

IMMUCELL CORP /DE/  
Form 10-K  
March 26, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

FORM 10-K

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

**For the fiscal year ended December 31, 2013**

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

**001-12934**

**(Commission file number)**

**ImmuCell Corporation**

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

**Delaware                      01-0382980  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) 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.

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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 28, 2013 was approximately \$8,308,000 based on the closing sales price on June 28, 2013 of \$3.76 per share.

The number of shares of the Registrant's common stock outstanding at March 19, 2014 was 3,027,034.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement to be filed in connection with the 2014 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

**ImmuCell Corporation**

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## 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**<sup>®</sup> 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**<sup>®</sup> 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 expect to continue this strategic focus. We have experienced consistent growth in product sales over the past three 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**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> and reduced product development spending on **Mast Out**<sup>®</sup>, we returned to profitability during the years ended December 31, 2012 and 2013.

During 2000, we began the development of **Mast Out**<sup>®</sup>, 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**<sup>®</sup> 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>0</sup>** in the areas of safety and effectiveness. Our primary focus, with respect to **Mast Out<sup>0</sup>**, has now turned to the manufacturing objectives required for FDA approval.

In 2006, we initiated our ongoing efforts to maintain compliance with current Good Manufacturing Practice (cGMP) regulations, which requires a sustained investment in personnel, facility improvements and new equipment that further increases the quality of all of our products. Compliance is required for **Wipe Out<sup>0</sup> Dairy Wipes** and for **Mast Out<sup>0</sup>** and may open access to international markets for **First Defense<sup>®</sup>** where such standards are imposed. At the same time, we are investigating new products utilizing the technology underlying **First Defense<sup>®</sup>** (milk antibodies) and **Mast Out<sup>0</sup>** (Nisin).

During the fifteen-year period that began January 1, 1999 (the year we first re-focused our business strategy on **First Defense<sup>®</sup>** and other products for the dairy and beef industries) and ended on December 31, 2013, we invested the aggregate of approximately \$18,570,000 in product development expenses, averaging approximately \$1,238,000 per year during this period. During these fifteen years, this financial strategy (which resulted in nine years of profits followed by four years of losses before returning to profitability in 2012 and 2013) has allowed us to fund our operations and improve our net financial position, as demonstrated in the following table (in thousands, except for percentages):

**ImmuCell Corporation**

	As of December 31, 1998	Net \$ increase over fifteen-year period	As of December 31, 2013	Net % increase over fifteen-year period	
Cash, cash equivalents and short-term investments	\$ 1,539	+\$ 3,716	=\$ 5,255	242	%
Net working capital	\$ 1,866	+\$ 4,766	=\$ 6,632	255	%
Total assets	\$ 3,145	+\$ 7,816	=\$ 10,961	249	%
Stockholders' equity	\$ 2,248	+\$ 7,148	=\$ 9,396	318	%

We had approximately 2,429,000 shares of common stock outstanding as of December 31, 1998 in comparison to 3,026,000 shares as of December 31, 2013. There were 479,633 and 231,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 1998 and 2013, respectively.

**Animal Health Products**

Our lead product, **First Defense**<sup>®</sup>, 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**<sup>®</sup> 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**<sup>®</sup> provides bovine antibodies that newborn calves need but are unable to produce on their own immediately after birth. **First Defense**<sup>®</sup> competes with scours vaccines that are given to the mother cow and to the calf. Despite the best-managed dam (mother cow) vaccine program, colostrum quality is variable. 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. Colostrum feeding must be delayed when a calf vaccine is used, and it is not a good calf health practice to delay the feeding of colostrum while waiting for a vaccine response to be mounted. The direct, two-part mode-of-action of **First Defense**<sup>®</sup> 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**<sup>®</sup> provides a guaranteed level of protection proven to reduce mortality and morbidity from two major causes of calf scours. **First Defense**<sup>®</sup> is convenient to use. A calf needs to receive only one bolus of **First Defense**<sup>®</sup> 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 2013 marked the 22<sup>nd</sup> anniversary of the original USDA approval of this product in 1991. During the third quarter of 2013, we sold the 13,000,000<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™**, 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. Due to natural variability in colostrum, newborn calves do not always get the antibodies they need from maternal colostrum. 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.

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.

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

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

## Sales and Markets

Our sales and marketing team currently consists of one director and three regional managers. Our office manager and facility manager support our sales efforts by performing the order entry, inside sales and shipping duties. 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<sup>®</sup>** 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<sup>®</sup> Dairy Wipes**, and **CMT** to distributors, bovine veterinarians and directly to producers.

**First Defense<sup>®</sup>** 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<sup>®</sup>** 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 16%, 20% and 19% of our total product sales for the years ended December 31, 2013, 2012 and 2011, respectively. The majority of these international sales were to Canada. We currently price our products in U.S. dollars. 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 such products, thereby leading to a potential reduction in demand. Conversely, to the extent that the value of the dollar declines with respect to any other currency, our competitive position may be enhanced. 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<sup>®</sup>** in North America, where there are approximately 9,000,000 dairy cows in the United States and 1,000,000 dairy cows in Canada. We believe that even greater market opportunities exist in other international territories. There are estimated to be approximately 23,000,000 dairy cows in the European Union, another 9,000,000 in China, another 8,000,000 in Russia, another 7,000,000 in Australia and New Zealand and another 800,000 in Japan. These figures do not consider potential sales in the beef markets. Industry practices, economic conditions and cause of disease may differ in these foreign markets from what we experience in the United States. We introduced **First Defense<sup>®</sup>** into South Korea in 2005 and its equivalent into Japan in 2007 through collaborations with in-country distributors.

## ImmuCell Corporation

With **Mast Out<sup>0</sup>**, we are working to expand our product line to include a treatment for the mother cow in addition to our preventative for the newborn calf. 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.

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. Due to milk discard requirements, 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. We believe **Mast Out<sup>0</sup>** 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>0</sup>** could be uniquely positioned in the market as both a treatment for subclinical mastitis and as a tool to prevent some cases of clinical mastitis. **Mast Out<sup>0</sup>** 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 concern. 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. New USDA regulations have been implemented to reduce the allowable level of somatic cell counts (SCC) in milk from 750,000 to 400,000 at the farm level in order to qualify for an EU export certification. This current environment could be favorable to the introduction of a new product such as **Mast Out<sup>0</sup>** as an alternative to traditional antibiotics. We

continue to believe that this innovative product opportunity justifies ongoing product development efforts.

## 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. Many may be capable of developing technologies and/or products that are superior to ours, or may be more successful in developing production capability or in obtaining required regulatory approvals.

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.

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Zoetis and Novartis 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. In addition to direct competition from oral antibody products, **First Defense**<sup>®</sup> also competes for market share against vaccine products that are used to increase the production of antibodies by the dam that can then be transferred through the mother's milk to the calf, and against vaccine products that are administered to the newborn calf. 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.

Zoetis sells a modified-live virus, vaccine product (Calf-Guard) for use in the prevention of scours in newborn calves. Like **First Defense**<sup>®</sup>, Calf-Guard 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 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. 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 includes a precaution that **First Defense**<sup>®</sup> should not be used in conjunction with such a vaccine. We do not understand why a similar precaution is not included in the Calf-Guard label. It is common practice to withhold colostrum when dosing a calf with Calf-Guard, but we encourage the feeding of four quarts of high quality colostrum immediately after birth when dosing a calf with **First Defense**<sup>®</sup>. That is standard practice for good calf health. We also compete for market share against a Novartis product (Bovine Ecolizer<sup>®</sup> + C20). This product carries claims to prevent scours in newborn calves caused by *E. Coli* and *Clostridium perfringens* and is purified from equine serum in contrast to the bovine colostrum used for **First Defense**<sup>®</sup>. These equine antibodies are not absorbed into the bloodstream and then re-secreted for additional protection like bovine antibodies are. 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**<sup>®</sup> **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**<sup>®</sup> **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**<sup>®</sup> because a second drying process is not required when using our product.

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 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 have activity 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.

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During the fourteen-year period that began on January 1, 2000 (the year we began the development of **Mast Out<sup>®</sup>**) and ended on December 31, 2013, we invested the aggregate of approximately \$9,493,000 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 Zoetis 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 market driven, largely 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 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. This risk of interference ranges from the less likely stopping of a cheese starter culture to a delay in the manufacturing process, which does happen at times for other reasons. 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. Milk from cows that have been treated with **Mast Out<sup>®</sup>** that is sold exclusively for fluid milk products presents no such risk.

