IMMUCELL CORP /DE/
Form 10-K
March 26, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2014

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

001-12934

(Commission file number)

ImmuCell Corporation

(Exact name of Registrant as specified in its charter)

Delaware	**01-0382980**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

56 Evergreen Drive, Portland, Maine 04103
(Address of principal executive offices) (Zip Code)

Registrant's telephone number: (207) 878-2770

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.10 per share

(Title of class)

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes £ No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No £

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes No £

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. Large accelerated filer £ Accelerated filer £ Non-accelerated filer £ Smaller reporting company

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes £ No

The aggregate market value of the voting and non-voting common equity held by non-affiliates at June 30, 2014 was approximately $9,582,000 based on the closing sales price on June 30, 2014 of $4.40 per share.

The number of shares of the Registrant’s common stock outstanding at March 18, 2015 was 3,028,034.

Documents incorporated by reference: Portions of the Registrant’s definitive Proxy Statement to be filed in connection with the 2015 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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PART I

ITEM 1 – DESCRIPTION OF BUSINESS

Summary

ImmuCell Corporation was founded in 1982 and completed an initial public offering of common stock in 1987. After achieving approval from the U.S. Department of Agriculture (USDA) to sell **First Defense®** in 1991, we focused most of our efforts during the 1990's developing human product applications of the underlying milk protein purification technology. Beginning in 1999, we re-focused our business strategy on **First Defense®** and other products for the dairy and beef industries. Our purpose is to create scientifically-proven and practical products that result in a measurable economic impact on animal health and productivity in the dairy and beef industries. We are investigating new products utilizing the technology underlying **First Defense®** (milk antibodies) and **Mast Out®** (Nisin). We have experienced consistent growth in product sales over the past four years. These animal health product opportunities are generally less expensive to develop than the human health product opportunities that we had worked on during the 1990's. As a result, we recorded nine consecutive years of profitability during the years ended December 31, 1999 to December 31, 2007. Our strategic decision to continue developing **Mast Out®** after the product rights were returned to us in 2007 caused us to increase our spending on product development expenses that had been funded by a partner from late 2004 to mid-2007. The resulting significant and controlled investment in the development of **Mast Out®** resulted in net losses for each year during the four-year period that began on January 1, 2008 and ended on December 31, 2011. Resulting principally from increased gross margin from sales of **First Defense®** and reduced product development spending on **Mast Out®**, we returned to profitability during the years ended December 31, 2012 and 2013. As anticipated, we incurred a net loss during the six-month period ended June 30, 2014 and the twelve-month period ended December 31, 2014 due to a non-recurring, infrequent and unusual investment pertaining to **Mast Out®**. As planned, we did return to profitability during the six-month period ended December 31, 2014.

During 2000, we began the development of **Mast Out®**, our Nisin-based treatment for subclinical mastitis in lactating dairy cows. No sales of this product can be made without prior approval of our New Animal Drug Application (NADA) by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA). Nisin is an antibacterial peptide that has been demonstrated in clinical studies to be an effective aid in the reduction of mastitis-causing organisms in dairy cows. Mastitis is a very common infection in dairy cows that results in inflammation of the mammary gland. Because dairy producers are required to discard milk for a period during and after treatment with all currently marketed mastitis treatment products due to concerns about antibiotic residue in milk, it is generally current practice to only treat mastitis when the disease has progressed to the clinical stage where the milk from an infected cow cannot be sold. We believe that **Mast Out®** could revolutionize the way that mastitis is treated by making earlier treatment of subclinically infected cows economically feasible by not requiring a milk discard during, or for a period

of time after, treatment. No other FDA-approved mastitis treatment product on the market can offer this value proposition. **Mast Out®** could also be used as a tool to improve milk quality, allowing producers to increase milk revenue by earning higher milk quality premiums. Regulatory achievements to-date have significantly reduced the product development risks for **Mast Out®** in the areas of safety and effectiveness. Our primary focus, with respect to **Mast Out®**, has now turned to the manufacturing objectives required for FDA approval.

As we make process improvements, we are investing in personnel, equipment and facility modifications to increase the efficiency and quality of our operations. In 2006, we initiated our ongoing efforts to maintain compliance with current Good Manufacturing Practice (cGMP) regulations in all of our manufacturing operations, which requires a sustained investment that further enhances the quality of all of our products. Compliance is required for **Wipe Out® Dairy Wipes** and for **Mast Out®** and may open access to international markets for **First Defense®** where such standards are imposed. We have elected to enforce these quality standards across all of our product lines. During the first quarter of 2013, the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA) conducted a routine inspection of our facilities and operations. The report from this inspection was very favorable, and we responded to the few, minor observations that were noted.

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During the sixteen-year period that began January 1, 1999 (the year we first re-focused our business strategy on **First Defense®** and other products for the dairy and beef industries) and ended on December 31, 2014, we invested the aggregate of approximately $20,749,000 in product development expenses, averaging approximately $1,297,000 per year during this period. During these sixteen years, we have funded our operations and improved our net financial position, as demonstrated in the following table (in thousands, except for percentages):

	As of December 31, 1998		Net $ increase over sixteen-year period		As of December 31, 2014	Net % increase over sixteen-year period	
Cash, cash equivalents, short-term investments and long-term investments	$ 1,539	+	$ 2,296	=	$ 3,835	149	%
Net working capital	$ 1,866	+	$ 2,594	=	$ 4,460	139	%
Total assets	$ 3,145	+	$ 7,907	=	$ 11,052	251	%
Stockholders' equity	$ 2,248	+	$ 7,010	=	$ 9,258	312	%

We had approximately 2,429,000 shares of common stock outstanding as of December 31, 1998 in comparison to 3,027,000 shares as of December 31, 2014. There were 479,633 and 253,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 1998 and 2014, respectively.

