IMMUCELL CORP /DE/
Form 10-K
March 25, 2016

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, 2015

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, 2015 was approximately $17,151,000 based on the closing sales price on June 30, 2015 of $7.85 per share.

The number of shares of the Registrant's common stock outstanding at March 17, 2016 was 4,178,844.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement to be filed in connection with the 2016 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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December 31, 2015

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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. During the first quarter of 2016, we sold 1.1 million shares of common stock in an underwritten public offering registered with the Securities and Exchange Commission (SEC), raising net proceeds of $5.3 million. Our purpose is to create scientifically-proven and practical products that improve animal health and productivity in the dairy and beef industries. We have developed products that provide significant, immediate immunity to newborn dairy and beef livestock and are also developing a product to address mastitis, the most significant cause of economic loss to the dairy industry. We have experienced consistent growth in product sales over the past five years. Our operations are generally profitable, except when we elect to make unusually large investments in product development expenses.

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. 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.

During 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 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. As we make process improvements, we are investing in personnel, equipment and facility modifications to increase the efficiency and quality of our operations.

We had approximately 2,429,000 shares of common stock outstanding as of December 31, 1998 in comparison to 3,055,000 shares as of December 31, 2015. There were approximately 480,000 and 238,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 1998 and 2015, respectively. During the seventeen years that we have been strategically focused on products for the dairy and beef industries, 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 seventeen-year period**		**As of December 31, 2015**	Net % increase over seventeen-year period	
Cash, cash equivalents, short-term investments and long-term investments	$ 1,539	+	$ 4,985	=	$ 6,524	324	%
Net working capital	$ 1,866	+	$ 5,190	=	$ 7,056	278	%
Total assets	$ 3,145	+	$ 11,456	=	$ 14,601	364	%
Stockholders’ equity	$ 2,248	+	$ 8,366	=	$ 10,614	372	%

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Animal Health Products

Our lead product, **First Defense**Ò, 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**Ò 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. We are a leader in the scours prevention market with this product. The third quarter of 2015 marked the 24th anniversary of the original USDA approval of this product in 1991. During the first quarter of 2016, we sold the 17,000,000th dose of **First Defense**Ò. 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**Ò **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 underlying Nisin technology. **Wipe Out**Ò **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**Ò **Dairy Wipes** are manufactured in compliance with cGMP regulations, as required by federal law.

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), *S. intermedius* and *S. 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.

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.

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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. **First Defense**Ò is sold primarily through major animal health distributors who, in turn, sell directly to veterinary clinics, fleet stores and direct to farms. We have experienced minimal bad debt with respect to this product. We provide for a 50% account credit for domestic distributors on expired **First Defense**Ò 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. 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**Ò **Dairy Wipes** and **CMT** to distributors, bovine veterinarians and directly to producers.

International product sales represented approximately 16%, 15% and 16% of our total product sales for the years ended December 31, 2015, 2014 and 2013, 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**Ò in North America, where there are approximately 39,800,000 dairy and beef cows in the United States and 4,750,000 dairy and beef cows in Canada. We believe that even greater market opportunities exist in other international territories. There are estimated to be approximately 66,400,000 dairy and beef cows in China, 35,550,000 in the European Union, 20,882,000 in Australia and New Zealand, 10,050,000 in Mexico, 1,405,000 in South Korea and 1,315,000 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**Ò into South Korea in 2005 and its equivalent into Japan in 2007 through collaborations with in-country distributors.

With **Mast Out**Ò, 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 in economic harm per year. The disease diminishes the saleable quantity and overall value of milk, in addition to causing other herd health and productivity losses. 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. 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 $15.00 per 100 pounds, a cow produces approximately $9 to $12 worth of milk per day. These estimated figures would result in milk discard costs ranging from approximately $32 (for 3.5 days of milk at 60 pounds per day) to $132 (for 11 days of milk at 80 pounds per day) per treated animal, which is a significant barrier to the routine treatment of subclinical mastitis with traditional antibiotics. We believe **Mast Out**Ò 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**Ò 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**Ò would not have to be moved, allowing this costly drop in production to be avoided. **Mast Out**Ò 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.

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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. This would not be a concern for **Mast Out**Ò because our active ingredient (Nisin) is not used for human health. 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. 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. The USDA's National Animal Health Monitoring System through its Dairy 2014 study suggests that 21% of all dairy cows are treated with a mastitis drug, of which approximately 51% are treated with third generation cephalosporins. Several major food processors and retailers have implemented policies addressing this growing public health concern that the overuse of antibiotics is contributing to a rising number of life-threatening human infections from antibiotic-resistant bacteria known as "superbugs". This current environment could be favorable to the introduction of a new product such as **Mast Out**Ò as an alternative to traditional antibiotics such as penicillin and cephalosporins. We believe that this changing environment of new regulations and public opinion supports the value of our ongoing product development efforts. Additionally, we believe that the use of **First Defense**Ò is consistent with this trend of reducing the use of antibiotics because the prevention of calf scours early in life with our purified milk antibodies can reduce the need for treatment antibiotics later in a calf's life.

It is difficult to estimate the potential size of the market for the treatment of subclinical mastitis because this disease is largely left untreated presently. 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**Ò claim spectrum. This compares to approximately 2% of the U.S. herd that is thought to be infected with clinical mastitis, where approximately $60,000,000 per year is spent on drug treatments. We have estimated that first year domestic sales of our product could be approximately $5,800,000 and that sales could grow to approximately $36,100,000 by the fifth year after market launch. Actual sales results could be higher or lower. Key assumptions underlying these estimates include there being 7,650,000 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 $9.99 per dose. We assumed that 2.2% of all cows in lactation would be treated during the first year after market launch and that 13.7% would be treated during the fifth year after market launch. The manufacturing facility that we are preparing to construct could have enough capacity to meet approximately 35% of the sales projected for the fifth year after product launch. We believe that similar market opportunities also exist outside of the United States and for the treatment of dry (non-lactating) cows.

Product Development

The majority of our product development spending is focused on the development of **Mast Out**®, our 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**Ò. 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 our topical wipe products, 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**Ò cure rates were associated with a statistically significant reduction in milk somatic cell count, which is an important measure of milk quality. Nisin is an antibacterial peptide known to be effective against most Gram-positive and some Gram-negative bacteria. 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.

It is generally current practice to treat mastitis only when the disease has progressed to the clinical stage where the milk from an infected cow cannot be sold. The use of all mastitis drugs currently on the market is permitted only if the milk from treated cows is discarded during treatment and for a period of time thereafter to allow the antibiotic residues to clear from milk that is to be consumed by humans. We have estimated that the cost of this discarded milk may be approximately $300 million per year. Because milk from cows with subclinical infections can be sold, this disease is largely left untreated to avoid the milk discard penalty. Subclinical mastitis is associated with reduced milk production (some have estimated approximately 1,500 pounds of lost milk, or about $240 at $16.00 per hundredweight, per infected cow), reduced milk premiums, reproduction inefficiencies and an increased incidence of clinical mastitis. We intend to introduce the first mastitis treatment that is not subject to milk discard or meat withhold requirements, which would be a significant competitive advantage for our product.

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In 2004, we entered into a product development and marketing agreement with Pfizer Animal Health (doing business as Zoetis since 2013) covering **Mast Out**Ò. Zoetis elected to terminate the agreement in 2007. We believe that this decision 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. Due to the zero milk discard feature, there is a risk that Nisin from the milk of cows treated with **Mast Out**Ò 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 a high enough percentage of milk from 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**Ò 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**Ò is used in accordance with the product label. We do not believe that a premium-priced product such as **Mast Out**Ò will be used as part of a whole herd ("blitz") treatment protocol, which reduces the risk of cheese interference. We do not see this as a significant problem as modern "precision dairying" practices support reducing the indiscriminate use of drug treatments.

Commercial introduction of **Mast Out**Ò in the United States is subject to approval of our NADA by the 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 and one administrative submission 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 submissions to the FDA 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 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**Ò 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 transfer our analytical method that measures Nisin residues in milk to a government laboratory. Due to unexpected regulatory demands and review delays, completion of the HFS Technical Section is currently anticipated during the middle of 2017.

5) Chemistry, Manufacturing and Controls (CMC): Obtaining FDA approval of the CMC Technical Section defines the critical path to FDA approval and to initial commercial sales. During the third quarter of 2014, we completed an investment in facility modifications and processing equipment necessary to produce the Drug Substance (the Active Pharmaceutical Ingredient, which is our pharmaceutical-grade Nisin) at small-scale. This small-scale facility has been used to i) test for and define the minor impurities in the Drug Substance, ii) establish the equivalence of the Drug Substance produced in this facility to the Drug Substance that was used in our pivotal batches for all clinical studies, iii) optimize process yields and iv) verify the cost of production. We believe these efforts will reduce risk as we invest in a commercial-scale production facility. We may make a first submission of the CMC Technical Section based on results from small-scale production batches to establish a path with the FDA, knowing that it will not be accepted as complete until we submit commercial-scale data.

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The construction of and the financing for the commercial-scale Drug Substance production facility is the most critical action in front of us on our path to regulatory approval. 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 required minimum volumes were too large to permit efficient, continuous production and that the cost of goods under this contract would not be commercially feasible. This contract was terminated during the fourth quarter of 2014 by mutual consent. We presented this product development 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 development and marketing license because it had determined that, in its opinion, it could not cost-effectively commercialize the product. While such a corporate partnership could have allowed us to avoid the large investment in a commercial-scale production facility, it would have taken a large share of the gross margin from product sales. We are encouraged by the regulatory and marketing 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 acquired land nearby to our existing Portland facility for this facility during the fourth quarter of 2015. During the first quarter of 2016, we raised equity financing and signed a bank debt commitment letter aggregating approximately $9.8 million. We are now preparing to construct our own facility for the commercial-scale production of the Drug Substance. We have estimated the cost to complete this project to be approximately $17,500,000. If we complete the construction and equipping of the Drug Substance facility during 2017, we could make the first commercial-scale CMC Technical Section submission to the FDA during late 2017 or 2018. It is common for the CMC Technical Section submission to require two, six-month review periods by the FDA.

We are party to a long-term, exclusive supply agreement with Plas-Pak Inc. of Norwich, Connecticut covering the proprietary syringe that was developed specifically for treating cows with **Mast Out**Ò. These syringes were used for all pivotal studies of **Mast Out**Ò. During the fourth quarter of 2015, this contract was extended through December 31, 2020.

Since 2010, we have been party to long-term, exclusive Contract Manufacture Agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved Drug Product (filled and packaged syringes) manufacturer, covering the formulating and sterile-filling of the Drug Substance into Drug Product for **Mast Out**Ò. Norbrook provided these services for clinical material used in all pivotal studies of **Mast Out**Ò. During the fourth quarter of 2015, we entered into a revised agreement with Norbrook covering the final development and commercial-scale (but not at small-scale) launch of **Mast Out**Ò after FDA approval. This means we would no longer seek FDA approval at small-scale, which would not have provided inventory for significant commercial sales.

6) Administrative Submission: 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. We will continue to provide detailed disclosures about the current status of this drug development process in our periodic filings with the SEC.

In addition to our work on **Mast Out**Ò, we are actively developing 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. If approved by the USDA, this would be the first passive antibody product on the market with disease claims against the three leading causes of calf scours, *E. coli*, coronavirus and rotavirus. Results from pilot studies completed during the first quarter of 2009 justified continued product development. We initiated a second pivotal effectiveness study at Cornell University College of Veterinary Medicine during the second quarter of 2014 and announced positive effectiveness results from this pivotal study during the first quarter of 2015. During the third quarter of 2015, we obtained concurrence from the USDA that we have been granted disease claims against bovine rotavirus. 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 2017. At the same time, we are working to expand our product development pipeline of bacteriocins that can be used as alternatives to traditional antibiotics. During the second quarter of 2015, we entered into an exclusive option agreement to license new bacteriocin technology from the University of Massachusetts Amherst. This technology focuses on bacteriocins having activity against Gram-negative infections for use in combating mastitis in dairy cattle. Subject to the availability of needed financial and other resources, we intend to begin new development projects that are aligned with our core competencies and market focus. We also remain interested in acquiring, on suitable terms, other new products and technologies that fit with our sales focus on the dairy and beef industries.

ImmuCell Corporation

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**Ò. We expect the FDA to grant a period of five years of market exclusivity for **Mast Out**Ò (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**Ò in preventing scours via oral delivery to newborn calves. Zoetis sells a modified-live virus, vaccine product (Calf-Guard®) for use in the prevention of scours in newborn calves, but we know that newborn calves respond poorly to vaccines and that the immune system must be given time to develop a response to vaccines. Like **First Defense**Ò, Calf-Guard® carries a claim against coronavirus infections, but this product does not carry a claim against *E. coli* infections like **First Defense**Ò does. Calf-Guard® carries a claim against rotavirus that **First Defense**Ò does not currently carry. **First Defense**Ò is priced at a premium to Calf-Guard®. It is common practice to delay colostrum feeding when dosing a calf with Calf-Guard® so that the antibodies in the colostrum do not inactivate the vaccine product. In contrast, we encourage the feeding of four quarts of high quality colostrum immediately after birth when dosing a calf with **First Defense**Ò, which is standard practice for good calf health. Because the antibodies in **First Defense**Ò 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**Ò 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**Ò or colostrum. The Elanco product (Bovine Ecolizer™ + C20) was acquired through Elanco's January 2015 acquisition of Novartis Animal Health and 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**Ò. 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. We believe that **First Defense**Ò offers two significant competitive advantages over these other USDA-approved scours preventatives. First, **First Defense**Ò is the only product that provides protection against both *E. coli* and coronavirus, the two leading causes of calf scours. Second, **First Defense**Ò, 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**Ò is easier to use, requires no mixing or refrigeration, and can be administered without delaying maternal colostrum.

First Defense® competes against scours vaccines sold by Zoetis and Merck 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. 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. We believe that the guaranteed dose of antibodies in **First Defense**Ò provides more consistent protection than such vaccine products.

There are many products on the market that may be used in place of **Wipe Out**Ò **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**Ò **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**Ò 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.

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.

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**Ò, 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**Ò. **Mast Out**Ò is regulated by the FDA, Center for Veterinary Medicine, which regulates veterinary drugs. Regulations in the European Union will likely require that **Mast Out**Ò 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**Ò **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.

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Employees

We currently employ 46 employees (including 5 part-time employees). Approximately 27 full-time equivalent employees are engaged in manufacturing operations, 7.5 full-time equivalent employees in sales and marketing, 4.5 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 17, 2016 were as follows:

MICHAEL F. BRIGHAM (Age: 55, 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: 39, 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.

JOSEPH H. CRABB, Ph.D. (Age: 61, 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.

Public Information

As a reporting company, we file quarterly and annual reports with the Securities and Exchange Commission (SEC) on Form 10-Q and Form 10-K. We also file current reports on Form 8-K, whenever events warrant or require such a filing. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information about us that we file electronically with the SEC at http://www.sec.gov. Our internet address is http://www.immucell.com.

