



ImmuCell

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THE EXECUTIVE INTERVIEW SERIES



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About ImmuCell, Inc.

ImmuCell Corporation is a growing animal health company that develops and markets scientifically-proven products that enhance the productive capabilities of newborn calves to the dairy and beef industries. The Company has developed and markets the First Defense product line that provides “immediate immunity” against aggressive pathogens, including e. coli and coronavirus, in newborn dairy and beef calves without the use of traditional antibiotics. This reduces the amount of antibiotics in the human food chain and it maximizes the productive capabilities of dairy and beef producers future operating assets – their newborn calves.

The Company is in the late stages of developing a novel product, Mast Out, that addresses mastitis in fully grown milking cows. Mastitis is the most significant cause of economic loss to the dairy industry totaling approximately \$2 BILLION annually. Mast Out treats infections in milk producing cows without the use of traditional antibiotics, and reduces the amount of antibiotics in the milk supply.

LYTHAM PARTNERS [LP] Michael, please give us a brief overview of ImmuCell Corporation.

MICHAEL BRIGHAM [MB] Sure. ImmuCell is an animal health company focused on the dairy and beef industries. Our commercialized products prevent infections, without using antibiotics, in newborn dairy and beef calves as they grow to maturity. We will soon (subject to FDA approval) offer dairy producers a mastitis treatment for their milk producing cows that is an alternative to traditional antibiotics. Our products help reduce the use of traditional antibiotics in production animals; which is a national priority. We all know about this public health problem. ImmuCell is on the leading-edge of providing viable solutions to maximize the productivity of dairy and beef producer’s assets while reducing the amount of antibiotics in the food chain. Our products provide protection from pathogens from “calves to cows.”

We're based in Portland, Maine. We have 45 employees and two primary products. One is commercialized – First Defense, for newborn dairy and beef calves; and the other, Mast Out, for milk producing cows, is in development subject to FDA approval. We have approximately \$10 million in annual sales. Over 90% of that comes from our primary commercial product – First Defense. We have reported positive net operating income for 11 consecutive quarters. We have about 4.85 million shares outstanding today.

[LP] Your commercialized product – First Defense – what does it do?

[MB] What First Defense does is prevent scours - which is uncontrolled diarrhea in a newborn calf; either dairy or beef. This is a very common problem as newborn calves have naïve immune systems and are exposed to lots of pathogens. So, First Defense protects that calf, getting her off to a good start.

[LP] What are the implications of a newborn calf getting scours?

[MB] There is a threefold impact. The first, most obvious impact is death; the loss of a future milk-producing asset. When our sales team is on a farm and the dairy or beef producer is experiencing death loss from scours, it's a relatively easy sale because the producer is seeing that significant problem very visibly. The second impact relates to the loss of future productivity from a calf that scours. We know a calf that scours, even if she does survive, will lag in terms of physical development, growth and milk production versus a calf that doesn't scour. When a calf gets infected, she's suffering and is weakened. She gains weight less quickly and she's more susceptible to other infections and will wean later and come into milk weaker. The producer's asset is diminished. Thirdly, if scours is not avoided, expensive treatments with antibiotics become necessary.

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[LP] So, how does First Defense protect against scours?

[MB] First Defense provides “Immediate Immunity;” which is how we position the product and how we market it. The calf is born with a naive immune system. This baby is looking for protection from its mother because it is not yet producing its own antibodies. So, the benefit of First Defense is to provide immunity from pathogens immediately after birth, in conjunction with the mother cow’s colostrum, which it receives as its first feeding. The data shows the best delivery is in the first 24 hours; it is most effective within the first 12 hours. So, First Defense delivers those antibodies when the calf needs them most; before its gut closes over; before its immune system starts to develop so that she can produce her own antibodies.

[LP] What is the economic benefit to dairy and beef producers for using First Defense in their newly born calves?

[MB] Well, as I said earlier, it’s to avoid death. The death of a calf – the loss of an asset - is very expensive, very visible, and it is very easy for the producer to measure that loss. But also, morbidity is very important too. We want calves to get off to a good start. We want calves to wean stronger and come into milk stronger. We want the producer to avoid the expense that has to be incurred - both the cost of drugs and the cost of labor - to deliver treatments to a calf that did not get a First Defense dose and ends up getting sick. So Immediate Immunity right after birth generates an economic benefit that the producer sees in the asset in which they are going to be investing in over the next two years before she comes into milk.

[LP] Why would a dairy or a beef producer decide not to use First Defense?