The commercial introduction of **Mast Out<sup>®</sup>** in the United States is subject to approval of our NADA by the FDA, which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets outside of the United States and 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 associated with *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, and coagulase-negative staphylococci in lactating dairy cattle.

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4) Human Food Safety (HFS): The HFS Technical Section submission was made during the fourth quarter of 2010. This Technical Section determines whether a milk discard period or meat withhold period during and after treatment with **Mast Out**<sup>®</sup> will be required. 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**<sup>®</sup> a zero milk discard period and a zero meat withhold period. 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 submitted a revised submission, which we believe to be responsive to the FDA's review comments, during the third quarter of 2013. The FDA has informed us that our method transfer to the FDA laboratory would be delayed until the first half of 2014 due to scheduling constraints at the FDA laboratory. Accordingly, our expectation for a Technical Section Complete Letter for the HFS Technical Section has now been pushed back to 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 commercial sales. We are party to agreements with three 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, we could have the pharmaceutical-grade Nisin produced for us under a Development and Manufacturing Agreement with Lonza Sales, Ltd. of Basel, Switzerland, which provides for the exclusive manufacture of the pharmaceutical-grade Nisin. The Lonza site in Europe is FDA-approved, compliant with cGMP regulations and subject to future FDA approval and inspection. Third, 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>. 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.

The selection of and (if applicable) the financing for the pharmaceutical-grade Nisin production facility is a critical decision. We had been considering four options: 1) having this work done by a qualified contract manufacturer, such as Lonza, 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 pharmaceutical-grade Nisin produced for us under contract in order to avoid the investment in a manufacturing facility. By the end of 2011, we determined that the large minimum production volumes and high cost imposed by the selected contract manufacturer might make the product commercially unsustainable. For this reason, we engaged an engineering firm to estimate the cost of controlling the production of the pharmaceutical-grade Nisin ourselves in a plant that we either built or leased. Because 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 because of the risk that the actual cost could be higher than we estimated, we investigated potential partnering arrangements. We presented this product opportunity to a variety of large and small

animal health companies. During the second quarter of 2013, we received a \$250,000 exclusive option payment from a prospective partner who later decided not to execute a license for the development and marketing of **Mast Out**<sup>®</sup>. We were informed by the prospective partner that it had determined that, in its opinion, it could not cost effectively commercialize the product. 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 novel treatment option available to dairy producers in order to reduce their reliance on penicillin and cephalosporin-based products. During the third quarter of 2013, we suspended our active pursuit of a partner for **Mast Out**<sup>®</sup> for the present time while continuing our pursuit of FDA approval by completing the HFS Technical Section and the CMC Technical Section on our own. While recognizing the commercial and near-term financial advantages which could have been realized via a partnering agreement with a larger company, 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. We believe that the evolution of our thinking relating to these strategic alternatives demonstrates the flexibility and creativity required to solve this challenge. We will continue to evaluate the four potential options, described above, as we actively pursue the alternative strategy discussed below.

During the third quarter of 2013, our Board of Directors approved the investment of approximately \$1,500,000 to acquire processing equipment and make modifications to our existing manufacturing facility necessary to produce pharmaceutical-grade Nisin for **Mast Out**<sup>®</sup>. The primary goals of this strategy are to: 1) establish the equivalence of the pharmaceutical-grade Nisin produced in this plant to the pharmaceutical-grade Nisin that was used in all completed clinical studies, 2) produce the validation batches required to complete the CMC Technical Section, 3) confirm process yields and the related cost of production and 4) produce inventory for test marketing and limited initial sales after approval. In short, we aim to secure regulatory approval of the product and demonstrate its commercial viability, despite the preliminary determination by a prospective partner (described above) that commercialization could not be achieved economically due principally to high production cost estimates. We believe this approach will enhance our position in any further financing or partnering discussions, should we elect to pursue either of these paths. This anticipated 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**<sup>®</sup>. This strategy allows us to control our decision of whether and when to invest in larger scale production on our own, or with a partner.

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Our goal is to make the first submission of the CMC Technical Section to the FDA at the end of 2014 or in early 2015. It is very common for the CMC Technical Section to require two, six-month review periods by the FDA. 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 by the end of 2015. However, it is possible that the achievement of this important milestone could be delayed into 2016. At some point, a further investment to increase our production capacity of pharmaceutical-grade Nisin would be required to meet anticipated market demand. Our options include doing the work on our own or through an alliance with others, the out-licensing of the product or the sale of the product rights.

In addition to our work on **Mast Out<sup>®</sup>**, we are actively exploring further improvements, extensions or additions to our current 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 Baylor College of Medicine covering certain rotavirus vaccine technology. 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 plan to initiate a second pivotal effectiveness study during the second quarter of 2014. This study could take approximately six months to conduct and evaluate and then, if positive results are obtained, it could take approximately another six months to achieve USDA approval of this additional claim. During the third quarter of 2012, we entered into an exclusive option to a license with North Carolina State University covering certain recombinant *Cryptosporidium parvum* vaccine technology. During the third quarter of 2013, we terminated the option to license this technology because the results from the pilot studies did not demonstrate sufficient effectiveness to justify a continued investment. 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 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.

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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.

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.

## 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 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 states have laws regulating the production, sale, distribution or use of biological products, and we may have to obtain approvals from regulatory authorities in states 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 28 full-time employees and 2 part-time employees. Approximately 14.75 full-time equivalent employees are engaged in manufacturing operations, 3.75 full-time equivalent employees in product development activities, 5.10 full-time equivalent employees in finance and administration and 5.40 full-time equivalent employees in sales and marketing. 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 26, 2014 were as follows:

**MICHAEL F. BRIGHAM** (Age: 53, 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.

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**JOSEPH H. CRABB, Ph.D.** (Age: 59, Officer since 1996, Director since 2001) served as Chairman 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

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; future sources of financial support for our product development, manufacturing and marketing efforts; 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 pharmaceutical-grade Nisin 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 pharmaceutical-grade Nisin for **Mast Out**<sup>®</sup>; factors that may affect the dairy and beef industries and future demand



for our products; 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", "fo" 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, the uncertainties associated with product development, pharmaceutical-grade Nisin 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.

*Projection of net income:* After nine consecutive years of reporting net income, we reported net losses for the four 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>0</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. Given our strategic decision to invest approximately an additional \$1,500,000 in the manufacture of pharmaceutical-grade Nisin, we expect to record a net loss during the first six months of 2014 and (despite a projected return to profitability during the last six months of 2014) during the year ending December 31, 2014. 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.

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*Reliance on sales of First Defense®:* We are heavily reliant on the market acceptance of **First Defense®** to generate product sales and fund our operations. 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, without the gross margin that we earned on sales of **First Defense®**.

*Concentration of sales:* During 2013, 83% of our product sales was made to customers in the U.S. dairy and beef industries in comparison to 80% during 2012. A large portion of our product sales (60%, 55% and 58% for the years ended December 31, 2013, 2012, and 2011, respectively) was made to two large distributors (adjusting for certain acquisitions made by those distributors). A large portion of our trade accounts receivable (65% and 47% as of December 31, 2013 and 2012, respectively) was due from these two distributors (also adjusting for certain acquisitions made by those 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 industry:* There were 87,700,000 head of cattle and calves (dairy and beef) in the United States as of January 1, 2014, which is down 2% from 89,300,000 as of January 1, 2013. There were 90,800,000 cattle and calves as of January 1, 2012. The January 2014 level is the lowest inventory of all cattle and calves since we had 82,100,000 head as of January 1, 1951. The size (annual average) of the U.S. dairy herd ranged from approximately 9,011,000 to 9,199,000 cows from 1998 to 2007. This annual average jumped to 9,315,000 cows in 2008, which is the highest number recorded during the sixteen-year period from 1998 to 2013. The average for 2013 was 9,219,000 which represents a slight reduction from the average of 9,232,000 reported for 2012. 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 is an industry benchmark that reflects the value of product used to make cheese. The Class III milk price (which is largely out of the direct control of individual dairy producers) is an important indicator because it defines our customers' revenue level. This average price for the month of January 2014 reached a recent high of \$21.15. The annual average price level for 2011 was higher than the annual average reached in any of the past 30 years, but then it declined in 2012 and did not fully recover to the 2011 level in 2013, as demonstrated in the following table:

Average Class III Milk Price for the year ended December 31,		Increase (Decrease)	
2010	2011		
\$ 14.41	\$ 18.37	27	%
2011	2012		
\$ 18.37	\$ 17.44	(5	)%
2012	2013		
\$ 17.44	\$ 17.99	3	%

The actual level of milk prices may be less important than its level relative to feed costs. The recent improvement in milk prices has been offset, in part, by higher 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. Whenever this ratio meets or exceeds 3.0, it is considered profitable to buy feed and produce milk. This benchmark level means that a dairy producer could buy 3.0 pounds of feed for every pound of milk sold. The 2012 ratio was the lowest recorded since this ratio was first reported in 1985. The following table demonstrates the volatility and the low values of this ratio recently:

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Milk-To-Feed Price Ratio for the		(Decrease)
year ended December 31,		Increase
2010	2011	
\$ 2.26	\$ 1.88	(17 )%
2011	2012	
\$ 1.88	\$ 1.52	(19 )%
2012	2013	
\$ 1.52	\$ 1.74	14 %

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. The industry data referred to above is compiled from USDA databases. 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<sup>0</sup>**) into such a market. Further, the loss of farms from which we buy raw material for **First Defense<sup>®</sup>** could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms on suitable terms.

