

**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, 2016

**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

(State or other jurisdiction of
incorporation or organization)

01-0382980

(I.R.S. Employer
Identification No.)

56 Evergreen Drive, Portland, Maine

(Address of principal executive offices)

04103

(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, 2016 was approximately \$22,866,000 based on the closing sales price on June 30, 2016 of \$6.90 per share.

The number of shares of the Registrant's common stock outstanding at March 20, 2017 was 4,848,390.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement to be filed in connection with the 2017 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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ITEM 1 – BUSINESS

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 ongoing and 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 current products and 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 and cost 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 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 expressions. In 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, customer acceptance of our new and existing products, alignment between our manufacturing resources and product demand, the uncertainties associated with product development and Drug Substance manufacturing, actual as compared to expected or estimated costs of expanding our manufacturing facilities, 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 under **Item 1A** below and uncertainties otherwise referred to in this Annual Report.

Summary

ImmuCell Corporation was founded in 1982 and completed an initial public offering of common stock in 1987. After achieving approval from the Center for Veterinary Biologics, 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 that improve animal health and productivity in the dairy and beef industries. We aim to capitalize on the growth in sales of **First Defense**[®] (a product that provides significant immediate immunity to newborn dairy and beef livestock) and to revolutionize the mastitis treatment paradigm (with a product we are developing to treat this most significant cause of economic loss to the dairy industry).

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). Regulatory achievements to date have significantly reduced the product development risks in the areas of safety and effectiveness. Our primary product development focus has now turned to the manufacturing objectives required for FDA approval.

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Since 2006, we have made 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. As we make process improvements, we continue to invest 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 (at the time we focused our strategy on products for the dairy and beef industries) in comparison to approximately 4,847,000 shares outstanding as of December 31, 2016. There were approximately 480,000 and 251,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 1998 and 2016, respectively. During 2016, we issued an aggregate of 1,783,690 shares of common stock, raising gross proceeds of approximately \$9,364,000 in two separate transactions. In order to minimize the dilutive effects of such transactions on our existing stockholders, we chose not to issue any form of convertible or preferred securities and issued these common shares without any warrants. We also raised up to approximately \$6.5 million in new debt availability (during the first quarter of 2016 and amended during the first quarter of 2017). We intend to use this new capital to complete the development of **Mast Out**[®] without relying on funding from a partner, thereby retaining control over all product rights and potential revenues.

Our operations are generally profitable, except when we elect to make unusually large investments in product development expenses. During these eighteen years in which we have 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 Eighteen- Year Period	=	As of December 31, 2016	Net % Increase Over Eighteen- Year Period
Cash, cash equivalents, short-term investments and long-term investments	\$1,539		\$9,085		\$10,624	590%
Net working capital	\$1,866		\$10,423		\$12,289	559%
Total assets	\$3,145		\$21,552		\$24,697	685%
Stockholders' equity	\$2,248		\$17,474		\$19,722	777%

Animal Health Products

Our lead product, **First Defense**[®], is manufactured from hyperimmune cows' colostrum (the milk that a cow produces immediately after giving birth) utilizing our proprietary vaccine and milk protein purification technologies. The target disease, bovine enteritis (calf scours), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. **First Defense**[®] is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against *E. coli* K99 and coronavirus (two leading causes of scours). We are working to add a third claim (rotavirus) to our product line during 2017. **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 2016 marked the 25th anniversary of the original USDA approval of this product in 1991. During the third quarter of 2016, we sold the 18,000,000th dose of **First Defense**[®]. We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product. In 2011, we began selling nutritional and feed supplement product

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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 are working to add USDA claims to these product formats. We utilize one liquid processing production line and two filling and formulating production lines and one quality system for all of our milk-based products.

During 1999, we acquired **Wipe Out**[®] **Dairy Wipes**, which has been our second leading source of product sales. **Wipe Out**[®] **Dairy Wipes** consist of towelettes that are pre-moistened with a Nisin-based formulation to prepare the teat area of a cow in advance of milking. **Wipe Out**[®] **Dairy Wipes** were manufactured in compliance with cGMP regulations, as required by federal law. As a product line extension, we developed 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 the first quarter of 2017 based on an extensive review of this product line, we discontinued the production and sale of the topical wipes product line due to its limited sales growth potential and minimal contribution to profits.

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.

In connection with our acquisition of certain gel formulation technologies during the first quarter of 2016, we also acquired certain products that we now produce and sell under private label relationships with Ridley, USA Inc. of Mankato, MN and Genex Cooperative Inc. of Shawano, WI.

Sales and Markets

Our sales and marketing team currently consists of one vice president, five regional managers and one inside sales and marketing employee. 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**[®] and **CMT** are 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 these products. 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 of **First Defense**[®] 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 sold **Wipe Out**[®] **Dairy Wipes** to distributors, bovine veterinarians and directly to producers.

International product sales represented approximately 13% and 16% of our total product sales for the years ended December 31, 2016 and 2015, respectively. The majority of these international sales were to Canada. We currently price our products in U.S. dollars. To the extent that the value of the dollar declines with respect to any other currency, our competitive position may be enhanced. Conversely, an increase in the value of the dollar in any country in which we sell products may have the effect of increasing the local price of our products, thereby leading to a potential reduction in demand. The value of the Canadian dollar has declined recently, but this has not correlated with a decrease in our sales into Canada. Generally, our international sales are generated through relationships with in-country distributors that have knowledge of the local regulatory and marketing requirements. We continue our efforts to grow sales of **First Defense**[®] in North America, where there are approximately 40,200,000 dairy and beef cows in the United States and 4,795,000 dairy and beef cows in Canada. We believe that even greater market opportunities exist in other international territories. There are estimated to be approximately 67,000,000 dairy and beef cows in China, 35,850,000 in the European Union, 20,306,000 in Australia and New Zealand, 10,175,000 in Mexico, 1,344,000 in South Korea and 1,340,000 in Japan. However, industry practices, economic conditions, cause of disease, distribution channels and regulatory requirements may differ in these international markets from what we experience in North America.

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We introduced **First Defense**[®] into South Korea in 2005 through Medexx Co., Ltd of Gyeonggi-do, Korea and its equivalent into Japan in 2007 through NYS Co., Ltd of Iwate, Japan. We entered into a distribution agreement with Beijing Starbiopharm Inc. of Beijing, China covering China during 2014. We entered into distribution contracts covering certain Middle Eastern countries with Triplest for Drugs and Trade of Madaba, Jordan during the first quarter of 2017 and covering Iran with Senikco, LLC of Laguna Niguel, CA during the fourth quarter of 2016.

With **Mast Out**[®], we are working to expand our product offerings to include an intramammary treatment for subclinical mastitis for the mother cow during lactation. 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. 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. Some industry experts have estimated that subclinical mastitis costs the U.S. dairy industry approximately \$1 billion per year. Our active ingredient, 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. 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 which would be a significant competitive advantage for our product. No other FDA-approved mastitis treatment product on the market can offer this value proposition. Because the milk from cows treated with traditional antibiotics must be discarded, most dairy producers simply do not treat subclinically infected cows. 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. 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 have estimated that the approximate cost to the U.S. dairy industry of this discarded milk may be around \$300 million per year. 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. The ability to treat such cases without a milk discard could revolutionize the way mastitis is managed in a herd. It is common practice to move sick cows from their regular herd group to a sick cow group for treatment and the related milk discard. This movement causes stress on the cow and a reduction in milk production. Cows treated with **Mast Out**[®] would not have to be moved, allowing this costly drop in production to be avoided. **Mast Out**[®] likely will be priced at a premium to the traditional antibiotic products currently on the market, which are all sold subject to a milk discard requirement. We believe that the product's value proposition demonstrates a return on investment to the producer that will justify this premium.

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. Many fear that the possible overuse of antibiotics in livestock undermines the effectiveness of drugs to combat human illnesses and contributes to a rising number of life-threatening human infections from antibiotic-resistant bacteria, commonly known as "superbugs". 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 antibiotics (including 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 FDA's Veterinary Feed Directive (VFD) became effective January 1, 2017 restricting the use of

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medically important antibiotics for performance purposes and requiring more oversight of antibiotic usage in food producing animals by a veterinarian, and more changes and restrictions are likely. Several major food processors and retailers have implemented policies addressing this growing public health concern. By reducing the risk of antibiotic residues and slowing the development of antibiotic-resistant organisms, we can improve food quality and preserve medically important antibiotics for human disease treatment. This would not be a concern for **Mast Out**[®] because Nisin is not used for human health. This current environment could be favorable to the introduction of a new product such as **Mast Out**[®] 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**[®] 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**[®] claim spectrum. This compares to approximately 2% of the U.S. herd that is thought to be infected with clinical mastitis, where approximately \$60 million per year is spent on drug treatments. We have estimated that first year domestic sales of our product could be approximately \$5.8 million and that annual sales could grow to approximately \$36.1 million by the fifth year after market launch. Actual sales results could be higher or lower. Key assumptions underlying these estimates include there being 7.65 million 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. We believe that similar market opportunities also exist outside of the United States and for the treatment of dry (non-lactating) cows. The manufacturing facility that we are constructing could have enough capacity to meet approximately \$13 million of the sales projected for the second or third year after product launch. Our construction plans allow for additional equipment to be installed in this facility in future years, which (when considered with anticipated yield improvements) could more than double the initial production capacity. This incremental investment would only be made after market acceptance of the product is demonstrated.

Product Development

The majority of our product development spending is focused on the development of **Mast Out**[®]. During the seventeen-year period that began on January 1, 2000 (the year we began the development of **Mast Out**[®]) and ended on December 31, 2016, we invested the aggregate of approximately \$12,409,000 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**[®], most of which was earned from 2001 to 2007.

During 2000, we acquired an exclusive license from Nutrition 21, Inc. (formerly Applied Microbiology Inc. or AMBI) to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Mast Out**[®]. In 2004, we paid Nutrition 21 approximately \$965,000 to buy out this royalty and milestone-based license to Nisin, thereby acquiring control of the animal health applications of Nisin. Nisin, is an antibacterial peptide known to be effective against most Gram-positive and some Gram-negative bacteria. We have more than fifteen years of experience manufacturing Nisin for our now discontinued topical wipes product line. In our pivotal effectiveness study, statistically significant **Mast Out**[®] cure rates were associated with a statistically significant reduction in milk somatic cell count, which is an important measure of milk quality. Nisin is a well characterized substance, having been used in food preservation applications for over 50 years. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes processing and purification methods to achieve pharmaceutical-grade purity.

In 2004, we entered into a product development and marketing agreement with Pfizer Animal Health (now known as Zoetis) covering **Mast Out**[®]. 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

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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**[®] 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**[®] that is sold exclusively for fluid milk products presents no such risk. We worked with scientists and mastitis experts to conduct a formal risk assessment to quantify the impact that milk from treated cows may have on cultured dairy products. This study concluded that the dilution of milk from treated cows through comingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when **Mast Out**[®] is used in accordance with the product label. We do not believe that a premium-priced product such as **Mast Out**[®] 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**[®] in the United States is subject to approval of our New Animal Drug Application (NADA) by the Food and Drug Administration (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**[®] 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. Completion of the HFS Technical Section is currently anticipated during the second half 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) expand our process knowledge and controls, ii) establish operating ranges for critical process parameters, iii) optimize process yields and iv) verify the cost of production. We believe these efforts will reduce risk as we invest in the commercial-scale production facility.

Implementing Nisin production at commercial scale is the most critical action in front of us on our path to regulatory approval. Our initial plan was to have Nisin 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.