[MB] Well, I’m really not sure, because at about \$6.50 a dose, why wouldn’t you? Why wouldn’t you invest \$6.50 into an asset right when it is born so it grows up stronger and two years later is a better producing asset. It is a preventative, so I guess some producers may think their calves won’t get sick and essentially roll the dice; and they may be right. Not all calves will get sick, but the cost of treating sick calves is high enough that \$6.50 is not a bad insurance policy. It should be noted that it is just \$6.50 one time - one dose per calf, that’s it! It’s not something you need to administer over a number of days. It’s once right after birth, and that’s enough to get her through that critical period right after birth.

[LP] What’s the essential difference in the active ingredients of First Defense and Mast Out?

[MB] First Defense is comprised of milk antibodies that are produced by mother cows for their baby calves. We’re purifying those antibodies into a very convenient and concentrated delivery format in the First Defense product for dairy and beef calves. We can deliver a very high level of antibodies in a dried powder capsule format, as well as a few other product formats. The active ingredient in Mast Out is a peptide called Nisin. This is a bacteriocin with broad spectrum antibacterial activities. We grow the Nisin through a fermentation process. It is derived from *Lactococcus lactis*. This product will be used to treat subclinical mastitis in lactating dairy cows when we get FDA approval for Mast Out.

[LP] ImmuCell’s SEC filings indicate that you’re working to add a claim against infections caused by rotavirus to the First Defense product. What is the importance of that, and where does it stand in the approval process?

[MB] Presently we have claims against *E. coli* and coronavirus. Rotavirus is another leading scours pathogen. We want to be the first trivalent scours preventative out there for newborn calves. In terms of the approval process, the efficacy work is done and we have concurrence with the USDA. In other words, our animal trials are complete, and we’re working through the remaining manufacturing objectives with the USDA. We expect to be able to launch that product in the second half of 2017.

[LP] You’ve developed a highly effective sales team, led by Bobbi Jo Brockmann. She is a strong leader and an industry expert. Give us an idea of how she’s developed the sales strategy for the Company and the growth that you’ve experienced over the past five or six years with First Defense.

[MB] Bobbi is a dynamic leader. She is great to work with. She does know the industry very well, and she is well known as a newborn calf expert both to distribution and to producers at the farm level. About seven years ago, before we hired Bobbi, we had just one person representing our product coast to coast. We have since hired 5 regional sales managers and 1 inside sales and marketing employee, reporting to Bobbi. We now have a presence in California, Texas, Idaho, Wisconsin, Ohio, Minnesota and Illinois. This gives us representation in the major U.S. dairy pockets. This group of seven people is doing a great job. They are the right people in the right places.

[LP] During 2015 and part of 2016 you had a backlog of orders, which is very unusual for ImmuCell. What happened?

[MB] You never want to be in a position where you can't supply everything that customer wants. We got into that position in early 2015, when sales really exploded above our capacity to produce. First Defense is a very difficult product to produce. So, there was no quick fix. We had to invest in new equipment, and we completed an investment to increase our liquid processing capacity by 50% during the fourth quarter of 2015. We also completed a separate investment to double our freeze-drying capacity at the end of the first quarter of 2016. With the expanded manufacturing capacity enabling more production, the backlog was worked off. So, in short, those investments took us about a year from start to finish, and they are now fully online.

[LP] What is your market share with First Defense?

[MB] We have a growing share of a growing market. Based on market research that we have access to, we had approximately 26% of the market in 2013, which grew to 33% in 2014, and was 39% in calendar year 2015. Due to the backlog in 2016 our market share slipped a bit to 37%. But with that backlog behind us, we are very optimistic heading into 2017 and beyond.

[LP] Michael, give us a sense of the current state of dairy economics?

[MB] Our customers are very accustomed to the ups and downs of the dairy economic cycle. For instance in 2014, we saw a very strong milk price, but that price fell off substantially in 2015 and dropped another 6% in 2016. What's promising is that milk prices strengthened a bit at the end of 2016 and into early 2017. Scours impacts dairy and beef operations economically in good times and bad, but a better milk price makes it easier for a dairy producer to invest in a dose of First Defense to protect his or her assets.

[LP] The topic of antibiotics in the human food chain continues to be a hot-button issue. How do First Defense and Mast Out fit in that discussion?

