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Q&A with Karl Pinto, CEO of Goodwin Biotechnology, Inc. a Contract Development and Manufacturing Organization helping Biotechnology Companies take their Biologics from Lab to the Clinic

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CEOCFO: ***Mr. Pinto, what is Goodwin Biotechnology Inc?***
Mr. Pinto: Goodwin Biotechnology is what we call a CDMO or Contract Development and Manufacturing Organization. We have infrastructure, capabilities and a lot of experience in developing and manufacturing bio-pharmaceutical products that are on their way to getting approved by the regulators. Actually, our specialty is biotechnology, so the products we make are called biologics. They are not small molecule pharmaceuticals, but they are, what we call in the business, large molecules, which are proteins and monoclonal antibodies, including ADCs (antibody-drug conjugates), typically cutting-edge therapeutic products that are fighting complex diseases like cancer, auto-immune, and other chronic conditions. So Goodwin Biotechnology is one of the world's oldest and most efficient CDMOs, taking our client's biological products from the lab to the clinic. We've done this consistently for over 25 years and worked with almost 500 products! We are based near Ft. Lauderdale, Florida and currently serve biotech clients from N. America, Europe, and Asia, so we are quite a global company.

CEOCFO: ***Do many of your clients work with you on the development process? Are more of them just coming for the manufacturing? What is the mix?***
Mr. Pinto: That is a very good question! A typical project for us, I would safely say, encompasses all of the above. By that I mean that most of our clients come to us when they are at the earlier stages of their product development. That means the product is typically still in the lab. They need a lot of further development work done to their basic technology that they have created or developed in their lab before it can be scalable and the industry level manufacturability of those products is achieved. What I mean by that is that in biotechnology or in the pharmaceutical/life sciences space the regulators are extremely, extremely strict and concerned about the manufacturability of a product, about the quality that is put into the product manufacture and about the consistency and traceability in the process, which means the consistency of the product that comes out. To insure these things there is a lot of work that needs to be done, from basic technology until you reach the level that the regulators would be happy with. That is where the development portion comes in. Therefore, I would say that a very high percentage of our projects have a very, very big development component to them. Once we have developed the process, we then manufacture the product at our facility under full GMP (Good Manufacturing Processes) conditions, and often fill them in vials before shipping them to the clinical sites for the trials.

CEOCFO: ***What might you look at early in a project that less knowledgeable people might stumble upon near the end? What can you prevent because of your knowledge and experience?***
Mr. Pinto: I think the portion of the industry that we play in itself is very specific and very specialized. While I would not generalize this one hundred percent, for the most part manufacturing small molecule pharmaceuticals is relatively much easier than what we do. When I say small molecule pharmaceuticals, I mean the regular liquids and tablet medicines that we buy at the pharmacy. They are basically chemicals. To synthesize or manufacture a chemical is much easier than manufacturing biologics – biologics are made from living systems. Therefore, by definition the portion of the industry we play in itself is very specific and very specialized. That is what we have been doing for the more than twenty five years as a company and a team. It is a very specialized capability set that we bring to the table. That is number one.

Number two is that we have traditionally followed a philosophy of being what we call a one-stop-shop. When a client of ours has developed certain technology in their lab, they come to a company like Goodwin to actually develop their process and scale it up and then manufacture product for them. Then they take it and get it approved by the regulators to be injected into human beings typically for a clinical trial. They expect us to do all those product specific tasks (development, manufacture, and product testing) as well as actually vial the product for them that would finally be shipped out to the clinical sites where the product is then administered/injected into patients for the clinical trials. There are many, many moving parts in a typical program like this which are all handled by Goodwin. The client typically deals with their single-point contact at Goodwin, usually his or her Goodwin project manager, that's all. We basically take care of the rest. Do we do everything under our roof? No, but I would say we directly do eighty to ninety percent of the scope. We outsource certain specific tasks that are required as part of the process and the project. However, those are done without giving the client any additional overhead in terms of managing those separate supplier relationships. Therefore, we do everything as part of the larger project for our clients. I think that is another differentiator that we bring to the table, being a true one-stop-shop.