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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 our Nisin in a plant of their 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, the partner would have taken a large share of the gross margin from all future **Mast Out**[®] 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. During the fourth quarter of 2015, we acquired land nearby to our existing Portland facility for the construction of our own facility for the commercial-scale production of Nisin. During the third quarter of 2016, we broke ground for this facility, and construction is now well underway and progressing on schedule and within budget. We plan to complete construction by the third quarter of 2017 and installation and qualification of equipment by the first quarter of 2018. To gain regulatory approval of this product, validation batches must be produced at commercial scale, and a detailed CMC Technical Section prepared and submitted to the FDA. We expect that two, six-month reviews of the CMC Technical Section by the FDA will be required. Additionally, successful FDA site inspections must be achieved.

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. Adherence to this timeline sets us up for anticipated regulatory approval in 2019.

We are party to a long-term, exclusive supply agreement with Nordson Corporation (formerly Plas-Pak Inc.) of Norwich, Connecticut covering the proprietary syringe that was developed specifically for treating cows with **Mast Out**[®]. These syringes were used for all pivotal studies of **Mast Out**[®]. During the fourth quarter of 2015, this contract was extended through December 31, 2020. A further extension past December 31, 2020 would be required, unless an alternative supplier is identified.

Since 2010, we have been party to a long-term, exclusive Contract Manufacture Agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved Drug Product (sterile-filled and packaged syringes) manufacturer, covering the formulation and sterile-filling of the Drug Substance into Drug Product for **Mast Out**[®]. Norbrook provided these services for clinical material used in all pivotal studies of **Mast Out**[®]. During the fourth quarter of 2015, we entered into a revised agreement with Norbrook covering the final development and commercial-scale launch of **Mast Out**[®] after FDA approval.

In addition to our work on **Mast Out**[®], 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, this would be the first passive antibody product on the market with USDA-approved disease claims providing immediate immunity against each of 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 for our product. We are now 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 of this product, **First Defense**[®] **Tri-Shield**[™], with the expanded claims during the second half of 2017. We intend to continue selling the bivalent formats of **First Defense**[®] as options for customers after the launch of **First Defense**[®] **Tri-Shield**[™]. We are currently working to establish USDA claims for our bivalent gel tube (expected during the second half of 2017) and bulk powder (expected during 2018) formulations of **First Defense Technology**[®]. At the same time, we are working to expand our product development pipeline of bacteriocins that

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can be used as alternatives to traditional antibiotics. During the second quarter of 2015, we entered into a three-year 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.

Competition

Our competition in the animal health market includes other biotechnology companies and major animal health companies. Many of these competitors have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do.

We would consider any company that sells an antibiotic to treat mastitis, such as Zoetis (formerly Pfizer Animal Health, a division of Pfizer, Inc.), Merck Animal Health and Boehringer Ingelheim, to be among the potential competitors for **Mast Out**[®]. We expect the FDA to grant a period of five years of market exclusivity for **Mast Out**[®] (meaning the FDA would not grant approval to a second NADA with the same active drug for a period of five years after the first NADA approval is granted) under Section 512(c)(2)F of the Federal Food, Drug, and Cosmetic Act.

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**[®] offers two significant competitive advantages. First, **First Defense**[®] is the only product that provides protection against both *E. coli* and coronavirus, the two leading causes of calf scours. Second, **First Defense**[®], being derived from colostrum, offers **Immediate Immunity**[™] through antibodies that function both at the gut level and are absorbed into the blood stream for future protection. To complement this, **First Defense**[®] is easier to use, requires no mixing or refrigeration, and can be administered without delaying maternal colostrum.

Zoetis sells a product that competes directly with **First Defense**[®] in preventing scours via oral delivery to newborn calves. Their product (Calf-Guard[®]) is a modified-live virus vaccine, 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**[®], Calf-Guard[®] carries a claim against coronavirus infections, but this product does not carry a claim against *E. coli* infections like **First Defense**[®] does. Calf-Guard[®] carries a claim against rotavirus that **First Defense**[®] does not currently carry. **First Defense**[®] is priced at a premium to Calf-Guard[®]. It is common practice to delay colostrum feeding when dosing a calf with Calf-Guard[®] so that the antibodies in the colostrum do not inactivate the vaccine product. There is no nutritional benefit to withholding milk from calves. In contrast, we encourage the feeding of four quarts of high quality colostrum immediately after birth when dosing a calf with **First Defense**[®], which is standard practice for good calf health. Because the antibodies in **First Defense**[®] would likely work to inactivate a modified-live vaccine, rendering it useless or less useful, our product label historically included a precaution that **First Defense**[®] should not be used within five days of such a vaccine. During the first quarter of 2015, the USDA granted us permission to remove this precaution from our label. We believe that this precaution should be required on the Calf-Guard[®] label to prevent inactivation of that product by **First Defense**[®] or colostrum.

Elanco Animal Health (a division of Eli Lilly and Company) and Boehringer Ingelheim also sell directly competitive products. 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**[®]. Equine antibodies are less efficiently absorbed into the bloodstream, so fewer antibodies are re-secreted for additional protection.

During the fourth quarter of 2016, Merck launched a new competitive product into this market space. This product (BOVILIS[®] Coronavirus) is a modified-live virus intranasal vaccine.

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Market research that we have access to suggests that we captured approximately 37% of the market comprised of the four leading scours preventatives given orally to newborn calves during 2016. This estimate is down from 39% during 2015 and up from 33% during 2014. This market share estimate has increased from 22% during 2012 and 26% during 2013 as the total market size has steadily increased. We will begin tracking the market share of the new Merck product during 2017.

First Defense[®] also 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**[®] provides more consistent protection than such vaccine products.

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, managerial and sales 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 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). 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, **Mast Out**[®], our mastitis treatment product under development, **Your Calf Crew**[®], a term used to describe our sales team and **First Defense Technology**[®], the product name we use for line extensions of **First Defense**[®] without disease claims. We utilize the trademark **Immediate Immunity**[™] in connection with the marketing of our products, and we intend to apply to register this mark and related design during 2017. The FDA has determined that the name **Mast Out**[®] is overly promotional. Rather than continuing an appeal of this decision, we have decided to select a new product name before market launch. During the first quarter of 2017, we sold our registered trademarks related to **Wipe Out**[®] **Dairy Wipes** when we discontinued that product line.

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 (Center for Veterinary Biologics). We have received USDA and Canadian Food Inspection Agency approval for **First Defense**[®]. **Mast Out**[®] is regulated by the FDA, Center for Veterinary Medicine, which regulates veterinary drugs. Regulations in the European Union will likely require that **Mast Out**[®] be sold subject to a milk discard requirement in that territory, although the duration of the milk discard requirement may be shorter than the discard requirement applicable to competitive antibiotic products in that market. The manufacture of **Wipe Out**[®] **Dairy Wipes** also was 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

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experts to assist us with or to perform international regulatory applications.

Employees

We currently employ 45 employees (including 6 part-time employees). Approximately 26.5 full-time equivalent employees are engaged in manufacturing operations, 7.5 full-time equivalent employees in sales and marketing, 3.5 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.

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>.

ITEM 1A – RISK FACTORS

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 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. We have been profitable since the second half of 2014 and expect this 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 the construction and equipment costs of our Nisin production plant to support the commercialization of **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, 2015 and 2016 without the gross margin that we earned on sales of **First Defense**[®], which accounted for 93% of our product sales during the years ended December 31, 2016 and 2015.

Product risks generally: The sale of our products is subject to financial, efficacy, regulatory, competitive and other market risks. Elevated standards to achieve and maintain regulatory compliance required to sell our products continue to evolve. 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.

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. We expect to be subject to similar regulatory risks for our anticipated rotavirus claim, and similar regulatory

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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 NADA approval, in accordance with the FDA's Compliance Policy Guide 7125.30 ("Teat Dips and Udder Washes for Dairy Cows and Goats"). 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 favorable, and we responded to the few, minor observations that were noted. During the third quarter of 2016, the FDA inspected our facilities and operations again. The report from this inspection noted five observations. We submitted our responses to the observations that were noted, and subsequently were informed that the FDA had closed its inspection. During the first quarter of 2017, we discontinued the manufacture and sale of this product, which reduces our exposure to an adverse action by the FDA in this respect to a minimal level.

Regulatory requirements for Mast Out[®]: The commercial introduction of **Mast Out[®]** in the United States will require us to obtain FDA approval for this product. Completing the development of **Mast Out[®]** through to the submission of the administrative NADA to the FDA involves risk. While three Technical Sections have been approved and the Human Food Safety Technical Section is near completion, the development process timeline has been extensive (17 years) and has involved multiple commercial production strategies. As such, the Chemistry, Manufacturing and Controls Technical Section has not yet been submitted for the Nisin Drug Substance or the Drug Product. To reduce the risk associated with this process, we have met with the FDA on multiple occasions to align on filing strategy and requirements. We have disclosed a timeline of events that could lead to approval during 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, such as Canada. 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[®]** than it is for other products on the market in Europe.

Concentration of sales: Approximately 99% and 97% of our product sales were made to customers in the dairy and beef industries throughout the world during the years ended December 31, 2016 and 2015, respectively. Approximately 85% and 83% of our product sales were made to customers in the U.S. dairy and beef industries during the years ended December 31, 2016 and 2015, respectively. A large portion of our product sales (60% and 62% during the years ended December 31, 2016 and 2015, respectively) was made to two large distributors. A large portion of our trade accounts receivable (64% and 52% as of December 31, 2016 and 2015, 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:

- The January count of all cattle and calves in the United States had steadily declined from 97,000,000 as of January 1, 2007 to 88,500,000 as of January 1, 2014. Then this figure increased to 89,100,000 as of January 1, 2015 and to 91,900,000 as of January 1, 2016. The U.S. cattle inventory as of January 1, 2017 totaled 93,600,000, which is 1.8% higher than January 1, 2016
- From 1998 through 2016, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 (2004) to the high of 9,332,000 (2016). The 2016 level exceeded the previous high during this nineteen-year period of 9,317,000 in 2015.
- 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

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(peaking at \$24.60 in September 2014) was the highest level since these prices were first reported in 1980. This strong price level declined to the average of \$15.80 during 2015 and further declined to \$14.87 during 2016. However, the average during the three-month period ended January 31, 2017 was \$16.98. 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)
<u>2012</u>	<u>2013</u>	
\$17.44	\$17.99	3%
<u>2013</u>	<u>2014</u>	
\$17.99	\$22.34	24%
<u>2014</u>	<u>2015</u>	
\$22.34	\$15.80	(29%)
<u>2015</u>	<u>2016</u>	
\$15.80	\$14.87	(6%)

- 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 and increased to 2.24 during 2016. 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)
<u>2012</u>	<u>2013</u>	
1.52	1.75	15%
<u>2013</u>	<u>2014</u>	
1.75	2.54	45%
<u>2014</u>	<u>2015</u>	
2.54	2.12	(16%)
<u>2015</u>	<u>2016</u>	
2.12	2.24	6%

- 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, but this average price has declined by 11% to \$1,768 during 2016. The industry data referred to above is compiled from USDA databases. The value of newborn bull calves had risen to the unusually high level of approximately \$300 to \$400 during 2015 but has declined to very little presently, depending on region. 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,

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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.

*Risks associated with **Mast Out**[®] funding strategy:* The construction of and the financing for the commercial-scale Nisin production plant is the most critical action in front of us on our path to U.S. regulatory approval for **Mast Out**[®]. We believe our current cash and investments, together with the available debt facility of up to approximately \$6.5 million and cash to be generated from operations, will be 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. We will not know whether we will receive the necessary regulatory approvals to manufacture and sell **Mast Out**[®], or whether the product will achieve market acceptance and profitability, until after we have completed construction of the production facility described elsewhere in this report, at the presently estimated cost of \$20 million. Absent sufficient sales of this new product at a profitable gross margin, we would be required to fund all debt service costs from sales of **First Defense**[®] which would reduce our expected profitability going forward.