*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<sup>0</sup>**, which requires (and will continue to require) a substantial investment. Our efforts will be subject to inspection and approval by the FDA. There is no assurance whether or when we will obtain all of the data necessary to support regulatory approval for this product.

*Risks associated with **Mast Out<sup>0</sup>** funding strategy:* Completing the development of **Mast Out<sup>0</sup>** through to the submission of the administrative NADA to the FDA involves a great deal of risk. Our current strategy is to invest approximately an additional \$1,500,000 in our small-scale pharmaceutical-grade Nisin production plant in order to gain NADA approval and obtain better production cost data. Uncertainty concerning the availability and terms of financing to develop a larger-scale production plant or alternatively the availability and terms of potential partnering arrangements is a risk to an optimal commercialization of **Mast Out<sup>0</sup>**.

*Uncertainty of market size and product sales estimates:* Even assuming that **Mast Out<sup>0</sup>** 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.

*Regulatory requirements for Mast Out<sup>®</sup>*: The commercial introduction of **Mast Out<sup>®</sup>** 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<sup>®</sup>**, 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<sup>®</sup>** in that territory. However, the assigned milk discard period may be shorter for **Mast Out<sup>®</sup>** than it is for other products on the market in Europe.

*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.

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*Regulatory requirements for Wipe Out<sup>®</sup> Dairy Wipes:* While the FDA regulates the manufacture and sale of **Wipe Out<sup>®</sup> 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<sup>®</sup> 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.

*Competition from others:* Many of our competitors are significantly larger and more diversified in the relevant markets, 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 and Novartis, among other companies, sell products that compete directly with **First Defense<sup>®</sup>** 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<sup>®</sup>** 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. We are dependent on our manufacturing facility and operations at 56 Evergreen Drive in Portland, Maine for the production of **First Defense<sup>®</sup>** and **Wipe Out<sup>®</sup> Dairy Wipes**. The specific antibodies that we purify for

**First Defense**<sup>®</sup> and the Nisin we produce by fermentation for **Wipe Out**<sup>®</sup> **Dairy Wipes** are not readily available from other sources. We expect to be dependent on Plas-Pak and Norbrook for a significant portion of the manufacture of **Mast Out**<sup>®</sup> if that product proceeds to commercialization, and we may become dependent on a collaborative partner for certain development, manufacturing and sales and marketing services. 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.

*Risks associated with USDA and international regulatory oversight:* **First Defense**<sup>®</sup> 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.

*Small size; dependence on key personnel:* We are a small company with 28 full-time and 2 part-time employees. As such, we rely on certain key employees to support different operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained. Our competitive position will be highly influenced by our ability to attract and retain key scientific, managerial and sales and marketing personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products and to continue to profitably sell our current products. We currently compete on the basis of product performance, price and distribution capability. We continue to monitor our network of independent distributors to maintain our competitive position.

## ImmuCell Corporation

*Exposure to risks associated with the financial downturn and global economic crisis:* The U.S. economy appears to be coming out of a recession, caused principally by the housing, credit and financial crises. 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 our ability to penetrate international markets.

*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 a risk that competitors could challenge the claims in patents that have been issued to us.

*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.

*No expectation to pay any dividends for the foreseeable future:* We do not anticipate paying any dividends to 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 and other factors our Board of Directors deems relevant.

*Market for common stock:* Our common stock trades on the NASDAQ Stock Market (NASDAQ: ICCG). 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.

*Stock market valuation:* There are companies in the animal health sector with market capitalization values that greatly exceed our market capitalization of under \$15,000,000. Some of these companies have no product sales. We currently have product sales in excess of \$6,000,000. Before gross margin from the sale of new products is achieved, our market capitalization may be heavily dependent on the perceived potential of our products under development.

*Provisions in our certificate of incorporation, our bylaws, our Common Stock Rights Plan or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock:* 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 you might otherwise receive a premium for your 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:

## ImmuCell Corporation

- limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the ability of our Board of Directors to make, alter or repeal our bylaws; and

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.

In addition, we are governed by 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 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 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 that you could receive a premium for your common stock in an acquisition.

*Cost burdens of our reporting obligations as a public company:* Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws and the provisions of the Sarbanes-Oxley Act of 2002.

## ITEM 2 – DESCRIPTION OF PROPERTY

We own a 27,750 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. The 2001 facility addition also added approximately 4,100 square feet of storage space on the second floor. In 2007, we completed a renovation project converting 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. As part of the 2007 project, we also added approximately 2,500 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 600 square feet to the second floor storage area. We funded these investments with available cash. During 2014, we plan to build a two-story addition connected to our facility to provide us with approximately 6,800 additional square feet for cold storage, production and warehouse space for our operations. The budget for the construction and related production equipment is approximately \$1,500,000. We expect to complete this construction project and begin utilizing the new space during the fourth quarter of 2014. These

investments are an integral part of our strategy to: 1) increase production capacity for our current products, 2) maintain compliance with cGMP regulations in all of our manufacturing operations and 3) better integrate the production of pharmaceutical-grade Nisin for **Mast Out<sup>®</sup>** into our operations.

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

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**ImmuCell Corporation****PART II****ITEM 5 – MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND 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 its 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, 2012 through December 31, 2013:

	2013 Three Months Ended				2012 Three Months Ended			
	March 31	June 30	September 30	December 31	March 31	June 30	September 30	December 31
High	\$4.50	\$ 3.95	\$ 5.10	\$ 4.86	\$6.08	\$ 6.80	\$ 7.00	\$ 5.50
Low	\$3.52	\$ 3.25	\$ 3.19	\$ 4.01	\$4.50	\$ 4.60	\$ 4.84	\$ 3.76

As of March 19, 2014, we had 8,000,000 common shares authorized and 3,027,034 common shares outstanding, and there were approximately 1,000 shareholders of record. The last sales price of our common stock on March 19, 2014 was \$4.60 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, 2013 or that could be granted in the future:

Number of shares to be	Weighted-average exercise price	Number of shares remaining available
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	issued upon exercise of outstanding options	of outstanding options	for future issuance under stock-based compensation plans (excluding shares reflected in first column of this table)
Equity compensation plans approved by stockholders	231,000	\$ 3.30	225,500
Equity compensation plans not approved by stockholders	—	—	—
Total	231,000	\$ 3.30	225,500

## 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,				
	2013	2012	2011	2010	2009
Statement of Operations Data:					
Product sales	\$6,007	\$5,390	\$ 5,111	\$ 4,386	\$ 4,506
Gross margin	3,061	3,054	2,814	2,302	2,398
Product development expenses	1,154	918	1,720	1,493	1,645
Selling and administrative expenses	1,926	1,892	1,726	1,500	1,283
Net operating (loss) income	(20 )	245	(633 )	(690 )	(530 )
Income (loss) before income taxes	205	192	(697 )	(683 )	(429 )
Net income (loss)	\$117	\$90	(\$410 )	(\$385 )	(\$216 )

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	Year Ended December 31,				
	2013	2012	2011	2010	2009
Per Common Share:					
Basic net income (loss)	\$0.04	\$0.03	\$(0.14)	\$(0.13)	\$(0.07)
Diluted net income (loss)	\$0.04	\$0.03	\$(0.14)	\$(0.13)	\$(0.07)
Cash dividend	—	—	—	—	—

