IMMUCELL CORP /DE/
Form 10-K
March 28, 2013

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, 2012

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

001-12934

(Commission file number)

ImmuCell Corporation

(Exact name of Registrant as specified in its charter)

Delaware	**01-0382980**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
56 Evergreen Drive, Portland, Maine	**04103**
(Address of principal executive offices)	**(Zip Code)**

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

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

None

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

Common Stock, par value $0.10 per share

(Title of class)

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ¨ No x

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 x

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 x 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 x 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. x

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 x

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates at June 29, 2012 was approximately $12,926,000 based on the closing sales price on June 29, 2012 of $5.85 per share.

The number of shares of the Registrant's common stock outstanding at March 20, 2013 was 3,019,034.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement to be filed in connection with the 2013 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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December 31, 2012

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PART I

ITEM 1 – DESCRIPTION OF BUSINESS

Summary

ImmuCell Corporation was founded in 1982 and completed an initial public offering of common stock in 1987. After achieving approval from the U.S. Department of Agriculture (USDA) to sell **First Defense®** in 1991, we focused most of our efforts during the 1990's developing human product applications of the underlying milk protein purification technology. Beginning in 1999, we re-focused on **First Defense®** and other products for the dairy industry. 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.

During 2000, we began the development of **Mast Out™**, our Nisin-based treatment for subclinical mastitis in lactating dairy cows. 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. By avoiding the milk discard penalty and making earlier treatment of subclinically infected cows economically feasible, we believe that **Mast Out™** could revolutionize the way that mastitis is treated. No other FDA-approved mastitis treatment product on the market can offer this value proposition. **Mast Out™** could also be used as a tool to improve milk quality, allowing producers to increase milk revenue by earning higher milk quality premiums. No sales of this product can be made without prior approval from the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA). Regulatory achievements to-date have significantly reduced the product development risks for **Mast Out™** in the areas of safety and effectiveness. Our primary focus has now turned to the commercial-scale manufacturing objectives required for FDA approval. We are actively engaged in pursuing the necessary financial support and resources to complete the **Mast Out™** product development initiative through any combination of available cash, debt, equity and/or investment from a partner.

During the thirteen-year period that began on January 1, 2000 and ended on December 31, 2012, we invested the aggregate of $16,603,000 in total product development expenses, while working on **Mast Out™** and other projects. Approximately 53% of this amount pertained directly to the development of **Mast Out™**. This estimated allocation to **Mast Out™** reflects only direct expenditures and includes no allocation of product development or administrative overhead expenses. Approximately $2,641,000 (which was all earned prior to 2008) of this investment was offset by product licensing revenues and grant income related to **Mast Out™** . We are engaged in negotiations with potential

partners that may fund the remaining investment, principally related to the manufacture of pharmaceutical-grade Nisin, that is required to bring **Mast Out**Ò to market. This strategic decision not to self-fund these large, late-stage development expenses, together with increased sales of **First Defense®**, allowed us to return to profitability during 2012.

Maintaining our compliance with current Good Manufacturing Practice (cGMP) regulations requires a sustained investment that we believe further increases our products' quality and may open access to international markets where such standards are imposed. At the same time, we are investigating ways to develop new products utilizing the technology underlying **First Defense®** (milk antibodies) and **Mast Out**Ò (Nisin).

With our 1999 shift to re-focus on animal health products, we were able to record net income for each year during the nine-year period that began on January 1, 1999 and ended on December 31, 2007. We believe that this conservative approach to financial management put us in a position to weather a general economic downturn like the one we have been experiencing, while funding a large amount of **Mast Out®** product development expenses. A significant and controlled investment in the development of **Mast Out®** resulted in net losses for each year during the four-year period that began on January 1, 2008 and ended on December 31, 2011. We had enough cash and short-term investments to fund these losses. We returned to profitability during 2012 based principally on a reduction in product development expenses and an increase in sales of **First Defense®**. During the fourteen-year period that began January 1, 1999 and ended on December 31, 2012, we invested an aggregate of $17,416,000 in product development expenses. During these fourteen years, this financial strategy (which resulted in nine years of profits followed by four years of losses before returning to profitability in 2012) has allowed us to fund our operations and improve our net financial position, as demonstrated in the following table (in thousands, except for percentages):

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	As of December 31, 1998		Net $ increase over fourteen-year period		As of December 31, 2012	Net % increase over fourteen-year period	
Cash, cash equivalents and short-term investments	$ 1,539	+	$ 3,375	=	$ 4,914	219	%
Net working capital	$ 1,866	+	$ 4,831	=	$ 6,697	259	%
Total assets	$ 3,145	+	$ 7,885	=	$ 11,030	251	%
Stockholders' equity	$ 2,248	+	$ 6,947	=	$ 9,195	309	%

We had approximately 2,429,000 shares of common stock outstanding as of December 31, 1998 in comparison to 3,019,000 shares as of December 31, 2012. There were approximately 480,000 and 213,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 1998 and 2012, respectively.