Uncertainty of market size and product sales estimates: Estimating the size of the market for **Mast Out**[®] 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, competition from existing products sold by substantially larger competitors, 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, Boehringer Ingelheim and Merck, among other companies, sell products that compete directly with **First Defense**[®] in preventing scours in newborn calves. The product sold by Elanco (which has a similar selling price to our product) experienced a lack of supply in the market during late 2014 and into the middle of 2015 but returned to the market in the latter part of 2015 and has regained a significant portion of the market share it had lost during this period. 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 (which we do have), 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**[®] 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. We are dependent on our manufacturing facility and operations in Portland, Maine for the production of **First Defense**[®] and will be dependent on the facility we are constructing in Portland for the production of **Mast Out**[®] when that product begins commercial sales. The specific antibodies that we purify from colostrum for **First Defense**[®] are not readily available from other sources. We are dependent on Nordson Corporation (formerly Plas-Pak Inc.) for the supply of the syringes used for our gel tube format of **First Defense Technology**[®] and expect to be dependent on this company for the supply of the syringes for **Mast Out**[®]. The supply contract covering the **Mast Out**[®] syringes would need to be extended past December 31, 2020 unless an alternative supplier is identified. We expect to be dependent on Norbrook for the sterile-filling and final packaging of our Drug Substance into Drug Product. We are evaluating alternative sources for these services for potential use post-approval. Given the requirement that such a facility be inspected and approved by the FDA, it could be costly and time-consuming to find and qualify an adequate alternative source for these services. Any significant damage to or other disruption in the services at any of these third party or company-owned 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.

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Small size; dependence on key personnel: We are a small company with 45 employees (including 6 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, manufacturing, managerial and sales and marketing personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products, to maintain regulatory compliance with current 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.

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 come out of a recession, which was caused principally by the housing, credit and financial crises that began around 2008. However, such recent positive indications could prove temporary and further downturn could occur. The credit markets continue to be very turbulent and uncertain. 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. Interest rates are trending higher, and a significant portion of our bank debt

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currently bears interest at variable rates. This extraordinary period of instability in the U.S. economy and the financial markets has been troubling for nearly all Americans. The European economy remains sluggish and precarious. Certain emerging markets also show signs of slower growth or, in some areas, downturns in economic performance. While we do price our products in U.S. dollars for all export markets, the strength of the dollar against weakening foreign currencies could reduce product demand in international markets. 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**[®] 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**[®], although presently we do not anticipate that this will be the case.

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 (NasdaqCM: ICCG). 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 \$27,000,000 as of March 20, 2017. Some of these companies have little or no product sales. We currently have annual product sales of almost \$10,000,000. 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. 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 –PROPERTIES

We own a 35,000 square foot (approximately) 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 at 33 Caddie Lane in Portland, Maine which is nearby to our facility at 56 Evergreen Drive for a total purchase price of \$278,000 on which we

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initiated construction of our Nisin production plant for **Mast Out**[®] during the third quarter of 2016.

During the first quarter of 2016, we paid \$20,500 for an option to purchase additional land nearby to the Nisin production plant. We allowed this option to expire as of December 31, 2016 and applied the option amount to the purchase of a 4,114 square foot facility adjacent to the Nisin production plant, during the first quarter of 2017, for \$445,000, net of the option payment. We intend to use the warehouse space primarily for storage of inventory, materials and equipment.

We rented approximately 640 square feet of office and warehouse space in New York to support our farm operations. During the first quarter of 2017, we exited this property and entered into a renewable, two-year lease for approximately 1,350 square feet of office, warehouse and garage space nearby.

During 2016, we rented approximately 3,266 square feet in Minnesota on a short-term basis, where we formulated our gel tube delivery format of **First Defense Technology**[®] and certain private label products. This lease expired during the first quarter of 2017, and we no longer utilize this space. The manufacturing of this product line was successfully transferred to the Portland facility during the first quarter of 2017.

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

In the ordinary course of business, we may become subject to periodic lawsuits, investigations and claims. Although we cannot predict with certainty the ultimate resolution of any such lawsuits, investigations and claims against us, we do not believe that any pending or threatened legal proceedings to which we are or could become a party will have a material adverse effect on our business, results of operations, or financial condition.

ITEM 4 – MINE SAFETY DISCLOSURES

None

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 20, 2017, we had 10,000,000 common shares authorized and 4,848,390 common shares outstanding, and there were approximately 850 shareholders of record. The last sales price of our common stock on March 20, 2017 was \$5.52 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, 2015 through December 31, 2016:

	2015				2016			
	Three Month Periods Ended				Three Month Periods Ended			
	March 31	June 30	September 30	December 31	March 31	June 30	September 30	December 31
High	\$7.22	\$8.69	\$11.40	\$7.80	\$8.29	\$7.38	\$8.24	\$7.99
Low	\$4.99	\$5.50	\$5.95	\$6.03	\$5.60	\$5.62	\$6.46	\$4.76

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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, 2016 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	251,000	\$3.89	155,500
Equity compensation plans not approved by stockholders	-	-	-
Total	251,000	\$3.89	155,500

ITEM 6 – SELECTED FINANCIAL DATA

You should read the following consolidated financial data in connection with **Part II, Item 7** “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the related notes appearing in **Part II, Item 8** “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K. We prepare our financial statements in conformity with accounting principles generally accepted in the United States of America (“GAAP”).

We derived the statements of operations and statements of cash flows data for the years ended December 31, 2016 and 2015, and the balance sheet data as of December 31, 2016 and 2015 from our audited financial statements appearing in **Part II, Item 8** of this Annual Report on Form 10-K. We derived the statements of operations and statements of cash flows data for the years ended December 31, 2014, 2013, and 2012, and the balance sheet data as of December 31, 2014, 2013, and 2012, from our audited financial statements that are not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results to be expected in any future period.

	During the Years Ended December 31,				
	<u>2016</u>	<u>2015</u>	<u>2014</u>	<u>2013</u>	<u>2012</u>
Statement of Operations Data:					
Product sales	\$9,544	\$10,229	\$7,597	\$6,007	\$5,390
Gross margin	5,421	6,251	4,449	3,061	3,054
Product development expenses	1,244	1,235	2,179	1,154	918
Selling and administrative expenses	3,286	2,893	2,476	1,926	1,892
Net operating income (loss)	890	2,122	(206)	(20)	245
Income (loss) before income taxes	758	2,064	(255)	205	192
Interest expense	162	84	58	67	75
Depreciation and amortization expenses	811	529	449	417	403
Net income (loss)	\$508	\$1,213	(\$167)	\$117	\$90
	During the Years Ended December 31,				
	<u>2016</u>	<u>2015</u>	<u>2014</u>	<u>2013</u>	<u>2012</u>
Per Common Share:					
Basic net income (loss)	\$0.12	\$0.40	(\$0.06)	\$0.04	\$0.03
Diluted net income (loss)	\$0.12	\$0.38	(\$0.06)	\$0.04	\$0.03
Cash dividend	\$0	\$0	\$0	\$0	\$0
Statement of Cash Flows Data:					
Net cash provided by (used for) operating activities	(\$324)	\$2,900	\$302	\$1,099	\$344

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As of December 31,

	<u>2016</u>	<u>2015</u>	<u>2014</u>	<u>2013</u>	<u>2012</u>
Balance Sheet Data:					
Cash, cash equivalents, short-term investments and long-term investments	\$10,624	\$6,534	\$3,835	\$5,255	\$4,914
Total assets	24,697	14,540	11,052	10,961	11,030
Net working capital	12,289	7,087	4,460	6,632	6,697
Stockholders' equity	\$19,722	\$10,614	\$9,258	\$9,396	\$9,195
Per Outstanding Common Share:					
Cash, cash equivalents, short-term investments and long-term investments	\$2.19	\$2.14	\$1.27	\$1.74	\$1.63
Stockholders' equity	\$4.07	\$3.47	\$3.06	\$3.11	\$3.05

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included in **Part II, Item 8** “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review **Part I, Item 1A** “Risk Factors” of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Liquidity and Capital Resources

We have funded most of our product development expenses principally from our gross margin on product sales. As anticipated, we incurred a net loss during the year ended December 31, 2014 due to an unusually large investment in a pilot 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 during 2015 and 2016. The table below summarizes the changes in selected, key accounts (in thousands, except for percentages):

	As of	As of	Increase	
	<u>December 31, 2016</u>	<u>December 31, 2015</u>	<u>Amount</u>	<u>%</u>
Cash, cash equivalents, short-term investments and long-term investments	\$10,624 ⁽¹⁾	\$6,534	\$4,091	63%
Net working capital	\$12,289	\$7,087	\$5,202	73%
Total assets	\$24,697	\$14,540	\$10,157	70%
Stockholders' equity	\$19,722	\$10,614	\$9,108	86%
Common shares outstanding	4,847	3,055	1,792	59%

⁽¹⁾ This cash balance does not include approximately \$343,000 being held temporarily in escrow against certain construction performance requirements related to our production facility for **Mast Out**[®].

Net cash (used for) operating activities amounted to (\$324,000) during the year ended December 31, 2016 in comparison to net cash provided by operating activities of \$2.9 million during the year ended December 31, 2015. Capital investments totaled \$3.6 million during the year ended December 31, 2016 compared to capital investments of \$2.7 million during the year ended December 31, 2015. As we progress our investment in the Nisin production facility, described below, we expect these investments of cash to increase. 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.

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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 \$4.2 million in connection with the 2015 financing. As of December 31, 2016, our outstanding bank debt balance was approximately \$3 million. We have a \$500,000 line of credit that is available as needed through August 29, 2017 and subject to extension by the bank after that date. There was no balance outstanding under this line of credit as of December 31, 2016. These credit facilities are subject to certain financial covenants. We are in compliance with all applicable covenants as of December 31, 2016.

During the first quarter of 2016, we entered into two bank debt agreements covering certain additional credit facilities with TD Bank N.A. aggregating up to approximately \$4.5 million. During the first quarter of 2017, we amended these agreements to increase the total amount of debt available up to approximately \$6.5 million and to make certain other modifications. As of March 20, 2017, we had not drawn proceeds under either of these credit facilities. These credit facilities are subject to certain financial covenants and are secured by substantially all of our assets. We are in compliance with all applicable covenants as of December 31, 2016. At this point, we anticipate that we may draw funds under these loans beginning during the second quarter of 2017.

During the first and fourth quarters of 2016, we issued an aggregate of approximately 1.8 million shares of common stock, raising net proceeds of approximately \$8.5 million in two separate transactions.

During the third quarter of 2016, we initiated construction of our Nisin production facility for **Mast Out**[®]. The estimated total cost of the Nisin facility is approximately \$20 million. Expenditures on this project are heavily weighted to the nine-month period ending September 30, 2017. We expect to fund remaining costs in excess of our current cash and investments with cash to be generated from operations during 2017 to 2018 and borrowings under the credit facilities described above. These costs are being capitalized on our balance sheet as construction in progress. Depreciation of these costs is expected to begin when the facility is placed into service, which could be before FDA approval of the product is achieved. The following table details the amount and timing of the expected investment:

<u>Period</u>	<u>Amount</u>
Year ended December 31, 2016	\$3,280,000 ⁽¹⁾
Estimated investment required to complete	16,720,000 ⁽²⁾
Estimated total investment	<u>\$20,000,000</u> ⁽³⁾

⁽¹⁾ Approximately \$1,200,000 of this amount was capitalized as of December 31, 2016 but not paid until 2017.