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ITEM 1A – RISK FACTORS

Safe Harbor Statement

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: projections of future financial performance; the scope and timing of future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis; future market share of and revenue generated by products still in development; future sources of financial support for our product development, manufacturing and marketing efforts; the future adequacy of our own manufacturing facilities or those of third parties with which we have contractual relationships to meet demand for our products on a timely basis; the amount and timing of future investments in facility modifications and production equipment; the future adequacy of our working capital and the availability of third party financing; timing and future costs of a facility to produce the Drug Substance (active pharmaceutical ingredient) for **Mast Out®**; the timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; future realization of deferred tax assets; costs associated with sustaining compliance with cGMP regulations in our current operations and attaining such compliance for the facility to produce the Drug Substance for **Mast Out®**; factors that may affect the dairy and beef industries and future demand for our products; the cost-effectiveness of additional sales and marketing expenditures and resources; the accuracy of our understanding of our distributors’ ordering patterns; anticipated changes in our manufacturing capabilities and efficiencies; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as “expects”, “may”, “anticipates”, “aims”, “intends”, “would”, “could”, “should”, “will”, “plans”, “believes”, “estimates”, “targets”, “projects”, “forecasts” and similar words and ex addition, there can be no assurance that future developments affecting us will be those that we anticipate. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, alignment between our manufacturing resources and product demand, the uncertainties associated with product development and Drug Substance manufacturing, our potential reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making by regulatory authorities, possible dilutive impacts on existing stockholders from any equity financing transactions in which we may engage, currency fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized below and uncertainties otherwise referred to in this Annual Report.

Projection of net income: Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Weaker than expected sales of **First Defense®** or continued or extended shortfalls in production relative to the growing product sales demand could lead to less profits or an operating loss. Large investments in product development (or cost overruns) can result in a net loss. Given our strategic decision to invest approximately $973,000 during 2014 in facilities for the manufacture of the Drug Substance at small-scale, we recorded a net (loss) of ($167,000) during the year ended December 31, 2014 as expected, despite a return to profitability during the last six months of 2014. We continued to be profitable during 2015. Subject to the temporary production constraints described above, we expect the sales growth trend for **First Defense®** and the recent profitability trend to continue.

*Reliance on sales of **First Defense®**:* We are heavily reliant on the market acceptance of **First Defense®** to generate product sales and fund our operations (including part of our planned expansion to commercialize **Mast Out®**). Our business would not have been profitable during the nine consecutive years in the period ended December 31, 2007, or during the years ended December 31, 2012, 2013 and 2015, without the gross margin that we earned on sales of **First Defense®**, which accounted for almost 93% of our product sales during 2015.

Product risks generally: The sale of our products is subject to financial, efficacy, regulatory, competitive and other market risks. We cannot be sure that we will be able to maintain the regulatory compliance required to continue selling our products. There is no assurance that we will continue to achieve market acceptance at a profitable price level or that we can continue to manufacture our products at a low enough cost to result in a sufficient gross margin to justify their continued manufacture and sale.

Product liability: The manufacture and sale of our products entails a risk of product liability. Our exposure to product liability is mitigated to some extent by the fact that our products are principally directed towards the animal health market. We have maintained product liability insurance in an amount which we believe is reasonable in relation to our potential exposure in this area. We have no history of claims of this nature being made.

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Protection of intellectual property: 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.

Regulatory requirements for ***First Defense®***: **First Defense®** is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the "Reference Standard"). Due to the unique nature of the **First Defense©** label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product. Similar regulatory oversight risks exist in territories outside of the United States where we sell our products.

Regulatory requirements for ***Wipe Out© Dairy Wipes***: While the FDA regulates the manufacture and sale of **Wipe Out© Dairy Wipes**, this type of product is permitted to be sold without a NADA approval, in accordance with the FDA's Compliance Policy Guide 7125.30 ("Teat Dips and Udder Washes for Dairy Cows and Goats"). This policy guide could be withdrawn at the FDA's discretion, in which case we would likely discontinue sales of the product. The manufacture of **Wipe Out© Dairy Wipes** is subject to Part 211 of the cGMP regulations. As a result, our operations are subject to inspection by the FDA. During the second quarter of 2007, the FDA inspected our facilities and operations and issued a Warning Letter to us, citing deficiencies in specific areas of the cGMP regulations. We filed an initial response to the FDA during the second quarter of 2007, and we responded to a request for additional information during the second quarter of 2008. During the first quarter of 2013, the FDA again inspected our facilities and operations. The report from this inspection was very favorable, and we responded to the few, minor observations that were noted. We remain subject to the risk of adverse action by the FDA in this respect.

Regulatory requirements for ***Mast Out©***: The commercial introduction of **Mast Out©** in the United States will require us to obtain appropriate FDA approval for this product. Completing the development of **Mast Out©** through to the submission of the administrative NADA to the FDA involves a great deal of risk. It presently is uncertain when or if this approval will be achieved, but we have disclosed a timeline of events that could lead to our achieving FDA approval during late 2018 or 2019. We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Mast Out©**, who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. International regulatory approvals would be required for sales outside of the United States. European regulatory authorities are not expected to approve a product with a zero milk discard claim, which would remove a significant competitive advantage of **Mast Out©** in

that territory. However, the assigned milk discard period may be shorter for **Mast Out**Ò than it is for other products on the market in Europe.

Concentration of sales: Approximately 83% of our product sales were made to customers in the U.S. dairy and beef industries during both of the years ended December 31, 2015 and 2014. Approximately 97% and 96% of our product sales were made to customers in the dairy and beef industries throughout the world during the years ended December 31, 2015 and 2014, respectively. A large portion of our product sales (62%, 61%, and 60% for the years ended December 31, 2015, 2014, and 2013, respectively) was made to two large distributors. A large portion of our trade accounts receivable (52% and 71% as of December 31, 2015 and 2014, respectively) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us.

Economics of the dairy and beef industries:

All cattle and calves in the United States as of January 1, 2016 totaled 92,000,000, which is 3.3% higher than January 1, 2015. Prior to January 1, 2015, the January count of cattle inventory had steadily declined from 97,000,000 as of January 1, 2007.

All cattle and calves in the United States as of July 1, 2015 totaled 98,400,000, which is 2.2% higher than July 1, 2014. This is the first increase in the July count of cattle inventory since 2006, suggesting the rebuilding of the U.S. herd has begun. The July 1, 2014 amount of 96,300,000 was the lowest inventory count as of July 1st in decades.

From 1998 through 2015, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 (2004) to the high of 9,315,000 (2015). The 2015 level exceeded the previous high during this eighteen-year period of 9,314,000 in 2008.

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While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk, demand for milk is also influenced by very volatile international demand for milk products. The Class III milk price (an industry benchmark that reflects the value of product used to make cheese) is an important indicator because it defines our customers' revenue level. This annual average milk price level (measured in dollars per hundred pounds of milk) for 2014 of $22.34 (peaking at $24.60 in September 2014) was the highest level since these records were first reported in 1980. This strong price level declined to the average of $15.80 during 2015. This price decreased further to $13.72 in January 2016. The recent annual fluctuations in this milk price level are demonstrated in the following table:

Average Class III Milk Price for the year ended December 31,		Increase (Decrease)	
2012	2013		
$17.44	$17.99	3	%
2013	2014		
$17.99	$22.34	24	%
2014	2015		
$22.34	$15.80	(29	%)

The actual level of milk prices may be less important than its level relative to feed costs. One measure of this relationship is known as the milk-to-feed price ratio, which represents the amount of feed that one pound of milk can buy. The annual average for this ratio of 1.52 in 2012 was the lowest recorded since this ratio was first reported in 1985. The highest annual average this ratio has reached since 1985 was 3.64 in 1987. Since this ratio reached 3.24 in 2005, it has not exceeded 3.0. The annual average of 2.54 for 2014 was the highest this ratio has been since it was 2.81 in 2007. This ratio dropped to an annual average of 2.12 during 2015. The following table demonstrates the annual volatility and the low values of this ratio recently:

Average Milk-To-Feed Price Ratio for the year ended December 31,		**Increase (Decrease)**	
2012	2013		
1.52	1.75	15	%
2013	2014		
1.75	2.54	45	%
2014	2015		
2.54	2.12	(16	%)

An increase in feed costs also has a negative impact on the beef industry. Widespread severe drought conditions in key U.S. agricultural regions during 2012 drove feed costs higher and the inventory of all cattle and calves lower. The positive trend in these market indices during 2013 and 2014 resulted in an increase in the value of milk cows. The 2014 annual average price for a milk cow increased by 32% to $1,835 in comparison to 2013. Previously, this annual average price since 1970 was only higher when it reached $1,840 in 2007 and $1,953 in 2008. This annual average price for 2015 increased by 9% to $1,993 in comparison to 2014. The industry data referred to above is compiled from USDA databases. Recently, the value of newborn bull calves has risen to the unusually high level of approximately $300 to $400. At this price, producers are more likely to invest in **First Defense®** for their bull calves. Given our focus on the dairy and beef industries, the volatile market conditions and the resulting financial insecurities of our primary end users are risks to our ability to maintain and grow sales at a profitable level. These factors also heighten the challenge of selling premium-priced animal health products (such as **Mast Out™**) into the dairy market.

Product development risks: The development of new products is subject to financial, scientific, regulatory and market risks. Our current business growth strategy relies heavily on the development of **Mast Out™**, which requires (and will continue to require) a substantial investment. Our efforts will be subject to inspection and approval by the FDA. There is no assurance whether or when we will obtain all of the data necessary to support regulatory approval for this product.

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*Risks associated with **Mast Out**Ò funding strategy:* The construction of and the financing for the commercial-scale Drug Substance production facility is the most critical action in front of us on our path to U.S. regulatory approval for **Mast Out**Ò. During the first quarter of 2016, we sold 1.1 million shares of common stock in an underwritten public offering registered with the SEC, raising $5.3 million in net proceeds. Also during the first quarter of 2016, we signed a commitment letter covering a $4.5 million bank debt facility. Together with our cash and investments, plus cash to be generated from operations, we believe that we will have adequate financing to complete the project. However, due to the risks described herein, we could fail to generate sufficient cash to fully fund that project, and we could experience cost overruns or delays.

Uncertainty of market size and product sales estimates: Even assuming that **Mast Out**Ò achieves regulatory approval in the United States with a zero milk discard requirement, estimating the size of the market for this product is subject to numerous uncertainties. Some of the uncertainties surrounding our product include market acceptance, the development of the subclinical mastitis treatment market, the effect of a premium selling price on market penetration, cost of manufacture and integration of milk from treated cows with susceptible cheese starter cultures.

Competition from others: Many of our competitors are significantly larger and more diversified in the relevant markets than we are and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. Zoetis, Elanco and Boehringer Ingelheim, among other companies, sell products that compete directly with **First Defense**Ò in preventing scours in newborn calves. The product sold by Elanco experienced a lack of supply in the market during late 2014 and into the middle of 2015, which appears to have been resolved. The product sold by Zoetis does carry a rotavirus claim, which we do not yet have, but it does not have an *E. coli* claim, and it sells for approximately half the price of our product. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Zoetis, Merck and Boehringer Ingelheim. There is no assurance that **Mast Out**Ò will compete successfully in this market. We may not be aware of other companies that compete with us or intend to compete with us in the future.

Access to raw materials: Our policy is to maintain more than one source of supply for the components used to manufacture and test our products that we obtain from third parties. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. The loss of farms from which we buy raw material for **First Defense**® could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms on suitable terms. We are dependent on our manufacturing facility and operations at 56 Evergreen Drive in Portland for the production of **First Defense**Ò and our topical wipes and will be dependent on the facility we are preparing to construct for the production of **Mast Out**Ò when that product begins commercial sales. The specific antibodies that we purify from colostrum for **First Defense**Ò and the Nisin we produce by fermentation for our topical wipes are not readily available from other sources. We expect to be dependent on Plas-Pak for the supply of the syringes used for **Mast Out**Ò. We expect to be dependent on Norbrook for the sterile-filling and final packaging of our Drug Substance into Drug Product. Given the requirement that such a facility be inspected and approved by the

FDA, it could be costly and time-consuming to find an adequate alternative source for these services. Any significant damage to or other disruption in the services at these facilities (including due to regulatory non-compliance) could adversely affect the production of inventory and result in significant added expenses and loss of future sales.

Risk of sales order backlog: Given our recent and significant increase in sales demand for **First Defense**Ò, our manufacturing resources (internal and third party) were no longer sufficient to avoid a backlog of orders. In response, we completed an investment to increase our liquid processing capacity by 50% during the fourth quarter of 2015 and our freeze drying capacity by 100% during the first quarter of 2016. Until we produce enough inventory to clear this backlog of orders, we are at risk of losing customers that are unable to acquire our product on a timely basis.

Small size; dependence on key personnel: We are a small company with 46 employees (including 5 part-time employees). As such, we rely on certain key employees to support different operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained. Our competitive position will be highly influenced by our ability to attract and retain key scientific, managerial and sales and marketing personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products 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.

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Failure to protect intellectual property: 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 safeguards 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. There is also a risk that competitors could challenge the claims in patents that have been issued to us.

Certain provisions might discourage, delay or prevent a change in control of our Company or changes in our management: Provisions of our certificate of incorporation, our bylaws, our Common Stock Rights Plan or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

limitations on the removal of directors; advance notice requirements for stockholder proposals and nominations;
the ability of our Board of Directors to alter or repeal our bylaws;
the ability of our Board of Directors to refuse to redeem rights issued under our Common Stock Rights Plan or otherwise to limit or suspend its operation that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors; and
Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could depress the trading price of our common stock or limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood of obtaining a premium for our common stock in an acquisition.

Cost burdens of our reporting obligations as a public company: Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws and the provisions of the Sarbanes-Oxley Act

of 2002.

Exposure to risks associated with the financial downturn and global economic crisis: The U.S. economy has technically come out of a recession, which was caused principally by the housing, credit and financial crises of the late 2000's. However, such recent positive indications could prove temporary and further downturn could occur, and the European economy remains sluggish and precarious. Certain emerging markets also show signs of slower growth or, in some areas, downturns in economic performance. The credit markets continue to be very turbulent and uncertain. This extraordinary period of instability in the U.S. economy and the financial markets has been troubling for nearly all Americans. Some observers believe that the housing market remains problematic for the overall U.S. economy, the United States has taken on too much national debt and the equity markets are overvalued (especially prior to the market correction of early 2016). A combination of the conditions, trends and concerns summarized above could have a corresponding negative effect on our business and operations, including the demand for our products in the U.S. market and our ability to penetrate international markets.

Bovine diseases: The potential for epidemics of bovine diseases such as Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) presents a risk to us and our customers. Documented cases of BSE in the United States have led to an overall tightening of regulations pertaining to ingredients of animal origin, especially bovine. **First Defense^{Ò}** is considered a veterinary medicine rather than a feed ingredient, and it is manufactured from bovine milk (colostrum), which is not considered a BSE risk material. Future regulatory action to increase protection of the human food supply could affect **First Defense^{Ò}**, although presently we do not anticipate that this will be the case.

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Biological terrorism: The threat of biological terrorism is a risk to both the economic health of our customers and our ability to economically acquire and collect good quality raw material from our contract farms. Any act of widespread bioterrorism against the dairy industry could adversely affect our operations.

Stock market valuation: Our common stock trades on The Nasdaq Stock Market (NASDAQ: ICCC). Our average daily trading volume (although it has increased recently) is lower than the volume for most other companies and the bid/ask stock price spread can be larger, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire. There are companies in the animal health sector with market capitalization values that greatly exceed our current market capitalization of approximately $25,000,000. Some of these companies have little or no product sales. We currently have annual product sales of over $10,000,000. The stock price of some of these companies has been volatile. Before gross margin from the sale of new products is achieved, our market capitalization may be heavily dependent on the perceived potential for growth from our products under development.