Animal Health Products

Our lead product, **First Defense®**, is manufactured from hyperimmune cows' colostrum (the milk that a cow produces immediately after giving birth) utilizing our proprietary vaccine and milk protein purification technologies. The target disease, bovine enteritis (calf scours), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. **First Defense®** is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against *E. coli* K99 and coronavirus (two leading causes of scours). **First Defense®** provides bovine antibodies that newborn calves need but are unable to produce on their own immediately after birth. Our milk antibody products provide **Immediate Immunity™** during the first few critical days of life when calves need this protection most. Studies have shown that calves that scour are more susceptible to other diseases later in life and under-perform calves that do not contract scours. The direct, two-part mode-of-action of **First Defense®** delivers specific immunoglobulins at the gut level to immediately protect against disease, while also providing additional antibodies that are absorbed into the bloodstream. These circulating antibodies function like a natural timed-release mechanism, as they are re-secreted into the gut later to provide extended protection. A single dose of **First Defense®** provides a guaranteed level of protection proven to reduce mortality and morbidity from two major causes of calf scours. **First Defense®** is convenient to use. A calf needs to receive only one bolus of **First Defense®** within the first

twelve hours after birth (the earlier the better). The product is stored at room temperature and no mixing is required before it is given to the calf. There is no required slaughter withdrawal period for calves that are given **First Defense®**. We are a leader in the scours prevention market with this product. The third quarter of 2014 marked the 23rd anniversary of the original USDA approval of this product in 1991. During the first quarter of 2015, we sold the 15,000,000th dose of **First Defense®**. We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product. In 2011, we began selling nutritional and feed supplement product applications (that are not delivered in the capsule format) of our **First Defense Technology™**, which is a unique whey protein concentrate that is purified utilizing our proprietary milk protein processing methods that does not carry the claims of our USDA-licensed product. We utilize one production line and one quality system for all of our milk-based products.

During 1999, we acquired **Wipe Out® Dairy Wipes**, which is our second leading source of product sales. That transaction included the purchase of certain equipment, trademarks and a license of intellectual property, including several issued patents, covering the product and rights to develop skin and environmental sanitizing applications of the Nisin technology. **Wipe Out® Dairy Wipes** consist of towelettes that are pre-moistened with a Nisin-based formulation to prepare the teat area of a cow in advance of milking. Milking regulations require that the teat area of cows be cleaned, sanitized and dried before each milking. Producers use a variety of methods including dips and paper or cloth towels. Our wipes are made from a non-woven fabric that is strong enough to allow for a vigorous cleaning. The wiping process can also help promote milk letdown. **Wipe Out® Dairy Wipes** are manufactured in compliance with cGMP regulations, as required by federal law.

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As a product line extension, we have been developing a pet application of the Nisin technology underlying **Wipe Out® Dairy Wipes**, since many skin infections in pets are caused by Nisin-susceptible bacteria. During 2006, we completed a collaborative study of Nisin susceptibility in methicillin-resistant staphylococcal isolates from dogs with skin infections (dermatitis) with investigators at the University of Pennsylvania School of Veterinary Medicine. One hundred isolates of methicillin-resistant canine *Staphylococcus aureus* (MRSA), *intermedius* and *schleiferi* were tested and found to be highly susceptible to Nisin's antibacterial activity. During 2008, we completed a clinical feasibility study in collaboration with the University of Tennessee to evaluate the effectiveness of Nisin impregnated wipes used to treat skin infections in dogs. During the first quarter of 2013, we initiated sales of Nisin-based wipes for pets in a 120-count canister (Preva™ wipes) to Bayer HealthCare Animal Health of St. Joseph, Missouri for commercial sales to pet owners.

During 2001, we began to offer our own, internally developed **California Mastitis Test (CMT)**. **CMT** can be used for bulk tank as well as individual cow sample monitoring and can be used to determine which quarter of the udder is mastitic. This test can be performed at cow-side for early detection of mastitis. **CMT** products are also made by other manufacturers and are readily available to the dairy producer. The wholesale price of our product is generally lower than the competitive products that were present in the market when we initiated commercial sales.

Sales and Markets

Our sales and marketing team currently consists of one vice president and five regional managers. Our inside sales and customer service representative performs the order entry and inside sales duties, and our facility manager processes all shipments. The manner in which we sell and distribute our products depends, in large measure, upon the nature of the particular product, its intended users and the country in which it is sold. The distribution channel selected is intended to address the particular characteristics of the marketplace for a given product. **First Defense®** is sold primarily through major animal health distributors who, in turn, sell directly to veterinary clinics, fleet stores and direct to farms. Sales are normally seasonal, with higher sales expected during the first quarter. Sales of this product into the beef industry are highly seasonal because most beef calves are born between January and April each year. Harsh winter weather and severe temperature fluctuations cause stress to calves, and calves under stress are more susceptible to scours. We sell **Wipe Out® Dairy Wipes**, and **CMT** to distributors, bovine veterinarians and directly to producers.