⁽²⁾ We expect most of this investment to be disbursed during the nine-month period ending September 30, 2017. Approximately \$12,320,000 of this amount was committed to vendors as of December 31, 2016.

⁽³⁾ This budget estimate does not include approximately \$278,000 that was invested in land for the facility, which was acquired during the fourth quarter of 2015.

During the third quarter of 2016, the City of Portland approved a Tax Increment Financing (TIF) credit enhancement package that reduces our real estate taxes on the Nisin production facility for **Mast Out**[®] that we are constructing by 65% over the eleven-year period ending June 30, 2028 and by 30% during the year ending June 30, 2029, at which time the rebate expires. The TIF is still subject to standard approvals by the State's Department of Economic and Community Development. The aggregate financial benefit was originally estimated to be approximately \$400,000 based on the then current \$3 million building cost estimate calculated during 2015 before the detailed design work and construction bidding was complete. Significant process-directed requirements to the building have since increased the estimated construction costs to approximately \$11 million. We believe the cost per square foot as currently estimated for a facility of this purpose is competitive and that the increase is largely the result of the preliminary engineering estimate from 2015 for a building shell being for much less of a structure that would not have satisfied our regulatory and Nisin production capacity needs. The value of the tax savings would increase in proportion to the increase in the cost of the building as assessed for city real estate tax purposes. The actual savings will be based on the assessed value of the building after construction is complete, which is likely to be less than its cost of construction.

During the early part of 2015, we invested \$644,000 to complete a 7,100 square foot addition to our Portland facility, providing cold storage, production and warehouse space required to increase our manufacturing capacity.

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Construction of the facility addition was initiated at the end of the third quarter of 2014. The total cost of this project was \$1,914,000. We completed an investment to increase our liquid processing capacity by 50% during the fourth quarter of 2015 and an investment to increase our freeze-drying capacity by 100% at the end of the first quarter of 2016. During 2015, we invested \$1,379,000 in these production capacity increases and \$430,000 in other capital expenditures. During 2016, we invested \$1,161,000 to complete these production capacity increases and \$345,000 in other capital expenditures.

Our capital expenditure investments from 2014 to 2016 were larger than our historical norm. As of January 1, 2017, we had additional authorization from our Board of Directors to spend up to approximately \$150,000 for new manufacturing equipment and other routine and necessary capital expenditures, which does not include the \$20 million budget for the Nisin production plant described above.

Results of Operations

2016 Compared to 2015

Product Sales

Product sales for the year ended December 31, 2016 decreased by 7%, or \$685,000, to \$9,544,000 from \$10,229,000 during 2015. During the year ended December 31, 2016, domestic product sales decreased by 4%, or \$311,000, and international sales decreased by 23%, or \$374,000, in comparison to 2015. Financial results for 2016 were impacted by the return to the market of a competitive product that was largely off the market from late 2014 to the middle of 2015. We believe that our increased investment in sales and marketing personnel and efforts is helping us introduce **First Defense**[®] to new customers, despite significant market volatility affecting both milk prices and feed costs. Product sales during 2015 and into the early part of 2016 benefited from relatively strong prices of milk, cows and calves as well as a stable to moderately lower cost of feed. Market conditions in the dairy and beef industries, including milk pricing and prices for bull calves, weakened during 2016 in comparison to 2015. This new level sales demand for **First Defense**[®] exceeded our production capacity and available inventory. As of December 31, 2015, we had a backlog of orders that aggregated approximately \$381,000 in comparison to no backlog as of December 31, 2016 or 2014. We completed the investments necessary 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 to meet the growing sales demand for **First Defense**[®], enabling us to build back target inventory levels during the fourth quarter of 2016. The prolonged period of order backlog (which began early in 2015 and extended through the middle of 2016) disrupted normal shipping patterns. The manufacturing issues that impacted our performance during 2015 and 2016 are behind us. Despite lower sales during 2016, revenue since 2012 has grown at a 15.4% compounded annual rate.

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 the **First Defense**[®] product line aggregated 92.9% and 92.8% of our total product sales during the years ended December 31, 2016 and 2015, respectively. Sales of the **First Defense**[®] product line decreased by 7% during the year ended December 31, 2016 in comparison to 2015. Domestic sales of the **First Defense**[®] product line decreased by 6%, and international sales decreased by 9%, during the year ended December 31, 2016 in comparison to 2015. We have realized positive sales growth of **First Defense**[®] and related product line extensions for twenty-one of the last twenty-five quarters, in comparison to the same quarters of the prior year.

We believe that the long-term growth in sales of the **First Defense**[®] product line 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, five regional managers and one inside sales and marketing employee. 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 and competitive 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

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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.

We are selling new product applications of **First Defense**[®] under the description **First Defense Technology**[®], which is a unique whey protein concentrate that is processed utilizing our proprietary colostrum (first 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. We are working to achieve USDA claims for this product format during 2018. 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 are working to achieve USDA claims for this product format during the second half of 2017.

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 of approximately 10% to the selling price of the gel tube format of **First Defense Technology**[®]. During 2016, we implemented a price increase of approximately 5% for **First Defense**[®]. 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.

Sales of products other than **First Defense**[®] aggregated 7% of our total product sales during the years ended December 31, 2016 and 2015. Since 1999, we have been selling **Wipe Out**[®] **Dairy Wipes** (our second leading source of product sales prior to 2017) for use in preparing the teat area of a cow for milking. We believe that sales growth potential for **Wipe Out**[®] **Dairy Wipes** is limited. 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 our Nisin-based topical wipes aggregated approximately \$350,000 during the year ended December 31, 2016, a 2% increase over 2015. The topical wipes product line contributed very little to our profits. During the first quarter of 2017, we discontinued the production and sale of this product line. In connection therewith, we wrote off \$38,000 worth of fixed assets and recognized \$45,000 from the sale of certain other fixed assets and product rights, resulting in a net gain of \$7,000. Sales of several other private label products that we acquired in connection with our January 2016 acquisition of certain gel formulation technology (our third leading source of animal health product sales) aggregated 2% of our total product sales during the year ended December 31, 2016. During the fourth quarter of 2016, we shut down the manufacturing site in Minnesota that had been used to produce these products and moved these operations to our Portland, Maine facility. We expect to realize reduced labor and overhead expenses and benefit from certain other operating efficiencies as a result of this consolidation. In connection therewith, we wrote off \$34,000 worth of fixed assets and recognized \$7,000 from the sale of certain other fixed assets, resulting in a net loss of \$27,000. Sales of our **California Mastitis Test (CMT)** (our fourth leading source of animal health product sales) decreased by 20% during the year ended December 31, 2016 in comparison to the same period during 2015. 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. No sales of these bulk reagents were recorded during 2016. Sales of these bulk reagents aggregated slightly more than 2% of total product sales during the year ended December 31, 2015.

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):

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	For the Years Ended		(Decrease)	
	December 31,		Amount	%
	2016	2015		
Gross margin	\$5,421	\$6,251	(\$830)	(13%)
Percent of product sales	57%	61%	(4%)	(7%)

The gross margin as a percentage of product sales was 57% and 61% during the years ended December 31, 2016 and 2015, respectively. This compares to gross margin percentages of 59% and 51% during the years ended December 31, 2014 and 2013, respectively. Our objective for the foreseeable future is to maintain the gross margin percentage over 55%, and we have achieved this annual objective since 2014. 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. This allowed us to increase our inventory balance to \$2,127,000 as of December 31, 2016. 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**[®] 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**[®] and **Wipe Out**[®] 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**[®] and a much lower gross margin on **Wipe Out**[®] Dairy Wipes.

Product Development Expenses

During the eighteen-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, 2016, we invested the aggregate of approximately \$23,229,000 in product development expenses, averaging approximately \$1,290,000 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 seventeen-year period that began on January 1, 2000 (the year we began the development of **Mast Out**[®]) and ended on December 31, 2016, we invested the aggregate of approximately \$12,409,000 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 increased by less than 1%, or \$9,000, to \$1,244,000 during the year ended December 31, 2016, as compared to \$1,235,000 during 2015. Product development expenses aggregated 13% and 12% of product sales during 2016 and 2015, respectively. The balance of our efforts have been primarily focused on other improvements, extensions or additions to our **First Defense**[®] product line, including 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 14%, or \$224,000, to \$1,831,000 during the year ended December 31, 2016, as compared to \$1,607,000 during 2015, increasing to 19% of product sales in 2016 from 16% in 2015. We continue to leverage the efforts of our small sales force by using animal health distributors. These expenses have increased due principally to a strategic decision to invest more to support **First Defense**[®] sales. Our current budgetary objective in 2017 is to invest up to 18% of product sales in sales and marketing expenses on an annual basis.

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Administrative Expenses

Administrative expenses increased by approximately 13%, or \$168,000, to \$1,455,000 during the year ended December 31, 2016 as compared to \$1,286,000 during 2015. 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)

Our net operating income during the year ended December 31, 2016 of \$890,000 was \$1,232,000 less than the net operating income of \$2,122,000 during 2015. We have now recorded positive net operating income for ten consecutive quarters. We recorded a net operating (loss) of (\$206,000) during the year ended December 31, 2014.

Other expenses, net

Interest income increased by approximately 185%, or \$35,000, to \$55,000 during the year ended December 31, 2016, in comparison to \$19,000 during 2015. Interest expense (including amortization of debt issuance costs of approximately \$9,000 and \$3,000 during the years ended December 31, 2016 and 2015, respectively) increased by approximately 93%, or \$78,000, to \$162,000 during the year ended December 31, 2016, in comparison to \$84,000 during 2015. The 2016 results include a net loss of \$27,000 related to our decision to shut down a production site in Minnesota. As a result, other expenses, net, aggregated \$132,000 and \$59,000 during the years ended December 31, 2016 and 2015, respectively.

Income Before Income Taxes and Net Income

Our income before income taxes of \$758,000 during the year ended December 31, 2016 compares to income before income taxes of \$2,064,000 during 2015. This decrease is largely attributable to the \$830,000 decrease in gross margin and the \$402,000 increase in operating expenses. We recorded income tax expense of 33% and 41% of the income before income taxes during the years ended December 31, 2016 and 2015, respectively. The decrease in our tax rate was largely the result of an increase in tax credits. Our net income of \$508,000, or \$0.12 per diluted share, during the year ended December 31, 2016 compares to net income of \$1,213,000, or \$0.38 per diluted share, during the year ended December 31, 2015.

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, 2016 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.

We sell products that provide immediate immunity to newborn dairy and beef cattle. We recognize revenue when four criteria are met. 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

ImmuCell Corporation

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 do not bill for or collect sales tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We offer a 50% account credit to domestic distributors on expired **First Defense**[®] product that is returned to us past its expiration date, which is generally two years past its date of manufacture. At the time of sale, we estimate returns and record a corresponding liability. We generally have experienced an immaterial amount of product returns.

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 AND SUPPLEMENTARY DATA

Our financial statements, together with the notes thereto and the reports of the independent registered public accounting firms thereon, are set forth on Pages F-1 through F-25 at the end of this report. The index to these financial statements is as follows:

Report of RSM US LLP, Independent Registered Public Accounting Firm	F-1
Report of Baker Newman & Noyes, LLC, Independent Registered Public Accounting Firm	F-2
Balance Sheets as of December 31, 2016 and 2015	F-3
Statements of Operations for the years ended December 31, 2016 and 2015	F-4
Statements of Comprehensive Income for the years ended December 31, 2016 and 2015	F-4
Statements of Stockholders' Equity for the years ended December 31, 2015 and 2016	F-5
Statements of Cash Flows for the years ended December 31, 2016 and 2015	F-6
Notes to Financial Statements	F-7 to F-25

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 completed its work in auditing the Company's financial statements as of and for the year ended December 31, 2015 and performed its customary more limited role with respect to a review of the Company's financial statements as of

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and for the quarter ended 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.