[MB] When we first started selling First Defense back in 1991 and started developing Mast Out in the early 2000's, the overuse of antibiotics and the development of "superbugs" that are resistant to commonly used antibiotics was not a big issue. I feel that the stars are now aligned in favor of ImmuCell for continued sale of First Defense and the introduction of Mast Out because both of our products address this issue of the overuse of antibiotics. Simply, with First Defense, you are able to prevent a disease that is commonly treated with antibiotics. In other words, we offer disease prevention to avoid antibiotic treatments for scours. With Mast Out, it's not a traditional antibiotic, like penicillin or cephalosporins, and it's not used in human medicine. So both products play very well into this very hot topic - this very important public health concern regarding the overuse of antibiotics.

[LP] What is Mast Out, and what condition does it address?

[MB] Mast Out is a new and novel treatment for subclinical mastitis in lactating cows. Mastitis is the biggest cause of economic harm to the dairy industry. The total economic impact of this disease is more than \$2 billion annually to the U.S. dairy industry. It's essentially inflammation of the mammary gland that leads ultimately to non-saleable milk and a nasty infection that can kill the cow. With a treatment for subclinical mastitis you can prevent some of the progression to clinical mastitis. It would be the first intramammary infusion that could be used without the requirement to discard milk during, and for a period of time after, treatment which is required of all other products to avoid antibiotic residues in milk that is consumed by humans.

[LP] The active ingredient in Mast Out – Nisin – has been around for quite a while. It is my understanding that virtually all of us have some level of exposure to Nisin on a regular basis. Can you talk about that?

[MB] Very true. Nisin was discovered more than 50 years ago. It's been used as a food preservative for many years. Tons and tons of Nisin per year are used in processed dairy products as a food preservative. It is a very crude preparation, say 2 or 3 percent pure Nisin. The FDA would never approve such a crude preparation for use as a drug. What we've done is invested in the purification of the same Nisin to a pharmaceutical-grade level of purity. That is the Nisin that we intend to put into Mast Out.

“...when you treat a cow with, say a penicillin or a cephalosporin product, you have to discard the milk during treatment and for a period of time after treatment. That's because we don't want to see the antibiotic residue in the milk be consumed by humans. So, with Mast Out, we have achieved a zero milk discard through the human food safety technical section. We will be the first to market with a product that can be used while milk is still being sold, and that is the big competitive advantage for Mast Out.

[LP] What is the difference between subclinical and clinical mastitis?

[MB] That is a good question because it is very important to understanding the value proposition of Mast Out. Subclinical mastitis is a state of the disease where the cow is sick, she is producing lower quality milk, but that milk is still saleable. So, the producer will continue to milk that cow and sell the lower quality milk; and get a lower price for it. When the disease progresses to the clinical stage, the cow is so sick that she doesn't want to be touched, much less milked, and the milk has an almost custard-like consistency because it's so full of somatic cells that it is not saleable. Today most treatments are reserved for the clinical stage of the disease where the milk is discarded due to low quality of that milk. Producers know that a subclinically infected cow is sick, but they ignore the disease in order to sell the milk.

[LP] Mast Out is in the regulatory approval process right now. When do you expect Mast Out to be approved by the regulatory authorities?

[MB] Mast Out is subject to FDA approval – from the Center for Veterinary Medicine at the FDA. We expect to get approval in 2019. The regulatory process is set up with five technical sections - three of which are already complete, and we have technical section complete letters from the FDA. A fourth technical section is nearing completion, and we expect to have that in the first quarter of 2018. We expect the technical section complete letter for the fifth and final section – having to do with manufacturing of the product – in 2019, along with the final administrative new animal drug application approval.

[LP] What is the prevalence of clinical and subclinical mastitis?

[MB] It is estimated that approximately 2% of the herd population in the U.S. suffers from clinical mastitis, where most treatments are delivered today. As it relates to subclinical mastitis the estimate is in the range of 20% to 30%. A cow infected with subclinical mastitis is “stuck between a rock and a hard place” because the dairy farmer KNOWS she is sick but cannot JUSTIFY the cost of dumped milk required to treat her. So, it's potentially a large market opportunity in the coming years for our Mast Out product.

[LP] In terms of competing mastitis treatments that are currently in the market, what will differentiate Mast Out from those existing mastitis treatments?

[MB] I touched on this answer when you asked me about subclinical versus clinical. What goes on today is that all current mastitis treatments are sold subject to a milk discard requirement. That means when you treat a cow with, say a penicillin or a cephalosporin product, you have to discard the milk during treatment and for a period of time after treatment. That's because we don't want to see the antibiotic residue in the milk be consumed by humans. So, with Mast Out, we have achieved a zero milk discard through the human food safety technical section. We will be the first to market with a product that can be used while milk is still being sold, and that is the big competitive advantage for Mast Out. That is what changes the market and the treatment paradigm because it opens up the ability to treat these sick cows early.

