

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

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

FORM 10-K

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

**For the fiscal year ended December 31, 2014**

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

**001-12934**

**(Commission file number)**

**ImmuCell Corporation**

**(Exact name of Registrant as specified in its charter)**

**Delaware**

**(State or other jurisdiction of  
incorporation or organization)**

**01-0382980**

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

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

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

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

**None**

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

**Common Stock, par value \$0.10 per share**

**(Title of class)**

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

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

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

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

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

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

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

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

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

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

**ImmuCell Corporation**

**TABLE OF CONTENTS**

**December 31, 2014**

**PART I**

ITEM 1. Description of Business	1
ITEM 1A.Risk Factors	11
ITEM 2. Description of Property	18
ITEM 3. Legal Proceedings	18
ITEM 4. Mine Safety Disclosures	18

**PART II**

ITEM 5. Market for Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	19
ITEM 6. Selected Financial Data	19
ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	20
ITEM 7A.Quantitative and Qualitative Disclosures about Market Risk	30
ITEM 8. Financial Statements	30
ITEM 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	30
ITEM 9A Controls and Procedures	30
ITEM 9B.Other Information	31

**PART III**

ITEM 10. Directors, Executive Officers and Corporate Governance	32
ITEM 11. Executive Compensation	32
ITEM 12.	32

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Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

ITEM 13. Certain Relationships and Related Transactions, and Director Independence	32
ITEM 14. Principal Accounting Fees and Services	32
ITEM 15. Exhibits and Financial Statement Schedules	32
Audited Financial Statements	F-1 to F-20
Signatures	

## ImmuCell Corporation

### PART I

#### ITEM 1 – DESCRIPTION OF BUSINESS

##### Summary

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

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

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

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

## ImmuCell Corporation

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

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

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

## Animal Health Products

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



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

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

## ImmuCell Corporation

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

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

## Sales and Markets

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

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

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

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

## ImmuCell Corporation

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

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

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

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

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

## ImmuCell Corporation

### Competition

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

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

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

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

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

## ImmuCell Corporation

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

## Product Development

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

During the fifteen-year period that began on January 1, 2000 (the year we began the development of **Mast Out**<sup>®</sup>) and ended on December 31, 2014, we invested the aggregate of approximately \$11,032,000 in the development of **Mast Out**<sup>®</sup>. This estimated allocation to **Mast Out**<sup>®</sup> 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**<sup>®</sup>.

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



Milk from cows treated with any of the intramammary mastitis treatment products on the market today must be discarded for a specified period of time during and after treatment. We believe that all milk from cows treated with **Mast Out**<sup>®</sup> will be saleable in the United States. This is a significant competitive advantage for our product. Due to this zero milk discard feature, there is a risk that Nisin from milk of cows treated with **Mast Out**<sup>®</sup> could interfere with the manufacture of certain (but not all) commercial cultured dairy products, such as some kinds of cheese and yogurt, if a process tank contains milk from a high enough percentage of treated cows. The impact of this potential interference ranges from a delay in the manufacturing process, which does happen at times for other reasons, to the less likely stopping of a cheese starter culture. Milk from cows that have been treated with **Mast Out**<sup>®</sup> 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**<sup>®</sup> is used in accordance with the product label. Monitoring of several important variables relevant to the manufacture of cheese would be advisable if **Mast Out**<sup>®</sup> were to be used as part of a whole herd (“blitz”) treatment protocol. We do not see this as a significant problem as modern “precision dairying” practices support reducing the indiscriminate use of drug treatments.

## ImmuCell Corporation

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

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

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

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

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

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

## ImmuCell Corporation

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

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

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

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

## ImmuCell Corporation

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

## Patents, Proprietary Information and Trademarks

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

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

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

## ImmuCell Corporation

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**<sup>®</sup>, our calf scours preventive product; **Wipe Out**<sup>®</sup> **Dairy Wipes** and the related design and the trademark “**One Step Cow Prep**”, our pre-milking wipe product; and **Mast Out**<sup>®</sup>, our mastitis treatment product under development. During the first quarter of 2015, we applied to register the following marks: **Immediate Immunity**<sup>™</sup>, **First Defense Technology**<sup>™</sup> and **Your Calf Crew**<sup>™</sup>.

## Government Regulation

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

## Employees

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

## Executive Officers of the Company



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

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

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

## **ImmuCell Corporation**

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

## **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**

### **Safe Harbor Statement**

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: projections of future financial performance; the scope and timing of future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis; future market share of and revenue generated by products still in development; future sources of financial support for our product development, manufacturing and marketing efforts; the future adequacy of our own manufacturing facilities or those of third parties with which we have contractual

relationships to meet demand for our products on a timely basis; the amount and timing of future investments in facility modifications and production equipment; the future adequacy of our working capital and the availability of third party financing; timing and future costs of a facility to produce the Drug Substance (active pharmaceutical ingredient) for **Mast Out**<sup>®</sup>; the timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; future realization of deferred tax assets; costs associated with sustaining compliance with cGMP regulations in our current operations and attaining such compliance for the facility to produce the Drug Substance for **Mast Out**<sup>®</sup>; 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, alignment between our manufacturing resources and product demand, the uncertainties associated with product development and Drug Substance manufacturing, our potential reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making by regulatory authorities, currency fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized below and uncertainties otherwise referred to in this Annual Report.

## ImmuCell Corporation

*Projection of net income:* After nine consecutive years of reporting net income, we reported net losses for the years ended December 31, 2008, 2009, 2010 and 2011, due in large part to our product development strategy. By reducing our investment in the development of **Mast Out**<sup>®</sup> and increasing sales of **First Defense**<sup>®</sup>, we were able to record net operating income of \$245,000 and net income of \$90,000 during the year ended December 31, 2012. We continued this positive trend by recording a net operating (loss) of just (\$20,000) and net income of \$117,000 during the year ended December 31, 2013. The 2013 results included a \$250,000 exclusive license option fee. Given our strategic decision to invest approximately \$973,000 during 2014 in facilities for the manufacture of the Drug Substance, we recorded a net (loss) of (\$167,000) during the year ended December 31, 2014 as expected, despite a return to profitability during the last six months of 2014. We expect the sales growth trend for **First Defense**<sup>®</sup>, and the profitability trend recorded during the last six months of 2014, to continue into 2015. 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. Stronger than expected sales of **First Defense**<sup>®</sup>, for example, could increase our net income. Conversely, weaker than expected sales of **First Defense**<sup>®</sup> could lead to less profits or an operating loss. Large investments in product development can result in a net loss.

*Reliance on sales of First Defense*<sup>®</sup>: We are heavily reliant on the market acceptance of **First Defense**<sup>®</sup> to generate product sales and fund our operations. 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 and 2013, or during the second half of 2014, without the gross margin that we earned on sales of **First Defense**<sup>®</sup>.

*Concentration of sales:* Approximately 83% of our product sales were made to customers in the U.S. dairy and beef industries during both of the years ended December 31, 2014 and 2013. During the year ended December 31, 2014, 96% of our product sales were made to customers in the dairy and beef industries throughout the world, in comparison to 97% during 2013. A large portion of our product sales (61%, 60% and 55% for the years ended December 31, 2014, 2013, and 2012, respectively) was made to two large distributors (adjusting for an acquisition made by one of these distributors). A large portion of our trade accounts receivable (71% and 65% as of December 31, 2014 and 2013, respectively) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us.

### *Economics of the dairy and beef industries:*

All cattle and calves in the United States as of July 1, 2014 totaled 95,000,000 head, which is 3% below the 97,800,000 head reported on July 1, 2012 (this data point was not reported as of July 1, 2013). The July 2014 amount was the lowest inventory count as of July 1<sup>st</sup> in decades. All cattle and calves in the United States as of January 1,

2015 totaled 89,800,000, which is 1.5% higher than January 1, 2014. According to a Purdue University Extension economist, this is the first increase in the cattle inventory since 2007 suggesting a faster rebuilding of the U.S. herd than had been anticipated.

From 1998 through 2014, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 (2004) to the high of 9,315,000 (2008). The average for 2013 was 9,215,000 which represents a slight reduction from the average of 9,232,000 reported for 2012. This average increased slightly to 9,255,000 during 2014.

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 milk price (measured in dollars per hundred pounds of milk) in each of the first eleven months of 2014 was the highest ever for those months, and nine out of ten of the highest Class III milk prices of all time occurred during 2014. The annual average price level for 2011 of \$18.37 was higher than the annual average reached in any of the previous 30 years. This annual average price level for 2014 of \$22.34 (peaking at \$24.60 in September 2014) was the highest level since these records were first reported in 1980. This strong price level has declined recently. The December 2014 price was \$17.82, and the January 2015 price was \$16.18, and the February 2015 price decreased further to \$15.46.

**ImmuCell Corporation**

The recent annual fluctuations in this milk price level are demonstrated in the following table:

<b>Average Class III Milk Price for (Decrease) the year (Increase) ended</b>		
<b>December 31,</b>		
<b>2011</b>	<b>2012</b>	
\$18.37	\$17.44	(5%)
<b>2012</b>	<b>2013</b>	
\$17.44	\$17.99	3%
<b>2013</b>	<b>2014</b>	
\$17.99	\$22.34	24%

The actual level of milk prices may be less important than its level relative to feed costs. The 2014 improvement in milk prices has been matched by slightly lower 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. It is considered profitable to buy feed and produce milk if this ratio meets or exceeds 3.0. This benchmark level means that a dairy producer could buy 3.0 pounds of feed for every pound of milk sold. The 2012 ratio of 1.52 was the lowest recorded since this ratio was first reported in 1985. The highest annual average this ratio has ever reached since 1985 was 3.64 in 1987. Since this ratio reached 3.24 in 2005, it has not exceeded this benchmark level of 3.0. The annual average of 2.54 for 2014 was the highest this ratio has been since 2007 (2.81). The following table demonstrates the annual volatility and the low values of this ratio recently:

<b>Average Milk-To-Feed Price Ratio (Decrease) for (Increase) the year ended</b>		
<b>December 31,</b>		
<b>2011</b>	<b>2012</b>	
\$1.88	\$1.52	(19%)
<b>2012</b>	<b>2013</b>	
\$1.52	\$1.74	14%

<b>2013</b>	<b>2014</b>	
\$1.74	\$2.54	45%

Approximately half of all U.S. dairy farms (more than 23,000) representing more than 60% of the nation's total milk production signed up for the Margin Protection Program (MPP) under the 2014 federal farm bill. This voluntary program provides financial assistance to participating farmers when the margin (the difference between the price of milk and feed costs) falls below the selected coverage level. To display the margin between milk revenue and the MPP feed cost over the years, Dr. D. Scott Brown of the University of Missouri charted the relationship of revenue to expenses graphically in the following table (the 2014 figures are preliminary and the 2015 figures are projected):

## ImmuCell Corporation

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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 recent positive trend in these market indices has resulted in an increase in the value of milk cows. The 2014 annual average price for a milk cow increased to \$1,835. This annual average price since 1970 was only higher when it reached \$1,840 in 2007 and \$1,953 in 2008. The industry data referred to above is compiled from USDA databases. Recently, the value of newborn bull calves has risen to the unusually high level of approximately \$300 to \$400. At this price, producers are more likely to invest in **First Defense**® for their bull calves. Given our focus on the dairy and beef industries, the financial insecurity of our primary end users is a risk to our ability to maintain and grow sales at a profitable level. It also heightens the challenge of selling premium-priced animal health products (such as **Mast Out**®) into such a market.