On May 20, 2016, we engaged RSM US LLP as our Independent Registered Public Accounting Firm for the year ending December 31, 2016. This decision was authorized by the Audit Committee of our Board of Directors and ratified by our Board of Directors. The Audit Committee and the Board of Directors determined that engaging a large, national firm is in the best interest of the Company at this stage in our development.

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, 2016. 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, 2016. Based on management's assessment and those criteria, management believes that the internal control over financial reporting as of December 31, 2016 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.

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ITEM 9B – OTHER INFORMATION

None

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers of the Company

Our executive officers as of March 20, 2017 were as follows:

MICHAEL F. BRIGHAM (Age: 56, 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 2012, serving as its Treasurer until June 2016 and is presently Vice Chair of the Board of Directors and Chair of the Governance Committee. 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: 40, Officer since February 2015, Director since March 2017) 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: 62, 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.

ELIZABETH L. WILLIAMS (Age: 61, Officer since April 2016) joined the Company during the second quarter of 2016 as Vice President of Manufacturing Operations. Previously, she led the U.S. Region for Zoetis as Vice President, Global Manufacturing and Supply. Prior to that, she held multiple Site Leader positions at Pfizer Animal Health facilities in Lincoln, Nebraska (2008-2011), Conshohocken, Pennsylvania (2006-2008) and Lee's Summit, Missouri (2003-2006). She led the manufacturing organization (1999-2003) and the Process and Product Development group (1995-1999), achieving registration, approval and successful scale-up of five new products at the Lee's Summit facility. She earned her Masters of Business Administration from Rockhurst University in Kansas City, Missouri and her Bachelor's degree in Biology from the University of Missouri.

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Information with respect to our directors is incorporated herein by reference to the section of our 2017 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, 2016. 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 2017 Proxy Statement titled “Executive Officer Compensation”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2016.

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 2017 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, 2016.

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 2017 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, 2016.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

Information regarding our principal accounting fees and services is incorporated by reference to the section of our 2017 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, 2016.

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 Certificate of Amendment to the Company’s Certificate of Incorporation effective June 16, 2016 (incorporated by reference to Exhibit 3.1 of the Company’s Amended Current Report on Form 8-K/A filed on June 16, 2016).
- 3.5 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).

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- 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).
- 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 Construction Loan Note for \$2,000,000 by the Company in favor of TD Bank N.A. dated March 28, 2016 (incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on March 31, 2016).
- 10.14 Term Loan Note for \$2,500,000 by the Company in favor of TD Bank N.A. dated March 28, 2016 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on March 31, 2016).
- 10.15 Second Amended and Restated Loan Agreement between the Company and TD Bank N.A. dated March 28, 2016 (incorporated by reference to Exhibit 99.3 of the Company's Current Report on Form 8-K filed on March 31, 2016).
- 10.16 Amended and Restated Promissory Note (\$2,560,000) given by the Company in favor of TD Bank N.A. dated March 1, 2017.
- 10.17 Amended and Restated Promissory Note (\$3,940,000) given by the Company in favor of TD Bank N.A. dated March 1, 2017.
- 10.18 Amendment to Construction Loan Agreement between the Company and TD Bank N.A. dated March 1, 2017.

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- 10.19⁽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).
- 10.20 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).
- 10.21 +Incentive Compensation Agreement dated March 6, 2017 between the Company and Bobbi Jo Brockmann (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on March 8, 2017).
- 10.22 +Incentive Compensation Agreement dated March 6, 2017 between the Company and Elizabeth L. Williams (incorporated by reference to Exhibit 99.3 of the Company's Current Report on Form 8-K filed on March 8, 2017).
- 10.23 Standard Form of Agreement between the Company and Consigli Construction Co. dated September 27, 2016 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the three-month period ended September 30, 2016).
- 10.24 Mortgage Loan Note for \$340,000 given by the Company in favor of TD Bank N.A. dated March 16, 2017.
- 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.
- 23.1 Consent of RSM US LLP.
- 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.

+ 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 sheet of ImmuCell Corporation (the Company) as of December 31, 2016, and the related statements of operations, comprehensive income, stockholders' equity and cash flows for the year then ended (collectively, the financial statements). 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 audit.

We conducted our audit 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 audit 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 audit provides 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, 2016, and the results of its operations and its cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

/s/ RSM US

Boston, Massachusetts
March 30, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
ImmuCell Corporation

We have audited the accompanying balance sheet of ImmuCell Corporation (the Company) as of December 31, 2015, and the related statements of operations, comprehensive income, stockholders' equity and cash flows for the year then ended. 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 audit.

We conducted our audit 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 audit 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 audit provides 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 the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

Portland, Maine
March 25, 2016

/s/ Baker Newman & Noyes
Limited Liability Company

ImmuCell Corporation

BALANCE SHEETS

	As of December 31,	
	2016	2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$5,150,344	\$1,573,328
Short-term investments	5,474,013	4,470,574
Inventory	2,126,899	870,207
Accounts receivable, net	992,390	718,103
Prepaid expenses and other current assets	604,482	247,476
Total current assets	14,348,128	7,879,688
PROPERTY, PLANT AND EQUIPMENT, net	9,846,293	5,718,814
LONG-TERM INVESTMENTS, net of current portion	-	489,648
DEFERRED TAX ASSETS	201,003	452,117
INTANGIBLE ASSETS, net	171,936	-
GOODWILL	95,557	-
OTHER ASSETS, net	34,264	-
TOTAL ASSETS	\$24,697,181	\$14,540,267
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$1,891,763	\$662,165
Current portion of bank debt	133,269	130,780
Deferred revenue	33,856	-
Total current liabilities	2,058,888	792,945
LONG-TERM LIABILITIES:		
Bank debt, net of current portion	2,878,805	3,054,977
Interest rate swaps	37,346	78,525
Total long-term liabilities	2,916,151	3,133,502
TOTAL LIABILITIES	4,975,039	3,926,447
CONTINGENT LIABILITIES AND COMMITMENTS (See Note 15)		
STOCKHOLDERS' EQUITY:		
Common stock, \$0.10 par value per share, 10,000,000 and 8,000,000 shares authorized, 5,044,838 and 3,261,148 shares issued and 4,847,390 and 3,055,034 shares outstanding, as of December 31, 2016 and 2015, respectively	504,484	326,115
Additional paid-in capital	18,526,383	10,150,190
Retained earnings	1,147,120	638,672
Treasury stock, at cost, 197,448 and 206,114 shares as of December 31, 2016 and 2015, respectively	(431,943)	(450,901)
Accumulated other comprehensive (loss)	(23,902)	(50,256)
Total stockholders' equity	19,722,142	10,613,820
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$24,697,181	\$14,540,267

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

ImmuCell Corporation

STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2016	2015
Product sales	\$9,543,961	\$10,228,689
Cost of goods sold	4,123,266	3,977,787
Gross margin	5,420,695	6,250,902
Sales and marketing expenses	1,831,317	1,606,898
Administrative expenses	1,454,839	1,286,373
Product development expenses	1,244,335	1,235,309
Operating expenses	4,530,491	4,128,580
NET OPERATING INCOME	890,204	2,122,322
Other expenses, net	131,882	58,774
INCOME BEFORE INCOME TAXES	758,322	2,063,548
Income tax expense	249,874	850,309
NET INCOME	\$508,448	\$1,213,239
Weighted average common shares outstanding:		
Basic	4,225,789	3,042,376
Diluted	4,336,229	3,165,735
NET INCOME PER SHARE:		
Basic	\$0.12	\$0.40
Diluted	\$0.12	\$0.38

STATEMENTS OF COMPREHENSIVE INCOME

	For the Years Ended December 31,	
	2016	2015
Net income	\$508,448	\$1,213,239
Other comprehensive income (loss):		
Interest rate swaps, before taxes	41,179	(39,708)
Income tax applicable to interest rate swaps	(14,825)	12,783
Other comprehensive income (loss), net of taxes	26,354	(26,925)
Total comprehensive income	\$534,802	\$1,186,314

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

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STATEMENTS OF STOCKHOLDERS' EQUITY

	<u>Common Stock</u>		Additional paid-in capital	Retained Earnings (Deficit)	<u>Treasury Stock</u>		Accumulated Other Comprehensive (Loss)	Total Stockholders' Equity
	Shares	Amount			Shares	Amount		
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	-	-	-	1,213,239	-	-	-	1,213,239
Other comprehensive (loss), net of taxes	-	-	-	-	-	-	(26,925)	(26,925)
Exercise of stock options	-	-	58,957	-	(28,000)	61,253	-	120,210
Tax benefits related to stock options	-	-	25,706	-	-	-	-	25,706
Stock-based compensation	-	-	23,222	-	-	-	-	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
Net income	-	-	-	508,448	-	-	-	508,448
Other comprehensive income, net of taxes	-	-	-	-	-	-	26,354	26,354
Public offering of common stock, net of \$586,779 of offering costs	1,123,810	112,381	5,200,842	-	-	-	-	5,313,223
Private placement of common stock, net of \$303,450 of placement costs	659,880	65,988	3,094,935	-	-	-	-	3,160,923
Exercise of stock options	-	-	13,017	-	(8,666)	18,958	-	31,975
Stock-based compensation	-	-	67,399	-	-	-	-	67,399
BALANCE,								
December 31, 2016	5,044,838	\$504,484	\$18,526,383	\$1,147,120	197,448	(\$431,943)	(\$23,902)	\$19,722,142

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

ImmuCell Corporation

STATEMENTS OF CASH FLOWS

	<u>For the Years Ended December 31,</u>	
	<u>2016</u>	<u>2015</u>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$508,448	\$1,213,239
Adjustments to reconcile net income to net cash (used for) provided by operating activities:		
Depreciation	783,275	525,918
Amortization	19,104	-
Non-cash interest expense	8,891	3,343
Deferred income taxes	236,289	821,469
Stock-based compensation	67,399	23,222
Loss (gain) on disposal of fixed assets	25,385	(3,984)
Provision for uncollectible accounts, net	3,234	1,898
Changes in:		
Accounts receivable, gross	(277,521)	249,290
Accrued interest income	(14,791)	(3,706)
Inventory	(1,143,693)	75,548
Prepaid expenses and other current assets	(391,270)	(59,672)
Accounts payable and accrued expenses	(182,508)	60,361
Deferred revenue	33,856	(6,690)
Net cash (used for) provided by operating activities	<u>(323,902)</u>	<u>2,900,236</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(3,586,349)	(2,719,189)
Acquisition of certain business assets	(368,219)	-
Maturities of investments	4,464,000	2,489,000
Purchases of investments	(4,963,000)	(4,455,000)
Proceeds from sale of fixed assets	30,939	66,215
Net cash used for investing activities	<u>(4,422,629)</u>	<u>(4,618,974)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from public offering, net	5,313,223	-
Proceeds from private placement, net	3,160,923	-
Proceeds from debt issuance	-	2,500,000
Debt principal repayments	(135,840)	(169,753)
Debt issuance costs	(46,734)	(34,125)
Proceeds from exercise of stock options	31,975	120,210
Tax benefits related to stock options	-	25,706
Net cash provided by financing activities	<u>8,323,547</u>	<u>2,442,038</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	3,577,016	723,300
BEGINNING CASH AND CASH EQUIVALENTS	1,573,328	850,028
ENDING CASH AND CASH EQUIVALENTS	<u>\$5,150,344</u>	<u>\$1,573,328</u>

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

CASH PAID FOR:

Income taxes	\$123,584	\$3,133
Interest expense	\$153,093	\$77,159

NON-CASH ACTIVITIES:

Change in capital expenditures included in accounts payable and accrued expenses	\$1,248,352	(\$249,873)
Net change in fair value of interest rate swaps	(\$26,354)	\$26,925
Fixed asset disposals, gross	\$140,901	\$283,594

See Note 8 for non-cash activities related to a 2016 business acquisition

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”, “we”, “us”, “our”) is an 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. The \$20,000,000 investment we are making in a Nisin production plant for **Mast Out**[®] is being funded from available cash and bank debt, together with cash flows from ongoing operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

We have prepared the accompanying audited financial statements reflecting all adjustments 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 2016 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 \$4,650,044 and \$1,073,028 as of December 31, 2016 and 2015, respectively. We account for investments in marketable securities in accordance with Codification Topic 320, *Investments – Debt and Equity Securities*. 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 net realizable value (determined as the estimated selling price in the normal course of business, less reasonably predictable costs of completion, disposal and transportation). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. See Note 4.