"Goodwin Biotechnology is one of the world's oldest and most efficient CDMOs, taking our client's biological products from the lab to the clinic."- Karl Pinto

Finally, specifically in response to your question about how we approach projects early to ensure we (or our clients) don't stumble later, over the years we have gained specific expertise in developing processes at the outset/start itself with the future in mind – this means that our work needs to be very scalable and consistent as manufacturing volumes increase, thus ensuring quality, timeliness, and eventually reducing the cost of goods at full-scale manufacturing.

CEOCFO: ***Where does cost it come into play for what you do? Are clients willing to pay for a higher level of expertise or do you have to meet the market price?***
Mr. Pinto: Cost is important anywhere, because money is being spent for expected output. Therefore, cost is very important. You have got to realize that we are working with our clients' development teams. From a client's standpoint, the funds spent come out of an R&D account (a cost center), which is usually fixed since these products are not yet generating revenues for the client. There is more flexibility in spend around revenue generating products, but we do not have that luxury. Therefore, we have to make sure that we deliver within the costs and the constraints of costs and timelines that we negotiate with the clients, as well as, of course, making sure that the competitive pressures are taken care of, because there is competition, no doubt. Having said that, we find that being able to deliver very high quality, highly regulated GMP output to the client in a timely manner is something, like I said, which is differentiable and people pay a lot for that capability and for that product. That is because not everyone can do that consistently, and clients understand that.

CEOCFO: ***How do you work with a client who has an idea and is so close to the idea they resist suggestions about how to move it forward or what might need to be tweaked?***
Mr. Pinto: That is a very good question! There is basic innovation, which are the actual patents or intellectual property within the therapeutic product or technology that our client typically owns through discovery, purchase, or license. That's what they bring to us. Then there are the developments and improvements in the process that go into converting that technology into a 'manufacturable' product – I call this Engineering. That's what we do. The nice thing about our business is that our clients view us as the experts in this aspect of what needs to get done. Therefore, while they do have a lot of involvement from a knowledge standpoint about everything that we are doing at every point, for the most part they leave it to us to decide the pathways to be taken within this whole Engineering process. On our part, neither do we go in and make suggestions to them about their basic product or technology, because that is really what their expertise is. It is a very symbiotic kind of relationship, a partnership if you will, where the client has their expertise and we have ours. We end

up complementing each other, rather than over-influencing each other with a cross pollination of ideas and approaches. That said, we are always welcoming of new ideas, suggestions and approaches since our industry is an ever evolving one.

CEOCFO: ***What is new in the manufacturing process?***
Mr. Pinto: Great question! To explain the first trend we see, here is a little background about the industry itself; pharmaceuticals. Traditionally, we have had products that are developed by big pharmaceutical companies. They spend hundreds of millions and sometimes billions of dollars, to bring these products to market. That money is spent largely in convincing the regulators, such as the FDA, that these products are safe and they are efficacious; that means that they do what they are supposed to be doing. You have a series of clinical trials that you undertake before you actually reach the end goal of a product approval. Traditionally, what has happened is that pharmaceutical companies have targeted products that have a huge potential market. That is because if you are going to push so much money into bringing a product to market you'd better have a huge market that the product is going to sell into, so that you can recover your investments and end up making a lot of money on your success. That has traditionally been the model, where you get what are called 'blockbuster products'. By the very name you know what that means; these are multi-billion dollar products that are meant for millions of patients. Unfortunately in that model, for every dozen or so products entering the clinic, only one gets approved on average! That model is becoming unsustainable. So over the last couple of decades or so, scientists are following a different approach to fighting disease. You have people doing very sophisticated research into why diseases are created in the first place within the human body. Therefore, you are treating the human body as a (very complex!) system and you are trying to figure out what is going wrong within that system for, let us say, a cancer tumor to start growing and continue thriving. More often than not, the answers to fighting these diseases are tending to be very patient specific. A therapy that would be good for you might not work for me, even though we seem to manifest with the same kind of condition. Therefore, there is this huge trend towards what is called personalized medicine and targeted therapies. These are very targeted towards particular, not only disease conditions, but specific patients frankly, based on the patients basics make up; the DNA of the patient. What this is doing more and more, is that it is making patient populations more targeted, limited, and product sizes smaller and smaller as it is not a "one-size-fits-all" approach any more. Let us say where a few years ago you needed to make a lot of product once you got approved, nowadays the product sizes are becoming smaller and smaller. That requires, for one thing, a much smaller manufacturing footprint for your manufacturing capacity. For biologics, now you need less and less of the large scale ten and twenty thousand liter bioreactors which you needed earlier to make huge volume products. That is because those are over capacity for what product sizes are trending towards. So I would say that smaller, more efficient manufacturing is one new manufacturing trend.

