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Artificial Intelligence Software Drives Safer Biotech Drug Development

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CEOCFO: ***Mr. Brandon, what is SentrySciences LLC?***
Mr. Brandon: SentrySciences is basically a value-added distribution partner that has evolved into a software technology company. We began our life 10 years ago in conjunction with a European distributor for scientific instruments used in cleanroom management and cleanroom particle detection. Then as we grew, we always knew that we wanted to differentiate ourselves and move on to something that would complement our offering and accelerate our growth. That is when we got into software through a licensing agreement of a patent with the University of Colorado in Boulder.

CEOCFO: ***What are you offering on a day-to-day basis?***
Mr. Brandon: What we are offering today are basically two product lines. One is services and products for cleanroom management, cleanroom particle detection and basically anything to do with monitoring clean environments for manufacturing. We look at all of the parameters that make that cleanroom operate, report on them and tell our customers whether the room is in spec or out of spec. The other product line is what we call ParticleSentry^{AI}. This is an artificial intelligence package combined with advanced computational statistics using flow imaging microscopy that essentially creates a fingerprint for proteinaceous drugs, to allow the customer to evaluate whether the drug stays within quality control parameters.

During the development cycle of proteinaceous drugs, the manufacturers, the discoverers are required by regulatory agencies to use an orthogonal technique to image the proteins in the drug and how the proteins aggregate to form larger particles. All of this becomes part of what is called the aggregate-control strategy. We take that pre-existing data base of images, and we use our artificial intelligence (AI) package to create fingerprints of the drug in its normal state. Using the metadata and images that are created during development and during all the stress testing they do on the drug product we can also create fingerprints for known excursions from the normal state.

Overall, by the time drug is through clinical trials and is ready to go to market, we have created a portfolio of information on the aggregation behavior of the proteins. During production, storage and shipment the manufacturer can say the drug is stable or has been affected by a known or unknown upset as indicated by the changes in the fingerprint. This is what the artificial intelligence software package is designed to do.

CEOCFO: ***How might a manufacturer be evaluating today? What techniques would they be using?***
Mr. Brandon: We have basically turned that whole regulatory scheme on its ear, because what they do today is they use a technique called light obscuration, which is a particle counting technique where you put a small sample through a laser

illuminated capillary, and the instrument counts and sizes the particles in solution. The problem with proteins is that they have a very low index contrast which makes the particles essentially invisible to light obscuration.

This shortcoming results in the need to use orthogonal techniques such as flow imaging microscopy. The problem that exists currently is the reliance on human analysis and interpretation of the protein particles. If I were to show you what is called a collage of particles from that imaging technique, I can guarantee the only thing that you would be able to notice is differences in size. We are taking that existing technique of flow imaging microscopy and other imaging techniques and removing the human element. We are using artificial intelligence to evaluate these particles and we look way beyond size and number. What we look for is consistency in morphology and consistency in surface texture. Therefore, it is a very different technique that, as I said, is turning the existing technology on its ear.

CEOCFO: ***Have manufacturers been looking for a better way? Do they even know it is possible? How are you getting them to notice Sentry Sciences?***
Mr. Brandon: We are getting them to notice, I guarantee that! We have the ear of many large pharmaceutical manufacturers. We also have the ear of the regulatory community, and we are working within the regulatory structure to validate this technique for use in manufacturing.

To answer the original question, yes; they are looking for a new technique. They recognize the shortcomings that exist today and the inability to adequately characterize protein aggregation in drug product. In fact, we first became aware of this technique at a conference in Breckenridge, Colorado, that is basically aimed at 'what do we do to improve these techniques for particle analysis.' There was a paper given at that conference describing our technology, and we subsequently approached the University of Colorado and were able to obtain an exclusive global license.

"We have solved the problem of old technology not meeting the needs of technology advances in the pharmaceutical industry and we are bringing that to market." Glenn Brandon

CEOCFO: ***How do you know when the AI is enough, when you have reached the tipping point, so you can be confident you have included as much as you possibly can at any given point in time?***
Mr. Brandon: That is a very good question. That is where the computational statistics come in. Just like the facial recognition software on your phone, for example, there are times when it is too dark, the sun is too bright or there is something that prevents it working and you have got to punch in your access code. To compensate for such challenges, we apply computational statistics post analysis by our AI software. It essentially crunches all of the data down to a 2D representation of all of that data. That data then positions itself in what we call a probability density function, a PDF. That is what becomes the fingerprint of the drug.