First Defense® is generally sold through large, financially strong distributors, which we believe has resulted in minimal bad debt with respect to this product. We provide for a 50% account credit for domestic distributors on expired **First Defense®** product, which has a two-year shelf life, resulting in an immaterial amount of returns. Promotional merchandise is given to certain customers at times because we believe it enhances brand recognition. Additionally, advertising, training meetings, incentive programs, direct mail initiatives and face-to-face solution selling are tactics we use to create brand loyalty.

International product sales represented approximately 15%, 16% and 20% of our total product sales for the years ended December 31, 2014, 2013 and 2012, respectively. The majority of these international sales were to Canada. We currently price our products in U.S. dollars. To the extent that the value of the dollar declines with respect to any other currency, our competitive position may be enhanced. Conversely, an increase in the value of the dollar in any country in which we sell products may have the effect of increasing the local price of our products, thereby leading to a potential reduction in demand. The value of the Canadian dollar has declined recently, but this has not correlated with a decrease in our sales into Canada. Generally, our international sales are generated through relationships with in-country distributors that have knowledge of the local regulatory and marketing requirements.

We continue our efforts to grow sales of **First Defense®** in North America, where there are approximately 38,200,000 dairy and beef cows in the United States and 4,859,000 dairy and beef cows in Canada. We believe that even greater market opportunities exist in other international territories. There are estimated to be approximately 61,300,000 dairy and beef cows in China, 35,500,000 in the European Union, 21,088,000 in Australia and New Zealand, 9,950,000 in Mexico, 1,430,000 in South Korea and 1,355,000 in Japan. However, industry practices, economic conditions and cause of disease may differ in these foreign markets from what we experience in North America. We introduced **First Defense®** into South Korea in 2005 and its equivalent into Japan in 2007 through collaborations with in-country distributors.

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With **Mast Out®**, we are working to expand our product line to include a treatment for subclinical mastitis for the mother cow. Mastitis (inflammation of the mammary gland) is the most costly and common disease affecting the dairy industry. It is estimated to cost the U.S. dairy industry approximately $2 billion per year. The disease diminishes the saleable quantity and overall value of milk, in addition to causing other herd health and productivity losses. These losses include the cost of treatment products, reduced milk production, discarded milk and increased cull cows. We estimate that the existing U.S. market for intramammary infusion antibiotics used to treat clinical mastitis infections in lactating cows is approximately $40,000,000 to $60,000,000 per year and that similar market opportunities also exist outside of the United States and for the treatment of dry (non-lactating) cows.

It is difficult to estimate the potential size of the subclinical mastitis market because this market is largely unserved at this point. We have estimated that first year sales of our product could be approximately $5,400,000 and that sales could grow to approximately $31,700,000 by the tenth year after market launch. Actual sales results could be higher or lower. Key assumptions underlying these estimates include there being 7,868,000 cows in lactation in the United States and the treatment of 1.15 quarters per cow on average with three doses per treatment at approximately $8.99 per dose. We believe that approximately 20-30% of the U.S. dairy herd is affected by subclinical mastitis caused by gram positive organisms falling within the **Mast Out®** claim spectrum. We assumed that 2.2% of all cows in lactation would be treated during the first year after market launch and that 13% would be treated during the tenth year after market launch. Achieving this level of sales would require a commercial-scale production plant that we do not have today.

While the benefit of treating clinical mastitis is widely known, subclinical mastitis (those cases where cows have infected udders, but still produce saleable milk) is associated with its own significant economic losses and is recognized as a substantial contributor to clinical mastitis cases. Some industry experts have estimated that subclinical mastitis costs the U.S. dairy industry approximately $1 billion per year. There is a growing awareness of the cascade of adverse events and conditions associated with subclinical mastitis, including reduced or foregone milk quality premiums, lower milk production, shorter shelf life for fluid milk, lower yields and less flavor for cheese, higher rates of clinical mastitis, lower conception rates, increased abortions and increased cull rates. It is difficult to evaluate the potential size of the as-yet undeveloped subclinical mastitis treatment market because intervention strategies for subclinical disease are considered inadequate and generally not cost-effective. Because the milk from cows treated with traditional antibiotics must be discarded, most dairy producers simply do not treat subclinically infected cows or they cull the affected animals from the herd. Common milk discard periods cover the duration of treatment and extend from 36 to 96 hours after last treatment, depending on the antibiotic. On average, a cow produces approximately 60 to 80 pounds of milk per day. While milk prices vary significantly, at an average value of $18.00 per 100 pounds, a cow produces approximately $10.80 to $14.40 worth of milk per day. These estimated figures would result in milk discard costs ranging from approximately $38 to $158 per treated animal, which is a significant barrier to the routine treatment of subclinical mastitis with traditional antibiotics. We believe **Mast Out®** (an alternative to traditional antibiotics) will not be subject to this milk discard requirement in the United States. The ability to treat such cases without a milk discard could revolutionize the way mastitis is managed in a herd. **Mast Out®** could be uniquely positioned in the market as a treatment for subclinical mastitis that prevents some subsequent cases of clinical mastitis. It is common practice to move sick cows from their regular herd group to a sick cow group for treatment and

the related milk discard. This movement causes stress on the cow and a reduction in milk production. Cows treated with **Mast Out®** would not have to be moved allowing this costly drop in production to be avoided. **Mast Out®** likely will be priced at a premium to the traditional antibiotic products currently on the market, which are all sold subject to a milk discard requirement. However, we believe that the product's value proposition demonstrates a return on investment to the producer that will justify this premium.