No expectation to pay any dividends or repurchase stock for the foreseeable future: We do not anticipate paying any dividends to, or repurchasing stock from, our stockholders for the foreseeable future. Instead, we expect to use cash to fund product development costs and investments in our facility and production equipment and to reduce debt. Any debt or equity financing we obtain to assist in funding our product development programs or expanding our facilities may include terms prohibiting or restricting our paying dividends or repurchasing stock for a lengthy period. Stockholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, contractual restrictions, restrictions imposed by applicable laws, current and anticipated needs for liquidity and other factors our Board of Directors deems relevant.

ITEM 2 – DESCRIPTION OF PROPERTY

We own a 34,850 square foot building at 56 Evergreen Drive in Portland, Maine. We currently use this space for substantially all of our office, laboratory and manufacturing needs. When we originally purchased this building in 1993, its size was 15,000 square feet, including 5,000 square feet of unfinished space on the second floor. In 2001, we completed a construction project that added approximately 5,200 square feet of new manufacturing space on the first floor and approximately 4,100 square feet of storage space on the second floor. In 2007, we built out the 5,000 square feet of unfinished space on the second floor into usable office space. After moving first floor offices into this new space on the second floor, we modified and expanded the laboratory space on the first floor and added approximately 2,500 additional square feet of storage space on the second floor. During 2009, we added 350 square feet of cold storage space connected to our first floor production area and added an additional 600 square feet to the second floor storage area. During the first quarter of 2015, we completed construction of a two-story addition connected to our

facility to provide us with approximately 7,100 additional square feet for cold storage, production and warehouse space for our operations.

During the fourth quarter of 2015, we exercised an option to acquire land nearby to our facility at 56 Evergreen Drive for a total purchase price of $238,000 on which we intend to construct our Nisin production plant. During the first quarter of 2016, we paid $20,500 for an option to purchase additional land nearby that could be used to construct an 8,000 square foot building should we decide to exercise the option before the end of 2016 for an additional $184,500.

We rent approximately 550 square feet of office and warehouse space in New York on a short-term basis to support our farm operations. Effective January 2016, we rent approximately 3,266 square feet in Minnesota on a short-term basis, where we formulate our gel tube delivery format of **First Defense Technology**™ and certain private label products.

We maintain property insurance in amounts that approximate replacement cost and a modest amount of business interruption insurance. We also maintain access to certain animals, primarily cows, through contractual relationships with commercial dairy farms.

ITEM 3 – LEGAL PROCEEDINGS

None

ITEM 4 – MINE SAFETY DISCLOSURES

None

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PART II

ITEM 5 – MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock trades on The Nasdaq Capital Market tier of The Nasdaq Stock Market under the symbol ICCC. No dividends have been declared or paid on the common stock since the Company's inception, and we do not anticipate or contemplate the payment of cash dividends in the foreseeable future. As of March 17, 2016, we had 8,000,000 common shares authorized and 4,178,844 common shares outstanding, and there were approximately 850 shareholders of record. The last sales price of our common stock on March 17, 2016 was $6.67 per share as quoted on The Nasdaq Stock Market. The following table sets forth the high and low sales price information for our common stock as reported by The Nasdaq Stock Market during the period January 1, 2014 through December 31, 2015:

	2014 Three Months Ended				2015 Three Months Ended			
	March 31	June 30	September 30	December 31	March 31	June 30	September 30	December 31
High	$4.95	$5.30	$ 5.68	$ 5.44	$7.22	$8.69	$ 11.40	$ 7.80
Low	$4.06	$3.30	$ 4.17	$ 3.96	$4.99	$5.50	$ 5.95	$ 6.03

Equity Compensation Plan Information

The table below summarizes the common stock reserved for issuance upon the exercise of stock options outstanding as of December 31, 2015 or that could be granted in the future:

	Number of shares to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of shares remaining available for future issuance under stock-based

				compensation plans (excluding shares reflected in first column of this table)
Equity compensation plans approved by stockholders	238,000	$	3.57	189,500
Equity compensation plans not approved by stockholders	0		0.00	0
Total	238,000	$	3.57	189,500

ITEM 6 – SELECTED FINANCIAL DATA

The selected financial data set forth below has been derived from our audited financial statements. The information should be read in conjunction with the audited financial statements and related notes appearing elsewhere in this Form 10-K and in earlier reports filed with the SEC (in thousands, except for per share amounts).

	During the Year Ended December 31,				
	2015	2014	2013	2012	2011
Statement of Operations Data:					
Product sales	$10,229	$ 7,597	$6,007	$5,390	$ 5,111
Gross margin	6,251	4,449	3,061	3,054	2,814
Product development expenses	1,235	2,179	1,154	918	1,720
Selling and administrative expenses	2,893	2,476	1,926	1,892	1,726
Net operating income (loss)	2,122	(206)	(20)	245	(633)
Income (loss) before income taxes	2,064	(255)	205	192	(697)
Interest expense	80	58	67	75	81
Depreciation and amortization expenses	529	449	417	403	418
Net income (loss)	$1,213	($167)	$117	$90	($410)

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	During the Year Ended December 31,				
	2015	2014	2013	2012	2011
Per Common Share:					
Basic net income (loss)	$0.40	$(0.06)	$0.04	$0.03	$(0.14)
Diluted net income (loss)	$0.38	$(0.06)	$0.04	$0.03	$(0.14)
Cash dividend	$0	$0	$0	$0	$0
Statement of Cash Flows Data:					
Net cash provided by (used for) operating activities	$2,900	$302	$1,099	$344	$(37)

	As of December 31,				
	2015	2014	2013	2012	2011
Balance Sheet Data:					
Cash, cash equivalents, short-term investments and long-term investments	$6,524	$3,835	$5,255	$4,914	$4,960
Total assets	14,601	11,052	10,961	11,030	10,991
Current liabilities	818	1,009	636	666	635
Net working capital	7,056	4,460	6,632	6,697	6,516
Long-term liabilities	3,169	785	929	1,170	1,336
Stockholders' equity	$10,614	$9,258	$9,396	$9,195	$9,020
Per Outstanding Common Share:					
Cash, cash equivalents, short-term investments and long-term investments	$2.14	$1.27	$1.74	$1.63	$1.65
Stockholders' equity	$3.47	$3.06	$3.11	$3.05	$3.00

ITEM 7 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Financial Condition

We aim to capitalize on the significant growth in sales of **First Defense**Ò and to revolutionize the mastitis treatment paradigm. Our strategy is focused on developing and selling products that improve animal health and productivity in the dairy and beef industries. These product opportunities are generally less expensive to develop than the human health product opportunities that we had worked on during the 1990's. We have funded most of our product development expenses principally from our gross margin on product sales. 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. This significant and controlled investment in the development of **Mast Out®** resulted in net losses for the four consecutive years ending December 31, 2008 to December 31, 2011. Having largely completed the significant clinical studies for **Mast Out®** and by increasing the gross margin earned from sales of **First Defense®**, we returned to profitability during the years ended December 31, 2012 and 2013. As anticipated, we incurred a net loss during the year ended December 31, 2014 due to an unusually large investment in a small-scale production plant for **Mast Out®**. After completing this investment, we did return to profitability, as planned, during the six-month period ended December 31, 2014 and continued this profitability throughout 2015.

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We had approximately $6,524,000 in available cash, cash equivalents, short-term investments and long-term investments as of December 31, 2015. The table below summarizes the changes in selected, key balance sheet items (in thousands, except for percentages):

	As of December 31, **2015**	As of December 31, **2014**	Increase $	Increase %
Cash, cash equivalents, short-term investments and long-term investments	$ 6,524	$ 3,835	$2,689	70%
Net working capital	7,056	4,460	2,596	58
Total assets	14,601	11,052	3,549	32
Stockholders' equity	$ 10,614	$ 9,258	$1,355	15%

Net cash provided by operating activities amounted to $2,900,000 during the year ended December 31, 2015 compared to net cash provided by operating activities of $302,000 during the year ended December 31, 2014. Capital investments of $2,719,000 during the year ended December 31, 2015 compared to capital investments of $1,536,000 during the year ended December 31, 2014. Together with gross margin earned from ongoing product sales, we believe that we have sufficient capital resources to meet our working capital requirements and to finance our ongoing business operations during at least the next twelve months.

During the third quarters of 2010 and 2015, we agreed to terms of certain credit facilities with TD Bank, N.A., which are secured by substantially all of our assets including our building, which was independently appraised at $4,180,000 in connection with the 2015 financing. As of December 31, 2015, our outstanding bank debt balance was approximately $3,227,000. We have a $500,000 line of credit that is available as needed. We chose debt financing at those times in order to take advantage of what we believed to be historically low interest rates, which may trend higher in the future.

During January 2016, we signed a commitment letter covering certain additional credit facilities with TD Bank N.A. aggregating approximately $4.3 million comprised of: (a) a $3.3 million construction loan, drawable over an 18-month period at up to 80% of the cost of equipment installed in the to be constructed commercial-scale production facility for **Mast Out**®, during which interest only will be payable at a variable rate equal to the 30-day LIBOR plus 2.25%, which converts to a seven-year term loan facility at the end of construction at the same interest rate with monthly principal and interest payments based on a seven-year amortization schedule and (b) a $1.0 million construction loan, drawable over a 12-month period at up to 75% of the appraised value of the to be constructed commercial-scale production facility for **Mast Out**®, during which interest only will be payable at a variable rate equal to the 30-day LIBOR plus 2.25%, which converts to a nine-year term loan facility at the end of construction at the same interest rate with monthly principal and interest payments based on a twenty-year amortization schedule. On

March 11, 2016 we signed a revised commitment letter decreasing the equipment loan component to $2.5 million and increasing the mortgage component to $2.0 million. These credit facilities are subject to customary closing conditions and certain financial covenants.

On October 28, 2015, we filed a registration statement on Form S-3 with the SEC for the potential issuance of up to $10,000,000 in equity (subject to certain limitations). This registration statement became effective on November 10, 2015. Under this form of registration statement, we are limited to raising gross proceeds of no more than one-third of the market capitalization of our common stock (as determined by the high price within the preceding 60 days leading up to a sale of securities) held by non-affiliates (non-insiders) of the Company within a twelve-month period. This limit was approximately $5,958,000, based on the closing price of $8.08 per share as of January 6, 2016. On February 3, 2016, we issued 1,123,810 shares of common stock at a price to the public of $5.25 per share, raising gross proceeds of approximately $5,900,000. The net proceeds raised were approximately $5,323,000 after deducting underwriting discounts and offering expenses.

While we may use the net proceeds from the equity offering to fund our growth plans and other general corporate purposes, we anticipate that the primary use of the net proceeds (along with the funds borrowed under the debt facilities described above) will be to fund a significant portion of the cost of building and equipping a commercial-scale pharmaceutical facility to produce Nisin (the Active Pharmaceutical Ingredient for **Mast Out**Ò). The estimated total cost of that facility is approximately $17,500,000. The remaining $7,700,000 of that cost not covered by the borrowing and stock sale proceeds will be funded from our existing cash and cash generated from operations in 2016 to 2018.

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During the third quarter of 2013, our Board of Directors approved the aggregate investment of approximately $3,000,000 in two projects. The first investment involved acquiring processing equipment and modifying a portion of our facility to create a small-scale production plant for the **Mast Out**Ò product development initiative. These expenses were not capitalized because this plant is not expected to support commercial sales. This project was substantially completed during the third quarter of 2014. This specifically targeted increase in product development expenses resulted in a net loss during the first six months of 2014. The second investment involved acquiring manufacturing equipment and constructing a two-story addition to our facility, providing us with approximately 7,100 square feet of cold storage, production and warehouse space to increase our commercial production capacity for **First Defense**Ò and other products. This project was initiated at the end of the third quarter of 2014 and was substantially completed during the first quarter of 2015. These expenses have been capitalized as they support the commercial sale of our existing products. The following table details the spending on these two projects:

	Expenses	Capital Expenditures	Total Expenses and Capital Expenditures
Three-month period ended December 31, 2013	$110,000	$ 21,000	$ 131,000
Year ended December 31, 2014	973,000	1,492,000	2,465,000
Nine-month period ended September 30, 2015	9,000	414,000	423,000
Total investment	$1,092,000	$ 1,927,000	$ 3,019,000

Separately, as of January 1, 2016, we had additional authorization from our Board of Directors to spend up to approximately $2,155,000 for new manufacturing equipment and other routine and necessary capital expenditures and for the acquisition of certain business assets from DAY 1™Technology, LLC. This amount does not include cash budgeted for the construction of a commercial-scale production facility for **Mast Out**Ò. This investment is in addition to the $1,790,000 that we invested in related capital expenditures during 2015. Most of this 2015 investment is intended to pay for the acquisition of **First Defense**Ò production equipment necessary to increase our liquid processing capacity by approximately 50% and our freeze-drying capacity by approximately 100%. We completed the investment to increase our liquid processing capacity during the fourth quarter of 2015 and the investment to increase our freeze-drying capacity during the first quarter of 2016. These investments, together with the 7,100 square foot facility addition, described above, are necessary to increase our manufacturing capacity to fill our current backlog of **First Defense**Ò orders and to meet the increased sales demand that we are experiencing.

During January 2016, we acquired certain business assets from DAY 1™Technology, LLC of Minnesota. The acquired rights and know-how are primarily related to formulating our bovine antibodies into a gel solution for an oral delivery option to newborn calves via a syringe (or “tube”). This product format offers customers an alternative delivery option to the bolus (the standard delivery format of the bivalent **First Defense**Ò product since first USDA approval and product launch in 1991) and could allow more significant penetration into the beef market. The formulation was developed by DAY 1™Technology for us and has been sold as a feed product without disease claims since 2012. This

purchase also includes certain other related private-label products that could generate approximately $300,000 in annual sales. Assets purchased in this transaction included inventory, machinery and equipment and certain intellectual property intangibles. The total purchase price was approximately $534,000, including estimated contingent payments due over the next three years.

Results of Operations

2015 Compared to 2014

Product Sales

Product sales for the year ended December 31, 2015 increased by 35%, or $2,632,000, to $10,229,000 from $7,597,000 in 2014. As of December 31, 2015, we had a backlog of orders aggregating approximately $381,000 in comparison to no backlog as of December 31, 2014. During the year ended December 31, 2015 domestic product sales increased by 33%, or $2,150,000, and international sales increased by 42%, or $482,000, in comparison to 2014. We believe that our increased investment in sales and marketing personnel and efforts is helping us introduce **First Defense**Ò to new customers and that our product sales benefited from the relatively strong prices of milk, cows and calves, as well as a stable to moderately lower cost of feed, despite significant market volatility affecting both milk prices and feed costs. We generally held our product selling prices without increase during the seven-year period ended December 31, 2007. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense®**. We did not implement another price increase until the third quarter of 2014. During 2015, we implemented an increase to the selling price of **First Defense Technology™**. This strategy recognizes that while selling a premium-priced product, we must be very efficient with our manufacturing costs to maintain a healthy gross margin. This positive trend has continued into the first quarter of 2016, and this new level of sales demand for **First Defense**Ò has exceeded our production capacity and available inventory. We have completed the investments necessary to increase our liquid processing capacity by 50% and our freeze drying capacity by 100% to meet the growing sales demand for **First Defense**Ò.