(d) Accounts Receivable

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful collection and product returns. Management determines the allowance for doubtful accounts on a monthly basis by identifying

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

troubled accounts and by using historical experience applied to an aging of accounts. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded as income when received. Accounts receivable are 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 accounts receivable. See Note 5.

(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 facility we are constructing to produce the active ingredient, Nisin, for **Mast Out**[®] will be depreciated over its useful life beginning when that facility is placed into service, which could be before the Food and Drug Administration (FDA) approval of the product is achieved. This facility is not yet placed in service. We are evaluating the estimated useful lives of the assets associated with this facility. Repairs to fixed assets that benefit more than a current period are capitalized and depreciated over their useful lives. See Note 7.

(f) **Intangible Assets and Goodwill**

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. We have recorded intangible assets related to customer relationships, non-compete agreements, and developed technology, each with defined useful lives. We have classified as goodwill the amounts paid in excess of fair value of the net assets (including tax attributes) acquired in purchase transactions.

We assess the impairment of intangible assets and goodwill that have indefinite lives on an annual basis (as of December 31st) and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We assess goodwill for impairment annually, at the reporting unit level whenever events or circumstances indicate impairment may exist. In evaluating goodwill for impairment, we have the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. The more likely than not threshold is defined as having a likelihood of more than 50 percent. If, after assessing the totality of events or circumstances, we determine that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, we would then perform step one of the two-step impairment test; otherwise, no further impairment test would be required. In contrast, we can opt to bypass the qualitative assessment for any reporting unit in any period and proceed directly to step one of the two-step impairment test. Doing so does not preclude us from performing the qualitative assessment in any subsequent period. Factors that could indicate that an impairment may exist include significant under-performance relative to plan or long-term projections, significant changes in business strategy and significant negative industry or economic trends. Although we believe intangible assets and goodwill are appropriately stated in the accompanying financial statements, changes in strategy or market conditions could significantly impact these judgements and require an adjustment to the recorded balance. No goodwill impairments were recorded during the year ended December 31, 2016. See Notes 2(h), 8 and 9 for additional disclosures.

(g) **Fair Value Measurements**

In determining fair value measurements, we follow the provisions of Codification Topic 820, *Fair Value Measurements and Disclosures*. Codification Topic 820 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. The topic provides a consistent definition of fair value which focuses on an exit price, which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The topic also prioritizes, within the measurement of fair value, the use of market-based information over entity-specific information and establishes a three-level hierarchy for fair value measurements based on the nature of inputs used in the valuation of an asset or liability as of the measurement date. At December 31, 2016 and 2015, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, other assets, accounts payable and accrued

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

liabilities approximate fair value because of their short-term nature. The amount outstanding under our bank debt facilities is measured at carrying value in our accompanying balance sheets. Our bank debt facilities are valued using Level 2 inputs. The estimated fair value of our bank debt facilities approximates their carrying value. The three-level hierarchy is as follows:

- Level 1 - Pricing inputs are quoted prices available in active markets for identical assets or liabilities as of the measurement date.
- Level 2 - Pricing inputs are quoted prices for similar assets or liabilities, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data.
- Level 3 - Pricing inputs are unobservable for the assets or liabilities, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the asset or liability.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, an asset's or liability's level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement in its entirety requires judgement, and considers factors specific to the investment.

Our held to maturity securities are comprised of investments in bank certificates of deposit. The value of these securities is disclosed in Note 3. We also hold money market mutual funds in a brokerage account, which are classified as cash equivalents and measured at fair value. The fair value of these investments is based on their closing published net asset value.

We assess the levels of the investments at each measurement date, and transfers between levels are recognized on the actual date of the event or change in circumstances that caused the transfer in accordance with our accounting policy regarding the recognition of transfers between levels of the fair value hierarchy. During the years ended December 31, 2016 and 2015, there were no transfers between levels. As of December 31, 2016 and 2015, our Level 1 assets measured at fair value by quoted prices in active markets consisted of bank savings accounts and money market funds. As of December 31, 2016 and 2015, our bank certificates of deposit were classified as Level 2 and were measured by significant other observable inputs. As of December 31, 2016 and 2015, our interest rate swaps were classified as Level 2 and were measured by observable market data in combination with expected cash flows for each instrument. There were no assets or liabilities measured at fair value on a nonrecurring basis as of December 31, 2016 or 2015.

	As of December 31, 2016			
	Level 1	Level 2	Level 3	Total
Cash and money market accounts	\$5,150,344	-	-	\$5,150,344
Bank certificates of deposit	-	\$5,474,013	-	5,474,013
Interest rate swaps	-	(37,346)	-	(37,346)
Total	\$5,150,344	\$5,436,667	-	\$10,587,011

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Cash and money market accounts	\$1,573,328	-	-	\$1,573,328
Bank certificates of deposit	-	\$4,960,222	-	4,960,222
Interest rate swaps	-	(78,525)	-	(78,525)
Total	\$1,573,328	\$4,881,697	-	\$6,455,025

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

(h) Valuation of Long-Lived Assets

We periodically evaluate our long-lived assets, consisting principally of fixed assets and amortizable intangible assets, for potential impairment. In accordance with the applicable accounting guidance for the treatment of long-lived assets, we review the carrying value of our long-lived assets or asset group that is held and used, including intangible assets subject to amortization, for impairment whenever events and circumstances indicate that the carrying value of the assets may not be recoverable. Under the held and used approach, the asset or asset group to be tested for impairment should represent the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities. We evaluate our long-lived assets whenever events or circumstances suggest that the carrying amount of an asset or group of assets may not be recoverable from the estimated undiscounted future cash flows. No impairment was recognized during the years ended December 31, 2016 or 2015.

(i) Concentration of Risk

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. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

	Year Ended December 31,	
	2016	2015
Patterson Companies, Inc. ⁽¹⁾	39%	42%
AmerisourceBergen Corporation ⁽²⁾	21%	20%

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, 2016	As of December 31, 2015
AmerisourceBergen Corporation ⁽²⁾	33%	27%
Patterson Companies, Inc. ⁽¹⁾	31%	26%
ANIMART LLC ⁽³⁾	*	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 acquisition of Animal Medic by ANIMART LLC (which closed during the third quarter of 2016) had occurred as of the beginning of the periods being reported.

*Amount is less than 10%.

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)

(j) 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 11.

(k) Revenue Recognition

We sell products that provide immediate immunity to newborn dairy and beef cattle. We recognize revenue when four criteria are met. 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 do not bill for or collect sales tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We offer a 50% account credit to domestic distributors on expired **First Defense**[®] product that is returned to us past its expiration date, which is generally two years past its date of manufacture. At the time of sale, we estimate returns and record a corresponding liability. We generally have experienced an immaterial amount of product returns.

(l) Expense Recognition

Advertising costs are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to \$114,860 and \$94,607 during the years ended December 31, 2016 and 2015, respectively. All product development expenses are expensed as incurred, as are all related patent costs. We capitalize costs to produce inventory during the production cycle, and these costs are charged to costs of goods sold when the inventory is sold to a customer.

(m) 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. Our tax returns for the years 2013 through 2016 are subject to audit. We have evaluated the positions taken on our filed tax returns. We have concluded that no uncertain tax positions exist as of December 31, 2016. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 14.

(n) 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

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

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 \$67,399 and \$23,222 during the years ended December 31, 2016 and 2015, respectively, which resulted in a decrease to income before income taxes of less than \$0.01 per share during each of the periods reported.

(o) Net Income Per Common Share

Net income 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 the period. The 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 weighted average and diluted number of shares outstanding consisted of the following:

	<u>Years Ended December 31,</u>	
	<u>2016</u>	<u>2015</u>
Weighted average number of shares outstanding	4,225,789	3,042,376
Effect of dilutive stock options	110,440	123,359
Diluted number of shares outstanding	<u>4,336,229</u>	<u>3,165,735</u>
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	<u>34,250</u>	<u>6,000</u>

(p) 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. Although we regularly assess these estimates, actual amounts could differ from those estimates. Changes in estimates are recorded during the period in which they become known. Significant estimates include our inventory, goodwill, accrued expenses and costs of goods sold accounts as well as amortization of our intangible assets.

(q) 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 to become 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 intend to utilize the modified retrospective method and have made a preliminary evaluation of the effect that ASU 2014-09 would have on our financial statements and related disclosures and do not expect ASU 2014-09 to have a material impact on our financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern*, which provides guidance regarding management's responsibility to assess whether substantial doubt exists regarding the ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting period, management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. This ASU is effective for the

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We implemented this guidance during 2016. The adoption of this guidance did not have a material impact on our financial statements.

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. This update is effective for the annual reporting periods beginning after December 15, 2015. During the first quarter of 2016, we adopted ASU 2015-03 and reclassified \$40,792 of debt issuance costs (net) from other assets to a reduction in our bank debt liability as of December 31, 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 did not have a material impact on our financial statements.