## Statement of Cash Flows Data:

Net cash provided by (used for) operating activities	\$1,099	\$344	\$(37 )	\$(809 )	\$(110 )
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	As of December 31,				
	2013	2012	2011	2010	2009
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$5,255	\$4,914	\$4,960	\$4,626	\$4,585
Total assets	10,961	11,030	10,991	10,751	9,985
Current liabilities	636	666	635	525	363
Net working capital	6,632	6,697	6,516	6,441	5,944
Long-term liabilities	929	1,170	1,336	944	—
Stockholders' equity	\$9,396	\$9,195	\$9,020	\$9,282	\$9,622

## Per Outstanding Common Share:

Cash, cash equivalents and short-term investments	\$1.74	\$1.63	\$1.65	\$1.56	\$1.54
Stockholders' equity	\$3.11	\$3.05	\$3.00	\$3.12	\$3.24

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

We had approximately \$5,255,000 in available cash, cash equivalents, and short-term investments as of December 31, 2013. The table below summarizes the changes in selected, key balance sheet items (in thousands, except for percentages):

2013	As of December 31, 2012	Increase (Decrease)	
		\$	%

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Cash, cash equivalents and short-term investments	\$ 5,255	\$ 4,914	342	7 %
Net working capital	6,632	6,697	(65 )	(1 )%
Total assets	10,961	11,030	(70 )	(1 )%
Stockholders' equity	\$ 9,396	\$ 9,195	201	2 %

Net cash provided by operating activities amounted to \$1,099,000 during the year ended December 31, 2013 compared to net cash provided by operating activities of \$344,000 during the year ended December 31, 2012. Capital investments of \$598,000 during 2013 compared to capital investments of \$275,000 during 2012. 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, 2013, our outstanding bank debt balance was approximately \$1,087,000. The \$500,000 line of credit is available as needed. We chose debt financing because we believe that in this market environment, the option to generate funds through the sale of equity securities at an acceptable level of stockholder dilution is 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 \$18,570,000 during the fifteen-year period ended December 31, 2013 was offset, in part, by \$4,130,000 in licensing revenue, technology sales and grant income. Our strategic decision to continue developing **Mast Out**<sup>®</sup> 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 are expected to increase again, as we invest to complete the regulatory approval process, resulting in a net loss during the first half of 2014. After completing this investment, we expect to return to breakeven or 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. We continue to look for new product acquisition opportunities that would have a strategic fit with the products that we currently sell.

We are making a sustained investment in increasing our current production capacity and maintaining compliance with current Good Manufacturing Practice (cGMP) regulations. Compliance with cGMP regulations is required for the production of **Mast Out**<sup>®</sup> and **Wipe Out**<sup>®</sup> **Dairy Wipes**, and we elected to enforce these quality standards across all of our product lines. As we make other process improvements, we are investing in personnel, equipment and facility modifications to increase the efficiency and quality of our operations. 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. As of January 1, 2014, we had remaining available authorization from our Board of Directors to spend up to approximately \$212,000 on routine capital expenditures. The figures described above do not include an investment in two additional projects aggregating approximately \$3,000,000 that have been approved by our Board of Directors. Approximately half of this additional investment is allocated to the investment in the facility addition and production equipment described under **ITEM 2 – DESCRIPTION OF PROPERTY**, above. The other half of this additional investment is allocated to our pharmaceutical-grade Nisin production plant, described in the next paragraph.

A significant investment primarily related to the manufacture of pharmaceutical-grade Nisin remains ahead to complete the **Mast Out**<sup>®</sup> product development initiative. During the third quarter of 2013, our Board of Directors approved the investment of approximately \$1,500,000 to acquire processing equipment and to modify a portion of our facility in Portland, Maine to produce pharmaceutical-grade Nisin for **Mast Out**<sup>®</sup>. We expect our facility to produce sufficient pharmaceutical-grade Nisin to complete our regulatory submission to the FDA and conduct test marketing of **Mast Out**<sup>®</sup> in the United States. An additional benefit of this investment is that the data we expect to collect on production yields should help us better understand the cost of producing inventory. We hope this will support and facilitate the raising of capital or the enlistment of a partner to fund expanded manufacturing capacity and the commercialization of **Mast Out**<sup>®</sup>. Approximately \$242,000 of this investment is expected to be capitalized and



depreciated over ten years. Approximately \$110,000 in expenses related to this project were incurred during the fourth quarter of 2013. We expect to expense the balance of this investment as incurred over the first and second quarters of 2014. This specifically targeted increase in product development expenses is expected to result in a net loss during the first six months of 2014 and (despite a projected return to profitability during the last six months of 2014) during the year ending December 31, 2014. This investment is discussed in greater detail under **ITEM 1 – DESCRIPTION OF BUSINESS, “Product Development,”** above.

## ImmuCell Corporation

### Results of Operations

#### *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**<sup>®</sup> 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**<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 our lead product, **First Defense**<sup>®</sup>, 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**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> during the last six consecutive quarters and for twelve of the last thirteen quarters, as demonstrated in the following table:

We believe that the long-term growth in sales of **First Defense**<sup>®</sup> 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 director and three regional sales and marketing managers. Our office manager and facilities manager support our sales efforts by performing all order entry, inside sales and shipping duties. 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>TM</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. Our communications campaign highlights how the unique features of **First Defense**<sup>0</sup> provide a dependable return on investment for producers. Effective for 2011 and for 2012, we entered into a sales and marketing collaboration with Agri Laboratories, Ltd of St. Joseph, Missouri (AgriLabs<sup>0</sup>), under which the AgriLabs<sup>0</sup> sales and marketing teams worked with us to expand market demand for **First Defense**<sup>0</sup>.

## ImmuCell Corporation

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 has 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.

We are selling new product applications of our **First Defense Technology**<sup>TM</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**<sup>TM</sup>, we are selling concentrated whey proteins in different formats. During the first quarter of 2011, we initiated sales of **First Defense Technology**<sup>TM</sup> 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<sup>®</sup> 150 Plus, a colostrum replacer with **First Defense Technology**<sup>TM</sup> **Inside**. During the first quarter of 2012, we initiated a limited launch of a tube delivery format of our **First Defense Technology**<sup>TM</sup> in a gel solution.

We sell topical wipes that are pre-moistened with a Nisin-based formulation in two product formats. Since 1999, we have been selling **Wipe Out<sup>®</sup> 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<sup>®</sup> Dairy Wipes** decreased by 7% during the year ended December 31, 2013 in comparison to the same period during 2012. 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<sup>®</sup> 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<sup>TM</sup> 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<sup>®</sup> 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.

### *Gross Margin*

We generally held our product selling prices without increase during the seven year period ended December 31, 2007. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense®**. We have implemented no significant price increases since then, believing that we could benefit more from higher unit sales than through a higher average selling price per unit. 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. Changes in the gross margin on product sales are summarized in the following table for the respective periods (in thousands, except for percentages):

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

	For the Six-Month			
	Periods Ended		(Decrease)	
	December 31,			
	2013	2012	Amount	%
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	Amount	%
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, and we expect our gross margin percentage to be in line with historical norms during 2014. A number of factors account for the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter. The gross margin on **First Defense**<sup>®</sup> 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. It is our production and customer service objective to ship orders within one day of receipt. We have been operating generally in accordance with this objective since the third quarter of 2009. However, during the first quarter of 2014

we have experienced a few, short delays in shipping customer orders of **First Defense**<sup>®</sup>, as we re-build our inventory on-hand to the desired levels. Given current production and sales projections, we do not expect to ask our customers to endure such shipment delays again after May 1, 2014.

#### *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. We also remain interested in acquiring other new products and technologies that fit with our sales focus on the dairy and beef industries.

## **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. 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 2014 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 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. At this stage in our development, we have limited our investment in investor relations spending. We provide a 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. At this time, our financial and time resources are committed principally to managing our commercial business and developing **Mast Out**<sup>®</sup>. Our Board of Directors is very involved with and supportive of this resource allocation and is considering the potential benefits of investing in a more actively managed investor relations program. While this strategy of providing cost-effective investor relations through our SEC reporting is subject to change, we believe that this strategy currently is in the best long-term interest of all stockholders.

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

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.