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Our lead product, **First Defense®**, continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent bovine enteritis (scours) in newborn calves. Sales of **First Defense®** and related product line extensions aggregated 92.8% and 91.6% of our total product sales during the years ended December 31, 2015 and 2014, respectively. Sales of **First Defense®** and related product line extensions increased by 36%, 27% and 14% during the years ended December 31, 2015, 2014 and 2013, respectively, in comparison to the prior years. Domestic sales of **First Defense®** and related product line extensions increased by 36%, and international sales increased by 41%, during the year ended December 31, 2015 in comparison to 2014. With the single exception of the second quarter of 2012, we have realized consistently positive sales growth of **First Defense®** and related product line extensions for twenty of the last twenty-one quarters, including the last fourteen consecutive quarters, in comparison to the same quarters of the prior year, as demonstrated in the following table:

We believe that the long-term growth in sales of **First Defense®** and related product line extensions may reflect, at least in part, the success of our strategic decision initiated in 2010 to invest in additional sales and marketing efforts. Our sales and marketing team currently consists of one vice president and five regional managers. Our inside sales and customer service representative performs all order entry and inside sales duties, and our facility manager processes all shipments. We launched a new communications campaign at the end of 2010 that continues to emphasize how the unique ability of **First Defense®** to provide **Immediate Immunity™** generates a dependable return on investment for dairy and beef producers. Preventing newborn calves from becoming sick helps them to reach their genetic potential.

Competition for resources that dairy producers allocate to their calf enterprises has been increased by the many new products that have been introduced to the calf market. Our sales are normally seasonal, with higher sales expected during the first quarter. Warm and dry weather reduces the producer's perception of the need for a disease preventative product like **First Defense®**, but heat stress on calves caused by extremely hot summer weather can increase the incidence of scours. Harsher winter weather benefits our sales. The animal health distribution segment has been aggressively consolidating over the last few years. Larger distributors have been acquiring smaller distributors. Beef herd numbers were reduced because of the 2012 drought conditions in many parts of North America. This has resulted in an increase in the value of newborn calves, as producers re-build their herd levels. Such an upswing increases a producer's likelihood to invest in **First Defense®** for their calf crop.

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We are selling new product applications of **First Defense**Ò product line under the description **First Defense Technology™**, which is a unique whey protein concentrate that is processed utilizing our proprietary milk protein purification methods, for the nutritional and feed supplement markets without the claims of our USDA-licensed product. Through our **First Defense Technology™**, we are selling concentrated whey proteins in different formats. During the first quarter of 2011, we initiated sales of **First Defense Technology™** in a bulk powder format (no capsule), which is delivered with a scoop and mixed with colostrum for feeding to calves. During the fourth quarter of 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start® 150 Plus and certain similar private label products, which are colostrum replacers with **First Defense Technology™ Inside**. During the first quarter of 2012, we initiated a limited launch of a tube delivery format of our **First Defense Technology™** in a gel solution.

We sell topical wipes that are pre-moistened with a Nisin-based formulation in two product formats. Since 1999, we have been selling **Wipe Out® Dairy Wipes** (our second leading source of product sales) for use in preparing the teat area of a cow for milking. Sales of **Wipe Out® Dairy Wipes** decreased by 3% during the year ended December 31, 2015 in comparison to the same period during 2014. We are competing aggressively on selling price to earn new business against less expensive products and alternative teat sanitizing methods. We believe that sales growth potential for **Wipe Out® Dairy Wipes** is limited because most of our sales of this product tend to be to smaller dairies that are under continued financial pressures, forcing many small dairy producers out of business. While our product is a high quality tool, there are less expensive ways to sanitize a cow's udder prior to milking, and many producers opt for a less expensive solution. 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. Sales of this product line extension decreased by 4% during the year ended December 31, 2015 in comparison to the same period during 2014.

Sales of our **California Mastitis Test (CMT)** (our third leading source of animal health product sales) increased by 33% during the year ended December 31, 2015 in comparison to the same period during 2014. We make and sell bulk reagents for Isolate™ (formerly known as Crypto-Scan®), which is a drinking water test that is sold by our distributor in Europe. Sales of Isolate™ increased by 46% during the year ended December 31, 2015 in comparison to the same period during 2014. Sales of these bulk reagents aggregated slightly more than 2% of total product sales during the years ended December 31, 2015 and 2014.

Gross Margin

Changes in the gross margin on product sales are summarized in the following table for the respective periods (in thousands, except for percentages):

	For the Three-Month Periods Ended December 31,		Increase	
	2015	2014	Amount	%
Gross margin	$1,658	$1,343	$315	23%
Percent of product sales	62 %	61 %	1 %	1 %

	For the Years Ended December 31,		Increase	
	2015	2014	Amount	%
Gross margin	$6,251	$4,449	$1,802	41%
Percent of product sales	61 %	59 %	3 %	4 %

The gross margin as a percentage of product sales was 61% and 59% during the years ended December 31, 2015 and 2014, respectively. This compares to gross margin percentages of 51% and 57% during the years ended December 31, 2013 and 2012, respectively. Our objective for the foreseeable future is to maintain the full-year gross margin percentage over 50%, and we have achieved this annual objective since 2009. Largely due to the significant increase in product sales experienced especially during the second half of 2014, our inventory balance was reduced to $946,000 as of December 31, 2014. As sales continued to increase during 2015, our inventory balance was further reduced to $870,000 as of December 31, 2015. During the first quarter of 2016, we completed an investment to increase our production capacity to build inventory levels and catch up with growing sales. A number of factors account for the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter. The gross margin on **First Defense**Ò is affected by biological yields from our raw material, which do vary over time. Like most U.S. manufacturers, we have been experiencing increases in the cost of raw materials that we purchase. The costs for production of **First Defense**Ò and **Wipe Out**Ò **Dairy Wipes** have increased due to increased labor costs and other expenses associated with our efforts to sustain compliance with cGMP regulations in our production processes. We have been able to minimize the impact of these cost increases by implementing yield improvements. Product mix also affects gross margin in that we earn a higher gross margin on **First Defense**Ò and a much lower gross margin on **Wipe Out**Ò **Dairy Wipes.**

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Product Development Expenses

During the seventeen-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, 2015, we invested the aggregate of approximately $21,984,000 in product development expenses, averaging approximately $1,293,000 per year during this period. Approximately $4,130,000 of this investment was offset by product licensing revenues, technology sales and grant income. During the sixteen-year period that began on January 1, 2000 (the year we began the development of **Mast Out™**) and ended on December 31, 2015, we invested the aggregate of approximately $11,811,000 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™**. Product development expenses decreased by 43%, or $944,000, to $1,235,000 during the year ended December 31, 2015, as compared to $2,179,000 during 2014. Product development expenses aggregated 12% and 29% of product sales in 2015 and 2014, respectively. Product development expenses were higher during 2014 as we completed our investment in a small-scale production plant for **Mast Out™**. The investment we are preparing to make in a commercial-scale production facility for **Mast Out™** will be capitalized as incurred and then depreciated against commercial sales after FDA approval and market launch. The balance of our efforts have been primarily focused on other improvements, extensions or additions to our **First Defense™** product line. The other improvements, extensions, or additions to our current product line include the potential to prevent scours in calves caused by pathogens other than those within the current **First Defense™** disease claims (*E. coli* K99 and coronavirus) such as rotavirus. We also remain interested in acquiring other new products and technologies that fit with our sales focus on the dairy and beef industries.

Sales and Marketing Expenses

Sales and marketing expenses increased by approximately 22%, or $290,000, to $1,607,000 in 2015, decreasing to 16% of product sales in 2015 from 17% in 2014. We continue to leverage the efforts of our small sales force by using veterinary distributors. These expenses have increased due principally to a strategic decision to invest more to support **First Defense™** sales. This investment may have created, at least in part, our recent increase in product sales. Our current budgetary objective in 2016 is to invest up to 18% of product sales in sales and marketing expenses on an annual basis.

Administrative Expenses

Administrative expenses increased by approximately 11%, or $127,000, to $1,286,000 during the year ended December 31, 2015 as compared to $1,159,000 during 2014. We strive to be efficient with these expenses while funding costs associated with complying with the Sarbanes-Oxley Act of 2002 and other costs associated with being a publicly-held company. Prior to 2014, we had limited our investment in investor relations spending. Beginning in the second quarter of 2014, we initiated an investment in a more actively managed investor relations program. Additionally, we continue to provide full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as in Current Reports on Form 8-K when legally required or deemed appropriate by management. Additional information about us is available in our annual Proxy Statement. All of these reports are filed with the SEC and are available on-line or upon request to the Company.

Net Operating Income (Loss)

The net operating income during the year ended December 31, 2015 of $2,122,000 improved from a net operating (loss) of ($206,000) during 2014. We recorded a net operating (loss) of ($20,000) during the year ended December 31, 2013.

Other expenses (revenues), net

Interest income increased by approximately 23%, or $4,000, to $19,000 during the year ended December 31, 2015, in comparison to $16,000 during 2014. Interest expense increased by approximately 39%, or $22,000, to $80,000 during the year ended December 31, 2015, in comparison to $58,000 during 2014. As a result, other expenses aggregated $59,000 and $49,000 during the years ended December 31, 2015 and 2014, respectively.

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Income (Loss) Before Income Taxes and Net Income (Loss)

Our income before income taxes of $2,064,000 during the year ended December 31, 2015 is in contrast to a (loss) before income taxes of ($255,000) during 2014. We recorded income tax expense (benefit) of 41% and (35%) of the income (loss) before income taxes during the years ended December 31, 2015 and 2014, respectively. Our net income of $1,213,000, or $0.38 per diluted share, during the year ended December 31, 2015 is in contrast to a net (loss) of ($167,000), or ($0.06) per share, during the year ended December 31, 2014.

2014 Compared to 2013

Product Sales

Product sales for the year ended December 31, 2014 increased by 26%, or $1,590,000, to $7,597,000 from $6,007,000 in 2013. Domestic product sales increased by 27%, or $1,376,000, during the year ended December 31, 2014, and international sales increased by 23%, or $214,000, in comparison to 2013. For the three-month period ended December 31, 2014, product sales increased by 41%, or $646,000, in comparison to the three-month period ended December 31, 2013. We believe that our increased investment in sales and marketing personnel and efforts is helping us introduce **First Defense**Ò to new customers and that our product sales benefited from the relatively strong prices of milk, cows and calves, as well as a stable to moderately lower cost of feed. We generally held our product selling prices without increase during the seven year period ended December 31, 2007. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense®**. We did not implement another price increase until the third quarter of 2014. This strategy recognizes that while selling a premium-priced product, we must be very efficient with our manufacturing costs to maintain a healthy gross margin.

Our lead product, **First Defense®**, continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent bovine enteritis (scours) in newborn calves. Sales of **First Defense®** and related product line extensions aggregated 91.6% and 91.4% of our total product sales during the years ended December 31, 2014 and 2013, respectively. Sales of **First Defense®** and related product line extensions increased by 27%, 14% and 5% during the years ended December 31, 2014, 2013 and 2012, respectively, in comparison to the prior years. Domestic sales of **First Defense®** and related product line extensions increased by 29%, and international sales increased by 15% during the year ended December 31, 2014 in comparison to 2013. Sales of **First Defense®** and related product line extensions increased by 44% and 43% during the three-month and six-month periods ended December 31, 2014, respectively, in comparison to 2013.

We sell topical wipes that are pre-moistened with a Nisin-based formulation in two product formats. Since 1999, we have been selling **Wipe Out**Ò **Dairy Wipes** (our second leading source of product sales) for use in preparing the teat area of a cow for milking. Sales of **Wipe Out**Ò **Dairy Wipes** decreased by 2% during the year ended December 31, 2014 in comparison to the same period during 2013. 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. Sales of this product line extension turned the 2% decrease in sales of **Wipe Out**Ò **Dairy Wipes** (discussed above) into an 8% aggregate increase in sales of all topical product applications during the year ended December 31, 2014 in comparison to the same period during 2013. Sales of our **California Mastitis Test (CMT)** (our third leading source of animal health product sales) increased by 8% during the year ended December 31, 2014 in comparison to the same period during 2013. We make and sell bulk reagents for Isolate™ (formerly known as Crypto-Scan®), which is a drinking water test that is sold by our distributor in Europe. Sales of Isolate™ increased by 111% during the year ended December 31, 2014 in comparison to the same period during 2013. Sales of these bulk reagents aggregated slightly more than 2% and slightly more than 1% of product sales during the years ended December 31, 2014 and 2013, respectively.

ImmuCell Corporation

Gross Margin

Changes in the gross margin on product sales are summarized in the following table for the respective periods (in thousands, except for percentages):

	For the Three-Month Periods Ended December 31,		Increase	
	2014	2013	Amount	%
Gross margin	$1,343	$608	$735	121%
Percent of product sales	61 %	39 %	22 %	56 %

	For the Years Ended December 31,		Increase	
	2014	2013	Amount	%
Gross margin	$4,449	$3,061	$1,388	45%
Percent of product sales	59 %	51 %	8 %	15%

The gross margin as a percentage of product sales was 59% and 51% during the years ended December 31, 2014 and 2013, respectively. This compares to gross margin percentages of 57% and 55% during the years ended December 31, 2012 and 2011, respectively. Our objective for the foreseeable future is to maintain the full-year gross margin percentage over 50%, and we have achieved this objective during all of the full-year periods being reported. The gross margin as a percentage of product sales was 61% and 44% during the six-month periods ended December 31, 2014 and 2013, respectively. We believe the 61% ratio during the second half of 2014 was unusually high and not sustainable over time going forward. We reduced production output during the last six months of 2013 in order to replace and repair certain pieces of critical process equipment, which resulted in an increase in cost of goods sold during that period. The use of more expensive subcontractors during this period also increased our costs. This production slow-down resulted in a few, short delays in shipping customer orders of **First Defense**Ò during the first quarter of 2014. These investments were completed during the fourth quarter of 2013, and our gross margin percentage was again in line with historical norms during 2014. Our inventory balance was reduced by 23%, or $366,000, to $1,207,000 at December 31, 2013 from $1,573,000 as of June 30, 2013. This level of investment as of June 30, 2013 helped us prevent a backlog of orders, while we slowed inventory production to replace and repair the critical pieces of process equipment, discussed above. Largely due to the significant increase in product sales experienced especially during the second half of 2014, our inventory balance was reduced to $946,000 as of December 31, 2014. A number of factors account for the variability in our costs, resulting in some fluctuations in

gross margin percentages from quarter to quarter. The gross margin on **First Defense**Ò is affected by biological yields from our raw material, which do vary over time. Like most U.S. manufacturers, we have been experiencing increases in the cost of raw materials that we purchase. The costs for production of **First Defense**Ò and **Wipe Out**Ò **Dairy Wipes** have increased due to increased labor costs and other expenses associated with our efforts to sustain compliance with cGMP regulations in our production processes. We have been able to minimize the impact of these cost increases by implementing yield improvements. Product mix also affects gross margin in that we earn a higher gross margin on **First Defense**Ò and a lower gross margin on **Wipe Out**Ò **Dairy Wipes**.