Many fear that the possible overuse of antibiotics in livestock may be a contributing factor to the rising problem of bacterial drug resistance, which undermines the effectiveness of drugs to combat human illnesses. The FDA is committed to addressing this public health risk. Citing concerns about untreatable, life-threatening infections in humans, new FDA and European regulations are aimed at restricting the use of cephalosporins in food animals and at improving milk quality. In late 2011, The Dutch Veterinary Society proposed strict guidelines for veterinary use of antibiotics in the EU. Regulators have recently increased their monitoring of antibiotic residues in milk and meat. During the first quarter of 2012, the USDA reduced the allowable level of somatic cell counts (SCC) in milk from 750,000 (cells per milliliter) to 400,000 at the individual farm level (not a blended calculation of comingled milk) in order to qualify for an EU health certification for export. This current environment could be favorable to the introduction of a new product such as **Mast Out®** as an alternative to traditional antibiotics. We continue to believe that this innovative product opportunity justifies ongoing product development efforts.

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Competition

Our competition in the animal health market includes other biotechnology companies and major animal health companies. Many of these competitors have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do. We would consider any company that sells an antibiotic to treat mastitis, such as Zoetis (formerly Pfizer Animal Health, a division of Pfizer, Inc.), Merck Animal Health and Boehringer Ingelheim, to be among the potential competitors for **Mast Out®**. We expect the FDA to grant a period of five years of market exclusivity for **Mast Out®** (meaning the FDA would not grant approval to a second NADA with the same active drug for a period of five years after the first NADA approval is granted) under Section 512(c)(2)F of the Federal Food, Drug, and Cosmetic Act.

Zoetis, Elanco Animal Health (a division of Eli Lilly and Company) and Boehringer Ingelheim sell products that compete directly with **First Defense®** in preventing newborn calf scours. We believe that **First Defense®** offers two significant competitive advantages over these other USDA-approved scours preventatives. First, **First Defense®** is the only product that provides protection against both *E. coli* and coronavirus, the two leading causes of calf scours. Second, **First Defense®**, being derived from colostrum, offers **Immediate Immunity™** through antibodies that function both at the gut level and are absorbed into the blood stream for future protection. To complement this, **First Defense®** is easier to use, requires no mixing or refrigeration, and can be administered without delaying maternal colostrum. We believe that the immediate and preformed immunity (**Immediate Immunity™**) that **First Defense®** provides to the calf is a competitive advantage over such vaccine products.

First Defense® competes against scours vaccines that are given to the dam (mother cow) to increase her production of antibodies that can then be transferred through her colostrum to the calf and against vaccines and other products that are given to newborn calves. Despite the best-managed dam vaccine program, colostrum quality is naturally variable and newborn calves do not always get the antibodies they need from maternal colostrum. Further, we know that newborn calves respond poorly, if at all, to vaccines and that the immune system must be given time to develop a response to vaccines. Zoetis sells a modified-live virus, vaccine product (Calf-Guard®) for use in the prevention of scours. Like **First Defense®**, Calf-Guard® carries a claim against coronavirus infections, but this product does not carry a claim against *E. coli* infections like **First Defense®** does. Calf-Guard® carries a claim against rotavirus that **First Defense®** does not currently carry. **First Defense®** is priced at a premium to Calf-Guard®. It is common practice to delay colostrum feeding when dosing a calf with Calf-Guard® to wait for a vaccine response to be mounted, but we encourage the feeding of four quarts of high quality colostrum immediately after birth when dosing a calf with **First Defense®**, which is standard practice for good calf health. Because the antibodies in **First Defense®** would likely work to inactivate a modified-live vaccine, rendering it useless or less useful, our product label historically included a precaution that **First Defense®** should not be used within five days of such a vaccine. During the first quarter of 2015, the USDA granted us permission to remove this precaution from our label because our product is compatible with the feeding of antibodies from colostrum. We believe that this precaution should be required on the Calf-Guard® label to prevent inactivation of that product by **First Defense®** or colostrum. We also compete for market share against an

Elanco product (Bovine Ecolizer® + C20). This product, which was acquired through Elanco's January 2015 acquisition of Novartis Animal Health, carries claims to prevent scours in newborn calves caused by *E. Coli* and *Clostridium perfringens*. We also compete for market share against a Boehringer Ingelheim product (Bar-Guard-99™). This product carries claims to prevent scours in newborn calves caused by *E. coli*. These latter two products are both derived from equine serum in contrast to the bovine colostrum used for **First Defense®**. Equine antibodies are less efficiently absorbed into the bloodstream, so fewer antibodies are re-secreted for additional protection. There are several other products on the market, some with claims and some without, that are delivered to newborn calves to prevent scours.

