting 2019/2020 so far. I think that when we last spoke, we had raised a fresh new round of funding and were bringing in some institutional investors in the second quarter of last year. Much has happened since then. We took in new capital because we had identified certain areas of growth for the company; we are now in different stages relating to that. It has actually manifested itself pretty nicely, even though this year has been a tough year for everyone, because of the pandemic and everything.

Even in the midst of Covid-19, the challenges related to employee safety, operational continuity and other business uncertainties, we have shown a steady increase in our revenue in the first half of this year. We have added to our employee base compared to a year ago. We have made quite a number of changes and upgrades to our facility. That still continues with the inclusion of a new Fill/Finish suite and fully automated machine. We are in the process of expanding our capacity. We are deploying more strategic, fundamental, longer term-oriented investments in a big way, objectively speaking.

CEOCFO: ***You licensed some technology back in November. How has that changed the quality and efficiency of what you do at Goodwin?***
Mr. Pinto: Yes, you are talking about our electronic quality solution, I believe. You know Lynn; implementation and execution of solutions like these need some time. Therefore, the way I would characterize it is that it is in the process of being fully deployed. We have been operating

almost thirty years in a particular way, our paper-based quality system, and are now changing or transitioning it to an automated, electronic system. Basically digitizing many aspects of what we do is not something that happens like a light switch. I think the key to understand the way we are going about it, the impact will be felt by us and our clients greatly, positively over the next few years. We will start seeing them towards the later part of this year. We have seen them in bits and pieces, here and there, but I think mainly the last, say, six to seven months have been in the implementation and deployment phase.

CEOCFO: ***Why did you decide to take the plunge? Why did you decide it was time to get more digital?***
Mr. Pinto: Very good question! Obviously, from a business standpoint, Lynn, using computing and IT and digital systems is becoming almost an imperative for most businesses, globally. It provides a great level of control, a greater level of visibility and far greater efficiencies throughout the organization. We have been taking steps in that direction, even though we are a small business ourselves. Now, particular to the technology that you talk about, moving our quality systems from paper-based systems to an electronic one, let me explain.

We are on a journey at Goodwin, from developing early-stage complex biopharmaceuticals we are gearing up to be able to support late stage and commercial product manufacturing. Now, when auditors or the regulatory authorities including the FDA and others, come in to audit and inspect sites like ours, they expect to see a very high, sophisticated level of control, consistency and traceability of your processes; every single piece of your process. An electronic system enables this far more efficiently than a paper based one does. Really, the FDA, we are talking about regulatory agencies worldwide, greatly encourage and prefer organizations like ours to move in that direction. That was one of the big reasons we did it, besides the business aspects and advantages that it provides us.

CEOCFO: ***Is being a single source solution gaining importance today?***
Mr. Pinto: Huge! Huge! It is funny you asked that question, but I just got an email yesterday, literally, from my head of business and he actually quoted a potential client of ours with a very interesting quote, saying that, "I wish I had come across a CDMO (that is what we are, a Contract Development and Manufacturing Organization) three years ago that could do both drug substance and drug product manufacturing. It would have simplified my supply chain so much! Coordinating two different companies and the shipments continues to be a challenge." That was an actual quote!

The point being, there are many companies that do drug substance, which is that they actually manufacture what is called a bulk drug. In our case, we do that in our bioreactors, because these are very complex biotech drugs. When patients are administered these drugs; they are delivered in the form of vials, and administered as injections usually. Therefore, finishing the product into those vials and into those injectables is something that is called drug product manufacturing. We have traditionally done this at our site for many years. Very few other

companies do both drug substance and drug product manufacturing ~~on~~ within the same site. There are companies much larger than ours that have the capability to do both of these, but they are typically on different sites at different facilities, sometimes in different countries. Thus, it becomes far more complex, expensive and sometimes risky to move the drug substance, which is typically in big barrels or bags, through the whole logistics system. Not to mention the complexity for clients to manage multiple supplier relationships. That is just an example.

We have stayed small, but in our smallness, we have been able to seamlessly integrate a lot of these things. We cannot do huge, huge volumes, but to the extent of our client base, they are the ones that typically need up to mid-volume requirements and we can handle all of those at our site itself and that is a huge advantage!