Product Development Expenses

Product development expenses increased by 89%, or $1,025,000, to $2,179,000 during the year ended December 31, 2014, as compared to $1,154,000 during 2013. Product development expenses aggregated 29% and 19% of product sales in 2014 and 2013, respectively. The majority of our product development budget from 2000 through 2014 has been focused on the development of **Mast Out**Ò. The balance of our efforts have been primarily focused on other improvements, extensions or additions to our **First Defense**Ò product line. The other improvements, extensions, or additions to our current product line include the potential to prevent scours in calves caused by pathogens other than those within the current **First Defense**Ò disease claims (*E. coli* K99 and coronavirus) such as rotavirus. We also remain interested in acquiring other new products and technologies that fit with our sales focus on the dairy and beef industries.

Sales and Marketing Expenses

Sales and marketing expenses increased by approximately 33%, or $330,000, to $1,317,000 in 2014, increasing to 17% of product sales in 2014 from 16% in 2013. We continue to leverage the efforts of our small sales force by using veterinary distributors. These expenses have increased due principally to a strategic decision to invest more to support **First Defense**Ò sales. This investment may have created, at least in part, our recent increase in product sales. Our current budgetary objective in 2015 is to invest up to 20% of product sales in sales and marketing expenses on an annual basis.

ImmuCell Corporation

Administrative Expenses

Administrative expenses increased by approximately 23%, or $220,000, to $1,159,000 during the year ended December 31, 2014 as compared to $939,000 during 2013. We strive to be efficient with these expenses while funding costs associated with complying with the Sarbanes-Oxley Act of 2002 and other costs associated with being a publicly-held company. Prior to 2014, we had limited our investment in investor relations spending. Beginning in the second quarter of 2014, we initiated an investment in a more actively managed investor relations program. Additionally, we continue to provide full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as in Current Reports on Form 8-K when legally required or deemed appropriate by management. Additional information about us is available in our annual Proxy Statement. All of these reports are filed with the SEC and are available on-line or upon request to the Company.

Net Operating (Loss) Income

The net operating (loss) during the year ended December 31, 2014 of ($206,000) increased from a net operating (loss) of ($20,000) during 2013. In contrast, we recorded net operating income of $245,000 during the year ended December 31, 2012.

Other (expenses) revenues, net

Interest income increased by approximately 24%, or $3,000, to $16,000 during the year ended December 31, 2014, in comparison to $12,000 during 2013. Interest expense decreased by approximately 13%, or $9,000, to $58,000 during the year ended December 31, 2014, in comparison to $67,000 during 2013. During the second quarter of 2013, we received a $250,000 exclusive option payment from a prospective partner for the development and marketing of **Mast Out®**. This payment was recorded as deferred revenue upon receipt. During the third quarter of 2013, this prospective partner decided not to execute a license after its final due diligence. Accordingly, the deferred revenue was recognized during the third quarter of 2013. At the same time, $48,000 in capitalized expenses pertaining to the development of **Mast Out®** were written off. During the first quarter of 2013, we received a payment of approximately $62,000, as an eligible member of the mutual insurance company that provided products liability insurance to us when it was acquired by another insurance company through a sponsored demutualization transaction that was effective as of January 1, 2013. No such similar sources of revenue occurred during 2014. As a result, other (expenses) of ($49,000) during the year ended December 31, 2014 contrast to other revenues of $225,000 during 2013.

(Loss) Income Before Income Taxes and Net (Loss) Income

Our (loss) before income taxes of ($255,000) during the year ended December 31, 2014 is in contrast to income before income taxes of $205,000 during 2013. We recorded an income tax (benefit) expense of (35%) and 43% of the (loss) income before income taxes during the years ended December 31, 2014 and 2013, respectively. Our net (loss) of ($167,000), or ($0.06) per share, during the year ended December 31, 2014 is in contrast to net income of $117,000, or $0.04 per share, during 2013.

Critical Accounting Policies

The financial statements are presented on the basis of accounting principles that are generally accepted in the United States. All professional accounting standards that were effective and applicable to us as of December 31, 2015 have been taken into consideration in preparing the financial statements. The preparation of financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, income taxes, contingencies and the useful lives and carrying values of intangible and long lived assets. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have chosen to highlight certain policies that we consider critical to the operations of our business and understanding our financial statements.

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We recognize revenue in accordance with Staff Accounting Bulletin (SAB) No. 104, “Revenue Recognition”, which supersedes SAB No. 101, “Revenue Recognition in Financial Statements”. SAB No. 104 requires that four criteria are met before revenue is recognized. These include i) persuasive evidence that an arrangement exists, ii) delivery has occurred or services have been rendered, iii) the seller’s price is fixed and determinable and iv) collectability is reasonably assured. We recognize revenue at the time of shipment (including to distributors) for substantially all products, as title and risk of loss pass to the customer on delivery to the common carrier after concluding that collectability is reasonably assured. We recognize service revenue at the time the service is performed. All product development costs and patent costs are expensed as incurred.

Inventory includes raw materials, work-in-process and finished goods and are recorded at the lower of standard cost which approximates cost on the first-in, first-out method or market (net realizable value). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We believe that neither inflation nor interest rates nor currency exchange rates have had a significant effect on our revenues and expenses. However, future increases in inflation or interest rates or the value of the U.S. dollar could affect our customers and the demand for our products. We hope to increase the level of our future sales of products outside the United States. The cost of our products to international customers could be affected by currency fluctuations. The decline of the U.S. dollar against other currencies could make our products less expensive to international customers. Conversely, a stronger U.S. dollar could make our products more costly for international customers. During 2010, we hedged our interest rate exposure to a $1,000,000 mortgage with an interest rate swap agreement that effectively converted a floating interest rate to the fixed rate of 6.04%. During 2015, we hedged our interest rate exposure to a $2,500,000 mortgage with an interest rate swap agreement that effectively converted a floating interest rate to the fixed rate of 4.38%.

ITEM 8 – FINANCIAL STATEMENTS

Our financial statements, together with the notes thereto and the report of the independent registered public accounting firm thereon, are set forth on Pages F-1 through F-21 at the end of this report. The index to these financial

statements is as follows:

ITEM 9 – CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On March 2, 2016, Baker Newman & Noyes, LLC (BNN) informed us of its decision not to submit a proposal for the Company's audit services for the year ending December 31, 2016. BNN believes that, in light of our future growth plans, we would be better served by a larger firm which provides these services to companies in our industry that are subject to the periodic reporting requirements of the Securities Exchange Act of 1934. BNN has agreed to complete its work in auditing the Company's financial statements as of and for the year ended December 31, 2015 and to perform its customary more limited role with respect to a review of the Company's financial statements as of and for the quarter ending March 31, 2016.

There were no disagreements between the Company and BNN on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of BNN, would have caused BNN to make reference to the subject matter of the disagreements in any of BNN's reports on the Company's financial statements, nor were there any "reportable events" as such term is described in Item 304(a)(1)(v) of Regulation S-K. None of such reports contained any adverse opinion or disclaimer of opinion or were qualified or modified as to uncertainty, audit scope or accounting principles.

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Because the Company had not had any indication prior to March 2, 2016 of the possibility of BNN withdrawing as its independent registered public accounting firm, the Company has not yet engaged another certifying independent accountant. The Company is in the process of requesting and reviewing proposals from alternative independent registered public accounting firms.

ITEM 9A – CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. Our management, with the participation of the individual who serves as our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (ii) is accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting. The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Management conducted an evaluation of the effectiveness of the internal controls over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. This evaluation included a review of the documentation of controls, evaluation of the design effectiveness of controls, testing the operating effectiveness of the controls and a conclusion on this evaluation. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2015. Based on management's assessment and those criteria, management believes that the internal control over

financial reporting as of December 31, 2015 was effective.

This Annual Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's internal control report was not subject to attestation by the Company's independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report.

Changes in Internal Controls over Financial Reporting. There was no change in our internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B – OTHER INFORMATION

None

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PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information with respect to our directors is incorporated herein by reference to the section of our 2016 Proxy Statement titled “Election of the Board of Directors”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2015. The information required by this item with respect to our executive officers is contained in Item 1 of Part I of this Annual Report on Form 10-K under the heading “Executive Officers of the Company”. There is no family relationship between any director, executive officer, or person nominated or chosen by the Company to become a director or executive officer.

ITEM 11 – EXECUTIVE COMPENSATION

Information regarding cash compensation paid to our executive officers is incorporated herein by reference to the section of our 2016 Proxy Statement titled “Executive Officer Compensation”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2015.

ITEM 12 – SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information regarding ownership of our common stock by certain owners and management is incorporated herein by reference to the section of our 2016 Proxy Statement titled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2015.

ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information regarding certain relationships and related transactions, and director independence is incorporated herein by reference to the section of our 2016 Proxy Statement titled “Certain Relationships and Related Transactions and Director Independence”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2015.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

Information regarding our principal accounting fees and services is incorporated by reference to the section of our 2016 Proxy Statement titled “Principal Accounting Fees and Services”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2015.

ITEM 15 – EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 of the Company’s 1987 Registration Statement No. 33-12722 on Form S-1 as filed with the Commission).
3.2	Certificate of Amendment to the Company’s Certificate of Incorporation effective July 23, 1990 (incorporated by reference to Exhibit 3.2 of the Company’s Annual Report on Form 10-K for the year ended December 31, 2008).
3.3	Certificate of Amendment to the Company’s Certificate of Incorporation effective August 24, 1992 (incorporated by reference to Exhibit 3.3 of the Company’s Annual Report on Form 10-K for the year ended December 31, 2008).
3.4	Bylaws of the Company as amended (incorporated by reference to Exhibit 3.4 of the Company’s Annual Report on Form 10-K for the year ended December 31, 2008).
4.1	Rights Agreement dated as of September 5, 1995, between the Company and American Stock Transfer and Trust Co., as Rights Agent, which includes as Exhibit A thereto the form of Right Certificate and as Exhibit B thereto the Summary of Rights to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Company’s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2009).
4.1A	First Amendment to Rights Agreement dated as of June 30, 2005 (incorporated by reference to Exhibit 4.1A of the Company’s Current Report on Form 8-K filed on July 5, 2005).
4.1B	Second Amendment to Rights Agreement dated as of June 30, 2008 (incorporated by reference to Exhibit 4.1A of the Company’s Annual Report on Form 10-K for the year ended December 31, 2008).

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4.1C	Third Amendment to Rights Agreement dated as of August 9, 2011 (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2011).
4.1D	Fourth Amendment to Rights Agreement dated as of June 16, 2014 (incorporated by reference to Exhibit 4.1D of the Company's Current Report on Form 8-K filed on June 17, 2014).
4.1E	Fifth Amendment to Rights Agreement dated as of April 15, 2015 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on April 15, 2015).
10.1+	Form of Indemnification Agreement (updated) entered into with each of the Company's Directors and Officers (incorporated by reference to Exhibit 10.3A to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2006).
10.2+	2000 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
10.3+	Form of Incentive Stock Agreement (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
10.4+	Amendment to Employment Agreement between the Company and Michael F. Brigham dated March 26, 2010 (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2009).
10.5+	Amendment to Employment Agreement between the Company and Joseph H. Crabb dated March 26, 2010 (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2009).
10.6+	2010 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2010).
10.7+	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2010).
10.8	Commercial Promissory Note for $1,000,000 between the Company and TD Bank, N.A. dated August 13, 2010 (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).
10.9	Line of Credit Agreement and Promissory Note for up to $500,000 between the Company and TD Bank, N.A. dated August 13, 2010 (incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).
10.10(1)	Loan Agreement between the Company and TD Bank, N.A. dated August 13, 2010 (incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).
10.11	Mortgage Loan Note for $2,500,000 between the Company and TD Bank, N.A. dated September 21, 2015 (incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on September 24, 2015).
10.12	Amended and Restated Loan Agreement between the Company and TD Bank, N.A. dated September 21, 2015 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on September 24, 2015).
10.13(1)	Contract Manufacture Agreement between the Company and Norbrook Laboratories Limited dated as of December 17, 2015 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on December 22, 2015).
10.14	Supply Agreement between the Company and Plas-Pak Industries, Inc. dated as of October 14, 2015 (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the

	three-month period ended September 30, 2015).
14	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14 of the Company's Current Report on Form 8-K filed on March 20, 2014).
16.1	Letter from Baker Newman & Noyes, LLC to the Securities and Exchange Commission (incorporated by reference to Exhibit 16.1 of the Company's Current Report on Form 8-K filed on March 7, 2016).
23	Consent of Baker Newman & Noyes, LLC.
31	Certifications required by Rule 13a-14(a).
32	Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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+ Management contract or compensatory plan or arrangement.

(1) Confidential treatment as to certain portions has been requested, which portions have been omitted and filed separately with the Securities and Exchange Commission

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ImmuCell Corporation

We have audited the accompanying balance sheets of ImmuCell Corporation (the Company) as of December 31, 2015 and 2014, and the related statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of ImmuCell Corporation as of December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

Portland, Maine /s/ Baker Newman & Noyes
March 25, 2016 Limited Liability Company

ImmuCell Corporation

BALANCE SHEETS

	As of December 31, 2015	2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$1,573,328	$850,028
Short-term investments	4,464,000	2,489,000
Inventory	870,207	945,755
Accounts receivable, net	754,104	1,005,292
Prepaid expenses and other assets	211,777	148,399
Current portion of deferred tax asset	0	30,463
Total current assets	7,873,416	5,468,937
PROPERTY, PLANT AND EQUIPMENT, net	5,718,814	3,837,647
LONG-TERM INVESTMENTS	487,000	496,000
LONG-TERM PORTION OF DEFERRED TAX ASSET	471,705	1,230,340
OTHER ASSETS, net	49,712	18,930
TOTAL ASSETS	$14,600,647	$11,051,854
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$662,165	$851,677
Current portion of bank debt	135,840	150,382
Deferred tax liability – current	19,588	0
Deferred revenue	0	6,690
Total current liabilities	817,593	1,008,749
LONG-TERM LIABILITIES:		
Long-term portion of bank debt	3,090,709	745,920
Interest rate swap	78,525	38,817
Total long-term liabilities	3,169,234	784,737
TOTAL LIABILITIES	3,986,827	1,793,486
STOCKHOLDERS' EQUITY:		
Common stock, $0.10 par value per share, 8,000,000 shares authorized, 3,261,148 shares issued at December 31, 2015 and 2014	326,115	326,115

Capital in excess of par value	10,150,190	10,042,305
Accumulated surplus (deficit)	638,672	(574,567)
Treasury stock, at cost, 206,114 and 234,114 shares at December 31, 2015 and 2014, respectively	(450,901)	(512,154)
Accumulated other comprehensive loss	(50,256)	(23,331)
Total stockholders' equity	10,613,820	9,258,368
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$14,600,647	$11,051,854

The accompanying notes are an integral part of these financial statements.

ImmuCell Corporation

STATEMENTS OF OPERATIONS

	For the Years Ended December 31,		
	2015	2014	2013
Product sales	$10,228,689	$7,596,874	$6,007,176
Cost of goods sold	3,977,787	3,147,837	2,946,570
Gross margin	6,250,902	4,449,037	3,060,606
Sales and marketing expenses	1,606,898	1,317,122	986,766
Administrative expenses	1,286,373	1,159,234	939,192
Product development expenses	1,235,309	2,179,079	1,154,200
Operating expenses	4,128,580	4,655,435	3,080,158
NET OPERATING INCOME (LOSS)	2,122,322	(206,398)	(19,552)
Other expenses (revenues), net	58,774	49,053	(224,812)
INCOME (LOSS) BEFORE INCOME TAXES	2,063,548	(255,451)	205,260
Income tax expense (benefit)	850,309	(88,292)	87,865
NET INCOME (LOSS)	$1,213,239	$(167,159)	$117,395
Weighted average common shares outstanding:			
Basic	3,042,376	3,027,001	3,019,407
Diluted	3,165,735	3,027,001	3,085,048
NET INCOME (LOSS) PER SHARE:			
Basic	$0.40	$(0.06)	$0.04
Diluted	$0.38	$(0.06)	$0.04

The accompanying notes are an integral part of these financial statements.