There are many products on the market that may be used in place of **Wipe Out® Dairy Wipes**, and our product sells at a premium to most of them. These products include teat dips, teat sprays and other disposable and washable towel products offered by several different companies. Competitive advantages of **Wipe Out® Dairy Wipes** include that they are convenient to use, they do not irritate the udder and they do not adulterate the milk. Our product is differentiated from most others as the **One Step Cow Prep®** because a second drying process is not required when using our product.

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We may not be aware of competition that we face, or may face in the future, from other companies. Our competitive position will be highly influenced by our ability to attract and retain key scientific and managerial personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products, to effectively promote and market our products, to have available properly licensed, efficient and effective raw material and finished product manufacturing resources and to continue to profitably sell our current products. We currently compete on the basis of product performance, price and distribution capability. We continue to monitor our network of independent distributors to maintain our competitive position.

Product Development

Our lead product development initiative is **Mast Out®**, a Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows. During 2000, we acquired an exclusive license from Nutrition 21, Inc. (formerly Applied Microbiology Inc. or AMBI) to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Mast Out®**. In 2004, we paid Nutrition 21 approximately $965,000 to buy out this royalty and milestone-based license to Nisin, thereby acquiring control of the animal health applications of Nisin. Nisin, the same active ingredient contained in **Wipe Out® Dairy Wipes**, is an antibacterial peptide known to be effective against most gram positive and some gram negative bacteria. In our pivotal effectiveness study, statistically significant **Mast Out®** cure rates were associated with a statistically significant reduction in milk somatic cell count, which is an important measure of milk quality. Nisin is a well characterized substance, having been used in food preservation applications for over 50 years. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes methods to achieve pharmaceutical-grade purity.

During the fifteen-year period that began on January 1, 2000 (the year we began the development of **Mast Out®**) and ended on December 31, 2014, we invested the aggregate of approximately $11,032,000 in the development of **Mast Out®**. This estimated allocation to **Mast Out®** reflects only direct expenditures and includes no allocation of product development or administrative overhead expenses. Approximately $2,891,000 of this investment was offset by product licensing revenues and grant income related to **Mast Out®**.

In 2004, we entered into a product development and marketing agreement with Pfizer Animal Health (now doing business as Zoetis since 2013) covering **Mast Out®**. Under that agreement (as amended and supplemented and later terminated), we received $2,375,000 in payments. Zoetis elected to terminate the agreement in 2007. Soon thereafter, Zoetis returned to us all rights, data, information, files, regulatory filings, materials and stocks of Nisin and Nisin producing cultures relating to the development of **Mast Out®**. We believe that the decision of Zoetis to terminate the agreement was not based on any unanticipated efficacy or regulatory issues. Rather, we believe the decision was primarily driven by a marketing concern relating to their fear that the milk from treated cows could interfere with the manufacture of certain cultured dairy products.

Milk from cows treated with any of the intramammary mastitis treatment products on the market today must be discarded for a specified period of time during and after treatment. We believe that all milk from cows treated with **Mast Out®** will be saleable in the United States. This is a significant competitive advantage for our product. Due to this zero milk discard feature, there is a risk that Nisin from milk of cows treated with **Mast Out®** could interfere with the manufacture of certain (but not all) commercial cultured dairy products, such as some kinds of cheese and yogurt, if a process tank contains milk from a high enough percentage of treated cows. The impact of this potential interference ranges from a delay in the manufacturing process, which does happen at times for other reasons, to the less likely stopping of a cheese starter culture. Milk from cows that have been treated with **Mast Out®** that is sold exclusively for fluid milk products presents no such risk. We worked with scientists and mastitis experts to conduct a formal risk assessment to quantify the impact that milk from treated cows may have on cultured dairy products. This study concluded that the dilution of milk from treated cows through comingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when **Mast Out®** is used in accordance with the product label. Monitoring of several important variables relevant to the manufacture of cheese would be advisable if **Mast Out®** were to be used as part of a whole herd (“blitz”) treatment protocol. We do not see this as a significant problem as modern “precision dairying” practices support reducing the indiscriminate use of drug treatments.

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The commercial introduction of **Mast Out®** in the United States is subject to approval of our New Animal Drug Application (NADA) by the U.S. Food and Drug Administration's Center for Veterinary Medicine (FDA), which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets outside of the United States, which would involve some similar and some different requirements. The NADA is comprised of five principal Technical Sections that are subject to the FDA's phased review. By statute, each Technical Section submission is generally subject to a six-month review cycle by the FDA. Each Technical Section can be reviewed and approved separately. Upon review and assessment by the FDA that all requirements for a Technical Section have been met, the FDA may issue a Technical Section Complete Letter. The current status of our work on these Technical Sections is as follows:

1) Environmental Impact: During the third quarter of 2008, we received the Environmental Impact Technical Section Complete Letter from the FDA.

2) Target Animal Safety: During the second quarter of 2012, we received the Target Animal Safety Technical Section Complete Letter from the FDA.

3) Effectiveness: During the third quarter of 2012, we received the Effectiveness Technical Section Complete Letter from the FDA. The draft product label carries claims for the treatment of subclinical mastitis in lactating cows associated with *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, and coagulase-negative staphylococci in lactating dairy cattle.