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

*Regulatory requirements for **Mast Out**®:* The commercial introduction of **Mast Out**® in the United States will require us to obtain appropriate FDA approval for this product. It presently is uncertain when or if this approval will be achieved. We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Mast Out**®, who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. International regulatory approvals would be required for sales outside of the United States. European regulatory authorities are not expected to approve a product with a zero milk discard claim, which would remove a significant competitive advantage of **Mast Out**® in that territory. However, the assigned milk discard period may be shorter for **Mast Out**® than it is for other products on the market in Europe.

*Risks associated with **Mast Out**® funding strategy:* Completing the development of **Mast Out**® through to the submission of the administrative NADA to the FDA involves a great deal of risk. Our current strategy is to build our own small-scale Drug Substance production plant in order to gain NADA approval, obtain better production cost data and test market the product. This facility must be approved by the FDA. Uncertainty concerning the availability and terms of financing to develop a larger-scale commercial production plant or alternatively the availability and terms of



potential partnering arrangements is a risk that, if materialized, could delay or preclude meaningful commercialization of **Mast Out**<sup>®</sup>.

## ImmuCell Corporation

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

*Competition from others:* Many of our competitors are significantly larger and more diversified in the relevant markets than we are and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. Zoetis, Elanco and Boehringer Ingelheim, among other companies, sell products that compete directly with **First Defense**® in preventing scours in newborn calves. 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. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. The loss of farms from which we buy raw material for **First Defense**® could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms on suitable terms. We are dependent on our manufacturing facility and operations at 56 Evergreen Drive in Portland, Maine for the production of **First Defense**® and **Wipe Out**® Dairy Wipes. The specific antibodies that we purify for **First Defense**® and the Nisin we produce by fermentation for **Wipe Out**® Dairy Wipes are not readily available from other sources. We will also be reliant on this facility for the production of the Drug Substance required to obtain regulatory approval. We expect to be dependent on Plas-Pak and (subject to the performance issues discussed above under **ITEM 1-DESCRIPTION OF BUSINESS, “Product Development”**) Norbrook for a significant portion of the manufacture of **Mast Out**® if that product proceeds to commercialization. Any significant damage to or other disruption in the services at these facilities could adversely affect the production of inventory and result in significant added expenses and loss of sales.

*Risk of sales order backlog:* Given our recent and significant increase in sales demand, our manufacturing resources (internal and third party) are no longer sufficient to avoid a backlog of orders. Until we complete the additional investments required to further increase our production capacity, we are at risk of losing customers that are unable to acquire our product on a timely basis. We understand that the competitive products marketed by Elanco and Boehringer Ingelheim are experiencing a disruption in supply to the market.

*Small size; dependence on key personnel:* We are a small company with 34 full-time employees and 1 part-time employee. As such, we rely on certain key employees to support different operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained. Our competitive position will be highly influenced by our ability to attract and retain key scientific, managerial and sales and marketing personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products and to continue to profitably sell our current products. We currently compete on the basis of product performance, price and distribution capability. We continue to monitor our network of independent distributors to maintain our competitive position.

*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.

## ImmuCell Corporation

*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. Any debt or equity financing we obtain to assist in funding our product development programs may include terms prohibiting or restricting our paying dividends or repurchasing stock for a lengthy period. Stockholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, contractual restrictions, restrictions imposed by applicable laws, current and anticipated needs for liquidity and other factors our Board of Directors deems relevant.

*Market for common stock:* Our common stock trades on the NASDAQ Stock Market (NasdaqCM: ICCC). Our average daily trading volume 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 has been a significant increase in the stock market activity of animal health companies since early 2013 in comparison to years past. Listed in chronological order by date of financing, companies such as Zoetis (ZTS), Aratana Therapeutics (PETX), Kindred (KIN), Phibro (PAHC), Parnell (PARN) and Nexvet Biopharma (NVET) have completed initial public offerings since 2013. The stock price of some of these companies has been volatile.

*Stock market valuation:* There are companies in the animal health sector with market capitalization values that greatly exceed our current market capitalization of approximately \$20,000,000. Some of these companies have no product sales. We currently have annual product sales approaching \$8,000,000. 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.

*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.

*Regulatory requirements for **First Defense**<sup>®</sup>:* **First Defense**<sup>®</sup> is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991. Similar regulatory oversight risks exist in territories outside of the United States where we sell our products. 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**<sup>®</sup> 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.

## ImmuCell Corporation

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

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

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

*Risks associated with USDA and international regulatory oversight:* **First Defense®** is subject to the jurisdiction of the Center for Veterinary Biologics, USDA. Similar regulatory oversight risks exist in territories outside of the United States where we sell our products.

*Exposure to risks associated with the financial downturn and global economic crisis:* The U.S. economy appears to be coming out of a recession, which was caused principally by the housing, credit and financial crises of the late 2000's. However, such recent positive indications could prove temporary and further downturn could occur, and the European economy remains sluggish and precarious. The credit markets continue to be very turbulent and uncertain. Sales and financial performance are still down at many businesses. This extraordinary period of instability facing the U.S. economy and the financial markets has been troubling for nearly all Americans. Some observers believe that the national unemployment rate is too high, 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. A continued and prolonged economic downturn 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**<sup>®</sup> 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**<sup>®</sup>, 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.

*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.

**ImmuCell Corporation**

**ITEM 2 – DESCRIPTION OF PROPERTY**

We own a 34,850 square foot building at 56 Evergreen Drive in Portland, Maine. We currently use this space for substantially all of our office, laboratory and manufacturing needs. When we originally purchased this building in 1993, its size was 15,000 square feet, including 5,000 square feet of unfinished space on the second floor. In 2001, we completed a construction project that added approximately 5,200 square feet of new manufacturing space on the first floor and approximately 4,100 square feet of storage space on the second floor. In 2007, we built out the 5,000 square feet of unfinished space on the second floor into usable office space. After moving first floor offices into this new space on the second floor, we modified and expanded the laboratory space on the first floor and added approximately 2,500 additional square feet of storage space on the second floor. During 2009, we added 350 square feet of cold storage space connected to our first floor production area and added an additional 600 square feet to the second floor storage area. During the third quarter of 2014, we initiated 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. This work was completed during the first quarter of 2015. We funded these investments with available cash.

We rent approximately 550 square feet of office and warehouse space in New York on a short-term basis to support our farm operations. We maintain property insurance in amounts that approximate replacement cost and a modest amount of business interruption insurance. We also maintain access to certain animals, primarily cows, through contractual relationships with commercial dairy farms.

**ITEM 3 – LEGAL PROCEEDINGS**

None

**ITEM 4 – MINE SAFETY DISCLOSURES**

None



**ImmuCell Corporation****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 ICCG. 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. 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, 2013 through December 31, 2014:

2014					2013				
Three Months Ended					Three Months Ended				
	March 31	June 30	September 30	December 31		March 31	June 30	September 30	December 31
High	\$4.95	\$5.30	\$5.68	\$5.44		\$4.50	\$3.95	\$5.10	\$4.86
Low	\$4.06	\$3.30	\$4.17	\$3.96		\$3.52	\$3.25	\$3.19	\$4.01

As of March 18, 2015, we had 8,000,000 common shares authorized and 3,028,034 common shares outstanding, and there were approximately 900 shareholders of record. The last sales price of our common stock on March 18, 2015 was \$6.45 per share as quoted on the NASDAQ Stock Market.

*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, 2014 or that could be granted in the future:

<b>Number of shares to be issued upon exercise of</b>	<b>Weighted-average exercise price of outstanding options</b>	<b>Number of shares remaining available for future issuance under stock-based compensation</b>
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	<b>outstanding options</b>		<b>plans (excluding shares reflected in first column of this table)</b>
Equity compensation plans approved by stockholders	253,000	\$ 3.42	202,500
Equity compensation plans not approved by stockholders	--	--	--
Total	253,000	\$ 3.42	202,500

**ITEM 6 – SELECTED FINANCIAL DATA**

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

	Year Ended December 31,				
	2014	2013	2012	2011	2010
Statement of Operations Data:					
Product sales	\$7,597	\$6,007	\$5,390	\$5,111	\$4,386
Gross margin	4,449	3,061	3,054	2,814	2,302
Product development expenses	2,179	1,154	918	1,720	1,493
Selling and administrative expenses	2,476	1,926	1,892	1,726	1,500
Net operating (loss) income	(206 )	(20 )	245	(633 )	(690 )
(Loss) income before income taxes	(255 )	205	192	(697 )	(683 )
Net (loss) income	\$(167 )	\$117	\$90	\$(410 )	\$(385 )

**ImmuCell Corporation**

	Year Ended December 31,				
	2014	2013	2012	2011	2010
Per Common Share:					
Basic net (loss) income	\$(0.06)	\$0.04	\$0.03	\$(0.14)	\$(0.13)
Diluted net (loss) income	\$(0.06)	\$0.04	\$0.03	\$(0.14)	\$(0.13)
Cash dividend	\$0	\$0	\$0	\$0	\$0