[LP] With regards to the antibiotic issue, what is Nisin categorized as?

[MB] In the broadest sense, it could be considered an antibiotic, but it is not a traditional antibiotic used in human medicine. It's not in the same family as penicillin or a cephalosporin. Because it is different in that way, and because of its immense safety record, we have achieved the zero-milk discard claim. Once we get full FDA approval, Mast Out will be very different from traditional antibiotics that are commonly administered to dairy cattle.

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[LP] As it relates to the actual dairy farmer and the milk producing operations, how does Mast Out impact the financials of the dairy farmer?

[MB] We expect the impact to be very significant. Healthy cows are good for a dairy farmer's financials. Essentially what's going on today is that the industry is ignoring a disease. They know those cows are sick; they know they have subclinical infection; they know those cows are walking around the barn shedding disease organisms. But that sickness is ignored. It is not being treated because the industry knows that if they treat that cow, they won't be able to sell her milk. So what ImmuCell is doing is bringing a product to market that erases that conflict and allows that producer to not ignore the sick cow. By treating the subclinical stage infection in that cow early, the milk quality goes up and the quantity of milk produced goes up. An unhealthy cow is stressed and is using energy to fight disease and is producing less milk as a result. The dairy financials are positively impacted by improved herd health, generating increased productivity and more revenue to the producer.

[LP] Is there a benefit to the farmer utilizing Mast Out on a prophylactic basis? In other words, getting ahead of the curve and making sure that their asset - the cow - doesn't become impaired.

[MB] Our label claim is going to be for the treatment of subclinical mastitis in lactating cows, which is an identifiable disease state. Indirectly, what that will do is effectively prevent some clinical infections by treating the subclinical condition early. If treatment of a subclinical infection allows a cow to not progress to the clinical stage infection, well then, in a way, we have prevented a disease.

[LP] In 2016, you hired Betsy Williams as your vice president of manufacturing operations. Tell us a bit about her background. What are her responsibilities at ImmuCell?

[MB] Betsy is a great hire for us. She comes with big pharma experience from Zoetis and Pfizer Animal Health. She has already made a significant contribution to the growth of our First Defense production capacity. Her key role here at ImmuCell is to get a Nisin manufacturing plant constructed and to get Mast Out through the final stages of the FDA approval process. She has great experience in both of those areas, and we are delighted to have her as part of the team during this critically important period in the history of the Company. We have photos on our website – www.immuCell.com - where you can see the progress that is being made on the construction of the Mast Out manufacturing facility.

[LP] Your public filings indicate that you expect to invest somewhere in the area of \$20 million to build that facility to produce Nisin for the Mast Out product. That's a lot of money. Why not get a contract manufacturer or a partner to produce the Nisin?

[MB] Well that's a good question. We did have a contract manufacturing organization, or CMO, several years ago – around 2011 – and we determined it was not going to work. The economics just were not right. We were in a position where we were not going to utilize the CMO's very large facility on a full-time basis and that created an imbalance where we were in conflict with the CMO wanting to run the plant straight out, and ImmuCell just wanting to have access to it for a short period of the year. The bottom line to all that was our costs of goods were unacceptable. In 2014, we mutually agreed to part ways. In 2013, 2014 and into 2015, we engaged in a very extensive partner search. The bottom line on that is that a deal could have been done, but we didn't feel that the terms offered would have been fair to our stockholders. What we've done instead is raise debt and equity to finance this final stage for the in-house manufacture of Nisin, and by doing so we retain all the sales and all the gross margin for the ICCC stockholders.

[LP] In closing, there's a lot going on at ImmuCell right now. This is an important period in the history of the Company. In terms of your vision as the chief executive officer of the Company, what will ICCC look like next three to four years as you continue to execute on your strategic plan?

[MB] We need to continue the good work that our sales team has been doing by introducing First Defense to new customers going forward. It is imperative that our product acceptance continues to spread throughout the dairy and beef and industries. First Defense sales have doubled since 2010, and we have every expectation that the sales team can continue their stellar performance. If Mast Out sales commence in 2019, we believe that product alone could double our sales again. Looking ahead, we are excited with our prospects for the coming years.

[LP] Michael, I want to thank you for taking time today and giving us an overview of ImmuCell. We'll look forward to staying in touch and seeing how your financial and operational performance continues to evolve. Thank you again.

If any of you reading this review are interested in learning more about the company, or if you would like to arrange a call with Michael Brigham, please don't hesitate to call Joe Diaz at Lytham Partners at 602-889-9660.

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