## ImmuCell Corporation

### *2012 Compared to 2011*

#### *Product Sales*

Product sales for the year ended December 31, 2012 increased by 5.5%, or \$279,000, to \$5,390,000 from \$5,111,000 in 2011. Domestic product sales increased by 4%, or \$155,000, during the year ended December 31, 2012, and international sales increased by 13%, or \$124,000, in comparison to 2011. For the three-month period ended December 31, 2012, product sales increased by 9%, or \$116,000, in comparison to the three-month period ended December 31, 2011. We believe our increased investment in sales and marketing personnel and efforts is helping us introduce **First Defense**<sup>®</sup> to new customers. We believe that sales of our products were influenced by the relatively strong prices of milk, cows and calves which gains were partially offset by the increased cost of feed.

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. While milk prices have improved recently, much of this gain has been offset by increases in the cost of feed. Even in this challenging market, 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. It is our production and customer service objective to ship orders within one day of receipt. We have been operating in accordance with this objective since the third quarter of 2009. Sales of **First Defense**<sup>®</sup> aggregated 89% of our total product sales during both of the years ended December 31, 2012 and 2011. Sales of **First Defense**<sup>®</sup> increased by 5% during the year ended December 31, 2012 in comparison to 2011. Domestic sales of **First Defense**<sup>®</sup> increased by 4%, and international sales increased by 10%. Sales of **First Defense**<sup>®</sup> are normally seasonal, with higher sales expected during the first quarter. With the single exception of the second quarter of 2012, we have been experiencing consistently positive sales growth of **First Defense**<sup>®</sup> since the fourth quarter of 2010, as demonstrated below:

5%: Fiscal Year 2012 over Fiscal Year 2011

16%: Fourth Quarter 2012 over Fourth Quarter 2011

9%: Third Quarter 2012 over Third Quarter 2011

(17%): Second Quarter 2012 under Second Quarter 2011

13%: First Quarter 2012 over First Quarter 2011

21%: Fiscal Year 2011 over Fiscal Year 2010

7%: Fourth Quarter 2011 over Fourth Quarter 2010

22%: Third Quarter 2011 over Third Quarter 2010

37%: Second Quarter 2011 over Second Quarter 2010

21%: First Quarter 2011 over First Quarter 2010

13%: Fourth Quarter 2010 over Fourth Quarter 2009

We believe that the growth in sales of **First Defense<sup>®</sup>** may reflect, at least in part, the success of our strategic decision first implemented in 2010 to invest in additional sales and marketing efforts. We launched a communications campaign at the end of 2010 that is highlighting how the unique features of **First Defense<sup>®</sup>** provide a dependable return on investment for producers. Effective for 2011 and for 2012, we entered into a sales and marketing collaboration with AgriLabs, under which the AgriLabs sales and marketing teams worked with us to expand market demand for **First Defense<sup>®</sup>**.

Through our **First Defense Technology<sup>™</sup>**, we are selling whey protein concentrate in different formats. During the first quarter of 2011, we initiated sales of our **First Defense Technology<sup>™</sup>** in a bulk powder format, which is delivered by dissolving our powder in liquid for feeding to calves. During the first quarter of 2012, we initiated a limited launch of a new format of our **First Defense Technology<sup>™</sup>** in a paste formulation that is delivered through an oral syringe. During the fourth quarter of 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start<sup>®</sup> 150 Plus, a colostrum replacer with **First Defense Technology<sup>™</sup> Inside**.

## ImmuCell Corporation

Sales of **Wipe Out<sup>®</sup> Dairy Wipes** decreased by 6% during the year ended December 31, 2012 in comparison to 2011. We believe that sales growth potential for **Wipe Out<sup>®</sup> 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 prior to milking, and many producers opt for a less expensive solution. We are competing aggressively on selling price to earn new business against less expensive products and alternative teat sanitizing methods. Sales of **CMT** decreased by 28% during the year ended December 31, 2012 in comparison to 2011.

We sell bulk reagents outside of the dairy and beef industries for use in a drinking water test that is sold by others known as Isolate<sup>™</sup> (formerly known as Crypto-Scan<sup>®</sup>). Sales of these bulk reagents aggregated 4% and 2% of product sales during the years ended December 31, 2012 and 2011, respectively. Sales of these bulk reagents increased by 92% during the year ended December 31, 2012 in comparison to 2011. Our animal health sales (total product sales less sales of these bulk reagents) increased by 4% during the year ended December 31, 2012 in comparison to 2011. This comparison demonstrates the growth of our core animal health business.

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 have implemented no significant price increases since then, believing that we could benefit more from higher unit sales than through a higher average selling price per unit.

### *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):

	Years Ended		Increase	
	December 31, 2012	2011	Amount	%
Gross margin	\$3,054	\$2,814	\$240	9%
Percent of product sales	57 %	55 %	2 %	3%

The gross margin as a percentage of product sales was 57% and 55% during the years ended December 31, 2012 and 2011, respectively. This compares to gross margin percentages of 52% and 53% for the years ended December 31,

2010 and 2009, respectively. Our current annual target is to maintain the gross margin percentage above 50%. A number of factors account for the variability in our costs. We expect some fluctuations in gross margin percentages from quarter to quarter. The gross margin on **First Defense<sup>®</sup>** is affected by biological yields from our raw material, which do fluctuate over time. More generally, costs for production of **First Defense<sup>®</sup>** and **Wipe Out<sup>®</sup> Dairy Wipes** have increased due to increased labor costs and expenses associated with our efforts to sustain compliance with cGMP regulations in our production processes. Like most U.S. manufacturers, we have been experiencing increases in the cost of raw materials that we purchase. 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 1%, or \$17,000, to \$1,649,000 at December 31, 2012 from \$1,666,000 at December 31, 2011. This level of investment was made in both periods to help prevent a potential backlog of orders. We have not experienced a backlog of orders since the third quarter of 2009.

### *Sales and Marketing Expenses*

Sales and marketing expenses increased by approximately 12%, or \$103,000, to \$973,000 in 2012, increasing to 18% of product sales in 2012 from 17% in 2011. We continue to leverage the efforts of our small sales force through 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 2013 is to invest up to 20% of product sales in sales and marketing expenses on an annual basis.

## ImmuCell Corporation

### *Administrative Expenses*

Administrative expenses increased by approximately 7%, or \$62,000, to \$918,000 during the year ended December 31, 2012 as compared to \$857,000 during 2011. 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. At this stage in our development, we have limited our investment in investor relations spending. We provide a full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year. Additional information about our business 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. Presently, our financial and time resources are committed principally to managing our commercial business and developing **Mast Out<sup>®</sup>**. Our Board of Directors is very involved with and supportive of this resource allocation. While this strategy of providing cost-effective investor relations through our SEC reporting is subject to change, we believe that this focus currently is in the best long-term interest of all stockholders.

### *Product Development Expenses*

Product development expenses decreased by 47%, or \$802,000, to \$918,000 during the year ended December 31, 2012, as compared to \$1,720,000 during 2011. We expected lower product development expenses during the year ended December 31, 2012. Product development expenses aggregated 17% and 34% of product sales in 2012 and 2011, respectively. The majority of our product development budget from 2000 through 2012 has been focused on the development of **Mast Out<sup>®</sup>**. Going forward, we expect to maintain a reduced level of product development expenses, which expenses will continue to be focused on **Mast Out<sup>®</sup>** and 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.

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

Interest income increased by approximately 11%, or \$2,000, to \$17,000 in 2012 in comparison to 2011. Interest expense aggregated \$75,000 and \$81,000 during 2012 and 2011, respectively.

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

Our income before income taxes of \$192,000 during the year ended December 31, 2012 is in contrast to a loss before income taxes of (\$697,000) during 2011. We recorded an income tax expense (benefit) of 53% and (41%) of the income (loss) before income taxes during the years ended December 31, 2012 and 2011, respectively. Our net income of \$90,000, or \$0.03 per share, during the year ended December 31, 2012 is in contrast to a net loss of (\$410,000), or (\$0.14) per share, during 2011.

**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, 2013 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. We do not anticipate that currency fluctuations will significantly affect our sales or the cost of operations. 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-19 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, 2013 and 2012	F-2
Statements of Operations for the years ended December 31, 2013, 2012 and 2011	F-3
Statements of Comprehensive Income (Loss) for the years ended December 31, 2013, 2012 and 2011	F-4
Statements of Stockholders' Equity for the years ended December 31, 2011, 2012 and 2013	F-5
Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011	F-6
Notes to Financial Statements	F-7 to F-19

**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, 2013. 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.

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## **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, 2013. Based on management's assessment and those criteria, management believes that the internal control over financial reporting as of December 31, 2013 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 2014 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, 2013. 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 2014 Proxy Statement titled “Executive Officer Compensation”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2013.