## Statement of Cash Flows Data:

Net cash provided by (used for) operating activities	\$302	\$1,099	\$344	\$(37 )	\$(809 )
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	As of December 31,				
	2014	2013	2012	2011	2010
Balance Sheet Data:					
Cash, cash equivalents, short-term investments and long-term investments	\$3,835	\$5,255	\$4,914	\$4,960	\$4,626
Total assets	11,052	10,961	11,030	10,991	10,751
Current liabilities	1,009	636	666	635	525
Net working capital	4,460	6,632	6,697	6,516	6,441
Long-term liabilities	785	929	1,170	1,336	944
Stockholders' equity	\$9,258	\$9,396	\$9,195	\$9,020	\$9,282

## Per Outstanding Common Share:

Cash, cash equivalents, short-term investments and long-term investments	\$1.27	\$1.74	\$1.63	\$1.65	\$1.56
Stockholders' equity	\$3.06	\$3.11	\$3.05	\$3.00	\$3.12

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

We had approximately \$3,835,000 in available cash, cash equivalents, short-term investments and long-term investments as of December 31, 2014. The table below summarizes the changes in selected, key balance sheet items (in thousands, except for percentages):

	As of December 31,		(Decrease) Increase	
	2014	2013	\$	%
Cash, cash equivalents, short-term investments and long-term investments	\$3,835	\$5,255	\$(1,420)	(27 %)
Net working capital	4,460	6,632	(2,172)	(33 %)
Total assets	11,052	10,961	91	0.8 %
Stockholders' equity	\$9,258	\$9,396	\$(138 )	(1.5 %)

Net cash provided by operating activities amounted to \$302,000 during the year ended December 31, 2014 compared to net cash provided by operating activities of \$1,099,000 during 2013. Capital investments of \$1,536,000 during 2014 compared to capital investments of \$598,000 during 2013. Together with gross margin earned from ongoing product sales, we believe that we have sufficient capital resources to meet our working capital requirements and to finance our ongoing business operations during at least the next twelve months.

During the third quarter of 2010, we agreed to terms of certain credit facilities with TD Bank, N.A. aggregating up to approximately \$2,100,000, which are secured by substantially all of our assets. These credit facilities are comprised of a \$1,000,000 ten-year mortgage loan, a \$600,000 fifty-four month note and a \$500,000 line of credit. Proceeds from the \$1,000,000 mortgage loan were received during the third quarter of 2010. Proceeds from the \$600,000 note were received during the first quarter of 2011. As of December 31, 2014, our outstanding bank debt balance was approximately \$896,000. The \$500,000 line of credit is available as needed. We chose debt financing because we believed that, in the market environment around 2010, the option to generate funds through the sale of equity securities at an acceptable level of stockholder dilution was unlikely.

## ImmuCell Corporation

Since 1999, our strategy has been focused on selling and developing products that improve animal health and productivity in the dairy and beef industries. These product opportunities are generally less expensive to develop than the human health product opportunities that we had worked on during the 1990's. We have funded most of our product development expenses principally from product sales and were profitable for each of the nine years in the period ended December 31, 2007. Our cumulative investment of approximately \$20,749,000 during the sixteen-year period ended December 31, 2014 was offset, in part, by \$4,130,000 in licensing revenue, technology sales and grant income. Our strategic decision to continue developing **Mast Out**® after the product rights were returned to us in 2007 caused us to increase our spending on product development expenses that were previously funded by a former partner from late 2004 to mid-2007. As a result, we incurred net losses of \$469,000, \$216,000, \$385,000 and \$410,000 during the years ended December 31, 2008, 2009, 2010 and 2011, respectively. Having largely completed the significant clinical studies, we reduced product development expenses during 2012, as anticipated, and were profitable during 2012 and 2013. These expenses increased again, as we invested to complete the regulatory approval process, resulting in a net loss during the first half of 2014. After completing this investment, we returned to profitable results during the second half of 2014. We may, on occasion, seek additional research grant support as a means of leveraging the funds that we are able to spend developing new products.

During the third quarter of 2013, our Board of Directors approved the aggregate investment of approximately \$3,000,000 in two projects. The first investment involved acquiring processing equipment and modifying a portion of our facility to produce the Drug Substance for **Mast Out**® to complete the **Mast Out**® product development initiative. This project was substantially completed during the third quarter of 2014. We hope the work performed in this plant will support and facilitate the raising of capital or the enlistment of a partner to fund expanded manufacturing capacity for the commercialization of **Mast Out**®. This specifically targeted increase in product development expenses resulted in a net loss during the first six months of 2014 and (despite a return to profitability during the last six months of 2014) during the year ended December 31, 2014. The purpose of this investment is discussed in greater detail under **ITEM 1 – DESCRIPTION OF BUSINESS, “Product Development,”** above. The second investment involved acquiring manufacturing equipment and constructing a two-story addition to our facility, providing us with approximately 7,100 square feet of cold storage, production and warehouse space to increase our production capacity. Additionally, this investment allows us to better integrate the production of pharmaceutical-grade Nisin into our operations. This project was initiated in September 2014 and was completed during February 2015. The following table details the spending on these two projects:

	Expenses	Capital Expenditures	Total Expenses and Capital Expenditures
Three-month period ended December 31, 2013	\$110,000	\$21,000	\$131,000
Year ended December 31, 2014	973,000	1,492,000	(1) 2,465,000
Fifteen-month period ended December 31, 2014	1,083,000	1,513,000	2,596,000
Budgeted and not yet spent	10,000	394,000	(2) 404,000
Total investment	\$1,093,000	\$1,907,000	\$3,000,000

<sup>(1)</sup>This figure includes approximately \$1,271,000 that was recorded as construction in progress as of December 31, 2014. Approximately \$230,000 of this construction in progress amount was capitalized during 2014 but was not paid for until 2015.

<sup>(2)</sup>We had made commitments to contractors and vendors to spend approximately \$326,000 of this amount as of December 31, 2014.

## ImmuCell Corporation

As of January 1, 2015, we had additional authorization from our Board of Directors to spend up to approximately \$1,640,000 on new manufacturing equipment and other routine and necessary capital expenditures. Most of this investment authorization is intended to pay for the acquisition of **First Defense**<sup>®</sup> production equipment to increase our liquid processing capacity by approximately 50% and our freeze-drying capacity by approximately 100%. We have already begun to increase our production capacity, but due to the long order lead time on some of this critical equipment, we do not expect to fully complete this investment program until the first quarter of 2016. These investments, together with the 7,100 square foot facility addition, described in the previous paragraph, are necessary to increase our production capacity to fill our current backlog of orders created by the increased sales demand that we are experiencing.

## Results of Operations

### *2014 Compared to 2013*

#### *Product Sales*

Product sales for the year ended December 31, 2014 increased by 26%, or \$1,590,000, to \$7,597,000 from \$6,007,000 in 2013. Domestic product sales increased by 27%, or \$1,376,000, during the year ended December 31, 2014, and international sales increased by 23%, or \$214,000, in comparison to 2013. For the three-month period ended December 31, 2014, product sales increased by 41%, or \$646,000, in comparison to the three-month period ended December 31, 2013. We believe that our increased investment in sales and marketing personnel and efforts is helping us introduce **First Defense**<sup>®</sup> to new customers and that our product sales benefited from the relatively strong prices of milk, cows and calves, as well as a stable to moderately lower cost of feed. We have not implemented significant or frequent price increases believing that we could benefit more from higher unit sales than through a higher average selling price per unit. 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**<sup>®</sup>. We did not implement another price increase until the third quarter of 2014. This strategy recognizes that while selling a premium-priced product, we must be very efficient with our manufacturing costs to maintain a healthy gross margin.

Our total product sales during the six-month period ended December 31, 2014 increased by 42%, or \$1,181,000, in comparison to the same period in 2013. This positive trend has continued into the first quarter of 2015, and this new level of sales demand for **First Defense**<sup>®</sup> has exceeded our production capacity and available inventory. We project that sales (shipped to customers) of **First Defense**<sup>®</sup> during the first quarter of 2015 will be approximately 62% over

the first quarter of 2014. Based upon orders received as of March 18, 2015 that we expect to be in excess of our finished goods inventory available to ship during the balance of the first quarter of 2015, we estimate that we will have a backlog of orders for **First Defense**<sup>®</sup> aggregating at least \$795,000 as of March 31, 2015. This estimate of the backlog as of March 31, 2015 will be further increased by orders received after March 18, 2015. The 62% projected increase in sales of **First Defense**<sup>®</sup> during the first quarter of 2015 over the first quarter of 2014 would be increased further to approximately 105% if we could ship the \$795,000 in orders discussed above before April 1, 2015. We are making the investments necessary to increase our production capacity to meet the growing sales demand for **First Defense**<sup>®</sup>.



## ImmuCell Corporation

Our lead product, **First Defense**<sup>®</sup>, continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent bovine enteritis (scours) in newborn calves. Sales of **First Defense**<sup>®</sup>, and related product line extensions aggregated 91.6% and 91.4% of our total product sales during the years ended December 31, 2014 and 2013, respectively. Sales of **First Defense**<sup>®</sup> and related product line extensions increased by 27%, 14% and 5% during the years ended December 31, 2014, 2013 and 2012, respectively, in comparison to the prior years. Domestic sales of **First Defense**<sup>®</sup> and related product line extensions increased by 29%, and international sales increased by 15% during the year ended December 31, 2014 in comparison to 2013. Sales of **First Defense**<sup>®</sup> and related product line extensions increased by 44% and 43% during the three-month and six-month periods ended December 31, 2014, respectively, in comparison to 2013. With the single exception of the second quarter of 2012, we have realized consistently positive sales growth of **First Defense**<sup>®</sup> and related product line extensions during the last ten consecutive quarters and for sixteen of the last seventeen quarters in comparison to the same quarters of the prior year, as demonstrated in the following table:

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

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

We are selling new product applications of **First Defense**<sup>®</sup> product line under the description **First Defense Technology**<sup>™</sup>, which is a unique whey protein concentrate that is processed utilizing our proprietary milk protein purification methods, for the nutritional and feed supplement markets without the claims of our USDA-licensed

product. Through our **First Defense Technology™**, we are selling concentrated whey proteins in different formats. During the first quarter of 2011, we initiated sales of **First Defense Technology™** in a bulk powder format (no capsule), which is delivered with a scoop and mixed with colostrum for feeding to calves. During the fourth quarter of 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start® 150 Plus, a colostrum replacer 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.