4) Human Food Safety (HFS): The HFS Technical Section submission was made during the fourth quarter of 2010. This Technical Section includes several subsections such as: a) toxicology, b) total metabolism, c) effects of drug residues in food on human intestinal microbiology, d) effects on bacteria of human health concern (antimicrobial resistance) and e) pivotal residue chemistry. During the second quarter of 2011, we announced that the FDA had accepted the subsections described above and granted **Mast Out®** a zero milk discard period and a zero meat withhold period during and after treatment. Before we can obtain this Technical Section Complete Letter, we must adapt our analytical method that measures Nisin residues in milk around the assigned tolerance limit and transfer that method to a FDA laboratory. We first submitted the validated analytical method to the FDA during the fourth quarter of 2012. We have submitted additional data, which we believe to be responsive to the FDA's review comments, during the third quarter of 2013 and the first quarter of 2014. We are working to complete the method transfer to the FDA laboratory. Due to additional regulatory requirements, completion of the HFS Technical Section is currently anticipated by the end of 2015.

5) Chemistry, Manufacturing and Controls (CMC): Obtaining FDA approval of the CMC Technical Section defines the critical path to approval of our NADA by the FDA and to initial commercial sales. We are party to agreements with two manufacturers to produce inventory for us utilizing our proprietary technologies and processes. First, a long-term, exclusive supply agreement with Plas-Pak Inc. of Norwich, Connecticut covers the proprietary syringe that was developed specifically for treating cows with **Mast Out®**. These syringes were used for all pivotal studies of **Mast Out®**. Second, an exclusive Contract Manufacture Agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved Drug Product manufacturer, covers the formulation of the pharmaceutical-grade Nisin into Drug Product, the sterile-fill of syringes and the final packaging. Norbrook provided these services for clinical material used in all pivotal studies of **Mast Out®**. Recent communications with Norbrook have given us significant concern about Norbrook's readiness to provide the services needed to address the FDA regulatory requirements followed by commercial-scale production services. We intend to continue to seek to work with Norbrook to arrive at a resolution satisfactory to us. However, there can be no assurance that we will be able to reach a workable arrangement with Norbrook on a timely basis or at all. As a result, we have begun to explore alternative ways of fulfilling these needs (while expressly reserving our legal rights under our contract with Norbrook). Because we have not yet identified another third party ready, willing and able to do so, we may need to conduct further modifications to our own facilities in order perform the sterile-fill of syringes. Due to the preliminary status of this contingency planning, we are unsure as to the cost of such alternatives or the impact of an alternative approach on our desired and previously projected timing for completing the CMC Technical Section and commercialization of **Mast Out®**. During the fourth quarter of 2012, we withdrew our first submission to the FDA of the CMC Technical Section because of changes we have made to our regulatory filing and manufacturing strategies. Our goal is to make the first submission of the CMC Technical Section to the FDA during the fourth quarter of 2015. Given our concerns with Norbrook as our Drug Product manufacturer, we may elect to submit the Drug Substance (Active Pharmaceutical Ingredient) portion of the CMC Technical Section first and follow with the Drug Product portion (formulation, sterile-fill and packaging) after the first FDA review of the Drug Substance submission. It is common for each CMC Technical Section submission to require two, six-month review periods by the FDA.

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The selection of and (if applicable) the financing for the Drug Substance (pharmaceutical-grade Nisin) commercial production facility is a critical decision. We have considered four options: 1) having this work done by a qualified contract manufacturer, 2) building a new facility, 3) leasing and modifying an existing facility or 4) transferring our technology to a partner's facility. Our initial plan was to have the Drug Substance produced for us under a Development and Manufacturing Agreement with Lonza Sales, Ltd. of Basel, Switzerland, in order to avoid the investment in a manufacturing facility. By the end of 2011, we determined that the cost of goods under this contract would not be commercially feasible and that the required minimum volumes were too large to permit efficient, continuous production. This contract was terminated during the fourth quarter of 2014 by mutual consent. During the latter part of 2012, we engaged an engineering firm to estimate the cost of controlling the production of the Drug Substance ourselves in a plant that we either built or leased. We do not have the estimated amount of approximately $13,000,000 to pay for this investment (without some combination of new debt, equity or partner funding), and there is a risk that the actual cost could be higher than we estimated. Alternatively, a somewhat smaller plant could cost a few million dollars less and still be able to meet market demand at launch and for a few years thereafter. We presented this product opportunity to a variety of large and small animal health companies. During the second quarter of 2013, we received a non-refundable $250,000 exclusive license option fee from a prospective partner that considered manufacturing the Drug Substance in a plant of its own. During the third quarter of 2013, this prospective partner decided not to execute a license for the development and marketing of **Mast Out®** because it had determined that, in its opinion, it could not cost effectively commercialize the product. While recognizing the commercial and near-term financial advantages which could have been realized via this partnering agreement, we believe that, among the currently available options, the greatest long-term value for our stockholders could be achieved by retaining full product ownership through an independent strategy at this stage. However, given the need to find funding for the commercial-scale Nisin plant described above, we are open to considering alternative partnering arrangements. We are encouraged by the feedback from prospective partners, following their due diligence, that our novel mastitis treatment can achieve FDA approval and have a significant, positive impact on the dairy industry. We continue to believe in the potential value of making this unique treatment option available to dairy producers in order to reduce their reliance on penicillin and cephalosporin-based products. We are continuing our pursuit of FDA approval by completing the HFS Technical Section and the CMC Technical Section on our own. We believe that the evolution of our thinking relating to these strategic alternatives demonstrates the flexibility and creativity required to solve this challenge and bring this ground-breaking product innovation to market.