**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 2014 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, 2013.

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

Information regarding certain relationships and related transactions is incorporated herein by reference to the section of our 2014 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, 2013.

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

Information regarding our principal accountant fees and services is incorporated by reference to the section of our 2014 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, 2013.

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

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

**ImmuCell Corporation**

- 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).  
Form of Indemnification Agreement (updated) entered into with each of the Company's Directors and Officers
- 10.1+(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).  
Amendment to Employment Agreement between the Company and Michael F. Brigham dated March 26, 2010
- 10.4+(incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2009).  
Amendment to Employment Agreement between the Company and Joseph H. Crabb dated March 26, 2010
- 10.5+(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).  
Development and Manufacturing Agreement between the Company and Lonza Sales, Ltd. dated July 15, 2010
- 10.8<sup>(1)</sup> (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).  
Commercial Promissory Note for \$1,000,000 between the Company and TD Bank, N.A. dated August 13, 2010
- 10.9 (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).  
Commercial Promissory Note for \$600,000 between the Company and TD Bank, N.A. dated August 13, 2010
- 10.10 (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).  
Line of Credit Agreement and Promissory Note for up to \$500,000 between the Company and TD Bank, N.A.
- 10.11 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).  
Loan Agreement between the Company and TD Bank, N.A. dated August 13, 2010 (incorporated by reference
- 10.12<sup>(1)</sup> to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).  
Contract Manufacture Agreement between the Company and Norbrook Laboratories Limited dated as of
- 10.13<sup>(1)</sup> 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).  
Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14 of the Company's Current Report on
- 14 Form 8-K filed on March 20, 2014).
- 23 Consent of Baker Newman & Noyes, LLC.

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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, 2013 and 2012, and the related statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2013. 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, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

Portland, Maine /s/ Baker Newman & Noyes  
March 26, 2014 Limited Liability Company



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

	As of December 31,	
	2013	2012
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$2,270,385	\$2,673,719
Short-term investments	2,985,000	2,240,000
Inventory	1,206,508	1,649,002
Accounts receivable, net	631,410	611,354
Prepaid expenses	159,117	157,930
Current portion of deferred tax asset	15,212	31,177
Total current assets	7,267,632	7,363,182
<b>PROPERTY, PLANT AND EQUIPMENT, net</b>	2,524,765	2,357,609
LONG-TERM PORTION OF DEFERRED TAX ASSET	1,154,681	1,245,982
<b>OTHER ASSETS, net</b>	13,636	63,634
<b>TOTAL ASSETS</b>	<b>\$10,960,714</b>	<b>\$11,030,407</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accrued expenses	\$293,076	\$255,568
Accounts payable	152,153	228,711
Current portion of bank debt	190,390	181,491
Total current liabilities	635,619	665,770
<b>LONG-TERM LIABILITIES:</b>		
Long-term portion of bank debt	896,224	1,086,568
Interest rate swap	33,002	83,386
Total long-term liabilities	929,226	1,169,954
<b>TOTAL LIABILITIES</b>	<b>1,564,845</b>	<b>1,835,724</b>
<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, 2013 and 2012	326,115	326,115
Capital in excess of par value	10,011,339	9,973,146
Accumulated deficit	(407,408 )	(524,803 )

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Treasury stock, at cost, 235,114 and 242,114 shares at December 31, 2013 and 2012, respectively	(514,341 )	(529,655 )
Accumulated other comprehensive loss	(19,836 )	(50,120 )
Total stockholders' equity	9,395,869	9,194,683
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 10,960,714</b>	<b>\$ 11,030,407</b>

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

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

	For the Years Ended December 31,		
	2013	2012	2011
Product sales	\$6,007,176	\$5,389,935	\$5,111,143
Cost of goods sold	2,946,570	2,335,676	2,297,339
Gross margin	3,060,606	3,054,259	2,813,804
Product development expenses	1,154,200	917,600	1,720,055
Sales and marketing expenses	986,766	973,217	869,869
Administrative expenses	939,192	918,441	856,606
Operating expenses	3,080,158	2,809,258	3,446,530
NET OPERATING (LOSS) INCOME	(19,552 )	245,001	(632,726 )
Other income (expenses), net	224,812	(52,849 )	(63,955 )
INCOME (LOSS) BEFORE INCOME TAXES	205,260	192,152	(696,681 )
Income tax expense (benefit)	87,865	102,640	(287,171 )
NET INCOME (LOSS)	\$117,395	\$89,512	\$(409,510 )
Weighted average common shares outstanding:			
Basic	3,019,407	3,018,296	2,984,749
Diluted	3,085,048	3,108,419	2,984,749
NET INCOME (LOSS) PER SHARE:			
Basic	\$0.04	\$0.03	\$(0.14 )
Diluted	\$0.04	\$0.03	\$(0.14 )

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

**ImmuCell Corporation****STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

	For the Years Ended December 31,		
	2013	2012	2011
Net income (loss)	\$ 117,395	\$ 89,512	\$ (409,510 )
Other comprehensive income (loss):			
Interest rate swap, before taxes	50,384	(15,486 )	(77,531 )
Income tax applicable to interest rate swap	(20,100 )	6,178	27,088
Other comprehensive income (loss), net of taxes	30,284	(9,308 )	(50,443 )
Total comprehensive income (loss)	\$ 147,679	\$ 80,204	\$ (459,953 )

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

## ImmuCell Corporation

## STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Capital in Excess of	Accumulated	Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Par Value	Deficit	Shares	Amount		
BALANCE, December 31, 2010	3,261,148	\$ 326,115	\$ 9,780,392	\$ (204,805 )	287,496	\$ (628,932)	\$ 9,631	\$ 9,282,401
Net loss	—	—	—	(409,510 )	—	—	—	(409,510 )
Other comprehensive loss, net of taxes	—	—	—	—	—	—	(50,443 )	(50,443 )
Exercise of stock options, net	—	—	78,832	—	(30,382 )	66,463	—	145,295
Tax benefits related to stock options	—	—	14,518	—	—	—	—	14,518
Stock-based compensation	—	—	38,172	—	—	—	—	38,172
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	—	—	—	89,512	—	—	—	89,512
Other comprehensive loss, net of taxes	—	—	—	—	—	—	(9,308 )	(9,308 )
Exercise of stock options	—	—	17,986	—	(15,000 )	32,814	—	50,800

Tax benefits related to stock options	—	—	7,261	—	—	—	—	7,261
Stock-based compensation	—	—	35,985	—	—	—	—	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	—	—	—	117,395	—	—	—	117,395
Other comprehensive income, net of taxes	—	—	—	—	—	—	30,284	30,284
Exercise of stock options	—	—	6,436	—	(7,000 )	15,314	—	21,750
Tax benefits related to stock options	—	—	398	—	—	—	—	398
Stock-based compensation	—	—	31,359	—	—	—	—	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

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

## ImmuCell Corporation

## STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,		
	2013	2012	2011
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income (loss)	\$ 117,395	\$ 89,512	\$(409,510 )
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:			
Depreciation	414,307	399,640	413,132
Amortization	2,894	2,876	5,240
Deferred income taxes	87,166	94,370	(302,500 )
Stock-based compensation	31,359	35,985	38,172
Loss on disposal of fixed assets	35,179	12,265	10,822
Changes in:			
Receivables	(20,056 )	(227,558 )	113,717
Inventory	442,494	17,463	(65,449 )
Prepaid expenses and other assets	45,917	(123,628 )	159,484
Accounts payable	(95,503 )	100,047	59,479
Accrued expenses	37,508	(48,332 )	(68,152 )
Deferred revenue	—	(8,250 )	8,250
Net cash provided by (used for) operating activities	1,098,660	344,390	(37,315 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property, plant and equipment	(597,697 )	(275,395 )	(243,735 )
Maturities of short-term investments	2,489,000	4,178,000	3,227,000
Purchases of short-term investments	(3,234,000)	(2,240,000)	(4,178,000)
Net cash (used for) provided by investing activities	(1,342,697)	1,662,605	(1,194,735)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from debt issuance	—	—	600,000
Debt principal repayments	(181,445 )	(172,853 )	(145,232 )
Proceeds from exercise of stock options	21,750	50,800	145,295
Tax benefits related to stock options	398	7,261	14,518
Net cash (used for) provided by financing activities	(159,297 )	(114,792 )	614,581
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(403,334 )</b>	<b>1,892,203</b>	<b>(617,469 )</b>
<b>BEGINNING CASH AND CASH EQUIVALENTS</b>	<b>2,673,719</b>	<b>781,516</b>	<b>1,398,985</b>
<b>ENDING CASH AND CASH EQUIVALENTS</b>	<b>\$2,270,385</b>	<b>\$2,673,719</b>	<b>\$781,516</b>
<b>INCOME TAXES PAID</b>	<b>\$—</b>	<b>\$708</b>	<b>\$510</b>