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STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	For the Years Ended December 31,		
	2015	2014	2013
Net income (loss)	$1,213,239	($167,159)	$117,395
Other comprehensive (loss) income:			
Interest rate swap, before taxes	(39,708)	(5,815)	50,384
Income tax applicable to interest rate swap	12,783	2,320	(20,100)
Other comprehensive (loss) income, net of taxes	(26,925)	(3,495)	30,284
Total comprehensive income (loss)	$1,186,314	($170,654)	$147,679

The accompanying notes are an integral part of these financial statements.

ImmuCell Corporation

STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		**Capital in Excess of**	**Accumulated (Deficit)**	Treasury Stock		**Accumulated Other Comprehensive (Loss)**	Total Stockholders'
	Shares	Amount	Par Value	Surplus	Shares	Amount	Income	Equity
BALANCE, December 31, 2012	3,261,148	$326,115	$9,973,146	($524,803)	242,114	($529,655)	($50,120)	$9,194,683
Net income	0	0	0	117,395	0	0	0	117,395
Other comprehensive income, net of taxes	0	0	0	0	0	0	30,284	30,284
Exercise of stock options	0	0	6,436	0	(7,000)	15,314	0	21,750
Tax benefits related to stock options	0	0	398	0	0	0	0	398
Stock-based compensation	0	0	31,359	0	0	0	0	31,359
BALANCE, December 31, 2013	3,261,148	326,115	10,011,339	(407,408)	235,114	(514,341)	(19,836)	9,395,869
Net (loss)	0	0	0	(167,159)	0	0	0	(167,159)
Other comprehensive (loss), net of taxes	0	0	0	0	0	0	(3,495)	(3,495)
Exercise of stock options	0	0	962	0	(1,000)	2,187	0	3,149
Stock-based compensation	0	0	30,004	0	0	0	0	30,004

BALANCE, December 31, 2014	3,261,148	326,115	10,042,305	(574,567)	234,114	(512,154)	(23,331)	9,258,368
Net income	0	0	0	1,213,239	0	0	0	1,213,239
Other comprehensive (loss), net of taxes	0	0	0	0	0	0	(26,925)	(26,925)
Exercise of stock options	0	0	58,957	0	(28,000)	61,253	0	120,210
Tax benefits related to stock options	0	0	25,706	0	0	0	0	25,706
Stock-based compensation	0	0	23,222	0	0	0	0	23,222
BALANCE, December 31, 2015	3,261,148	$326,115	$10,150,190	$ 638,672	206,114	$ (450,901)	$ (50,256)	$10,613,820

The accompanying notes are an integral part of these financial statements.

ImmuCell Corporation

STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,		
	2015	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$1,213,239	($167,159)	$ 117,395
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	525,918	446,045	414,307
Amortization	3,343	2,876	2,894
Deferred income taxes	821,469	(88,590)	87,166
Stock-based compensation	23,222	30,004	31,359
(Gain) loss on disposal of fixed assets	(3,984)	4,519	35,179
Changes in:			
Receivables	251,188	(373,882)	(20,056)
Inventory	75,548	260,753	442,494
Prepaid expenses and other assets	(63,378)	2,548	45,917
Accounts payable and accrued expenses	60,361	178,560	(57,995)
Deferred revenue	(6,690)	6,690	0
Net cash provided by operating activities	2,900,236	302,364	1,098,660
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(2,719,189)	(1,535,558)	(597,697)
Maturities of investments	2,489,000	2,985,000	2,489,000
Purchases of investments	(4,455,000)	(2,985,000)	(3,234,000)
Proceeds from sale of fixed assets	66,215	0	0
Net cash (used for) investing activities	(4,618,974)	(1,535,558)	(1,342,697)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from debt issuance	2,500,000	0	0
Debt principal repayments	(169,753)	(190,312)	(181,445)
Debt issuance costs	(34,125)	0	0
Proceeds from exercise of stock options	120,210	3,149	21,750
Tax benefits related to stock options	25,706	0	398
Net cash provided by (used for) financing activities	2,442,038	(187,163)	(159,297)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	723,300	(1,420,357)	(403,334)
BEGINNING CASH AND CASH EQUIVALENTS	850,028	2,270,385	2,673,719
ENDING CASH AND CASH EQUIVALENTS	$1,573,328	$ 850,028	$ 2,270,385

INCOME TAXES PAID	$3,133	$ 252	$ 0
INTEREST EXPENSE PAID	$77,159	$ 58,413	$ 67,015
NON-CASH ACTIVITIES:			
Capital expenditures included in accounts payable and accrued expenses	$1,510	$ 251,383	$ 23,495
Net change in fair value of interest rate swap	$26,925	$ 3,495	($30,284)

The accompanying notes are an integral part of these financial statements.

ImmuCell Corporation

Notes to Audited Financial Statements

1. BUSINESS OPERATIONS

ImmuCell Corporation (the Company) is a growing animal health company whose purpose is to create scientifically-proven and practical products that improve animal health and productivity in the dairy and beef industries. The Company was originally incorporated in Maine in 1982 and reincorporated in Delaware in 1987, in conjunction with its initial public offering of common stock. We market products that provide immediate immunity to newborn dairy and beef cattle. We are developing product line extensions of our existing products and are in the late stages of developing a novel product that addresses mastitis, the most significant cause of economic loss to the dairy industry. These products help reduce the need to use traditional antibiotics in food producing animals. The Company is subject to certain risks associated with its stage of development including dependence on key individuals, competition from other larger companies, the successful sale of existing products and the development and acquisition of additional commercially viable products with appropriate regulatory approvals, where applicable. These and other risks to our company are further detailed under **PART I: ITEM 1A – RISK FACTORS**.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of presentation

We have prepared the accompanying audited financial statements reflecting all adjustments, all of which are of a normal recurring nature, that are, in our opinion, necessary in order to ensure that the financial statements are not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP in these footnotes are to the FASB *Accounting Standards Codification*™ (Codification). Certain prior year accounts have been reclassified to conform with the 2015 financial statement presentation.

(b) Cash, Cash Equivalents, Short-Term Investments and Long-Term Investments

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits of $250,000 per financial institution per depositor are maintained in money market accounts at financial institutions that are secured, in part, by the Securities Investor Protection Corporation. Amounts in excess of these FDIC limits per bank that are not invested in securities backed by the U.S. government aggregated $1,073,028 and $566,637 as of December 31, 2015 and 2014, respectively. Short-term investments are classified as held to maturity and are comprised principally of certificates of deposit that mature in more than three months from their purchase dates and not more than twelve months from the balance sheet date. Long-term investments are classified as held to maturity and are comprised principally of certificates of deposit that mature in more than twelve months from the balance sheet date. Short-term and long-term investments are held at different financial institutions that are insured by the FDIC, within the FDIC limits per financial institution. See Note 3.

(c) Inventory

Inventory includes raw materials, work-in-process and finished goods and is recorded at the lower of cost, on the first-in, first-out method, or market (net realizable value). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. See Note 4.

(d) Trade Receivables

Trade receivables are carried at the original invoice amount less an estimate made for doubtful collection. Management determines the allowance for doubtful accounts on a monthly basis by identifying troubled accounts and by using historical experience applied to an aging of accounts. Trade receivables are written off when deemed uncollectible. Recoveries of trade receivables previously written off are recorded as income when received. A trade receivable is considered to be past due if any portion of the receivable balance is outstanding for more than 30 days. Interest is charged on past due trade receivables. See Note 5.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

(e) Property, Plant and Equipment

We depreciate property, plant and equipment on the straight-line method by charges to operations in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The cost of our building (which was acquired in 1993) and the 2001 and 2007 additions thereto are being depreciated through 2023. We are depreciating the building addition that was completed during the first quarter of 2015 over twenty-five years. Related building improvements are depreciated over ten year periods. Large and durable fixed assets are depreciated over their useful lives that are generally estimated to be five to ten years. Other fixed assets and computer equipment are depreciated over their useful lives that are generally estimated to be five and three years, respectively. See Note 7.

(f) Intangible Assets

We amortize intangible assets on the straight-line method by charges to operations in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. In connection with certain credit facilities entered into during the third quarters of 2010 and 2015, we incurred debt issue costs of $26,489 and $34,125, respectively, which costs are being amortized to other expenses, net over the terms of the credit facilities. See Notes 6 and 9.

We continually assess the realizability of these assets in accordance with the impairment provisions of Codification Topic 360, *Accounting for the Impairment or Disposal of Long-Lived Assets*. If an impairment review is triggered, we evaluate the carrying value of long-lived assets by determining if impairment exists based on estimated undiscounted future cash flows over the remaining useful life of the assets and comparing that value to the carrying value of the assets. If the carrying value of the asset is greater than the estimated future cash flows, the asset is written down to its estimated fair value. The cash flow estimates that are used contain our best estimates, using appropriate and customary assumptions and projections at the time. We also review the estimated useful life of intangible assets at the end of each reporting period, making any necessary adjustments.

(g) Disclosure of Fair Value of Financial Instruments and Concentration of Risk

Financial instruments consist mainly of cash, cash equivalents, short-term investments, long-term investments, accounts receivable, accounts payable, bank debt and interest rate swaps. Financial instruments that potentially subject the Company to concentrations of credit risk are principally cash, cash equivalents, short-term investments, long-term investments and accounts receivable. We make short-term and long-term investments in financial instruments that are insured by the FDIC. We account for fair value measurements in accordance with Codification Topic 820, *Fair Value Measurements and Disclosures*, which defines fair value, establishes a framework for measuring fair value and requires additional disclosures about fair value measurements. The estimated fair value of cash, cash equivalents, short-term investments, long-term investments, accounts receivable and accounts payable approximate their carrying value due to their short maturities. The estimated fair value of bank debt approximates its carrying value because the interest rates are variable. Interest rate swaps are carried at fair value. See Note 9.

Concentration of credit risk with respect to accounts receivable is principally limited to certain customers to whom we make substantial sales. To reduce risk, we routinely assess the financial strength of our customers and, as a consequence, believe that our accounts receivable credit risk exposure is limited. We maintain an allowance for potential credit losses, but historically we have not experienced significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area.

We believe that supplies and raw materials for the production of our products are available from more than one vendor or farm. Our policy is to maintain more than one source of supply for the components used in our products. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

(h) Interest Rate Swap Agreements

All derivatives are recognized on the balance sheet at their fair value. We entered into interest rate swap

agreements in 2010 and 2015. On the dates the agreements were entered into, we designated the derivatives as hedges of the variability of cash flows to be paid related to our long-term debt. The agreements have been determined to be highly effective in hedging the variability of identified cash flows, so changes in the fair market value of the interest rate swap agreements are recorded as comprehensive income (loss), until earnings are affected by the variability of cash flows (e.g. when periodic settlements on a variable-rate asset or liability are recorded in earnings). We formally documented the relationship between the interest rate swap agreements and the related hedged items. We also formally assess, both at the interest rate swap agreements' inception and on an ongoing basis, whether the agreements are highly effective in offsetting changes in cash flow of hedged items. See Note 9.

(i) Revenue Recognition

We recognize revenue in accordance with Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition". SAB No. 104 requires that four criteria are met before revenue is recognized. These include i) persuasive evidence that an arrangement exists, ii) delivery has occurred or services have been rendered, iii) the seller's price is fixed and determinable and iv) collectability is reasonably assured. We recognize revenue at the time of shipment (including to distributors) for substantially all products, as title and risk of loss pass to the customer on delivery to the common carrier after concluding that collectability is reasonably assured. We recognize service revenue at the time the service is performed.

(j) Expense Recognition

Advertising costs are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to $94,607, $66,193 and $151,080 during the years ended December 31, 2015, 2014 and 2013, respectively. All product development expenses are expensed as incurred, as are all related patent costs.

(k) Income Taxes

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. We believe it is more likely than not that the deferred tax assets will be realized through future taxable income and future tax effects of temporary differences between book income and taxable income. Accordingly, we have not established a valuation allowance for the deferred tax assets. Codification Topic 740-10 clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position must meet before being recognized in the financial statements. In the ordinary course of business, there are transactions and calculations where the ultimate tax outcome is uncertain. In addition, we are subject to periodic audits and examinations by the Internal Revenue Service and other taxing authorities. We have evaluated the positions taken on our filed tax returns. We have concluded that no uncertain tax positions exist as of December 31, 2015. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 11.

(l) Stock-Based Compensation

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model. Accordingly, we recorded compensation expense pertaining to stock-based compensation of $23,222, $30,004 and $31,359 during the years ended December 31, 2015, 2014 and 2013 respectively, which resulted in a decrease to income before income taxes of approximately $0.01 per share during each of the periods reported. Codification Topic 718 requires us to reflect gross tax savings resulting from tax deductions in excess of expense reflected in our financial statements as a financing cash flow.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

(m) Net Income (Loss) Per Common Share

Net Income (Loss) per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share.* The basic Net Income per share has been computed by dividing Net Income by the weighted average number of common shares outstanding during this period. Diluted Net Income per share has been computed by dividing Net Income by the weighted average number of shares outstanding during the period plus all outstanding stock options with an exercise price that is less than the average market price of the common stock during the period less the number of shares that could have been repurchased at this average market price with the proceeds from the hypothetical stock option exercises. The Net (Loss) per common share in 2014 has been computed by dividing the Net (Loss) by the weighted average number of common shares outstanding during the period, without giving consideration to outstanding stock options because the impact would be anti-dilutive. For additional disclosures regarding outstanding common stock options, see Note 12(a) and the table below:

	Year Ended December 31,		
	2015	2014	2013
Weighted average number of shares outstanding	3,042,376	3,027,001	3,019,407
Effect of dilutive stock options	123,359	0	65,641
Diluted number of shares outstanding	3,165,735	3,027,001	3,085,048
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	6,000	253,000	63,875

(n) Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual amounts could differ from those estimates.

(o) New Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. ASU 2014-09 was initially effective for the Company on January 1, 2017. Early application was not permitted. In July 2015, the FASB approved a one-year deferral in the effective date to January 1, 2018, with the option of applying the standard on the original effective date. ASU 2014-09 permits the use of either the retrospective or cumulative effect transition method. We have evaluated the effect that ASU 2014-09 would have on our financial statements and related disclosures. We expect that ASU 2014-09 will have no significant effect on our ongoing financial reporting, but we continue to evaluate this pending accounting standard.