## ImmuCell Corporation

We sell topical wipes that are pre-moistened with a Nisin-based formulation in two product formats. Since 1999, we have been selling **Wipe Out® Dairy Wipes** (our second leading source of product sales) for use in preparing the teat area of a cow for milking. Sales of **Wipe Out® Dairy Wipes** decreased by 2% during the year ended December 31, 2014 in comparison to the same period during 2013. We are competing aggressively on selling price to earn new business against less expensive products and alternative teat sanitizing methods. We believe that sales growth potential for **Wipe Out® Dairy Wipes** is limited because most of our sales of this product tend to be to smaller dairies that are under continued financial pressures. Such pressures are forcing many small dairy producers out of business. While our product is a high quality tool, there are less expensive ways to sanitize a cow's udder prior to milking, and many producers opt for a less expensive solution. During the first quarter of 2013, we initiated sales of Nisin-based wipes for pets in a 120-count canister (Preva™ wipes) to Bayer HealthCare Animal Health of St. Joseph, Missouri for commercial sales to pet owners. Sales of this product line extension turned the 2% decrease in sales of **Wipe Out® Dairy Wipes** (discussed above) into an 8% aggregate increase in sales of all topical product applications during the year ended December 31, 2014 in comparison to the same period during 2013.

Sales of our **California Mastitis Test (CMT)** (our third leading source of product sales) increased by 8% during the year ended December 31, 2014 in comparison to the same period during 2013. We make and sell bulk reagents for Isolate™ (formerly known as Crypto-Scan), which is a drinking water test that is sold by our distributor in Europe. Sales of Isolate™ increased by 111% during the year ended December 31, 2014 in comparison to the same period during 2013. Sales of these bulk reagents aggregated slightly more than 2% and slightly more than 1% of product sales during the years ended December 31, 2014 and 2013, respectively.

### Gross Margin

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

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

Increase

For the  
Six-Month  
Periods Ended  
December 31,

	2014	2013	Amount	%
Gross margin	\$2,421	\$1,224	\$1,196	98 %
Percent of product sales	61 %	44 %	17 %	39 %

For the Years  
Ended  
December 31,

	2014	2013	Amount	%
Gross margin	\$4,449	\$3,061	\$1,388	45 %
Percent of product sales	59 %	51 %	8 %	15 %

The gross margin as a percentage of product sales was 59% and 51% during the years ended December 31, 2014 and 2013, respectively. This compares to gross margin percentages of 57% and 55% during the years ended December 31, 2012 and 2011, respectively. Our objective for the foreseeable future is to maintain the full-year gross margin percentage over 50%, and we have achieved this objective during all of the full-year periods being reported. The gross margin as a percentage of product sales was 61% and 44% during the six-month periods ended December 31, 2014 and 2013, respectively. We believe the 61% ratio during the second half of 2014 was unusually high and not sustainable over time going forward. We reduced production output during the last six months of 2013 in order to replace and repair certain pieces of critical process equipment, which resulted in an increase in cost of goods sold during that period. The use of more expensive subcontractors during this period also increased our costs. This production slow-down resulted in a few, short delays in shipping customer orders of **First Defense**® during the first quarter of 2014. These investments were completed during the fourth quarter of 2013, and our gross margin percentage was again in line with historical norms during 2014. Our inventory balance was reduced by 23%, or \$366,000, to \$1,207,000 at December 31, 2013 from \$1,573,000 as of June 30, 2013. This level of investment as of June 30, 2013 helped us prevent a backlog of orders, while we slowed inventory production to replace and repair the critical pieces of process equipment, discussed above. Largely due to the significant increase in product sales experienced especially during the second half of 2014, our inventory balance was reduced to \$946,000 as of December 31, 2014. We are investing in production growth during 2015 to increase our inventory levels and keep up with growing sales. A number of factors account for the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter. The gross margin on **First Defense**® 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 lower gross margin on **Wipe Out**® **Dairy Wipes**.

## ImmuCell Corporation

### *Product Development Expenses*

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

### *Sales and Marketing Expenses*

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

### *Administrative Expenses*

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

*Net Operating (Loss) Income*

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

## ImmuCell Corporation

### *Other (expenses) revenues, net*

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

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

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

### *2013 Compared to 2012*

#### *Product Sales*

Product sales for the year ended December 31, 2013 increased by 11.5%, or \$617,000, to \$6,007,000 from \$5,390,000 in 2012. Domestic product sales increased by 18%, or \$763,000, during the year ended December 31, 2013, and international sales decreased by 13%, or \$146,000, in comparison to 2012. For the three-month period ended December 31, 2013, product sales increased by 10%, or \$138,000, in comparison to the three-month period ended December 31, 2012. We believe that our increased investment in sales and marketing personnel and efforts is helping

us introduce **First Defense**® to new customers and that our product sales benefited from the relatively strong prices of milk, cows and calves, which gains were partially offset by the increased cost of feed. 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.



## ImmuCell Corporation

Sales of our lead product, **First Defense®**, and the related product line extensions aggregated 91% and 89% of our total product sales during the years ended December 31, 2013 and 2012, respectively. Sales of **First Defense®** increased by 14%, 5% and 21% during the years ended December 31, 2013, 2012 and 2011, respectively, in comparison to the prior years. Sales of **First Defense®** increased by 17% and 16% during the three-month and six-month periods ended December 31, 2013, respectively, in comparison to 2012. Domestic sales of **First Defense®** increased by 18%, and international sales decreased by less than 1% during the year ended December 31, 2013 in comparison to 2012. With the single exception of the second quarter of 2012, we have realized consistently positive sales growth of **First Defense®** during the last six consecutive quarters and for twelve of the last thirteen quarters, as demonstrated in the following table:

Competition for resources that dairy producers allocate to their calf enterprises has been increased by the many new products that have been introduced to the calf market. Our sales are normally seasonal, with higher sales expected during the first quarter. Warm and dry weather reduces the producer's perception of the need for **First Defense®**. Heat stress on calves caused by extremely hot summer weather can increase the incidence of scours. The severe heat and drought conditions during the summer of 2012 in many key agricultural regions in North America caused a significant increase in the cost of feed that has offset some improvement in milk prices. The combination of mild weather during the spring 2012 beef calving season and the increasing cost of feed created a very challenging environment in which to sell a disease prevention product. The harsher winter weather in late 2013 and early 2014 may have benefited our sales. The animal health distribution segment has been aggressively consolidating over the last few years. Larger distributors have been acquiring smaller distributors. Although beef herd numbers are down currently because of the 2012 drought conditions in many parts of North America, the value of newborn calves has increased as producers re-build their herd levels. Such an upswing increases a producer's likelihood to invest in **First Defense®** for their calf crop.

Sales of **Wipe Out® Dairy Wipes** decreased by 7% during the year ended December 31, 2013 in comparison to the same period during 2012. We competed aggressively on selling price to earn new business against less expensive products and alternative teat sanitizing methods. We believe that sales growth potential for **Wipe Out® Dairy Wipes** is limited because most of our sales of this product tend to be to smaller dairies that are under continued financial pressures. Such pressures are forcing many small dairy producers out of business. While our product is a high quality tool, there are less expensive ways to sanitize a cow's udder prior to milking, and many producers opt for a less expensive solution. During the first quarter of 2013, we initiated sales of Nisin-based wipes for pets in a 120-count canister (Preva™ wipes) to Bayer HealthCare Animal Health of St. Joseph, Missouri for commercial sales to pet owners. This new source of sales turned the 7% decrease in sales of **Wipe Out® Dairy Wipes** into a 21% aggregate increase in sales of all topical product applications during the year ended December 31, 2013 in comparison to the same period during 2012.

Sales of our **California Mastitis Test (CMT)** (our third leading source of product sales) decreased by 7% during the year ended December 31, 2013 in comparison to the same period during 2012. We make and sell bulk reagents for Isolate™ (formerly known as Crypto-Scan®), which is a drinking water test that is sold by our distributor in Europe. Sales of Isolate™ decreased by 61% during the year ended December 31, 2013 in comparison to the same period during 2012. Sales of these bulk reagents aggregated slightly more than 1% and slightly less than 4% of product sales during the years ended December 31, 2013 and 2012, respectively. This decrease was largely the result of the timing of an order that was moved from the fourth quarter of 2013 to the first quarter of 2014.

**ImmuCell Corporation***Gross Margin*

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

	For the Three-Month Periods Ended December 31,				(Decrease)	
	2013	2012	<b>Amount</b>		<b>%</b>	
Gross margin	\$608	\$750	\$(143 )		(19 %)	
Percent of product sales	39 %	53 %	(14 %)		(26 %)	

	For the Six-Month Periods Ended December 31,				(Decrease)	
	2013	2012	<b>Amount</b>		<b>%</b>	
Gross margin	\$1,223	\$1,371	\$(148 )		(11 %)	
Percent of product sales	44 %	55 %	(11 %)		(20 %)	

	For the Years Ended December 31,				Increase (Decrease)	
	2013	2012	<b>Amount</b>		<b>%</b>	
Gross margin	\$3,061	\$3,054	\$6		0.2 %	
Percent of product sales	51 %	57 %	(6 %)		(10 %)	

The gross margin as a percentage of product sales was 51% and 57% during the years ended December 31, 2013 and 2012, respectively. This compares to gross margin percentages of 55% and 52% during the years ended December 31, 2011 and 2010, respectively. Our objective is to maintain the full-year gross margin percentage over 50%, and we have achieved this objective during all of the full-year periods being reported. We reduced production output during the last six months of 2013 in order to replace and repair certain pieces of critical process equipment, which resulted in an increase in cost of goods sold during that period. These investments were completed during the fourth quarter of 2013. 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**<sup>®</sup> and **Wipe Out**<sup>®</sup> **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**<sup>®</sup> and a lower gross margin on **Wipe Out**<sup>®</sup> **Dairy Wipes**. Our inventory balance was reduced by 27%, or \$442,000, to \$1,207,000 as of December 31, 2013 from \$1,649,000 as of December 31, 2012. Our inventory balance was reduced by 23%, or \$366,000, to \$1,207,000 at December 31, 2013 from \$1,573,000 as of June 30, 2013. This level of investment as of December 31, 2012 and June 30, 2013 helped us prevent a backlog of orders, while we slowed inventory production to replace and repair certain pieces of critical process equipment during the second half of 2013.