INTEREST EXPENSE PAID	\$67,015	\$75,681	\$78,737
NON-CASH ACTIVITIES:			
Capital expenditures included in accounts payable and accrued expenses	\$23,495	\$4,550	\$25,762
Net change in fair value of interest rate swap	\$(30,284	) \$9,308	\$50,443

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



## **ImmuCell Corporation**

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

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

ImmuCell Corporation's (the Company) 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 is subject to certain risks associated with its stage of development including dependence on key individuals, competition from other larger companies, the successful sales 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 make the financial statements 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>TM</sup> (Codification). Certain prior year accounts have been reclassified to conform with the 2013 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 \$1,770,000 and \$2,173,000 at December 31, 2013 and 2012, respectively. Short-term investments are classified as held to maturity and are comprised principally of certificates of deposits 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 2014 building addition 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 6.

#### **(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 7 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 and cash equivalents, short-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 and accounts receivable. We invest our short-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 and cash equivalents, short-term investments, accounts receivable and accounts payable approximate their carrying value due to their short maturity. 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 income (loss), until earnings are affected by the variability of cash flows (e.g. when periodic settlements on a variable-rate asset or liability are recorded in earnings). We formally documented the relationship between the interest rate swap 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. All product development costs and patent costs are expensed as incurred.

#### **(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 \$151,080, \$174,314 and \$4,658 during the years ended December 31, 2013, 2012 and 2011, 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, 2013. 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 the 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 \$31,359, \$35,985, and \$38,172 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, 2013, 2012 and 2011, 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 Income (Loss) Per Common Share**

The net income (loss) per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*. The basic net income per share has been computed by dividing the net income by the weighted average number of common shares outstanding during this period. The diluted net income per share has been computed by dividing the net income by the weighted average number of shares outstanding during the period plus all outstanding stock options with an exercise price that is less than the average market price of the common stock during the period less the number of shares that could have been repurchased at this average market price with the proceeds from the hypothetical stock option exercises. The net loss per common share 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.

	Year Ended December 31,		
	2013	2012	2011
Weighted average number of shares outstanding	3,019,407	3,018,296	2,984,749
Effect of dilutive stock options	65,641	90,123	—
Diluted number of shares outstanding	3,085,048	3,108,419	2,984,749
Stock options not included in the calculation because the effect would be anti-dilutive	63,875	39,750	236,000

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 income (loss), the components of net income (loss), and the components of other comprehensive income (loss) either in a single continuous statement of comprehensive income (loss) or in two separate but consecutive statements. We elected to present two separate but consecutive statements. The statements of other comprehensive income (loss) immediately follow the statements of operations and include the components of other comprehensive income (loss) and a total for other comprehensive income (loss), along with a total for comprehensive income (loss). The adoption of Topic 220 only impacts the presentation of the financial statements.

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

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

	As of December 31,		(Decrease)
	2013	2012	Increase
Cash and cash equivalents	\$2,270,385	\$2,673,719	\$(403,334)
Short-term investments	2,985,000	2,240,000	745,000
Total	\$5,255,385	\$4,913,719	\$341,666



**ImmuCell Corporation****Notes to Audited Financial Statements (continued)****4. INVENTORY**

Inventory consisted of the following:

	As of December 31,		Increase
	2013	2012	(Decrease)
Raw materials	\$270,355	\$198,441	\$71,914
Work-in-process	783,060	986,243	(203,183 )
Finished goods	153,093	464,318	(311,225 )
Total	\$1,206,508	\$1,649,002	\$(442,494 )

**5. ACCOUNTS RECEIVABLE**

Accounts receivable consisted of the following:

	As of December 31,		Increase
	2013	2012	(Decrease)
Trade accounts receivable	\$609,638	\$589,257	\$ 20,381
Allowance for bad debt and product returns	(13,952 )	(15,111 )	1,159
Trade accounts receivable, net	595,686	574,146	21,540
Other receivables	35,676	36,860	(1,184 )
Income taxes receivable	48	348	(300 )
Accounts receivable, net	\$631,410	\$611,354	\$ 20,056

**6. PROPERTY, PLANT AND EQUIPMENT**

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

As of December 31,

	2013	2012	Increase
Laboratory and manufacturing equipment	\$3,182,686	\$3,029,559	\$153,127
Building and improvements	2,940,239	2,785,698	154,541
Office furniture and equipment	354,243	312,979	41,264
Construction in progress	9,600	—	9,600
Land	50,000	50,000	—
Property, plant and equipment, gross	6,536,768	6,178,236	358,532
Less: accumulated depreciation	4,012,003	3,820,627	191,376
Property, plant and equipment, net	\$2,524,765	\$2,357,609	\$167,156

## 7. OTHER ASSETS

Other assets consisted of the following:

	As of December 31,	
	2013	2012
Security deposits	\$ 750	\$ 250
Debt issue costs	26,489	26,489
Other <sup>(1)</sup>	—	47,604
Other assets, gross	27,239	74,343
Less: accumulated amortization of debt issue costs	13,603	10,709
Other assets, net	\$ 13,636	\$ 63,634

<sup>(1)</sup>This asset was written off to product development expenses during the third quarter of 2013. See Note 10.

**ImmuCell Corporation****Notes to Audited Financial Statements (continued)****8. ACCRUED EXPENSES**

Accrued expenses consisted of the following:

	As of December 31,	
	2013	2012
Professional fees	\$50,500	\$48,378
Payroll	75,310	131,524
Other	167,266	75,666
Total	\$293,076	\$255,568

**9. BANK DEBT**

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, 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 3.42% as of December 31, 2013 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 income (loss), 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. The notional amount of the interest rate swap was \$850,864 as of December 31, 2013. Payments required by the interest rate swap totaled \$23,096, \$23,903 and \$25,094 during the years ended December 31, 2013, 2012 and 2011, respectively. As the result of our decision to hedge this interest rate risk, we recorded other comprehensive income (loss), net of taxes, in the amount of \$30,284, (\$9,308) and (\$50,443) during the years ended December 31, 2013, 2012 and 2011, 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. The \$500,000 line of credit is available as needed

and has been extended through May 31, 2014 and is renewable annually thereafter. The line of credit was unused as of December 31, 2013 and 2012. 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, 2013. Principal payments due under debt outstanding as of December 31, 2013 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, 2014	\$ 50,900	\$ 139,490	\$ 190,390
Year ending December 31, 2015	54,044	96,260	150,304
Year ending December 31, 2016	57,384	—	57,384
Year ending December 31, 2017	61,056	—	61,056
Year ending December 31, 2018	64,876	—	64,876
After December 31, 2018	562,604	—	562,604
Total	\$ 850,864	\$ 235,750	\$ 1,086,614

**ImmuCell Corporation****Notes to Audited Financial Statements (continued)****10. OTHER INCOME (EXPENSES), NET**

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

	Year Ended December 31,		
	2013	2012	2011
License option fee <sup>(1)</sup>	\$250,000	\$—	\$—
Royalty income	(3,000 )	15,166	11,190
Interest income	12,493	17,202	15,499
Interest expense	(66,689 )	(75,274 )	(81,397 )
Debt issuance amortization	(2,894 )	(2,876 )	(5,240 )
Other gains (losses)	34,902	(7,067 )	(4,007 )
Other income (expenses), net	\$224,812	\$(52,849)	\$(63,955)

<sup>(1)</sup> 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, \$47,604 in capitalized expenses pertaining to the development of **Mast Out**<sup>®</sup> were written off.