In April 2015, the FASB issued ASU No. 2015-03, *Interest-Imputation of Interest*, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. Under current guidance, our debt issuance costs are reflected as a deferred charge, within other long-term assets on our balance sheets. This update is effective for the annual reporting periods beginning after December 15, 2015. In August 2015, the FASB confirmed that ASU No. 2015-03 did not address the presentation or subsequent measurement of debt issuance costs related to line-of-credit arrangements. For line-of-credit arrangements, borrowers have the option of presenting debt issuance costs as an asset which is subsequently amortized ratably over the term of the line-of-credit arrangement, regardless of whether there are any related outstanding borrowings. ASU No. 2015-03 is not expected to have a material impact on our financial statements.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

In July 2015, the FASB issued ASU No. 2015-11, *Inventory*, which simplifies the existing guidance which requires entities to subsequently measure inventory at the lower of cost or market value. Under ASU No. 2015-11, an entity should measure inventory valued using a first-in, first-out or average cost method at the lower of cost or net realizable value, which is defined as the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This update is effective for public business entities during fiscal years beginning after December 15, 2016. Early adoption is permitted. ASU 2015-11 is not expected to have a material impact on our financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes*, which simplifies the existing guidance which requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. Under ASU No. 2015-17, an entity should classify all deferred tax liabilities and assets as noncurrent within the statement of financial position. The amendments apply to all entities that present a classified statement of financial position and are effective for the public business entities for annual periods beginning after December 15, 2016, including interim periods therein. Earlier application is permitted. In 2016, we intend to early adopt ASU No. 2015-17, which is not expected to have a material impact on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which requires lessees to put most leases on their balance sheet but recognize expenses on their income statements in a manner similar to today's accounting. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods therein. Early adoption is permitted. We are not subject to material lease obligations, and we do not expect ASU 2016-02 to have a material impact on our financial statements.

3. CASH, CASH EQUIVALENTS, SHORT-TERM INVESTMENTS AND LONG-TERM INVESTMENTS

Cash, cash equivalents, short-term investments and long-term investments consisted of the following:

As of December 31,		**Increase (Decrease)**

	2015	2014	
Cash and cash equivalents	$1,573,328	$850,028	$723,300
Short-term investments	4,464,000	2,489,000	1,975,000
Subtotal	6,037,328	3,339,028	2,698,300
Long-term investments	487,000	496,000	(9,000)
Total	$6,524,328	$3,835,028	$2,689,300

4. INVENTORY

Inventory consisted of the following:

	As of December 31,		(Decrease) Increase
	2015	2014	
Raw materials	$284,331	$306,444	($22,113)
Work-in-process	452,024	355,745	96,279
Finished goods	133,852	283,566	(149,714)
Total	$870,207	$945,755	($75,548)

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

5. ACCOUNTS RECEIVABLE

Accounts receivable consisted of the following:

	As of December 31,		**(Decrease) Increase**
	2015	2014	
Trade accounts receivable, gross	$736,195	$1,004,990	($268,795)
Accumulated allowance for bad debt and product returns	(18,092)	(16,194)	(1,898)
Trade accounts receivable, net	718,103	988,796	(270,693)
Other receivables	36,001	16,496	19,505
Accounts receivable, net	$754,104	$1,005,292	($251,188)

6. PREPAID EXPENSES AND OTHER ASSETS

Prepaid expenses and other assets consisted of the following:

	As of December 31,		**Increase (Decrease)**
	2015	2014	
Prepaid expenses and other assets	$183,396	$133,119	$ 50,277
Security deposits	28,381	15,280	13,101
Current subtotal	211,777	148,399	63,378
Debt issue costs	60,614	26,489	34,125
Accumulated amortization of debt issue costs	(19,822)	(16,479)	(3,343)
Security deposits	8,920	8,920	0
Long-term subtotal	49,712	18,930	30,782

Total	$261,489	$167,329	$ 94,160

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following, at cost:

	As of December 31,		Increase (Decrease)
	2015	2014	
Laboratory and manufacturing equipment	$3,766,556	$3,522,465	$244,091
Building and improvements	4,716,204	2,969,891	1,746,313
Office furniture and equipment	568,188	470,607	97,581
Construction in progress[1]	1,084,924	1,270,672	(185,748)
Land	333,486	50,000	283,486
Property, plant and equipment, gross	10,469,358	8,283,635	2,185,723
Accumulated depreciation	(4,750,544)	(4,445,988)	(304,556)
Property, plant and equipment, net	$5,718,814	$3,837,647	$1,881,167

[1] As of December 31, 2015, construction in progress consisted principally of partial payments towards new manufacturing equipment. As of December 31, 2014, construction in progress consisted of a building addition that was completed during the first quarter of 2015.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of December 31,		Increase (Decrease)
	2015	2014	
Accounts payable – capital	$1,510	$251,383	($249,873)
Accounts payable – trade	199,105	204,810	(5,705)
Accrued payroll	242,690	145,176	97,514
Accrued clinical studies	68,428	131,945	(63,517)
Accrued professional fees	56,450	42,250	14,200
Accrued other	93,982	76,113	17,869
Total	$662,165	$851,677	($189,512)

9. BANK DEBT

We have in place certain credit facilities with TD Bank, N.A. (a wholly owned subsidiary of TD Financial Group, which is a multinational bank with approximately $944 billion in assets and over 22 million clients worldwide) which are secured by substantially all of our assets. Proceeds from the $1,000,000 mortgage note were received during the third quarter of 2010. Based on a 15-year amortization schedule, a balloon principal payment of approximately $451,885 will be due during the third quarter of 2020. Proceeds from the $2,500,000 mortgage note were received during the third quarter of 2015. Based on a 20-year amortization schedule, a balloon principal payment of approximately $1,550,007 will be due during the third quarter of 2025. We hedged our interest rate exposure on these mortgage notes with interest rate swap agreements that effectively converted floating interest rates based on the one-month LIBOR plus a bank profit margin to the fixed rates of 6.04% and 4.38%, respectively. As of December 31, 2015, the variable rates on these two mortgage notes were 3.57% and 2.65%, respectively. All derivatives are recognized on the balance sheet at their fair value. At the time of the closings and thereafter, the agreements were determined to be highly effective in hedging the variability of the identified cash flows and have been designated as cash flow hedges of the variability in the hedged interest payments. Changes in the fair value of the interest rate swap agreements are recorded in other comprehensive (loss) income, net of taxes. The original notional amounts of the interest rate swap agreements of $1,000,000 and $2,500,000 amortize in accordance with the amortization of the mortgage notes. The notional amount of the interest rate swaps was $3,226,549 as of December 31, 2015. Payments required by the interest rate swaps totaled $32,515, $22,116 and $23,096 during the years ended December 31, 2015,

2014 and 2013 respectively. As the result of our decision to hedge this interest rate risk, we recorded other comprehensive (loss) income, net of taxes, in the amount of ($26,925), ($3,495) and $30,284 during the years ended December 31, 2015, 2014 and 2013, respectively, which reflects the change in the fair value of the interest rate swap assets (liabilities), net of taxes. The fair values of the interest rate swaps have been determined using observable market-based inputs or unobservable inputs that are corroborated by market data. Accordingly, the interest rate swaps are classified as level 2 within the fair value hierarchy provided in Codification Topic 820, *Fair Value Measurements and Disclosures*. Proceeds from a $600,000 note bearing interest at 4.25% were received during the first quarter of 2011. This note was repaid during the third quarter of 2015. The $500,000 line of credit is available as needed and has been extended through May 31, 2016 and is renewable annually thereafter. The line of credit was unused as of December 31, 2015, 2014 and 2013. Interest on any borrowings against the line of credit would be variable at the higher of 4.25% per annum or the one-month LIBOR plus 3.5% per annum. These credit facilities are subject to certain financial covenants. We are in compliance with all applicable covenants as of December 31, 2015. Principal payments due under debt outstanding as of December 31, 2015 are reflected in the following table by the year that payments are due:

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

Period	$1,000,000 Mortgage Note	$2,500,000 Mortgage Note	Total
Year ending December 31, 2016	$57,384	$78,456	$135,840
Year ending December 31, 2017	61,056	82,308	143,364
Year ending December 31, 2018	64,876	86,097	150,973
Year ending December 31, 2019	68,908	89,997	158,905
Year ending December 31, 2020	493,696	94,005	587,701
After December 31, 2020	0	2,049,766	2,049,766
Total	$745,920	$2,480,629	$3,226,549

10. OTHER EXPENSES (REVENUES), NET

Other expenses (revenues), net, consisted of the following:

	Year Ended December 31,		
	2015	2014	2013
License option fee[1]	$0	$0	($250,000)
Royalty income	0	0	3,000
Interest income	(19,169)	(15,552)	(12,493)
Interest expense	80,235	57,827	66,689
Debt issuance amortization	3,343	2,876	2,894
Other (gains) losses	(5,635)	3,902	(34,902)
Other expenses (revenues), net	$58,774	$49,053	($224,812)

[1] During the second quarter of 2013, we received a $250,000 exclusion option fee from a prospective partner for the development and marketing of **Mast Out^{Ò}**. This payment was recorded as deferred revenue upon receipt. During the third quarter of 2013, this prospective partner decided not to execute a license after its final due diligence. Accordingly, the deferred revenue was recognized during the third quarter of 2013. At the same time, $47,604 in capitalized expenses pertaining to the development of **Mast Out^{Ò}** were written off.

11. INCOME TAXES

Our income tax expense (benefit) aggregated $850,309, ($88,292) and $87,865 (amounting to 41%, (35%) and 43% of the income (loss) before income taxes, respectively) for the years ended December 31, 2015, 2014 and 2013, respectively.

In 2015, we utilized approximately $1,700,000 of net operating loss carryforwards to offset otherwise taxable income. As of December 31, 2015, we have federal net operating loss carryforwards of approximately $115,000 that expire in 2031, if not utilized before then. Additionally, we have federal general business tax credit carryforwards of approximately $262,000 that expire in 2027 through 2034, if not utilized before then, as well as approximately $78,000 of state tax credits. The $965,000 licensing payment that we made during the fourth quarter of 2004 was treated as an intangible asset and is being amortized over 15 years, for tax return purposes only. Approximately $1,112,000 of our investment in a small-scale facility to produce the Drug Substance (our Active Pharmaceutical Ingredient, Nisin) for **Mast Out**Ò was expensed as incurred for our books. Included in this amount is approximately $820,000 that was capitalized and is being depreciated over statutory periods for tax return purposes only.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

The income tax provision consisted of the following:

	Year Ended December 31,		
	2015	2014	2013
Current-state	$3,150	$ 252	$301
Federal	641,733	(77,986)	74,713
State	205,426	(10,558)	12,851
Deferred	847,159	(88,544)	87,564
Total	$850,309	($88,292)	$87,865

The actual income tax (benefit) expense differs from the expected tax computed by applying the U.S. federal corporate tax rate of 34% to income before income tax as follows:

	Year Ended December 31,		
	2015	2014	2013
Computed expected tax expense (benefit)	$701,607	($86,853)	$69,788
State income taxes, net of federal expense (benefit)	32,699	(6,968)	8,482
Share-based compensation	(7,524)	10,201	10,526
Research and development tax credit	(42,664)	(19,405)	(21,887)
State income tax rate change, net of federal [1]	109,112	0	0
Other	57,079	14,733	20,956
Total income tax (benefit) expense	$850,309	($88,292)	$87,865

[1] This impact is due to the actual state tax rate in 2015 being lower than the expected state tax rate used in computing prior deferred taxes.

The significant components of our deferred tax asset consisted of the following:

As of December 31,

	2015	2014
Product rights	$91,344	$130,036
Property, plant and equipment	(26,717)	225,229
Federal and state tax credits	339,585	266,078
Federal net operating loss carryforward	39,241	464,998
State net operating loss carryforward	0	165,901
Interest rate swap	28,253	15,486
Prepaid expenses and other	(19,589)	(6,925)
Deferred tax asset	$452,117	$1,260,803

Deferred tax assets are recognized only when it is probable that sufficient taxable income will be available in future periods against which deductible temporary differences and credits may be utilized. However, the amount of the deferred tax asset could be reduced if projected income is not achieved due to various factors, such as unfavorable business conditions. If projected income is not expected to be achieved, we would decrease the deferred tax asset to the amount that we believe can be realized.

Net operating loss carryforwards, credits, and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service. Section 382 of the Internal Revenue Code contains provisions that could place annual limitations on the future utilization of net operating loss carryforwards and credits in the event of a change in ownership of the Company, as defined.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

The Company files income tax returns in the U.S. federal jurisdiction and several state jurisdictions. With few exceptions, the Company is no longer subject to income tax examinations by tax authorities for years before 2012. We currently have no tax examinations in progress. We also have not paid additional taxes, interest or penalties as a result of tax examinations nor do we have any unrecognized tax benefits for any of the periods in the accompanying financial statements.

12. STOCKHOLDERS' EQUITY

(a) Stock Option Plans

In June 2000, our stockholders approved the 2000 Stock Option and Incentive Plan (the "2000 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at i) no less than fair market value on the date of grant in the case of incentive stock options and ii) no less than 85% of fair market value on the date of grant in the case of non-qualified stock options. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. Originally, 250,000 shares of common stock were reserved for issuance under the 2000 Plan. The stockholders of the Company approved an increase in this number to 500,000 shares in June 2001. All options granted under the 2000 Plan expire no later than ten years from the date of grant. The 2000 Plan expired in February 2010, after which date no further options could be granted under the 2000 Plan. However, outstanding options under the 2000 Plan may be exercised in accordance with their terms.

In June 2010, our stockholders approved the 2010 Stock Option and Incentive Plan (the "2010 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at i) no less than fair market value on the date of grant in the case of incentive stock options and ii) no less than 85% of fair market value on the date of grant in the case of non-qualified stock options. At that time, 300,000 shares of common stock were reserved for issuance under the 2010 Plan. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. All options granted under the 2010 Plan expire no later than ten years from the date of grant.

Activity under the stock option plans described above was as follows:

	2000 Plan	2010 Plan	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2012	163,500	49,500	$ 3.13	$185,000
Grants	0	26,000	$ 4.67	
Terminations	0	(1,000)	$ 3.15	
Exercises	(6,000)	(1,000)	$ 3.11	
Outstanding at December 31, 2013	157,500	73,500	$ 3.30	$223,000
Grants	0	25,000	$ 4.69	
Terminations	0	(2,000)	$ 5.75	
Exercises	0	(1,000)	$ 3.15	
Outstanding at December 31, 2014	157,500	95,500	$ 3.42	$364,000
Grants	0	16,000	$ 7.40	
Terminations	0	(3,000)	$ 4.95	
Exercises	(26,000)	(2,000)	$ 4.29	
Outstanding at December 31, 2015	131,500	106,500	$ 3.57	$945,000
Exercisable at December 31, 2015	131,500	41,500	$ 2.90	$803,000
Reserved for future grants	0	189,500		

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

During the year ended December 31, 2015, eleven employees exercised stock options covering the aggregate of 28,000 shares. These options were exercised for cash, resulting in total proceeds of $120,210. During the year ended December 31, 2014, one employee exercised stock options covering 1,000 shares. These options were exercised for cash, resulting in total proceeds of $3,149. During the year ended December 31, 2013, four employees exercised stock options covering the aggregate of 7,000 shares. These options were exercised for cash, resulting in total proceeds of $21,750. At December 31, 2015, 238,000 shares of common stock were reserved for future issuance under all outstanding stock options described above, and an additional 189,500 shares of common stock were reserved for the potential issuance of stock options in the future under the 2010 Plan. The weighted average remaining life of the options outstanding under the 2000 Plan and the 2010 Plan as of December 31, 2015 was approximately four years and three months. The weighted average remaining life of the options exercisable under these plans as of December 31, 2015 was approximately three years. The exercise prices of the options outstanding as of December 31, 2015 ranged from $1.70 to $7.54 per share. The 16,000 stock options granted during 2015 had exercise prices between $6.05 and $7.54 per share. The 25,000 stock options granted during 2014 had exercise prices between $4.25 and $4.80 per share. The 26,000 stock options granted during 2013 had exercise prices between $4.15 and $4.69 per share. The aggregate intrinsic value of options exercised during 2015, 2014 and 2013 approximated $110,000, $1,000 and $8,000, respectively. The weighted-average grant date fair values of options granted during 2015, 2014 and 2013 were $3.46, $2.26 and $2.23 per share, respectively. As of December 31, 2015, total unrecognized stock-based compensation related to non-vested stock options aggregated $120,619. That cost is expected to be recognized at a declining rate over the remaining vesting period of the outstanding non-vested stock options, including $43,116 during 2016. The fair value of each stock option grant has been estimated on the date of grant by an independent appraiser using the Black-Scholes option pricing model, for the purpose discussed in Note 2(1), with the following weighted-average assumptions:

	2015		2014		2013	
Risk-free interest rate	2.0	%	2.0	%	1.6	%
Dividend yield	0	%	0	%	0	%
Expected volatility	47	%	49	%	49	%
Expected life	6 years		6 years		6 years	

The risk-free interest rate is based on U.S. Treasury yields for a maturity approximating the expected option term, while the other assumptions are derived from averages of our historical data.