In the biologics manufacturing industry, the second trend we see is that the manufacturing technologies themselves have progressed in such a way that you can get a lot more product out from a smaller manufacturing footprint today, than you could even five years ago! Product yields have increased very, very significantly, really, from what they used to be. That is another manufacturing trend.

I think a third powerful trend is the increasing use of disposable, or "use-and-throw' technologies and products within the manufacturing environment. Today you have more and more sterile, single-use, disposable products and approaches that go into manufacturing processes. This ensures reduced contamination risks, reduced costs of cleaning and sterilization, and increased overall manufacturing efficiency. The use of disposables and single-use approaches is another huge trend in manufacturing within our industry.

CEOCFO: ***What is ahead for Goodwin Biotechnology Inc?***
Mr. Pinto: What is ahead? Goodwin has traditionally been playing in a niche that services, I would say, small to mid-sized clientele. A small to mid-sized company that has a great new technology might find it really hard to work with a large, multibillion dollar CDMO, of which there are quite a few I might add, due to an aggressive consolidation in the industry the past few years. For one thing, these large CDMOs are very expensive. The second is that small clients do not get the time of day with the large guys, because these CDMOs greatly prefer working on and are looking for huge projects. Therefore, it has always been Goodwin's strategy to be sized small enough, to be able to satisfy clients within this (what we believe to be) under-served space. But for us, satisfaction is not enough; it is customer delight that we pride ourselves on – that's why a majority of our business is repeat or referral business. We try and ensure this through our greatly personalized engagement model and the flexibility that we bring to these clients. Therefore, we are able to service them really well with the level of quality and the compliance requirements that the FDA and the other regulators demand. There is no negotiation there, so the product that we deliver has to be of the highest quality. By the way, although a large part of our business comes from smaller to mid-sized clients, we have worked and do currently work with some really large

pharmaceutical companies as well. Strategically, I would say that we want to continue to service that small to mid-sized client base and we want to continue to service them well beyond what our current service cycle allows for. Let me just explain that a little bit. Our clients' products go through Pre-clinical, Phase I, Phase II, and Phase III clinical trials. We develop and we manufacture their product for them. As the client goes along progressively from Phase I trials to Phase II trials to Phase III trials, depending on the product, it could take two or three years or sometimes even longer. Sometimes they fail at one of these stages, but eventually the strong products do progress. We currently have the ability to manufacture product for our clients up to Phase III. That is the function of the capacity and the compliance levels at which we currently operate. However, once the client is approved in Phase III then they have got to manufacture commercial product. Manufacturing commercial product is not something that Goodwin has done before, so that would be one of the current focus areas for Goodwin. I will say that we are seriously considering and planning for it as a strategic next step for us within the next twelve to twenty four months; to be able to manufacture commercial product for our clients and for other clients who want commercial product manufactured.

The second initiative is the development and further strengthening of certain core technologies that we already have and we already possess, which are actually becoming very popular in the marketplace. When I say marketplace I mean the kinds of therapeutic solutions that are being made available to patients more and more, especially with these targeted therapies and personalized medicines becoming the order of the day. One of these technology areas is the area of ADCs or Antibody Drug Conjugates, where Goodwin has the unique ability and certain proprietary technologies where we conjugate or enjoin monoclonal antibodies to certain other molecules, including cytotoxic substances which often greatly improves the capabilities of the drug. It is a very core technology area that we have been developing for more than 15 years and we see more and more clients come to us because we have this capability set. Therefore, expanding that part of the business is another strategic focus area for the company.