**11. INCOME TAXES**

Our income tax expense (benefit) aggregated \$87,865, \$102,640 and (\$287,171) (amounting to 43%, 53% and (41%) of the income (loss) before income taxes, respectively) for the years ended December 31, 2013, 2012 and 2011, respectively. The income tax provision consisted of the following:

	Year Ended December 31,		
	2013	2012	2011
Current	\$301	\$708	\$510
Federal	74,713	89,788	(250,899)

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State	12,851	12,144	(36,782 )
Deferred	87,564	101,932	(287,681)
Total	\$87,865	\$102,640	\$(287,171)

The actual income tax expense (benefit) 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,		
	2013	2012	2011
Computed expected tax expense (benefit)	\$69,788	\$65,332	\$(236,871)
State income taxes, net of federal expense (benefit)	8,482	8,015	(24,276 )
Share-based compensation	10,526	9,766	8,042
Research and development tax credit	(21,887)	(10,813 )	(23,796 )
Other	20,956	30,340	(10,270 )
Total income tax expense (benefit)	\$87,865	\$102,640	\$(287,171)

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

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

	As of December 31,	
	2013	2012
Deferred revenue and other reserves	\$5,565	\$6,028
Product rights	165,527	201,000
Depreciation	8,215	8,355
Research and development tax credit	235,567	207,529
Federal net operating loss carryforward	525,012	592,774
State net operating loss carryforward	201,698	238,536
Interest rate swap	13,166	33,263
Prepaid expenses and other	15,143	(10,326 )
Deferred tax asset	\$1,169,893	\$1,277,159

We have a state net operating loss carryforward of approximately \$2,259,000 that expires in 2028, 2029, 2030 and 2031, if not utilized before then, and a federal net operating loss carryforward of approximately \$1,544,000 that expires in 2029, 2030 and 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 \$1,258,000 of our planned investment to produce pharmaceutical-grade Nisin for **Mast Out<sup>®</sup>** is being expensed as incurred for our books (including approximately \$110,000 during the fourth quarter of 2013), but this investment will be capitalized and depreciated over statutory periods for tax return purposes.

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 2010. 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, the 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.



## ImmuCell Corporation

### Notes to Audited Financial Statements (continued)

In June 2010, the 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.

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, 2010	249,000	24,500	\$ 3.36	None
Grants	—	25,000	\$ 5.72	
Terminations	(31,500 )	—	\$ 5.05	
Exercises	(31,000 )	—	\$ 4.79	
Outstanding at December 31, 2011	186,500	49,500	\$ 3.19	\$ 344,000
Grants	—	2,000	\$ 5.93	
Terminations	(8,000 )	(2,000 )	\$ 4.75	
Exercises	(15,000 )	—	\$ 3.39	
Outstanding at December 31, 2012	163,500	49,500	\$ 3.13	\$ 185,000
Grants	—	26,000	\$ 4.67	
Terminations	—	(1,000 )	\$ 3.15	
Exercises	(6,000 )	(1,000 )	\$ 3.11	
Outstanding at December 31, 2013	157,500	73,500	\$ 3.30	\$ 223,000
Exercisable at December 31, 2013	157,500	21,500	\$ 2.75	\$ 271,000
Reserved for future grants	—	225,500		

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. During the year ended December 31, 2011, eight employees exercised stock options covering the aggregate of 31,000 shares. Of these options, 30,000 were exercised for cash, resulting in total proceeds of \$145,295, and 1,000 were exercised by the surrender of 618 shares of common stock with a fair market value of \$3,200 at the time of exercise. At December 31, 2013, 231,000 shares of common stock were reserved for future issuance under all outstanding stock options described above, and an additional 225,500 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, 2013 was approximately five years and seven months. The weighted average remaining life of the options exercisable under these plans as of December 31, 2013 was approximately three years and eleven months. The exercise price of the options outstanding as of December 31, 2013 ranged from \$1.70 to \$7.00 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 25,000 stock options granted during 2011 had exercise prices between \$4.91 and \$5.75 per share. The aggregate intrinsic value of options exercised during 2013, 2012 and 2011 approximated \$8,000, \$25,000 and \$49,000, respectively. The weighted-average grant date fair values of options granted during 2013, 2012 and 2011 were \$2.23, \$2.86 and \$2.40 per share, respectively. As of December 31, 2013, total unrecognized stock-based compensation related to non-vested stock options aggregated \$74,763. That cost is expected to be recognized at a declining rate over the remaining vesting period of the outstanding non-vested stock options, including \$24,121 during 2014. The fair value of each stock option grant has been estimated on the date of grant by an independent appraiser using the Black-Scholes option pricing model, for the purpose discussed in Note 2(1), with the following weighted-average assumptions:

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

	2013	2012	2011		
Risk-free interest rate	1.6	% 0.97	% 1.1	%	
Dividend yield	0	% 0	% 0	%	
Expected volatility	49	% 48.7	% 47.6	%	
Expected life	6 years	6.5 years	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.

**(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.

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## ImmuCell Corporation

### Notes to Audited Financial Statements (continued)

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. No other changes have been made to the terms of the Rights or the Rights Agreement.

Our Board of Directors believes that there is a risk that, given the product development progress we have made to-date, 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.

### 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, 2013. 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, 2013 we had committed to contracts and purchase orders covering approximately \$984,000 related to our planned investment to produce pharmaceutical-grade Nisin for **Mast Out**<sup>®</sup>.

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, 2013.

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%, 80% and 81% for the years ended December 31, 2013, 2012 and 2011, 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 14%, 16% and 17% of our total product sales for the years ended December 31, 2013, 2012 and 2011, respectively. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

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

	Year Ended		
	December 31,		
	2013	2012	2011
Animal Health International, Inc. <sup>(1)</sup>	38 %	35 %	38 %
MWI Veterinary Supply Company <sup>(2)</sup>	22 %	20 %	20 %

(1) Assumes that the June 2011 acquisition of Animal Health International by Lextron had occurred as of the beginning of the periods being reported.

(2) Assumes that the November 2013 acquisition of IVESCO, the October 2011 acquisition of Micro Beef Technologies and the March 2011 acquisition of Nelson Laboratories by MWI had each occurred as of the beginning of the periods being reported.

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,	
	2013	2012
Animal Health International, Inc.	39 %	28 %
MWI Veterinary Supply Company <sup>(1)</sup>	26 %	19 %
Robert J. Matthews Company	10 %	*
TCS BioSciences, Ltd.	*	15 %

\*Amount is less than 10%.

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

**15. RELATED PARTY TRANSACTIONS**

Dr. David S. Tomsche (Chairman 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<sup>®</sup>**, **Wipe Out<sup>®</sup> Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased \$395,042, \$326,513 and \$295,164 of products from ImmuCell during the years ended December 31, 2013, 2012 and 2011, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of \$6,010, \$1,000 and \$0 to these affiliate companies during the years ended December 31, 2013, 2012 and 2011, respectively. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated \$31,445 and \$27,348 as of December 31, 2013 and 2012, 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 \$56,036, \$51,145 and \$48,038 into the plan for the years ended December 31, 2013, 2012 and 2011, respectively.



## 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, 2013, 2012 and 2011, respectively:

	Three Months Ended			
	March 31	June 30	September 30	December 31
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 )
Fiscal 2011:				
Product sales	\$ 1,555,701	\$ 1,247,443	\$ 1,003,451	\$ 1,304,548
Gross margin	868,235	694,526	526,034	725,009
Product development expenses	472,134	672,763	304,082	271,076
Net operating (loss) income	(16,858 )	(432,860 )	(192,390 )	9,382
Net loss	(23,113 )	(258,218 )	(127,649 )	(530 )
Net loss per common share:				
Basic	\$ (0.01 )	\$ (0.09 )	\$ (0.04 )	\$ (0.00 )
Diluted	\$ (0.01 )	\$ (0.09 )	\$ (0.04 )	\$ (0.00 )

## **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, 2014, the date we have issued this Annual Report on Form 10-K.

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**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, 2014 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 19, 2014 By: /s/ Michael F. Brigham  
Michael F. Brigham

President, Chief Executive Officer,

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Principal Financial Officer and Director

Date: March 19, 2014 By: /s/ Joseph H. Crabb  
Joseph H. Crabb, Ph.D., Director

Date: March 19, 2014 By: /s/ David S. Cunningham  
David S. Cunningham, Director

Date: March 19, 2014 By: /s/ Linda Rhodes  
Linda Rhodes, VMD, Ph.D., Director

Date: March 19, 2014 By: /s/ Jonathan E. Rothschild  
Jonathan E. Rothschild, Director

Date: March 19, 2014 By: /s/ David S. Tomsche  
David S. Tomsche, DVM, 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.