At the beginning of the third quarter of 2014, we substantially completed an investment in facility modifications and processing equipment necessary to produce Drug Substance at small-scale. The four primary goals of this investment are to: 1) establish the equivalence of the Drug Substance produced in this plant to the Drug Substance that was used in our clinical studies, 2) produce the validation batches required to complete the CMC Technical Section, 3) optimize process yields and verify the related cost of production and 4) produce inventory for test marketing and limited initial sales in the United States after FDA approval. In short, we aim to secure regulatory approval of the product and demonstrate its commercial viability. In preparation for the submission of the CMC Technical Section to the FDA, we are validating this new equipment and production space while optimizing the production process. We believe that success with these efforts will enhance our position in any further financing or partnering discussions, should we elect to pursue either of these paths to fund expanded manufacturing capacity for the commercialization of **Mast Out®**. This investment and the resulting short-term loss is the vehicle by which we expect to optimize the long-term value of this asset for our stockholders. We intend to take all appropriate steps to pursue a successful commercialization of

Mast Out®. This strategy allows us to advance the regulatory approval process while controlling our decision of whether and when to invest in large-scale production on our own, or with a partner.

After obtaining the final Technical Section Complete Letter and after preparing materials responsive to other administrative requirements, the administrative NADA submission will be assembled for review by the FDA. This final administrative submission is subject to a statutory sixty-day review period. Given this, we believe we could be in a position to achieve the NADA approval and test market the product around the end of 2016. The concerns discussed above related to the sterile-filling of the **Mast Out**® syringes could cause this timeline to be extended by at least one year. At some point, a further investment to increase our production capacity of Drug Substance would be required to meet anticipated market demand. Our options include doing the work on our own (with externally generated financing) or through an alliance with others, the out-licensing of the product or the sale of the product rights.

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In addition to our work on **Mast Out®**, we are actively exploring further improvements, extensions or additions to our current **First Defense®** product line. For example, we currently are developing treatments that could prevent calf scours caused by enteric pathogens in addition to *E. coli* K99 and bovine coronavirus (the current disease claims for **First Defense®**). In connection with that effort, during the second quarter of 2009 we entered into an exclusive license with the Baylor College of Medicine covering the underlying rotavirus vaccine technology used to generate the specific antibodies. This perpetual license (if not terminated for cause) is subject to milestone and royalty payments. Results from pilot studies completed during the first quarter of 2009 justified continued product development. We completed a pivotal effectiveness study of this experimental formulation during the third quarter of 2011 without seeing the anticipated level of effectiveness needed for regulatory approval and market acceptance. After optimizing the challenge model, we directed our efforts to conducting additional pilot studies of different formulations of this antibody preparation. Having achieved positive results from these pilot studies, we initiated a second pivotal effectiveness study at Cornell University College of Veterinary Medicine during the second quarter of 2014 and completed the enrollment of calves during the fourth quarter of 2014. During the first quarter of 2015, we announced positive results from this pivotal study. If approved by the USDA, this would be the first passive antibody product with disease claims against the three leading causes of calf scours, *E. coli*, coronavirus and rotavirus, providing **Immediate Immunity™** to newborn calves. Having submitted these results to the USDA for review, we are working to complete the other laboratory and manufacturing objectives required for product license approval. This could position us to achieve product licensure and market launch in 2016. As additional opportunities arise to commercialize our own technology, or licensable technology, we may begin new development projects. While we continue to pursue internally funded product development programs, we also remain interested in acquiring new products and technologies that fit with our sales and marketing focus on the dairy and beef industries.

Patents, Proprietary Information and Trademarks

In connection with the December 1999 acquisition of **Wipe Out® Dairy Wipes** and the April 2000 license to all veterinary applications of Nisin from Nutrition 21, Inc., we acquired a license to six patents. In November 2004, we bought out certain future milestone and royalty obligations under the 1999 and 2000 licenses, which principally resulted in a fully paid, perpetual license related to the animal health applications of Nisin. Five of these six patents have expired. In 2004, we were issued U.S. Patent No. 6,794,181 entitled “Method of Purifying Lantibiotics” covering a manufacturing process for Drug Substance (pharmaceutical-grade Nisin).

During 2000, we were issued U.S. Patent No. 6,074,689 entitled “Colonic Delivery of Protein or Peptide Compositions” covering the method of formulation that can be used to deliver proteins to the colon. In 1999, we acquired an exclusive license for pharmaceutical applications to U.S. Patent No. 5,773,000 entitled “Therapeutic Treatment of *Clostridium difficile* Associated Diseases” from GalaGen, Inc. In 2002, we acquired ownership of this patent from the court administering the bankruptcy proceedings of GalaGen. These patents are included in a royalty-bearing license we granted to Immuron, Ltd. (formerly known as Anadis) of Australia in 2008 for their use in the development of milk antibody products for humans.