CEOCFO: ***There is a section on your site called, "A passion for the patient." Would you tell us about that and why that is so important for Goodwin?***
Mr. Pinto: You know Lynn, we all have livelihoods. You do this for a living, interviewing people and gaining insights into what they are doing. You thoughtfully ask the questions and get them to answer stuff. What I do is I make medicines. I am extremely fortunate that my career, from a personal standpoint, my livelihood, is something that often provides life to others, literally. The drugs that we make here oftentimes save patients' lives. Many of our drugs are, for example, oncology drugs, cancer drugs, so translating that kind of sense and appreciation into everything we do becomes really, really important. Therefore, the point being, this passion that we have for what we do transcends not only for me, but all our employees, across every aspect of our organization.

It is continuous improvement. We have to be constantly, constantly improving on what and how we do things. Ultimately each of us asks ourselves (and I think this is fundamentally in our DNA): what I do impacts the output of the company; thus, would I inject that drug into my own child if she was in need of it?

CEOCFO: ***Do you find that philosophy helps attract employees to Goodwin?***
Mr. Pinto: It does. But I would not say an across the board yes, Lynn, because ultimately people are looking for a job, for a livelihood. You do have highly-skilled scientists and other people who are fundamentally motivated in this way and that is quite the perfect employee. However, I think it is up to us, as leadership, as management, as people who are building cultures and environments within companies such as ours, to inculcate this sense and sensibility into each and every one of our staff.

I feel pretty comfortable saying that we have been doing a good job in that respect and pretty much all of our employees, at least have a good understanding of why we do this, so it is not only about what you do, it is about why you do it. I guess, everyone has a different way of looking at it as some level, but yes - the "why" of what we do is very, very important and evident to pretty much each and every one of our staff and their families. This certainly has a large impact on employee retention.

CEOCFO: ***Goodwin stands ready to prioritize any project aimed at addressing the Corona virus pandemic. How do you reach out on that? Are people taking advantage? How are you able to ramp up if some big projects come your way needing that priority?***

Mr. Pinto: That is a very good question. I think that everyone, the world frankly, in the last five or six months, has become far more knowledgeable about our space, the biopharmaceutical industry. That's because this pandemic has led to far more recognition and concern relating to the progress and issues around therapeutics and vaccines than there ever was before. This also puts our industry under a sort of a spotlight, because we are the ones who are contributing towards and have a very real responsibility around these very important solutions. It is often said that things will return back to normal only after we get a vaccine and/or a therapeutic against Covid-19!

How Goodwin has managed to navigate and evolve during this time is very interesting. We announced a few months ago that we are keeping certain capacity ready to deploy for Covid-19 related products. This includes resources, staffing and investment. The result of this is that we have taken on a few new projects which are specifically focused on COVID-19 solutions, particularly therapeutics for COVID-19. This is a combination of new products as well as existing products which are being repurposed against Covid-19. Additionally, we are also talking to multiple new clients who have promising solutions for COVID-19.

In addition to increasing the number of employees towards supporting these kinds of requests, we have also learnt importantly that these are not just typical projects. For one thing, everyone needs to get these solutions far faster than we ever had to deliver in the past. You have the regulatory authorities looking at fast tracking potentially viable therapeutics and vaccines into the main stream. Therefore, as suppliers into this industry we have had to also modify, improve and change certain ways we do things in order to deliver high quality services and products faster and more efficiently to our clients. We have been fairly successful at, for example, cutting down timelines for projects that used to typically take 12-18 months. We are doing these now in eight to ten months! That's is about a thirty to forty percent increase in efficiency as far as timeline deliverables go! I think, while that is necessary today, it is going to impact our business longer term as well, because we'll be able to leverage these efficiencies and new approaches far into the future, so that we can provide stronger, better and higher quality services to our clients, even after the pandemic is done!

CEOCFO: ***What is the takeaway for our readers? What should people remember about Goodwin Biotechnology?***

Mr. Pinto: I think the takeaway for readers should be that the biopharmaceutical industry is making great strides towards responding, not only to the pandemic that we have recently seen, but to improving itself for the longer-term benefit of human kind. Goodwin Biotechnology is fortunate to be at the cutting edge of that as a company, because we get to work with products that are very nascent in their life cycle, the development stage. Being able to do our job better and faster and more efficiently promises to have a very positive impact towards healthcare into the future. While I speak for myself and Goodwin, I think that is the

larger message and result that we are going to see from the biopharmaceutical industry as a whole going forward into the future. Therefore, things are good! Things are moving along quite nicely, and we are lucky to be doing what we do!