#### *Product Development Expenses*

Product development expenses increased by 26%, or \$237,000, to \$1,154,000 during the year ended December 31, 2013, as compared to \$918,000 during 2012. Product development expenses aggregated 19% and 17% of product sales in 2013 and 2012, respectively. The majority of our product development budget from 2000 through 2013 has been focused on the development of **Mast Out**<sup>®</sup>. The balance of our efforts have been primarily focused on other improvements, extensions or additions to our **First Defense**<sup>®</sup> product line. The other improvements, extensions, or additions to our current product line include the potential to prevent scours in calves caused by pathogens other than those within the current **First Defense**<sup>®</sup> disease claims (*E. coli* K99 and coronavirus) such as rotavirus.

## ImmuCell Corporation

### *Sales and Marketing Expenses*

Sales and marketing expenses increased by approximately 1%, or \$14,000, to \$987,000 in 2013, decreasing to 16% of product sales in 2013 from 18% in 2012. We continue to leverage the efforts of our small sales force by using veterinary distributors.

### *Administrative Expenses*

Administrative expenses increased by approximately 2%, or \$21,000, to \$939,000 during the year ended December 31, 2013 as compared to \$918,000 during 2012. 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.

### *Other revenues (expenses), net*

During the second quarter of 2013, we received a \$250,000 exclusive option payment from a prospective partner for the development and marketing of **Mast Out**<sup>®</sup>. This payment was recorded as deferred revenue upon receipt. During the third quarter of 2013, this prospective partner decided not to execute a license after its final due diligence. Accordingly, the deferred revenue was recognized during the third quarter of 2013. At the same time, \$48,000 in capitalized expenses pertaining to the development of **Mast Out**<sup>®</sup> were written off. During the first quarter of 2013, we received a payment of approximately \$62,000, as an eligible member of the mutual insurance company that provided products liability insurance to us when it was acquired by another insurance company through a sponsored demutualization transaction that was effective as of January 1, 2013. Interest income decreased by approximately 27%, or \$5,000, to \$12,000 in 2013, in comparison to \$17,000 during 2012. Interest expense decreased by approximately 11%, or \$9,000, to \$67,000 in 2013, in comparison to \$75,000 during 2012.

### *Income Before Income Taxes and Net Income*

Our income before income taxes of \$205,000 during the year ended December 31, 2013 compares to income before income taxes of \$192,000 during 2012. We recorded an income tax expense of 43% and 53% of the income before

income taxes during the years ended December 31, 2013 and 2012, respectively. Our net income of \$117,000, or \$0.04 per share, during the year ended December 31, 2013 compares to net income of \$90,000, or \$0.03 per share, during 2012.

### **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, 2014 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 recognize revenue in accordance with Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition", which supersedes SAB No. 101, "Revenue Recognition in Financial Statements". SAB No. 104 requires that four criteria are met before revenue is recognized. These include i) persuasive evidence that an arrangement exists, ii) delivery has occurred or services have been rendered, iii) the seller's price is fixed and determinable and iv) collectability is reasonably assured. We recognize revenue at the time of shipment (including to distributors) for substantially all products, as title and risk of loss pass to the customer on delivery to the common carrier after concluding that collectability is reasonably assured. We recognize service revenue at the time the service is performed. All product development costs and patent costs are expensed as incurred.

## ImmuCell Corporation

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. 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%. The interest rate on our \$600,000 note is variable. If the London Interbank Offered Rate plus 3.25% exceeds 4.25%, our interest payments will increase over the current amount.

## ITEM 8 – FINANCIAL STATEMENTS

Our financial statements, together with the notes thereto and the report of the independent registered public accounting firm thereon, are set forth on Pages F-1 through F-20 at the end of this report. The index to these financial statements is as follows:

Report of Baker Newman & Noyes, LLC, Independent Registered Public Accounting Firm	F-1
Balance Sheets as of December 31, 2014 and 2013	F-2
Statements of Operations for the years ended December 31, 2014, 2013 and 2012	F-3
Statements of Comprehensive (Loss) Income for the years ended December 31, 2014, 2013 and 2012	F-4
Statements of Stockholders' Equity for the years ended December 31, 2012, 2013 and 2014	F-5
Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012	F-6
Notes to Financial Statements	F-7 to F-20

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

None

## **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, 2014. 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.

30



## **ImmuCell Corporation**

*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, 2014. Based on management's assessment and those criteria, management believes that the internal control over financial reporting as of December 31, 2014 was effective.

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

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

## **ITEM 9B – OTHER INFORMATION**

None



**ImmuCell Corporation**

**PART III**

**ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information with respect to our directors is incorporated herein by reference to the section of our 2015 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, 2014. The information required by this item with respect to our executive officers is contained in Item 1 of Part I of this Annual Report on Form 10-K under the heading “Executive Officers of the Company”. There is no family relationship between any director, executive officer, or person nominated or chosen by the Company to become a director or executive officer.

**ITEM 11 – EXECUTIVE COMPENSATION**

Information regarding cash compensation paid to our executive officers is incorporated herein by reference to the section of our 2015 Proxy Statement titled “Executive Officer Compensation”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2014.

**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 2015 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, 2014.

**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 2015 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, 2014.

#### **ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES**

Information regarding our principal accounting fees and services is incorporated by reference to the section of our 2015 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, 2014.

#### **ITEM 15 – EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

**ImmuCell Corporation**

- 4.1A First Amendment to Rights Agreement dated as of June 30, 2005 (incorporated by reference to Exhibit 4.1A of the Company's Current Report on Form 8-K filed on July 5, 2005).
- 4.1B Second Amendment to Rights Agreement dated as of June 30, 2008 (incorporated by reference to Exhibit 4.1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
- 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).
- 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 Commercial Promissory Note for \$600,000 between the Company and TD Bank, N.A. dated August 13, 2010 (incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).
- 10.10 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).
- 10.11<sup>(1)</sup> 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).
- 10.12<sup>(1)</sup> Contract Manufacture Agreement between the Company and Norbrook Laboratories Limited dated as of September 27, 2010 (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, 2010).
- 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).
- 23 Consent of Baker Newman & Noyes, LLC.

- 31 Certifications required by Rule 13a-14(a).  
32 Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS XBRL Instance Document.

101.SCH XBRL Taxonomy Extension Schema Document.

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB XBRL Taxonomy Extension Label Linkbase Document.

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

+ Management contract or compensatory plan or arrangement.

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

## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

ImmuCell Corporation

We have audited the accompanying balance sheets of ImmuCell Corporation (the Company) as of December 31, 2014 and 2013, and the related statements of operations, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of ImmuCell Corporation as of December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

Portland, Maine /s/ Baker Newman & Noyes  
March 26, 2015 Limited Liability Company

**ImmuCell Corporation****BALANCE SHEETS**

	As of December 31,	
	2014	2013
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$850,028	\$2,270,385
Short-term investments	2,489,000	2,985,000
Inventory	945,755	1,206,508
Accounts receivable, net	1,005,292	631,410
Prepaid expenses and other assets	148,399	159,117
Current portion of deferred tax asset	30,463	15,212
Total current assets	5,468,937	7,267,632
 PROPERTY, PLANT AND EQUIPMENT, net	 3,837,647	 2,524,765
 LONG-TERM PORTION OF DEFERRED TAX ASSET	 1,230,340	 1,154,681
 LONG-TERM INVESTMENTS	 496,000	 0
 OTHER ASSETS, net	 18,930	 13,636
 TOTAL ASSETS	 \$11,051,854	 \$10,960,714
 <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$851,677	\$445,229
Current portion of bank debt	150,382	190,390
Deferred revenue	6,690	0
Total current liabilities	1,008,749	635,619
 <b>LONG-TERM LIABILITIES:</b>		
Long-term portion of bank debt	745,920	896,224
Interest rate swap	38,817	33,002
Total long-term liabilities	784,737	929,226
 TOTAL LIABILITIES	 1,793,486	 1,564,845
 <b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$0.10 par value per share, 8,000,000 shares authorized, 3,261,148 shares issued at December 31, 2014 and 2013	326,115	326,115
Capital in excess of par value	10,042,305	10,011,339



Accumulated deficit	(574,567 )	(407,408 )
Treasury stock, at cost, 234,114 and 235,114 shares at December 31, 2014 and 2013, respectively	(512,154 )	(514,341 )
Accumulated other comprehensive loss	(23,331 )	(19,836 )
Total stockholders' equity	9,258,368	9,395,869
 TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	 \$11,051,854	 \$10,960,714

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

F-2

**ImmuCell Corporation****STATEMENTS OF OPERATIONS**

	For the Years Ended December 31,		
	2014	2013	2012
Product sales	\$ 7,596,874	\$6,007,176	\$5,389,935
Cost of goods sold	3,147,837	2,946,570	2,335,676
Gross margin	4,449,037	3,060,606	3,054,259
Product development expenses	2,179,079	1,154,200	917,600
Sales and marketing expenses	1,317,122	986,766	973,217
Administrative expenses	1,159,234	939,192	918,441
Operating expenses	4,655,435	3,080,158	2,809,258
NET OPERATING (LOSS) INCOME	(206,398 )	(19,552 )	245,001
Other (expenses) revenues, net	(49,053 )	224,812	(52,849 )
(LOSS) INCOME BEFORE INCOME TAXES	(255,451 )	205,260	192,152
Income tax (benefit) expense	(88,292 )	87,865	102,640
NET (LOSS) INCOME	(\$167,159 )	\$117,395	\$89,512
Weighted average common shares outstanding:			
Basic	3,027,001	3,019,407	3,018,296
Diluted	3,027,001	3,085,048	3,108,419
NET (LOSS) INCOME PER SHARE:			
Basic	(\$0.06 )	\$0.04	\$0.03
Diluted	(\$0.06 )	\$0.04	\$0.03

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

**ImmuCell Corporation**

**STATEMENTS OF COMPREHENSIVE (LOSS) INCOME**

	For the Years Ended December		
	31,		
	2014	2013	2012
Net (loss) income	(\$167,159)	\$117,395	\$89,512
Other comprehensive (loss) income:			
Interest rate swap, before taxes	(5,815 )	50,384	(15,486)
Income tax applicable to interest rate swap	2,320	(20,100 )	6,178
Other comprehensive (loss) income, net of taxes	(3,495 )	30,284	(9,308 )
Total comprehensive (loss) income	(\$170,654)	\$147,679	\$80,204