Animal Health Products

Our lead product, **First Defense**Ò, is manufactured from cows' colostrum using our proprietary vaccine and milk protein purification technologies. The target disease, bovine enteritis (calf scours), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. **First Defense**Ò is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against *E. coli* K99 and coronavirus (two leading causes of scours). We are a leader in the scours prevention market with this product. During the third quarter of 2012, we sold the 12,000,000th dose of **First Defense**Ò. The third quarter of 2012 marked the 21st anniversary of the original USDA approval of this product in 1991. We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product.

Due to natural variability in colostrum, newborn calves do not always get the antibodies they need from maternal colostrum. **First Defense**® provides bovine antibodies that newborn calves need but are unable to produce on their own immediately after birth. **First Defense**® 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 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. **First Defense**® provides immediate and preformed immunity (**Immediate Immunity**)™ when calves need it most - during the first few critical days of life. The direct, two-part mode-of-action of **First Defense**® delivers specific immunoglobulins at the gut level to immediately protect against disease, while also providing additional antibodies that are absorbed into the bloodstream. These circulating antibodies function like a natural timed-release mechanism, as they are re-secreted into the gut later to provide extended protection. A single dose of **First Defense**® provides a guaranteed level of protection proven to reduce mortality and morbidity from two major causes of calf scours. Studies have shown that calves that

scour are more susceptible to other diseases and under-perform calves that do not contract scours. **First Defense®** is convenient to use. A calf needs to receive only one bolus of **First Defense®** within the first twelve hours after birth. The 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®**.

During 1999, we acquired **Wipe OutÒ Dairy Wipes**, which is our second leading source of product sales revenue. 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 OutÒ Dairy Wipes** consist of biodegradable 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 for 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 but still biodegradable for disposal. The wiping process can also help promote milk letdown. **Wipe OutÒ 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 our Nisin and **Wipe Out® Dairy Wipes** technologies, 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 canine staphylococcal isolates 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 made our first significant sale of Nisin-based wipes for pets in a 120-count canister to Bayer Animal Health of St. Joseph, Missouri.

During 2001, we began to offer our own, internally developed **California Mastitis Test (CMT)**. **CMT** can be used for bulk tank as well as individual cow sample monitoring and can be used to determine which quarter of the udder is mastitic. This test can be performed at cow-side for early detection of mastitis. **CMT** products are also made by other manufacturers and are readily available to the dairy producer. 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 two regional managers. Our office manager and facility manager support our sales efforts by performing the order entry, inside sales and shipping duties. Effective for 2011 and 2012, we entered into a sales and marketing collaboration with Agri Laboratories Ltd. of St. Joseph, Missouri, (AgriLabs©), under which the AgriLabs sales and marketing teams worked with us to expand market demand for **First Defense©**. This agreement was not extended beyond December 31, 2012. The manner in which we sell and distribute our products depends, in large measure, upon the nature of the particular product, its intended users and the country in which it is sold. The distribution channel selected is intended to address the particular characteristics of the marketplace for a given product. **First Defense©** is sold primarily through major veterinarian distributors. Sales are normally seasonal, with higher sales expected during the first quarter. Harsh winter weather and severe temperature fluctuations cause stress to calves, and calves under stress are more susceptible to scours. Sales of this product into the beef industry are highly seasonal because most beef calves are born between January and April each year and our product is designed to be administered to calves immediately after birth. We sell **Wipe Out© Dairy Wipes**, and **CMT** to distributors, bovine veterinarians and directly to producers. Sales and marketing expenses amounted to 18%, 17% and 15% of product sales in the years ended December 31, 2012, 2011 and 2010, respectively. Our budget guideline for 2013 is to invest up to 20% of product sales in sales and marketing expenses.

First Defense© is generally sold through large, financially strong distributors, which we believe has resulted in minimal bad debt with respect to this product. We provide for a 50% account credit for domestic distributors on

expired **First Defense**Ò product, which has a two-year shelf life, resulting in an immaterial amount of returns. Promotional merchandise is given to certain customers at times because we believe it enhances brand recognition. Additionally, advertising, training meetings, incentive programs, direct mail initiatives and face-to-face solution selling are tactics we use to create brand loyalty.

International product sales represented approximately 20%, 19% and 18% of our total product sales for the years ended December 31, 2012, 2011 and 2010, 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**Ò 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 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**Ò into South Korea in 2005 and its equivalent into Japan in 2007 through collaborations with in-country distributors.