(b) Common Stock Rights Plan

In September 1995, our Board of Directors adopted a Common Stock Rights Plan (The Rights Plan) and declared a dividend of one common share purchase right (a “Right”) for each of the then outstanding shares of the common stock of the Company. Each Right entitles the registered holder to purchase from the Company one share of common stock at an initial purchase price of $70.00 per share, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement between the Company and American Stock Transfer & Trust Co., as Rights Agent.

The Rights (as amended) become exercisable and transferable apart from the common stock upon the earlier of i) 10 days following a public announcement that a person or group (Acquiring Person) has, without the prior consent of the Continuing Directors (as such term is defined in the Rights Agreement), acquired beneficial ownership of 20% or more of the outstanding common stock or ii) 10 days following commencement of a tender offer or exchange offer the consummation of which would result in ownership by a person or group of 20% or more of the outstanding common stock (the earlier of such dates being called the Distribution Date).

Upon the Distribution Date, the holder of each Right not owned by the Acquiring Person would be entitled to purchase common stock at a discount to the initial purchase price of $70.00 per share, effectively equal to one half of the market price of a share of common stock on the date the Acquiring Person becomes an Acquiring Person. If, after the Distribution Date, the Company should consolidate or merge with any other entity and the Company were not the surviving company, or, if the Company were the surviving company, all or part of the Company’s common stock were changed or exchanged into the securities of any other entity, or if more than 50% of the Company’s assets or earning power were sold, each Right would entitle its holder to purchase, at the Rights’ then-current purchase price, a number of shares of the acquiring company’s common stock having a market value at that time equal to twice the Right’s exercise price.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

At any time after a person or group becomes an Acquiring Person and prior to the acquisition by such person or group of 50% or more of the outstanding common stock, the Board of Directors of the Company may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of common stock per Right (subject to adjustment). At any time prior to 14 days following the date that any person or group becomes an Acquiring Person (subject to extension by the Board of Directors), the Board of Directors of the Company may redeem the then outstanding Rights in whole, but not in part, at a price of $0.005 per Right, subject to adjustment.

On June 8, 2005, our Board of Directors voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years, to September 19, 2008. As of June 30, 2005, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. On June 6, 2008 our Board of Directors voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years, to September 19, 2011 and to increase the ownership threshold for determining “Acquiring Person” status from 15% to 18%. As of June 30, 2008, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase. On August 5, 2011, our Board of Directors voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2014 and to increase the ownership threshold for determining “Acquiring Person” status from 18% to 20%. As of August 9, 2011, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase. On June 10, 2014, our Board of Directors voted to authorize an amendment to the Rights Agreement to extend the final expiration date by an additional three years to September 19, 2017. As of June 16, 2014, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. No other changes have been made to the terms of the Rights or the Rights Agreement.

During the second quarter of 2015, we amended our Common Stock Rights Plan by removing a provision that prevented a new group of directors elected following the emergence of an Acquiring Person (an owner of more than 20% of our stock) from controlling the Rights Plan by maintaining exclusive authority over the Rights Plan with pre-existing directors. We did this because such provisions have come to be viewed with disfavor by Delaware courts.

Our Board of Directors believes that there is some risk that the potential value of the **Mast Out®** product development initiative is not fairly reflected in the market price of our common stock, as it fluctuates from time to time, and that opportunistic buyers could take advantage of that disparity to the detriment of our stockholders. If this were to happen and result in a potential threat through an unsolicited acquisition effort or otherwise, our Board of Directors feels that the Rights Plan could enhance stockholder value by providing management with negotiating leverage.

13. COMMITMENTS AND CONTINGENT LIABILITIES

Our bylaws, as amended, in effect provide that the Company will indemnify its officers and directors to the maximum extent permitted by Delaware law. In addition, we make similar indemnity undertakings to each director through a separate indemnification agreement with that director. The maximum payment that we may be required to make under such provisions is theoretically unlimited and is impossible to determine. We maintain directors' and officers' liability insurance, which may provide reimbursement to the Company for payments made to, or on behalf of, officers and directors pursuant to the indemnification provisions. Our indemnification obligations were grandfathered under the provisions of Codification Topic 460*, Guarantees*. Accordingly, we have recorded no liability for such obligations as of December 31, 2015. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

As of December 31, 2015, we had committed approximately $173,000 to capital expenditures, $525,000 to the production of inventory and an additional $222,000 to other obligations.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

We enter into agreements with third parties in the ordinary course of business under which we are obligated to indemnify such third parties from and against various risks and losses. The precise terms of such indemnities vary with the nature of the agreement. In many cases, we limit the maximum amount of our indemnification obligations, but in some cases those obligations may be theoretically unlimited. We have not incurred material expenses in discharging any of these indemnification obligations, and based on our analysis of the nature of the risks involved, we believe that the fair value of the liabilities potentially arising under these agreements is minimal. Accordingly, we have recorded no liabilities for such obligations as of December 31, 2015.

The development, manufacturing and marketing of animal health care products entails an inherent risk that liability claims will be asserted against us. We feel that we have reasonable levels of liability insurance to support our operations.

14. SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

We principally operate in the business segment described in Note 1. Pursuant to Codification Topic 280, *Segment Reporting*, we operate in one reportable business segment, that being the development, acquisition, manufacture and sale of products that improve the health and productivity of cows for the dairy and beef industries. Almost all of our internally funded product development expenses are in support of such products. The significant accounting policies of this segment are described in Note 2.

Our primary customers for the majority of our product sales (83% for each of the years ended December 31, 2015, 2014 and 2013) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 14%, 13% and 14% of our total product sales for the years ended December 31, 2015, 2014 and 2013, respectively. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

	Year Ended December 31,		
	2015	2014	2013
Animal Health International, Inc.[1]	42%	38 %	38 %
MWI Animal Health [2] [3]	20%	23 %	22 %

Accounts receivable due from significant customers amounted to the percentages of total trade accounts receivable as detailed in the following table:

	As of December 31,	
	2015	2014
MWI Animal Health[2]	27 %	26 %
Animal Health International, Inc.[1]	26 %	45 %
ANIMART LLC[4]	11 %	*

[1]During June 2015, Patterson Companies, Inc. (NASDAQ: PDCO) acquired Animal Health International, Inc.

[2]During March 2015, AmerisourceBergen Corporation (NYSE: ABC) acquired MWI Animal Health.

[3]Assumes that the November 2013 acquisition of IVESCO by MWI had occurred as of the beginning of the periods being reported.

[4]Assumes that the acquisition of Animal Medic by ANIMART LLC had occurred as of the beginning of the periods being reported.

*Amount is less than 10%.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

15. RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone Inc. (formerly Stearns Veterinary Outlet, Inc.), a domestic distributor of ImmuCell products (**First Defense**Ò, **Wipe Out**Ò **Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased $573,165, $426,358 and $395,042 of products from ImmuCell during the years ended December 31, 2015, 2014 and 2013, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of $3,222, $7,330 and $6,010 to these affiliate companies during the years ended December 31, 2015, 2014 and 2013, respectively. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated $36,528 and $18,796 as of December 31, 2015 and 2014, respectively.

16. EMPLOYEE BENEFITS

We have a 401(k) savings plan (the Plan) in which all employees completing one month of service with the Company are eligible to participate. Participants may contribute up to the maximum amount allowed by the Internal Revenue Service. Since August 2012, we have matched 100% of the first 3% of each employee's salary that is contributed to the Plan and 50% of the next 2% of each employee's salary that is contributed to the Plan. Under this matching plan, we paid $73,514, $65,633 and $56,036 into the plan for the years ended December 31, 2015, 2014 and 2013, respectively.

17. UNAUDITED QUARTERLY FINANCIAL DATA

The following tables present the quarterly information for the years ended December 31, 2015, 2014 and 2013, respectively:

	Three Months Ended			
	March 31	June 30	September 30	December 31
Fiscal 2015:				

Product sales	$ 3,101,491	$ 1,960,363	$ 2,472,428	$ 2,694,407
Gross margin	1,850,925	1,130,574	1,611,902	1,657,502
Product development expenses	330,665	271,759	301,746	331,139
Net operating income	820,052	213,983	626,850	461,437
Net income	479,082	94,058	351,292	288,807
Net income per common share:				
Basic	$ 0.16	$ 0.03	$ 0.12	$ 0.09
Diluted	$ 0.15	$ 0.03	$ 0.11	$ 0.09
Fiscal 2014:				
Product sales	$ 2,081,752	$ 1,539,719	$ 1,770,129	$ 2,205,275
Gross margin	1,149,895	878,523	1,077,896	1,342,722
Product development expenses	594,209	760,672	361,232	462,965
Net operating income (loss)	12,561	(458,667)	40,853	198,856
Net (loss) income	(13,335)	(294,781)	10,330	130,626
Net (loss) income per common share:				
Basic	($0.00)	($0.10)	$ 0.00	$ 0.04
Diluted	($0.00)	($0.10)	$ 0.00	$ 0.04
Fiscal 2013:				
Product sales	$ 1,846,734	$ 1,366,493	$ 1,234,701	$ 1,559,248
Gross margin	1,053,567	783,677	615,717	607,644
Product development expenses	266,479	271,858	290,853	325,010
Net operating income (loss)	326,666	23,722	(159,967)	(209,975)
Net income (loss)	204,310	6,452	57,336	(150,703)
Net income (loss) per common share:				
Basic	$ 0.07	$ 0.00	$ 0.02	($0.05)
Diluted	$ 0.07	$ 0.00	$ 0.02	($0.05)

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

18. SUBSEQUENT EVENTS

We have adopted the disclosure provisions of Codification Topic 855-10-50-1, *Subsequent Events*, which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued. Entities are required to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. Codification Topic 855-10-50-1 requires additional disclosures only, and therefore did not have an impact on our financial condition, results of operations, earnings per share or cash flows. Public entities must evaluate subsequent events through the date that financial statements are issued. Accordingly, we have evaluated subsequent events through the time of filing on March 25, 2016, the date we have issued this Annual Report on Form 10-K.

On January 4, 2016, we acquired certain business assets from DAY 1™ Technology, LLC of Minnesota. The acquired rights and know-how are primarily related to formulating our bovine antibodies into a gel solution for oral delivery to newborn calves via a syringe (or “tube”). This product format offers customers an alternative delivery option to the bolus (the standard delivery format of the bivalent **First Defense®** product since first USDA approval and product launch in 1991) and could allow more significant penetration into the beef market. The formulation was developed by DAY 1™ Technology for us and has been sold as a feed product without disease claims since 2012. This purchase also includes certain other related private-label products that could generate approximately $300,000 in annual sales. The estimated fair values of the assets purchased in this transaction included inventory of $113,000, machinery and equipment of $132,000 in addition to certain intellectual property intangibles. The total purchase price was approximately $534,000. Approximately $368,000 of this amount was paid as of the closing date, and the remaining balance will be paid upon successful technology transfer and as a royalty on related product sales made through December 31, 2018. The impact of the acquisition on our proforma prior year operations is not significant.

On February 3, 2016, we sold 1,123,810 shares of common stock at a price to the public of $5.25 per share in an underwritten public offering raising gross proceeds of approximately $5,900,000. The net proceeds, (after deducting underwriting discounts and other expenses related to the issuance) of approximately $5,323,000 will be used to construct and equip a facility that will produce Nisin, the active ingredient in **Mast Out®**.

During January 2016, we signed a commitment letter covering certain credit facilities with TD Bank N.A. aggregating approximately $4.3 million comprised of: (a) a $3.3 million construction loan, drawable over an 18-month period at

up to 80% of the cost of equipment installed in the to be constructed commercial-scale production facility for **Mast Out®**, during which interest only will be payable at a variable rate equal to the 30-day LIBOR plus 2.25%, which converts to a seven-year term loan facility at the end of construction at the same interest rate with monthly principal and interest payments based on a seven-year amortization schedule and (b) a $1.0 million construction loan, drawable over a 12-month period at up to 75% of the appraised value of the to be constructed commercial-scale production facility for **Mast Out®**, during which interest only will be payable at a variable rate equal to the 30-day LIBOR plus 2.25%, which converts to a nine-year term loan facility at the end of construction at the same interest rate with monthly principal and interest payments based on a twenty-year amortization schedule. On March 11, 2016 we signed a revised commitment letter decreasing the equipment loan component to $2.5 million and increasing the mortgage component to $2.0 million. These credit facilities are subject to customary closing conditions and certain financial covenants.

During the first quarter of 2016, we paid $20,500 for an option to purchase additional land nearby to our Portland facility that could be used to construct an 8,000 square foot building should we decide to exercise the option before the end of 2016 for an additional $184,500.

ImmuCell Corporation

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ImmuCell Corporation
Registrant

Date: March 25, 2016 By: /s/ Michael F. Brigham
Michael F. Brigham

President, Chief Executive Officer and Principal Financial Officer

POWER OF ATTORNEY

We, the undersigned directors of ImmuCell Corporation, hereby severally constitute and appoint Michael F. Brigham our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for us and in our stead, in any and all capacities, to sign any and all amendments to this report and all documents relating thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing necessary or advisable to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or to be done by virtue hereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Date: March 17, 2016 By: /s/ Michael F. Brigham
Michael F. Brigham

President, Chief Executive Officer,

Principal Financial Officer and Director

Date: March 17, 2016 By: /s/ Joseph H. Crabb
Joseph H. Crabb, Ph.D., Director

Date: March 17, 2016 By: /s/ David S. Cunningham
David S. Cunningham, Director

Date: March 17, 2016 By: /s/ Linda Rhodes
Linda Rhodes, VMD, Ph.D., Director

Date: March 17, 2016 By: /s/ Jonathan E. Rothschild
Jonathan E. Rothschild, Director

Date: March 17, 2016 By: /s/ David S. Tomsche
David S. Tomsche, DVM, Director

Date: March 17, 2016 By: /s/ Paul R. Wainman
Paul R. Wainman, Director

ImmuCell Corporation

EXHIBIT INDEX

Exhibit 23	Consent of Baker Newman & Noyes, LLC
Exhibit 31	Certifications required by Rule 13a-14(a)
Exhibit 32	Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.