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

**ImmuCell Corporation****STATEMENTS OF STOCKHOLDERS' EQUITY**

	Common Shares	Stock Amount	Capital in Excess of Par Value	Accumulated Deficit	Treasury Shares	Stock Amount	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
BALANCE, December 31, 2011	3,261,148	\$ 326,115	\$ 9,911,914	(\$ 614,315 )	257,114	(\$ 562,469 )	(\$ 40,812 )	\$ 9,020,433
Net income	0	0	0	89,512	0	0	0	89,512
Other comprehensive (loss), net of taxes	0	0	0	0	0	0	(9,308 )	(9,308 )
Exercise of stock options	0	0	17,986	0	(15,000 )	32,814	0	50,800
Tax benefits related to stock options	0	0	7,261	0	0	0	0	7,261
Stock-based compensation	0	0	35,985	0	0	0	0	35,985
BALANCE, December 31, 2012	3,261,148	326,115	9,973,146	(524,803 )	242,114	(529,655 )	(50,120 )	9,194,683
Net income	0	0	0	117,395	0	0	0	117,395
Other comprehensive income, net of taxes	0	0	0	0	0	0	30,284	30,284
Exercise of stock options	0	0	6,436	0	(7,000 )	15,314	0	21,750

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Tax benefits related to stock options	0	0	398	0	0	0	0	398
Stock-based compensation	0	0	31,359	0	0	0	0	31,359
BALANCE, December 31, 2013	3,261,148	326,115	10,011,339	(407,408)	235,114	(514,341)	(19,836)	9,395,869
Net (loss)	0	0	0	(167,159)	0	0	0	(167,159 )
Other comprehensive (loss), net of taxes	0	0	0	0	0	0	(3,495 )	(3,495 )
Exercise of stock options	0	0	962	0	(1,000 )	2,187	0	3,149
Stock-based compensation	0	0	30,004	0	0	0	5 0	30,004
BALANCE, December 31, 2014	3,261,148	\$326,115	\$10,042,305	(\$574,567 )	234,114	(\$512,154 )	(\$23,331 )	\$9,258,368

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

## ImmuCell Corporation

## STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,		
	2014	2013	2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net (loss) income	(\$ 167,159 )	\$ 117,395	\$ 89,512
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation	446,045	414,307	399,640
Amortization	2,876	2,894	2,876
Deferred income taxes	(88,590 )	87,166	94,370
Stock-based compensation	30,004	31,359	35,985
Loss on disposal of fixed assets	4,519	35,179	12,265
Changes in:			
Receivables	(373,882 )	(20,056 )	(227,558 )
Inventory	260,753	442,494	17,463
Prepaid expenses and other assets	2,548	45,917	(123,628 )
Accounts payable and accrued expenses	178,560	(57,995 )	51,715
Deferred revenue	6,690	0	(8,250 )
Net cash provided by operating activities	302,364	1,098,660	344,390
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property, plant and equipment	(1,535,558)	(597,697 )	(275,395 )
Maturities of short-term investments	2,985,000	2,489,000	4,178,000
Purchases of short-term investments	(2,489,000)	(3,234,000)	(2,240,000)
Purchases of long-term investments	(496,000 )	0	0
Net cash (used for) provided by investing activities	(1,535,558)	(1,342,697)	1,662,605
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Debt principal repayments	(190,312 )	(181,445 )	(172,853 )
Proceeds from exercise of stock options	3,149	21,750	50,800
Tax benefits related to stock options	0	398	7,261
Net cash (used for) financing activities	(187,163 )	(159,297 )	(114,792 )
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(1,420,357)</b>	<b>(403,334 )</b>	<b>1,892,203</b>
<b>BEGINNING CASH AND CASH EQUIVALENTS</b>	<b>2,270,385</b>	<b>2,673,719</b>	<b>781,516</b>
<b>ENDING CASH AND CASH EQUIVALENTS</b>	<b>\$ 850,028</b>	<b>\$ 2,270,385</b>	<b>\$ 2,673,719</b>
<b>INCOME TAXES PAID</b>	<b>\$ 252</b>	<b>\$ 0</b>	<b>\$ 708</b>

INTEREST EXPENSE PAID	\$ 58,413	\$ 67,015	\$75,681
NON-CASH ACTIVITIES:			
Capital expenditures included in accounts payable and accrued expenses	\$ 251,383	\$ 23,495	\$4,550
Net change in fair value of interest rate swap	\$ 3,495	(\$30,284	) \$9,308

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

F-6

## **ImmuCell Corporation**

### **Notes to Audited Financial Statements**

#### **1. BUSINESS OPERATIONS**

ImmuCell Corporation (the Company) is a growing animal health company whose purpose is to create scientifically-proven and practical products that result in a measurable economic impact on 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. The Company has developed products that provide significant, immediate immunity to newborn dairy and beef cattle and is in the late stages of developing a new product that addresses mastitis, the most significant cause of economic loss to the dairy industry. 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.

#### **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

##### **(a) Basis of presentation**

We have prepared the accompanying audited financial statements reflecting all adjustments, all of which are of a normal recurring nature, that are, in our opinion, necessary in order to ensure that the financial statements are not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP in these footnotes are to the FASB *Accounting Standards Codification*<sup>™</sup> (Codification). Certain prior year accounts have been reclassified to conform with the 2014 financial statement presentation.

##### **(b) Cash, Cash Equivalents and Short-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 \$567,000 and \$1,770,000 at December 31, 2014 and 2013, respectively. Short-term investments are classified as held to maturity and are comprised principally of certificates of deposit that mature in more than three months from their purchase dates and not more than twelve months from the balance sheet date and are held at different financial institutions that are insured by the FDIC, within the FDIC limits per financial institution. See Note 3.

**(c) Inventory**

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

**(d) Trade Receivables**

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

**ImmuCell Corporation**

**Notes to Audited Financial Statements (continued)**

**(e) Property, Plant and Equipment**

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

**(f) Intangible Assets**

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

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

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

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

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

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

## **ImmuCell Corporation**

### **Notes to Audited Financial Statements (continued)**

#### **(h) Interest Rate Swap Agreement**

All derivatives are recognized on the balance sheet at their fair value. We entered into an interest rate swap agreement in 2010. On the date the agreement was entered into, we designated the derivative as a hedge of the variability of cash flows to be paid related to our long-term debt. The agreement has 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 agreement are recorded as comprehensive (loss) income, 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 agreement and the related hedged items. We also formally assess, both at this interest rate swap agreement's inception and on an ongoing basis, whether the agreement is highly effective in offsetting changes in cash flow of hedged items. See Note 9.

#### **(i) Revenue Recognition**

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

#### **(j) Expense Recognition**

Advertising costs are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to \$66,193, \$151,080 and \$174,314 during the years ended December 31, 2014, 2013 and 2012, respectively. All product development expenses are expensed as incurred, as are all related patent costs.

#### **(k) Income Taxes**

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. We believe it is more likely than not that the deferred tax assets will be realized through future taxable income and future tax effects of temporary differences between book income and taxable income. Accordingly, we have not established a valuation allowance for the deferred tax assets. Codification Topic 740-10 clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position must meet before being recognized in the financial statements. In the ordinary course of business, there are transactions and calculations where the ultimate tax outcome is uncertain. In addition, we are subject to periodic audits and examinations by the Internal Revenue Service and other taxing authorities. We have evaluated the positions taken on our filed tax returns. We have concluded that no uncertain tax positions exist as of December 31, 2014. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 11.

### **(I) Stock-Based Compensation**

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, as detailed in Note 12(a). Accordingly, we recorded \$30,004, \$31,359, and \$35,985 of compensation expense pertaining to stock-based compensation, which resulted in a decrease (increase) in income (loss) before income taxes of approximately \$0.01 per share during the years ended December 31, 2014, 2013 and 2012, respectively. Codification Topic 718 requires us to reflect gross tax savings resulting from tax deductions in excess of expense reflected in our financial statements as a financing cash flow.

**ImmuCell Corporation****Notes to Audited Financial Statements (continued)****(m) Net (Loss) Income Per Common Share**

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

	Year Ended December 31,		
	2014	2013	2012
Weighted average number of shares outstanding	3,027,001	3,019,407	3,018,296
Effect of dilutive stock options	0	65,641	90,123
Diluted number of shares outstanding	3,027,001	3,085,048	3,108,419
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	253,000	63,875	39,750

For additional disclosures regarding the outstanding common stock options, see Note 12(a).

**(n) Use of Estimates**

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

**(o) New Accounting Pronouncements**

We adopted Accounting Standards Update (ASU) No. 2011-05, *Presentation of Comprehensive Income (Loss)* (Topic 220) during the three-month period ended March 31, 2012, and retrospective application was required. Under ASU 2011-05, we have the option to present the total of comprehensive (loss) income, the components of net (loss) income, and the components of other comprehensive (loss) income either in a single continuous statement of comprehensive (loss) income or in two separate but consecutive statements. We elected to present two separate but consecutive statements. The statements of other comprehensive (loss) income immediately follow the statements of operations and include the components of other comprehensive (loss) income and a total for other comprehensive (loss) income, along with a total for comprehensive (loss) income. The adoption of Topic 220 only impacts the presentation of the financial statements.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), 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 is effective for the Company on January 1, 2017. Early application is not permitted. ASU 2014-09 permits the use of either the retrospective or cumulative effect transition method. We have evaluated the effect that ASU 2014-09 would have on our financial statements and related disclosures. We expect that ASU 2014-09 will have no significant effect on our ongoing financial reporting, but we continue to evaluate this pending accounting standard.