In the future, we may file additional patent applications for certain products under development. There can be no assurance that patents will be issued with respect to any pending or future applications. In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. Instead, we have sought (and may seek in the future) to maintain the confidentiality of any relevant proprietary technology through operational measures and contractual agreements. Reliance upon trade secret, rather than patent, protection may cause us to be vulnerable to competitors who successfully replicate our manufacturing techniques and processes. Additionally, there can be no assurance that others may not independently develop similar trade secrets or technology or obtain access to our unpatented trade secrets or proprietary technology. Other companies may have filed patent applications and may have been issued patents involving products or technologies potentially useful to us or necessary for us to commercialize our products or achieve our business goals. There can be no assurance that we will be able to obtain licenses to such patents on terms that are acceptable.

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We have registered certain trademarks with the U.S. Patent and Trademark Office in connection with the sale of our products. We own federal trademark registrations of the following trademarks: ImmuCell; **First Defense®**, our calf scours preventive product; **Wipe Out® Dairy Wipes** and the related design and the trademark "**One Step Cow Prep®**", our pre-milking wipe product; and **Mast Out®**, our mastitis treatment product under development. During the first quarter of 2015, we applied to register the following marks: **Immediate Immunity™**, **First Defense Technology™** and **Your Calf Crew™**.

Government Regulation

We believe that we are in compliance with current regulatory requirements relating to our business and products. The manufacture and sale of animal health biologicals within the United States is generally regulated by the USDA. We have received USDA and Canadian Food Inspection Agency approval for **First Defense®**. **Mast Out®** is regulated by the FDA, Center for Veterinary Medicine, which regulates veterinary drugs. Regulations in the European Union will likely require that **Mast Out®** be sold subject to a milk discard requirement in that territory, although the duration of the milk discard requirement may be shorter than the discard requirement applicable to competitive antibiotic products in that market. The manufacture of **Wipe Out® Dairy Wipes** also is regulated by the FDA. Comparable agencies exist in foreign countries and foreign sales of our products will be subject to regulation by such agencies. Many countries have laws regulating the production, sale, distribution or use of biological products, and we may have to obtain approvals from regulatory authorities in countries in which we propose to sell our products. Depending upon the product and its applications, obtaining regulatory approvals may be a relatively brief and inexpensive procedure or it may involve extensive clinical tests, incurring significant expenses and an approval process of several years' duration. We generally rely on in-country experts to assist us with or to perform international regulatory applications.

Employees

We currently employ 34 full-time employees and 1 part-time employee. Approximately 17 full-time equivalent employees are engaged in manufacturing operations, 7.5 full-time equivalent employees in sales and marketing, 5.5 full-time equivalent employees in product development activities and 4.5 full-time equivalent employees in finance and administration. At times, manufacturing personnel are also utilized, as needed, in the production of clinical material for use in product development. All of our employees are required to execute non-disclosure, non-compete and invention assignment agreements intended to protect our rights in our proprietary products. We are not a party to any collective bargaining agreement and consider our employee relations to be excellent.

Executive Officers of the Company

Our executive officers as of March 18, 2015 were as follows:

MICHAEL F. BRIGHAM (Age: 54, Officer since 1991, Director since 1999) was appointed to serve as President and Chief Executive Officer in February 2000, while maintaining the titles of Treasurer and Secretary, and was appointed to serve as a Director of the Company in March 1999. He previously had been elected Vice President of the Company in December 1998 and had served as Chief Financial Officer since October 1991. He has served as Secretary since December 1995 and as Treasurer since October 1991. Prior to that, he served as Director of Finance and Administration since originally joining the Company in September 1989. Mr. Brigham has been a member of the Board of Directors of the United Way of York County since 2011, serving as its Treasurer. Mr. Brigham served as the Treasurer of the Board of Trustees of the Kennebunk Free Library from 2005 to 2011. He re-joined the Finance Committee of the library in 2012. Prior to joining the Company, he was employed as an audit manager for the public accounting firm of Ernst & Young. Mr. Brigham earned his Masters in Business Administration from New York University in 1989.

BOBBI JO BROCKMANN (Age: 38, Officer since February 2015) was promoted to Vice President of Sales and Marketing in February 2015. She joined the Company as Director of Sales and Marketing in January 2010. Prior to that, she had been employed as Director of Sales since May 2008 and Sales Manager from February 2004 to April 2008 at APC, Inc. of Ankeny, Iowa, a developer and marketer of functional protein products for animal health and nutrition. Prior to that, she held other sales and marketing positions at APC, W & G Marketing Company, Inc. of Ames, Iowa, The Council for Agricultural Science and Technology of Ames, Iowa and Meyocks Group Advertising of West Des Moines, Iowa after graduating from Iowa State University.

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JOSEPH H. CRABB, Ph.D. (Age: 60, Officer since 1996, Director since 2001) served as Chair of the Board of Directors from June 2009 to February 2013. He was appointed a Director of the Company in March 2001, having previously served in that capacity during the period from March 1999 until February 2000. Before that, he was elected Vice President of the Company in December 1998, while maintaining the title of Chief Scientific Officer. He has served as Chief Scientific Officer since September 1998. Prior to that, he served as Vice President of Research and Development since March 1996. Prior to that, he served as Director of Research and Development and Senior Scientist since originally joining the Company in November 1988. Concurrent with his employment, he has served on national study sections and advisory panels, served as a peer reviewer, and held several adjunct faculty positions. Prior to joining the Company in 1988, Dr. Crabb earned his Ph.D. in Biochemistry from Dartmouth Medical School and completed postdoctoral studies in microbial pathogenesis at Harvard Medical School, where he also served on the faculty.