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 with early adoption permitted. We adopted ASU 2015-11 during the third quarter of 2016, and it did not 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 one noncurrent deferred tax liability or asset (net) 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 was permitted. During the first quarter of 2016, we adopted ASU No. 2015-17 early and reclassified \$19,588 of current deferred tax liabilities to long-term, which amount was netted against our long-term deferred tax asset, as of December 31, 2015. ASU No. 2015-17 did not 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. Based on our current lease agreements, 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.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation*, which simplifies several aspects of the accounting for share-based payment transactions, including income tax consequences, recognition of stock compensation award forfeitures, classification of awards as either equity or liabilities, the calculation of diluted shares outstanding and classification on the statement of cash flows. The most significant change resulting from these amendments is recording all the tax effects related to share-based payments at settlement through the income statement. Under existing guidance, tax benefits in excess of compensation costs ("windfalls") are recorded in equity. Similarly, tax deficiencies below compensation costs ("shortfalls") are recorded in equity to the extent of previous windfalls, while shortfalls in excess of this are recorded to the income statement. Furthermore, the new guidance is expected to increase the dilutive effect of share-based payment awards as a result of no longer assuming that tax benefits are used to purchase our common stock under the treasury method. The amendments also provide an alternative to estimating stock award forfeitures and instead recording at the time of forfeiture. This update is effective for public business entities during fiscal years beginning after December 15, 2016 with early adoption permitted. We adopted ASU 2016-09 during 2016, and it did not have a material impact on our financial statements.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

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

Cash, cash equivalents, short-term investments and long-term investments (at amortized cost plus accrued interest) consisted of the following:

	As of December 31,		Increase (Decrease)
	2016	2015	
Cash and cash equivalents	\$5,150,344	\$1,573,328	\$3,577,016
Short-term investments	5,474,013	4,470,574	1,003,439
Subtotal	10,624,357	6,043,902	4,580,455
Long-term investments	-	489,648	(489,648)
Total	\$10,624,357	\$6,533,550	\$4,090,807

Held to maturity securities (certificates of deposit) are carried at amortized cost. The cost of securities sold is determined based on the specific identification method. Realized gains and losses, and declines in value judged to be other than temporary, are included in investment income. As of December 31, 2016 and 2015, the fair value of held to maturity securities consisted of the following:

	As of December 31,	
	2016	2015
Amortized cost	\$5,450,000	\$4,951,000
Accrued interest	24,013	9,222
Gross unrealized gains	2,073	25
Gross unrealized losses	(59)	(6,277)
Estimated fair value	\$5,476,027	\$4,953,970

4. INVENTORY

Inventory consisted of the following:

	As of December 31,		Increase
	2016	2015	
Raw materials	\$318,443	\$284,331	\$34,112
Work-in-process	968,810	452,024	516,786
Finished goods	839,646	133,852	705,794
Total	\$2,126,899	\$870,207	\$1,256,692

5. ACCOUNTS RECEIVABLE

Accounts receivable consisted of the following:

	As of December 31,		Increase (Decrease)
	2016	2015	
Trade accounts receivable, gross	\$1,013,716	\$736,195	\$277,521
Allowance for bad debt and product returns	(21,326)	(18,092)	(3,234)
Trade accounts receivable, net	\$992,390	\$718,103	\$274,287

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of December 31,		(Decrease)
	2016	2015	Increase
Prepaid expenses	\$126,523	\$183,217	(\$56,694)
Other receivables	144,848	26,958	117,890
Security deposits ⁽¹⁾	333,111	37,301	295,810
Total	<u>\$604,482</u>	<u>\$247,476</u>	<u>\$357,006</u>

⁽¹⁾ This balance as of December 31, 2016 included an option payment of \$20,500 towards land (which we did not exercise) that was subsequently applied to the purchase of a warehouse facility during the first quarter of 2017.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

	Estimated Useful Lives (in years)	As of December 31,		Increase
		2016	2015	(Decrease)
Laboratory and manufacturing equipment	5-10	\$5,562,938	\$3,766,556	\$1,796,382
Building and improvements	10-33	5,037,512	4,716,204	321,308
Office furniture and equipment	5-10	653,462	568,188	85,274
Construction in progress ⁽¹⁾		3,694,509	1,084,924	2,609,585
Land		347,114	333,486	13,628
Property, plant and equipment, gross		<u>15,295,535</u>	<u>10,469,358</u>	4,826,177
Accumulated depreciation		(5,449,242)	(4,750,544)	(698,698)
Property, plant and equipment, net		<u>\$9,846,293</u>	<u>\$5,718,814</u>	<u>\$4,127,479</u>

⁽¹⁾ As of December 31, 2016, construction in progress consisted principally of initial costs incurred in connection with the building and equipping of our Nisin production plant for **Mast Out**[®]. As of December 31, 2015, construction in progress consisted principally of partial payments towards new manufacturing equipment related to expanding our production capacity for **First Defense**[®].

8. BUSINESS ACQUISITION

On January 4, 2016, we acquired certain business assets and processes 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**[®] product since first approval by the U.S. Department of Agriculture (USDA) and product launch in 1991) and could allow more market penetration. The formulation was developed 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. The total purchase price was approximately \$532,000. Approximately \$368,000 of this amount was paid as of the closing date. A technology transfer payment of \$97,000 was made during the third quarter of 2016. There are also royalty payments owed based on a percentage of sales made through December 31, 2018. There is no limit to the royalty amount. As of January 4, 2016, we estimated the aggregate royalties to be paid would be approximately \$67,000, which was recorded in accounts payable and accrued expenses on the accompanying balance sheet. As of December 31, 2016, this amount

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Notes to Audited Financial Statements (continued)

was estimated to be approximately \$30,000. We made payments of \$8,200 for the year ended December 31, 2016. The estimated fair values of the assets purchased in this transaction included inventory of \$113,000, machinery and equipment of \$132,000, a developed technology intangible of \$191,000 (which includes an immaterial amount of value associated with customer relationships and a non-compete agreement, and was valued using the relief from royalty method) and goodwill of \$96,000. The intangible assets and goodwill are deductible for tax return purposes. The goodwill arising from the acquisition consists largely of the estimated value of anticipated growth opportunities arising from synergies and efficiencies. The measurement period for the transaction was closed as of June 30, 2016, and we continue to assess any impairment of these assets acquired in accordance with our policies. The impact of the acquisition on our pro forma prior year operations is not material. As of December 31, 2016, we vacated the rented facility in Minnesota that had been used to produce the gel solution format of our product and certain other related private-label products. This resulted in the termination of employment of four employees, as these production functions were consolidated into our Portland facility, which enables us to better utilize existing infrastructure and larger scale equipment to improve operating efficiencies.

9. INTANGIBLE ASSETS

The intangible assets described in Note 8 are being amortized to cost of goods sold over their useful lives, which are estimated to be 10 years. Intangible amortization expense was \$19,104 during the year ended December 31, 2016. The net value of these intangibles was \$171,936 as of December 31, 2016. A summary of intangible amortization expense estimated for the five years beginning January 1, 2017 and thereafter is as follows:

Period	Amount
Year ending December 31, 2017	\$19,104
Year ending December 31, 2018	\$19,104
Year ending December 31, 2019	\$19,104
Year ending December 31, 2020	\$19,104
Year ending December 31, 2021	\$19,104
After December 31, 2021	\$76,416
Total	\$171,936

Intangible assets as of December 31, 2016 consisted of the following:

	As of December 31, 2016		
	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	\$184,100	(\$18,410)	\$165,690
Customer relationships	1,300	(130)	1,170
Non-compete agreements	5,640	(564)	5,076
Total	\$191,040	(\$19,104)	\$171,936

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of December 31,		Increase (Decrease)
	2016	2015	
Accounts payable – capital	\$1,249,862	\$1,510	\$1,248,352
Accounts payable – trade	257,397	199,105	58,292
Accrued payroll	200,477	242,690	(42,213)
Accrued clinical studies	-	68,428	(68,428)
Accrued professional fees	82,500	56,450	26,050
Accrued other	101,527	93,982	7,545
Total	\$1,891,763	\$662,165	\$1,229,598

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Notes to Audited Financial Statements (continued)

11. BANK DEBT

During the first quarter of 2016, we entered into bank debt agreements covering certain additional credit facilities with TD Bank N.A. aggregating up to approximately \$4.5 million. As a result of loan amendments entered into with TD Bank N.A. on March 1, 2017, these credit facilities now aggregate up to approximately \$6.5 million, subject to certain restrictions as defined in the agreements. The first instrument is comprised of a construction loan of up to \$2.5 million and not to exceed 80% of the cost of equipment installed in the to-be-constructed commercial-scale Nisin production facility for **Mast Out**[®]. Effective March 1, 2017, this loan amount was increased by \$1.44 million to \$3.94 million. As amended, interest only will be payable at a variable rate equal to the one-month LIBOR plus a margin of 2.25% through July 2018, at which time the loan converts to a seven-year term loan facility at the same variable interest rate with monthly principal and interest payments due based on a seven-year amortization schedule. The second instrument is comprised of a construction loan of up to \$2.0 million and not to exceed 80% (75% prior to the March 1, 2017 amendment) of the appraised value of the to-be-constructed commercial-scale Nisin production facility in Portland, Maine. Effective March 1, 2017, this loan amount was increased by \$560,000 to \$2.56 million. As amended, interest only will be payable at a variable rate equal to the one-month LIBOR plus a margin of 2.25% through January 2018, at which time the loan converts to a nine-year term loan facility at the same variable interest rate with monthly principal and interest payments due based on a twenty-year amortization schedule with a balloon principal payment of approximately \$1.654 million due in January 2027. These credit facilities are secured by substantially all of our assets and are subject to certain financial covenants. There were no amounts outstanding under these facilities as of December 31, 2016.

Additionally, we have in place certain credit facilities with TD Bank N.A. not to exceed 80% of the appraised value of our corporate headquarters and production and research facility in Portland, which are secured by substantially all of our assets and are subject to certain financial covenants. Proceeds from the \$1.0 million mortgage note were received during the third quarter of 2010. Based on a 15-year amortization schedule, a balloon principal payment of \$451,885 will be due during the third quarter of 2020. Proceeds from the \$2.5 million mortgage note were received during the third quarter of 2015. Based on a 20-year amortization schedule, a balloon principal payment of approximately \$1.55 million will be due during the third quarter of 2025. Principal payments (net of debt issuance costs) due under debt outstanding as of December 31, 2016 (which does not include the debt proceeds not yet drawn under the credit facilities entered into during the first quarter of 2016 and subsequently amended during the first quarter of 2017, as discussed above) are reflected in the following table by the year that payments are due:

<u>Period</u>	<u>\$1,000,000 Mortgage Note</u>	<u>\$2,500,000 Mortgage Note</u>	<u>Debt Issuance Costs</u>	<u>Total</u>
Year ending December 31, 2017	\$61,056	\$82,308	(\$10,095)	\$133,269
Year ending December 31, 2018	64,876	86,097	(10,095)	140,878
Year ending December 31, 2019	68,908	89,997	(10,095)	148,810
Year ending December 31, 2020	493,696	94,005	(9,462)	578,239
Year ending December 31, 2021	-	98,538	(8,448)	90,090
After December 31, 2021	-	1,951,228	(30,440)	1,920,788
Total	<u>\$688,536</u>	<u>\$2,402,173</u>	<u>(\$78,635)</u>	<u>\$3,012,074</u>

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 margin of 3.25% and 2.25% to the fixed rates of 6.04% and 4.38%, respectively. As of December 31, 2016, the variable rates on these two mortgage notes were 3.93% and 2.99%, 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 income (loss), 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 \$3,090,709 as of December 31, 2016. 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*.

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Notes to Audited Financial Statements (continued)

	Year Ended December 31,	
	2016	2015
Payments required by interest rate swaps	\$58,346	\$32,515
Other comprehensive income (loss) net of taxes	\$26,354	(\$26,925)

In connection with the credit facilities entered into during the third quarters of 2010 and 2015 and the first quarter of 2016, we incurred debt issue costs of \$26,489, \$34,125 and \$46,734, respectively, which costs are being recorded as a component of other expenses over the terms of the credit facilities.

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 with TD Bank N.A. was first entered into during the third quarter of 2010 and has been renewed approximately annually since then and is available as needed and has been extended through August 29, 2017. The line of credit, which is subject to certain financial covenants, was unused as of December 31, 2016 and 2015. 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.

12. STOCKHOLDERS' EQUITY

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 were 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 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, resulting in net proceeds to the Company of approximately \$5,313,000 after deducting underwriting discounts and offering expenses incurred in connection with the equity financing. On October 21, 2016, we closed on a private placement of 659,880 shares of common stock to nineteen institutional and accredited investors at \$5.25 per share, raising gross proceeds of approximately \$3,464,000 resulting in net proceeds to the Company of approximately \$3,161,000 after deducting placement agent fees and other estimated expenses incurred in connection with the equity financing.

At the June 15, 2016 Annual Meeting of Stockholders, our stockholders voted to approve an amendment to the Company's Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 8,000,000 to 10,000,000.