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Estimated to cost the U.S. dairy industry approximately $2 billion per year, mastitis (inflammation of the mammary gland) is the most costly and common disease affecting the dairy industry. 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 U.S. market for antibiotics used to treat clinical mastitis (those cases where cows are producing abnormal milk that cannot be sold) in lactating cows is approximately $40,000,000 per year and that similar market opportunities also exist outside of the United States and for the treatment of dry (non-lactating) cows. Some observers believe the market could be larger.

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 significant contributor to clinical mastitis cases. There is a growing awareness of the cascade of adverse events and conditions associated with subclinical mastitis, including reduced or foregone milk quality premiums, lower milk production, shorter shelf life for fluid milk, lower yields and less flavor for cheese, higher rates of clinical mastitis, lower conception rates, increased abortions and increased cull rates. It is difficult to evaluate the potential size of the as-yet undeveloped subclinical mastitis treatment market. Some industry experts have estimated that subclinical mastitis costs the U.S. dairy industry approximately $1 billion per year. Current 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 80 pounds of milk per day. While milk prices vary significantly, at an average value of $15 per 100 pounds, a cow produces approximately $12 worth of milk per day. Milk discard costs, ranging from approximately $40 to $100 per treated animal, are a significant barrier to the routine treatment of subclinical mastitis. We believe **Mast Out**Ò could expand the subclinical mastitis treatment market niche largely because it would not be subject to this milk discard requirement. The ability to treat such cases without a milk discard could revolutionize the way mastitis is managed in a herd. **Mast Out**Ò could be uniquely positioned in the market as both a treatment for subclinical mastitis and as a tool to prevent some cases of clinical mastitis.

Mast OutÒ 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, even in this economically challenging dairy economy.

The FDA is expected to grant a period of five years of market exclusivity for **Mast Out**Ò (meaning the FDA would not grant approval to a second and similar NADA 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. Regulations in the European Union will likely require that **Mast Out**Ò be sold subject to a milk discard requirement in that territory, although the duration of the

milk discard requirement may be shorter than the discard requirement applicable to competitive products on the market.

Many fear that the possible overuse of antibiotics in livestock may undermine the effectiveness of drugs to combat human illnesses and may be a contributing factor to the rising problem of bacterial drug resistance. 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. New USDA regulations have been implemented to reduce the allowable level of somatic cell counts in milk to 400,000 (previously 750,000) at the farm level in order to qualify for an EU export certification. In late 2011, The Dutch Veterinary Society proposed strict guidelines for veterinary use of antibiotics in the EU. Additionally, regulators have recently increased their monitoring of antibiotic residues in milk and meat. This current environment could be favorable to the introduction of a new product such as **Mast Out**Ò as an alternative to traditional antibiotics. We continue to believe that this product opportunity justifies ongoing product development efforts.

Product Development

Our lead product development initiative is **Mast Out®**, a Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows. As anticipated, we reduced product development expenses during 2012 primarily because we spent less money on the development of **Mast Out**Ò with the significant clinical studies now largely complete. Product development expenses decreased by approximately 47%, or $802,000, to $918,000 during the year ended December 31, 2012 in comparison to $1,720,000 during the same period in 2011.

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

In 2004, we entered into a product development and marketing agreement with Zoetis Inc. (formerly Pfizer Animal Health, a division of Pfizer, Inc.) covering **Mast Out**Ò. 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**Ò. 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 use of **Mast Out**Ò might cause a potential problem, where the milk from treated cows could interfere with the manufacture of certain cultured dairy products.

Due to the zero milk discard feature, there is a risk that Nisin from milk of cows treated with **Mast Out**Ò could interfere with the manufacture of certain (but not all) commercial cultured dairy products, such as some kinds of cheese and yogurt, if a process tank contains milk from a high enough percentage of treated cows. We have conducted 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 commingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when **Mast Out**Ò is used in accordance with the product label. Milk from treated cows that is sold exclusively for fluid milk products presents no such risk.

Commercial introduction of **Mast Out**Ò in the United States is subject to approval of our New Animal Drug Application (NADA) by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA), which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets outside of the United States and would involve some similar and some different requirements. In 2007, we began the production of pivotal batches of drug product to fulfill the regulatory requirements of effectiveness, stability, target animal safety and human food safety. The NADA is comprised of five principal Technical Sections subject to the FDA’s phased review of a NADA. By statute, each Technical Section submission is generally subject to a six-month review cycle by the FDA. 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.

4) Human Food Safety (HFS): The HFS Technical Section submission was made during the fourth quarter of 2010. This Technical Section determines if a milk discard period or meat withhold period 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**Ò a zero milk discard time and a zero meat withhold period. Before we can obtain the Technical Section Complete Letter, we must adapt our analytical method that measures Nisin residues in milk around the newly assigned tolerance limit and transfer that method to a FDA laboratory. We submitted the validated analytical method to the FDA during the fourth quarter of 2012. We now expect to receive the HFS Technical Section Complete Letter from the FDA during the second half of 2013.