**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 consisted of the following:

	As of December 31,		(Decrease)
	2014	2013	Increase
Cash and cash equivalents	\$850,028	\$2,270,385	(\$1,420,357 )
Short-term investments	2,489,000	2,985,000	(496,000 )
Subtotal	3,339,028	5,255,385	(1,916,357)
Long-term investments	496,000	0	496,000
Total	\$3,835,028	\$5,255,385	(\$1,420,357 )

**4. INVENTORY**

Inventory consisted of the following:

	As of December 31,		Increase
	2014	2013	(Decrease)
Raw materials	\$306,444	\$270,355	\$ 36,089
Work-in-process	355,745	783,060	(427,315)
Finished goods	283,566	153,093	130,473
Total	\$945,755	\$1,206,508	(\$260,753 )

**5. ACCOUNTS RECEIVABLE**

Accounts receivable consisted of the following:

	As of December 31,		Increase
	2014	2013	(Decrease)



Trade accounts receivable, gross	\$1,004,990	\$609,638	\$395,352
Accumulated allowance for bad debt and product returns	(16,194 )	(13,952 )	(2,242 )
Trade accounts receivable, net	988,796	595,686	393,110
Other receivables	16,496	35,676	(19,180 )
Income taxes receivable	0	48	(48 )
Accounts receivable, net	\$1,005,292	\$631,410	\$373,882

## 6. PREPAID EXPENSES AND OTHER ASSETS

Prepaid expenses and other assets consisted of the following:

	As of December 31,		(Decrease)
	2014	2013	Increase
Prepaid expenses and other assets	\$133,119	\$159,117	(\$25,998 )
Security deposits	15,280	0	15,280
Current subtotal	148,399	159,117	(10,718 )
Debt issue costs	26,489	26,489	0
Accumulated amortization of debt issue costs	(16,479 )	(13,603 )	(2,876 )
Security deposits	8,920	750	8,170
Long-term subtotal	18,930	13,636	5,294
Total	\$167,329	\$172,753	(\$5,424 )

**ImmuCell Corporation****Notes to Audited Financial Statements (continued)****7.PROPERTY, PLANT AND EQUIPMENT**

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

	As of December 31,		Increase
	2014	2013	(Decrease)
Laboratory and manufacturing equipment	\$3,522,465	\$3,182,686	\$339,779
Building and improvements	2,969,891	2,940,239	29,652
Office furniture and equipment	470,607	354,243	116,364
Construction in progress <sup>(1)</sup>	1,270,672	9,600	1,261,072
Land	50,000	50,000	0
Property, plant and equipment, gross	8,283,635	6,536,768	1,746,867
Accumulated depreciation	(4,445,988)	(4,012,003)	(433,985 )
Property, plant and equipment, net	\$3,837,647	\$2,524,765	\$1,312,882

<sup>(1)</sup> As of December 31, 2014, construction in progress consisted of a building addition that was completed during the first quarter of 2015.

**8.ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consisted of the following:

	As of December 31,		Increase
	2014	2013	(Decrease)
Accounts payable – capital	\$251,383	\$23,496	\$227,887
Accounts payable – trade	204,810	199,716	5,094
Accrued payroll	145,176	75,310	69,866
Accrued clinical studies	131,945	0	131,945
Accrued professional fees	42,250	50,500	(8,250 )
Accrued other	76,113	96,207	(20,094 )
Total	\$851,677	\$445,229	\$406,448

F-12

## ImmuCell Corporation

### Notes to Audited Financial Statements (continued)

#### 9.BANK DEBT

During the third quarter of 2010, we agreed to terms of certain credit facilities with TD Bank, N.A. (a wholly owned subsidiary of TD Financial Group, which is a multinational bank with approximately \$944 billion in assets and over 22 million clients world wide) aggregating up to approximately \$2,100,000, which are secured by substantially all of our assets. These credit facilities are comprised of a \$1,000,000 ten-year mortgage loan, a \$600,000 fifty-four month note and a \$500,000 line of credit, which is renewable annually. Proceeds from the \$1,000,000 mortgage 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 in the third quarter of 2020. We hedged our interest rate exposure on this mortgage loan with an interest rate swap agreement that effectively converted a floating interest rate based on the London Interbank Offered Rate (LIBOR) of 3.41% as of December 31, 2014 to the fixed rate of 6.04%. All derivatives are recognized on the balance sheet at their fair value. The agreement has been determined to be highly effective in hedging the variability of the identified cash flows and has been designated as a cash flow hedge of the variability in the hedged interest payments. Changes in the fair value of the interest rate swap agreement are recorded in other comprehensive (loss) income, net of taxes. The original notional amount of the interest rate swap agreement of \$1,000,000 amortizes in accordance with the amortization of the mortgage loan. The notional amount of the interest rate swap was \$799,964 as of December 31, 2014. Payments required by the interest rate swap totaled \$22,116, \$23,096 and \$23,903 during the years ended December 31, 2014, 2013 and 2012, respectively. As the result of our decision to hedge this interest rate risk, we recorded other comprehensive (loss) income, net of taxes, in the amount of (\$3,495), \$30,284, and (\$9,308) during the years ended December 31, 2014, 2013 and 2012, respectively, which reflects the change in fair value of the interest rate swap (liability) asset, net of taxes. The fair value of the interest rate swap has been determined using observable market-based inputs or unobservable inputs that are corroborated by market data. Accordingly, the interest rate swap is classified as level 2 within the fair value hierarchy provided in Codification Topic 820, *Fair Value Measurements and Disclosures*. Proceeds from the \$600,000 note were received during the first quarter of 2011. Interest on the note is variable at the higher of 4.25% per annum or the LIBOR plus 3.25% per annum. As of December 31, 2014, the effective interest rate on this note was 4.25%. The \$500,000 line of credit is available as needed and has been extended through May 31, 2015 and is renewable annually thereafter. The line of credit was unused as of December 31, 2014 and 2013. Interest on any borrowings against the line of credit would be variable at the higher of 4.25% per annum or the LIBOR plus 3.5% per annum. These credit facilities are subject to certain financial covenants. We are in compliance with all applicable covenants as of December 31, 2014. Principal payments due under debt outstanding as of December 31, 2014 are reflected in the following table by the year that payments are due:

Period	\$1,000,000 mortgage	\$600,000 note	Total
Year ending December 31, 2015	\$ 54,044	\$ 96,338	\$ 150,382
Year ending December 31, 2016	57,384	0	57,384

Year ending December 31, 2017	61,056	0	61,056
Year ending December 31, 2018	64,876	0	64,876
Year ending December 31, 2019	68,908	0	68,908
After December 31, 2019	493,696	0	493,696
Total	\$ 799,964	\$ 96,338	\$ 896,302

**10. OTHER (EXPENSES)  
REVENUES, NET**

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

	Year Ended December 31,		
	2014	2013	2012
License option fee <sup>(1)</sup>	\$ 0	\$ 250,000	\$ 0
Royalty income	0	(3,000 )	15,166
Interest income	15,552	12,493	17,202
Interest expense	(57,827)	(66,689 )	(75,274)
Debt issuance amortization	(2,876 )	(2,894 )	(2,876 )
Other gains (losses)	(3,902 )	34,902	(7,067 )
Other (expenses) revenues, net	(\$49,053 )	\$ 224,812	(\$52,849 )

<sup>(1)</sup> During the second quarter of 2013, we received a \$250,000 exclusive option fee from a prospective partner for the development and marketing of **Mast Out**<sup>®</sup>. This payment was recorded as deferred revenue upon receipt. During the third quarter of 2013, this prospective partner decided not to execute a license after its final due diligence. Accordingly, the deferred revenue was recognized during the third quarter of 2013. At the same time, \$47,604 in capitalized expenses pertaining to the development of **Mast Out**<sup>®</sup> were written off.

**ImmuCell Corporation****Notes to Audited Financial Statements (continued)****11.INCOME TAXES**

Our income tax (benefit) expense aggregated (\$88,292), \$87,865 and \$102,640 (amounting to 35%, 43% and 53% of the (loss) income before income taxes, respectively) for the years ended December 31, 2014, 2013 and 2012, respectively. The income tax provision consisted of the following:

	Year Ended December 31,		
	2014	2013	2012
Current	\$ 252	\$301	\$708
Federal	(77,986)	74,713	89,788
State	(10,558)	12,851	12,144
Deferred	(88,544)	87,564	101,932
Total	(\$88,292 )	\$87,865	\$102,640

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

	Year Ended December 31,		
	2014	2013	2012
Computed expected tax (benefit) expense	(\$86,853 )	\$69,788	\$65,332
State income taxes, net of federal (benefit) expense	(6,968 )	8,482	8,015
Share-based compensation	10,201	10,526	9,766
Research and development tax credit	(19,405)	(21,887)	(10,813 )
Other	14,733	20,956	30,340
Total income tax (benefit) expense	(\$88,292 )	\$87,865	\$102,640

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

As of December 31,  
2014                      2013

Product rights	\$ 130,036	\$ 165,527
Property, plant and equipment	225,229	52,094
Research and development tax credit	266,078	235,567
Federal net operating loss carryforward	464,998	525,012
State net operating loss carryforward	165,901	201,698
Interest rate swap	15,486	13,166
Prepaid expenses and other	(6,925 )	(23,171 )
Deferred tax asset	\$ 1,260,803	\$ 1,169,893

We have a state net operating loss carryforward of approximately \$1,858,000 that expires in 2028 through 2031, if not utilized before then, and a federal net operating loss carryforward of approximately \$1,368,000 that expires in 2029 through 2031, 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 to produce pharmaceutical-grade Nisin for **Mast Out**® was expensed as incurred for our books. Included in this amount is approximately \$820,000 (\$65,000 during the fourth quarter of 2013 and \$755,000 during the year ended December 31, 2014) that will be capitalized and depreciated over statutory periods for tax return purposes only.

## **ImmuCell Corporation**

### **Notes to Audited Financial Statements (continued)**

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

Net operating loss carryforwards, credits, and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service. Section 382 of the Internal Revenue Code contains provisions that could place annual limitations on the future utilization of net operating loss carryforwards and credits in the event of a change in ownership, 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 2011. We currently have no tax examinations in progress. We also have not paid additional taxes, interest or penalties as a result of tax examinations nor do we have any unrecognized tax benefits for any of the periods in the accompanying financial statements.