It almost looks like a fingerprint, because it is a density distribution, much like a topographical map. The computational statistics are essentially eliminating the outliers to a point where they become statistically insignificant. If we were just using the AI it would take a PhD to examine the data that we produce. We simplify it dramatically, with the statistical analysis that we do.

CEOCFO: ***How do you stay on top of any changes in current drugs as well as new ones?***
Mr. Brandon: What we are doing is we are really focused on the protein side of things. We see that it as the growth market of the future. That is not to say there are other things out there where we can have an impact, like cell therapy, and someday we may be able to help that market space as well. However, right now we are really focused on proteins. If your question relates to an individual drug changing, that is really at the heart of our technology.

As these drugs change, we notice that change and we notice very small changes. Things like if a manufacturer changes the vial that they ship the drugs in, we notice the change in that. It is just a simple as that. It could be a way the manufacturer cleans the glass. It could be the chemical composition of the glass. When a manufacturer makes a change like that, we see how that change affects the drug product with our software.

CEOCFO: ***Would you tell us a little bit more about the other side of what you are doing as far as the aseptic manufacturing environments?***

Mr. Brandon: The other side of our business is really driven by the FDA and the environment in which drugs are required to be manufactured. All drugs that are injected required to be manufactured in a sterile environment. We have a software package that we configure to monitor a variety of different instrumentations that are placed in the manufacturing environment to determine whether or not they are meeting the sterile requirements of the FDA.

These systems are all validated by our organization as a service. We do the calibration of all the systems to keep them current and appropriate for the FDA. What really drives this is inspection by the FDA at these manufacturing sites. Therefore, when the FDA comes in, the producer has to have the appropriate data to demonstrate that they are meeting sterility requirements.

CEOCFO: ***What is the competitive landscape in this area?***
Mr. Brandon: That is the reason why we moved into the AI side of it. It is a market that is not enormous. There are limited numbers of manufacturers. Therefore, what we are really trying to do with the ParticleSentry^{AI} is differentiate our company with the ability to do both the environmental management and the product quality management. There are a number of competitors out there and, like every market space; we have our 800-pound gorilla who pretty much dominates the market.

We have grown because we modelled our business differently. It is a very low overhead business; we are able to come in and be competitive and still be profitable. That is really where we are at with that regard in the competitive space. We are trying to reshape it, so that we are doing, not only environmental management, but also product quality management. It is all in one package, so to speak.

CEOCFO: ***Would the same people be buying both of your products?***
Mr. Brandon: Absolutely! That is really what we hoped to be able to do; to use both sides of our business to drive the other side, if we get an inquiry to one product, we introduce the potential for both.

CEOCFO: ***Are you seeking funding, investment or partnerships as you grow the business?***
Mr. Brandon: We absolutely are! Over the COVID period we were fortunate, more so than other businesses, because we were in a position to serve the people who were trying to stop it. During that time we were able to acquire all outstanding shares from our previous partners, the Europeans, so that was part of the initiative or the impetus that drove our name change, from PMT USA to SentrySciences.

At this point, we are putting together an advisory board for the new company and we are determining how to best move forward in the future and we are certainly seeking increased funding to accelerate our growth. Because we have been around awhile and we are profitable and have ongoing revenues, we are just not sure whether we want to go after structured debt or sell equity at this point.

CEOCFO: ***When you explain to people what you are doing, do they get it right away? Do they recognize the value or is there still some trepidation with AI in general?***
Mr. Brandon: I think the people that matter get it right away. I think that is because the industry has been creeping towards this target for 10 years. They really have struggled to get there, and I believe it is because their approach has been different than ours. If you can imagine, we have got all of these particles and drug products and the drug product itself is particulate in nature, and when you are looking to see changes in it, it is kind of like looking for a needle in a haystack. You can approach it with AI in 2 different ways. That is really what the core of our patent is.

To this point, people have always used supervised learning to try to define every possible needle and that is impossible. There is always another needle. Therefore, you are always going to have some shortcoming if you try it in that direction. What our patented technology says is, forget defining the needles. We are going to define the haystack, so that when a needle shows up, we know it is there. That is the difference between our technology and that is really the way we explain it. It really does sink in right away.

CEOCFO: ***Why should SentrySciences, LLC and what you can do standout?***
Mr. Brandon: It is because we have approached a problem that has existed in this industry and has been debated in conference after conference and has been a topic where people say, "We have got to do something different, but we do not know what it is." That is really what we have solved. We have solved the problem of old technology not meeting the needs of technology advances in the pharmaceutical industry and we are bringing that to market.