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

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Notes to Audited Financial Statements (continued)

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 and subsequently no additional shares have been reserved for 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 ⁽¹⁾
Outstanding at December 31, 2014	157,500	95,500	\$3.42	\$364,000
Grants	-	16,000	\$7.40	
Terminations	-	(3,000)	\$4.95	
Exercises	(26,000)	(2,000)	\$4.29	
Outstanding at December 31, 2015	131,500	106,500	\$3.57	\$945,000
Grants	-	46,000	\$6.98	
Terminations	(5,000)	(12,000)	\$6.16	
Exercises	-	(16,000)	\$5.59	
Outstanding at December 31, 2016	126,500	124,500	\$3.89	\$517,000
Exercisable at December 31, 2016	126,500	26,500	\$2.52	\$524,000
Reserved for future grants	-	155,500		

⁽¹⁾Intrinsic value is the difference between the fair market value as of the date indicated and as of the date of the option grant.

	Number of Shares	Weighted Average Fair Value at Grant Date
Non-vested stock options as of January 1, 2016	65,000	\$5.35
Non-vested stock options as of December 31, 2016	98,000	\$6.03
Stock options granted during the year ended December 31, 2016	46,000	\$6.98
Stock options that vested during the year ended December 31, 2016	1,000	\$4.15
Stock options that were forfeited during the year ended December 31, 2016	17,000	\$6.16

During the year ended December 31, 2016, one employee and one director exercised stock options covering the aggregate of 16,000 shares of which 6,000 were exercised for cash, resulting in total proceeds of \$31,900, and 10,000 of these options were exercised by the surrender of 7,334 shares of common stock with a fair market value of \$57,425 at the time of exercise and \$75 in cash. 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. At December 31, 2016, 251,000 shares of common stock were reserved for future issuance under all outstanding stock options described above, and an additional 155,500 shares of common stock were reserved for the

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Notes to Audited Financial Statements (continued)

potential issuance of stock option grants 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, 2016 was approximately 4 years and 4 months. The weighted average remaining life of the options exercisable under these plans as of December 31, 2016 was approximately 2 years and 4 months. The exercise prices of the options outstanding as of December 31, 2016 ranged from \$1.70 to \$8.21 per share. The 46,000 stock options granted during 2016 had exercise prices between \$6.27 and \$8.21 per share. The 16,000 stock options granted during 2015 had exercise prices between \$6.05 and \$7.54 per share. The aggregate intrinsic value of options exercised during 2016 and 2015 approximated \$32,000 and \$110,000, respectively. The weighted-average grant date fair values of options granted during 2016 and 2015 were \$4.16 and \$3.46 per share, respectively. As of December 31, 2016, total unrecognized stock-based compensation related to non-vested stock options aggregated \$204,360, which will be recognized over a weighted average period of two years and eleven months. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, for the purpose discussed in Note 2(n), with the following weighted-average assumptions for the years ended December 31, 2016 and 2015:

	2016	2015
Risk-free interest rate	1.2%	2.0%
Dividend yield	0%	0%
Expected volatility	63%	47%
Expected life	6.5 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.

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.

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

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Notes to Audited Financial Statements (continued)

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.

13. OTHER EXPENSES, NET

Other expenses, net, consisted of the following:

	Year Ended December 31,	
	2016	2015
Interest expense	\$161,697	\$83,578
Interest income	(54,662)	(19,169)
Other losses (gains)	24,847	(5,635)
Other expenses, net	<u>\$131,882</u>	<u>\$58,774</u>

14. INCOME TAXES

Our income tax expense aggregated \$249,874 and \$850,309 during the years ended December 31, 2016 and 2015, respectively. In 2015, we utilized \$1,625,653 of net operating loss carryforwards to offset otherwise taxable income. As of December 31, 2015, we had federal net operating loss carryforwards of \$125,797 (that expire in 2031, (if not utilized before then) of which approximately \$98,000 is expected to be utilized against taxable income during 2016. As of December 31, 2016, we have federal general business tax credit carryforwards of approximately \$292,000 that expire in 2027 through 2034 (if not utilized before then) and state tax credit carryforwards of approximately \$152,000 that expire in 2023 through 2036 (if not utilized before then). 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**[®] 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.

The provision for income taxes is determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the estimated future tax effects of temporary differences between book and tax treatment of assets and liabilities and carryforwards to the extent they are realizable. We record a

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Notes to Audited Financial Statements (continued)

valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. While we consider future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of the net recorded amount, a reduction of the valuation allowance would increase income in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax asset in the future, a reduction to the deferred tax asset would be charged to income in the period such determination was made.

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.

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 2013. 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.

The income tax provision consisted of the following:

	<u>Year Ended December 31,</u>	
	<u>2016</u>	<u>2015</u>
Federal	-	-
State	\$13,585	\$3,150
Current	<u>\$13,585</u>	<u>\$3,150</u>
Federal	252,659	641,733
State	(16,370)	205,426
Deferred	<u>236,289</u>	<u>847,159</u>
Total	<u>\$249,874</u>	<u>\$850,309</u>

The actual income tax 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:

	<u>Year Ended December 31,</u>			
	<u>2016</u>		<u>2015</u>	
	<u>\$</u>	<u>%</u>	<u>\$</u>	<u>%</u>
Computed expected tax expense/rate	\$257,829	34.00%	\$701,607	34.00%
State income taxes, net of federal expense	38,855	5.12	44,754	2.17
Share-based compensation	13,362	1.76	(7,524)	(0.36)
Tax credits	(70,967)	(9.36)	(54,719)	(2.65)
State income tax rate change, net of federal ⁽¹⁾	-	-	109,112	5.29
Other	10,795	1.43	57,079	2.76
Total income tax expense/rate	<u>\$249,874</u>	<u>32.95%</u>	<u>\$850,309</u>	<u>41.21%</u>

⁽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.

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Notes to Audited Financial Statements (continued)

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

	As of December 31,	
	2016	2015
Product rights	\$68,197	\$91,344
Property, plant and equipment	(307,976)	(26,717)
Federal and state tax credits	292,516	339,585
Federal net operating loss carryforward	8,856	39,241
State tax credits carryover	100,528	-
Interest rate swap	13,437	28,253
Prepaid expenses and other	(6,240)	(19,589)
UNICAP	31,685	-
Deferred tax asset	\$201,003	\$452,117

15. CONTINGENT LIABILITIES AND COMMITMENTS

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, 2016. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

The development, manufacturing and marketing of animal health care products entails an inherent risk that liability claims will be asserted against us during the normal course of business. We are aware of no such claims against us as of the date of this filing. We feel that we have reasonable levels of liability insurance to support our operations.

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, 2016.

We are committed to purchasing certain key parts (syringes) and services (formulation, filling and packaging of Drug Product) pertaining to **Mast Out**[®] exclusively from two contractors. If we do not commercialize the product by the end of 2019, we would be liable for a \$100,000 termination fee under one of such agreements.

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 for our product line extension that is under development. This perpetual license (if not terminated for cause) is subject to a milestone payment of \$150,000 upon regulatory approval and a royalty equal to 4% of sales above current sales of our bivalent product plus a growth assumption.

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Notes to Audited Financial Statements (continued)

During the third quarter of 2016, we initiated construction of our Nisin production facility for **Mast Out**[®]. The estimated total cost of the Nisin facility is \$20,000,000. As of December 31, 2016, we had incurred approximately \$3,280,000 of capital expenditures related to this project, of which \$2,080,000 had been paid as of year-end. The majority of this investment is expected to be paid during the nine-month period ending September 30, 2017. As of December 31, 2016, we had committed \$12,320,000 of the remaining \$17,920,000 expected to be paid on this project. Approximately \$8,865,000 of these capital expenditures is committed under a guaranteed maximum price contract with our construction management firm, net of payments made. This contract includes provisions that could reduce the amount of the commitment generally by the amount not expended or committed by the construction manager at the time of an unexpected and unlikely early termination. We expect to fund the remaining costs in excess of our current cash and investments with cash to be generated from operations during 2017 and borrowings under the credit facilities described in Note 11. Additionally, as of December 31, 2016, we had committed \$617,000 to the production of inventory and \$100,000 to other obligations.

16. SEGMENT 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 single operating segment is defined as the component of our business for which financial information is available and evaluated regularly by our chief operating decision-maker in deciding how to allocate resources and in assessing performance. Our chief operating decision-maker is our President and CEO.

Sales of the **First Defense**[®] product line aggregated 93% of our total product sales during the years ended December 31, 2016 and 2015. Our primary customers for the majority of our product sales (85% and 83% for the years ended December 31, 2016, and 2015 respectively) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 13% and 14% of our total product sales for the years ended December 31, 2016 and 2015, respectively.

17. 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**[®], **Wipe Out**[®] **Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased \$551,020 and \$573,165 of products from ImmuCell during the years ended December 31, 2016 and 2015, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of \$5,286 and \$3,222 to these affiliate companies during the years ended December 31, 2016 and 2015, respectively, that were expensed as incurred. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated \$3,221 and \$36,528 as of December 31, 2016 and 2015, respectively.

18. 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 \$74,507 and \$73,514 into the plan for the years ended December 31, 2016 and 2015, respectively.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

19. UNAUDITED QUARTERLY FINANCIAL DATA

The following tables present the quarterly information for the years ended December 31, 2016 and 2015, respectively:

	Three Months Ended			
	March 31	June 30	September 30	December 31
Fiscal 2016:				
Product sales	\$2,986,359	\$2,375,662	\$1,968,122	\$2,213,818
Gross margin	1,757,560	1,239,861	1,204,627	1,218,647
Product development expenses	302,443	380,434	307,721	253,737
Net operating income	698,964	21,465	50,467	119,309
Net income (loss)	452,448	(9,155)	34,870	30,285
Net income (loss) per common share:				
Basic	\$0.12	(\$0.00)	\$0.01	\$0.01
Diluted	\$0.11	(\$0.00)	\$0.01	\$0.01
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

20. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of filing on March 30, 2017, the date we have issued this Annual Report on Form 10-K. As of such date, except as described below, there were no material, reportable subsequent events.

During the first quarter of 2017, we acquired a 4,114 square foot building that is adjacent to our Nisin production plant for additional warehousing and storage space. The purchase price was \$465,500, and we financed this purchase, in part, with a mortgage loan in the amount of \$340,000 bearing interest at a variable rate equal to the one-month LIBOR plus a margin of 2.25% with monthly principal and interest payments due for ten years based on a twenty-year amortization schedule.

During the first quarter of 2017, we amended two loan agreements, as described in Note 11, increasing the total available loan amount from up to approximately \$4.5 million to up to approximately \$6.5 million.

During the first quarter of 2017, we discontinued the production and sale of our topical wipes product line. In connection therewith, we wrote off approximately \$38,000 worth of fixed assets and recognized \$45,000 from the sale of certain other fixed assets and product rights, resulting in a net gain of approximately \$7,000.

During the first quarter of 2017, our \$500,000 line of credit was extended through August 29, 2017.

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.

Date: March 30, 2017 By: ImmuCell Corporation
Registrant
/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 21, 2017 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer,
Principal Financial Officer and Director

Date: March 21, 2017 By: /s/ Bobbi Jo Brockmann
Bobbi Jo Brockmann, Director

Date: March 21, 2017 By: /s/ Joseph H. Crabb
Joseph H. Crabb, Ph.D., Director

Date: March 21, 2017 By: /s/ David S. Cunningham
David S. Cunningham, Director

Date: March 21, 2017 By: /s/ Linda Rhodes
Linda Rhodes, VMD, Ph.D., Director

Date: March 21, 2017 By: /s/ Jonathan E. Rothschild
Jonathan E. Rothschild, Director

Date: March 21, 2017 By: /s/ David S. Tomsche
David S. Tomsche, DVM, Director

Date: March 21, 2017 By: /s/ Paul R. Wainman
Paul R. Wainman, Director