## **12.STOCKHOLDERS' EQUITY**

### **(a) Stock Option Plans**

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



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

F-15

**ImmuCell Corporation****Notes to Audited Financial Statements (continued)**

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

	2000 Plan	2010 Plan	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2011	186,500	49,500	\$ 3.19	\$ 344,000
Grants	0	2,000	\$ 5.93	
Terminations	(8,000 )	(2,000 )	\$ 4.75	
Exercises	(15,000 )	0	\$ 3.39	
Outstanding at December 31, 2012	163,500	49,500	\$ 3.13	\$ 185,000
Grants	0	26,000	\$ 4.67	
Terminations	0	(1,000 )	\$ 3.15	
Exercises	(6,000 )	(1,000 )	\$ 3.11	
Outstanding at December 31, 2013	157,500	73,500	\$ 3.30	\$ 223,000
Grants	0	25,000	\$ 4.69	
Terminations	0	(2,000 )	\$ 5.75	
Exercises	0	(1,000 )	\$ 3.15	
Outstanding at December 31, 2014	157,500	95,500	\$ 3.42	\$ 364,000
Exercisable at December 31, 2014	157,500	42,500	\$ 3.08	\$ 357,000
Reserved for future grants	0	202,500		

During the year ended December 31, 2014, one employee exercised stock options covering 1,000 shares. These options were exercised for cash, resulting in total proceeds of \$3,149. During the year ended December 31, 2013, four employees exercised stock options covering the aggregate of 7,000 shares. These options were exercised for cash, resulting in total proceeds of \$21,750. During the year ended December 31, 2012, one employee exercised 15,000 stock options. These options were exercised for cash, resulting in total proceeds of \$50,800. At December 31, 2014, 253,000 shares of common stock were reserved for future issuance under all outstanding stock options described above, and an additional 202,500 shares of common stock were reserved for the potential issuance of stock options in the future under the 2010 Plan. The weighted average remaining life of the options outstanding under the 2000 Plan and the 2010 Plan as of December 31, 2014 was approximately four years and nine months. The weighted average remaining life of the options exercisable under these plans as of December 31, 2014 was approximately four years. The exercise prices of the options outstanding as of December 31, 2014 ranged from \$1.70 to \$7.00 per share. The 25,000 stock options granted during 2014 had exercise prices between \$4.25 and \$4.80 per share. The 26,000 stock options granted during 2013 had exercise prices between \$4.15 and \$4.69 per share. The 2,000 stock options granted

during 2012 had exercise prices between \$5.61 and \$6.25 per share. The aggregate intrinsic value of options exercised during 2014, 2013 and 2012 approximated \$1,000, \$8,000 and \$25,000, respectively. The weighted-average grant date fair values of options granted during 2014, 2013 and 2012 were \$2.26, \$2.23 and \$2.86 per share, respectively. As of December 31, 2014, total unrecognized stock-based compensation related to non-vested stock options aggregated \$95,560. That cost is expected to be recognized at a declining rate over the remaining vesting period of the outstanding non-vested stock options, including \$26,778 during 2015. The fair value of each stock option grant has been estimated on the date of grant by an independent appraiser using the Black-Scholes option pricing model, for the purpose discussed in Note 2(l), with the following weighted-average assumptions:

	2014		2013		2012	
Risk-free interest rate	2.0	%	1.6	%	0.97	%
Dividend yield	0	%	0	%	0	%
Expected volatility	49	%	49	%	48.7	%
Expected life	6 years		6 years		6.5 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.

## **ImmuCell Corporation**

### **Notes to Audited Financial Statements (continued)**

#### **(b) Common Stock Rights Plan**

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

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

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

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

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

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

## **ImmuCell Corporation**

### **Notes to Audited Financial Statements (continued)**

#### **13.COMMITMENTS AND CONTINGENT LIABILITIES**

Our bylaws, as amended, in effect provide that the Company will indemnify its officers and directors to the maximum extent permitted by Delaware law. In addition, we make similar indemnity undertakings to each director through a separate indemnification agreement with that director. The maximum payment that we may be required to make under such provisions is theoretically unlimited and is impossible to determine. We maintain directors' and officers' liability insurance, which may provide reimbursement to the Company for payments made to, or on behalf of, officers and directors pursuant to the indemnification provisions. Our indemnification obligations were grandfathered under the provisions of Codification Topic 460, *Guarantees*. Accordingly, we have recorded no liability for such obligations as of December 31, 2014. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

As of December 31, 2014 we had committed to contracts and purchase orders covering approximately \$326,000 related to our 7,100 square foot facility addition and an additional \$550,000 principally related to the production of inventory.

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 these agreements is minimal. Accordingly, we have recorded no liabilities for such obligations as of December 31, 2014.

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

#### **14.SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION**

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

Our primary customers for the majority of our product sales (83%, 83% and 80% for the years ended December 31, 2014, 2013 and 2012, 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%, 14% and 16% of our total product sales for the years ended December 31, 2014, 2013 and 2012, respectively. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

	Year Ended December 31,			
	2014	2013	2012	
Animal Health International, Inc.	38%	38%	35%	
MWI Veterinary Supply Company <sup>(1)</sup>	23%	22%	20%	

<sup>(1)</sup> Assumes that the November 2013 acquisition of IVESCO by MWI had occurred as of the beginning of the periods being reported.

**ImmuCell Corporation****Notes to Audited Financial Statements (continued)**

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,	
	2014	2013
Animal Health International, Inc.	45 %	39 %
MWI Veterinary Supply Company	26 %	26 %
Robert J. Matthews Company	*	10 %

\*Amount is less than 10%.

**15. RELATED PARTY TRANSACTIONS**

Dr. David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone Inc. (formerly Stearns Veterinary Outlet, Inc.), a domestic distributor of ImmuCell products (**First Defense®**, **Wipe Out® Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased \$426,358, \$395,042 and \$326,513 of products from ImmuCell during the years ended December 31, 2014, 2013 and 2012, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of \$7,330, \$6,010 and \$1,000 to these affiliate companies during the years ended December 31, 2014, 2013 and 2012, respectively. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated \$18,796 and \$31,445 as of December 31, 2014 and 2013, respectively.

**16. EMPLOYEE BENEFITS**

We have a 401(k) savings plan (the Plan) in which all employees completing one month of service with the Company are eligible to participate. Participants may contribute up to the maximum amount allowed by the Internal Revenue Service. Prior to August 2012 we matched 50% of each employee's contribution to the plan up to a maximum match of 4% of each employee's base compensation. 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 \$65,633, \$56,036 and \$51,145 into the plan for the years ended December 31, 2014, 2013 and 2012, respectively.

F-19

**ImmuCell Corporation****Notes to Audited Financial Statements (continued)****17.UNAUDITED QUARTERLY FINANCIAL DATA**

The following tables present the quarterly information for the years ended December 31, 2014, 2013 and 2012, respectively:

	Three Months Ended			
	March 31	June 30	September 30	December 31
Fiscal 2014:				
Product sales	\$ 2,081,752	\$ 1,539,719	\$ 1,770,129	\$ 2,205,275
Gross margin	1,149,895	878,523	1,077,896	1,342,722
Product development expenses	594,209	760,672	361,232	462,965
Net operating income (loss)	12,561	(458,667 )	40,853	198,856
Net (loss) income	(13,335 )	(294,781 )	10,330	130,626
Net (loss) income per common share:				
Basic	(\$0.00 )	(\$0.10 )	\$ 0.00	\$ 0.04
Diluted	(\$0.00 )	(\$0.10 )	\$ 0.00	\$ 0.04
Fiscal 2013:				
Product sales	\$ 1,846,734	\$ 1,366,493	\$ 1,234,701	\$ 1,559,248
Gross margin	1,053,567	783,677	615,717	607,644
Product development expenses	266,479	271,858	290,853	325,010
Net operating income (loss)	326,666	23,722	(159,967 )	(209,975 )
Net income (loss)	204,310	6,452	57,336	(150,703 )
Net income (loss) per common share:				
Basic	\$ 0.07	\$ 0.00	\$ 0.02	(\$0.05 )
Diluted	\$ 0.07	\$ 0.00	\$ 0.02	(\$0.05 )
Fiscal 2012:				
Product sales	\$ 1,717,109	\$ 1,175,126	\$ 1,076,749	\$ 1,420,951
Gross margin	1,012,568	670,518	620,958	750,215
Product development expenses	247,807	211,706	223,771	234,316
Net operating income (loss)	281,233	37,397	(86,126 )	12,497
Net income (loss)	154,761	15,187	(63,574 )	(16,862 )
Net income (loss) per common share:				
Basic	\$ 0.05	\$ 0.01	(\$ 0.02 )	(\$0.01 )
Diluted	\$ 0.05	\$ 0.01	(\$ 0.02 )	(\$0.01 )

## 18.SUBSEQUENT EVENTS

We have adopted the disclosure provisions of Codification Topic 855-10-50-1, *Subsequent Events*, which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued. Entities are required to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. Codification Topic 855-10-50-1 requires additional disclosures only, and therefore did not have an impact on our financial condition, results of operations, earnings per share or cash flows. Public entities must evaluate subsequent events through the date that financial statements are issued. Accordingly, we have evaluated subsequent events through the time of filing on March 26, 2015, the date we have issued this Annual Report on Form 10-K.

F-20

**ImmuCell Corporation**

**Signatures**

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

ImmuCell Corporation  
Registrant

Date: March 26, 2015 By: /s/ Michael F. Brigham  
Michael F. Brigham

President, Chief Executive Officer and  
Principal Financial Officer

**POWER OF ATTORNEY**

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

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

Date: March 18, 2015 By: /s/ Michael F. Brigham  
Michael F. Brigham, President,  
Chief Executive Officer,  
Principal Financial Officer and Director

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Date: March 18, 2015 By:/s/ Joseph H. Crabb  
Joseph H. Crabb, Ph.D., Director

Date: March 18, 2015 By:/s/ David S. Cunningham  
David S. Cunningham, Director

Date: March 18, 2015 By:/s/ Linda Rhodes  
Linda Rhodes, VMD, Ph.D., Director

Date: March 18, 2015 By:/s/ Jonathan E. Rothschild  
Jonathan E. Rothschild, Director

Date: March 18, 2015 By:/s/ David S. Tomsche  
David S. Tomsche, DVM, Director

Date: March 18, 2015 By:/s/ Paul R. Wainman  
Paul R. Wainman, Director

**ImmuCell Corporation**

**EXHIBIT INDEX**

Exhibit 23 Consent of Baker Newman & Noyes, LLC

Exhibit 31 Certifications required by Rule 13a-14(a)

Exhibit 32 Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101.INS XBRL Instance Document.

101.SCH XBRL Taxonomy Extension Schema Document.

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB XBRL Taxonomy Extension Label Linkbase Document.

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.