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5) Chemistry, Manufacturing and Controls (CMC): 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 **Mast Out**Ò. These syringes were used for all pivotal studies of **Mast Out**Ò. Second, a Development and Manufacturing Agreement with Lonza Sales, Ltd. of Basel, Switzerland provides for the exclusive manufacture of the Active Pharmaceutical Ingredient (API). 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 API 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**Ò. The selection of and financing for the API production facility is a critical decision. We have been considering four options: 1) having this work done by a qualified contract manufacturer, 2) building a new facility, 3) leasing and modifying an existing facility and 4) transferring our technology to a partner's facility. Leasing an existing facility or transferring the technology to a partner's facility would provide us with more control and flexibility with regards to production volumes and costs than would be possible if we relied on a contract manufacturer to produce the API for us and could be less expensive and quicker to market than building a new facility. We estimate that it would take approximately eighteen months to two years to complete the necessary facility modifications and equipment installations. 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. As soon as we have prepared all of the relevant information, we expect to make a revised first submission for a six-month review cycle by the FDA. We anticipate that our second submission would include the three, required validation batches produced at the FDA-inspected commercial production facility. After completing this work, we would be eligible to receive the CMC Technical Section Complete Letter from the FDA following a six-month review cycle.

Obtaining FDA approval of the CMC Technical Section defines the critical path to the submission of the administrative NADA to the FDA and ultimately to NADA approval and commercial sales. After obtaining the final Technical Section omplete Letter and after preparing materials responsive to other administrative requirements, the administrative NADA submission can be assembled for review by the FDA. This final administrative submission would be subject to a statutory sixty-day review period.

In addition to our work on **Mast Out**Ò, we are actively exploring further improvements, extensions or additions to our current product line. For example, we currently are developing treatments that could prevent bovine enteritis (calf scours) caused by enteric pathogens other than *E. coli* K99 and bovine coronavirus (the current disease claims for **First Defense**®). In connection with that effort, during the second quarter of 2009 we entered into an exclusive license with 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. We are currently conducting additional pilot studies of different formulations of this antibody preparation. If positive results from these pilot studies are achieved, a second pivotal

effectiveness study could be initiated during the second half of 2013. 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* technology that may have utility in the development of a dry (non-lactating) cow vaccine. We are developing 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. 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.

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Competition

Our competition in the animal health market includes other biotechnology companies and major animal health companies. Many of these competitors have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do. 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, Merck Animal Health and Boehringer Ingelheim, to be among the potential competitors for **Mast Out**Ò.

We may not be aware of competition that we face 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.

We believe that **First Defense**Ò offers two significant competitive advantages over other oral antibody products on the market. First, its capsule form does not require refrigeration and provides ease of administration. Second, **First Defense**Ò provides protection against the leading cause of calf scours (*E. coli*) and additional protection against coronavirus, another leading cause of the disease. In addition to direct competition from oral antibody products, **First Defense**Ò 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**)™ that **First Defense**Ò provides to the calf is a competitive advantage over the vaccine products. **First Defense**Ò also competes against scours preventives that are not licensed by the USDA.

There are many products on the market that may be used in place of **Wipe Out**Ò **Dairy Wipes**, and our product sells at a premium to most of them. These products include teat dips, teat sprays and other disposable and washable towel products offered by several different companies. Competitive advantages of **Wipe Out**Ò **Dairy Wipes** include that they are convenient to use, they do not irritate the udder, they do not adulterate the milk and they are biodegradable.

Patents, Proprietary Information and Trademarks

In connection with the December 1999 acquisition of **Wipe Out® Dairy Wipes** and the April 2000 license to all veterinary applications of Nisin from Nutrition 21, Inc., we acquired a license to six patents. In November 2004, we bought out certain future milestone and royalty obligations under the 1999 and 2000 licenses, which principally resulted in a fully paid, perpetual license related to the animal health applications of Nisin. Four of these six patents have expired or are expiring and one of the two longer-term patents may be subject to a patent term extension. 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.

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

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We have registered certain trademarks with the U.S. Patent and Trademark Office in connection with the sale of our products. We own federal trademark registrations of the following trademarks: ImmuCell, **First Defense**Ò, our calf scours preventive product; **Wipe Out**Ò **Dairy Wipes** and the related design and the trademark "**One Step Cow Prep**Ò", our pre-milking wipe product; and **Mast Out**Ò, 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**Ò (our scours preventive product). **Mast Out**Ò is regulated by the FDA, Center for Veterinary Medicine, which regulates veterinary drugs. The manufacture of **Wipe Out**Ò **Dairy Wipes** also is regulated by the FDA, Center for Veterinary Medicine. 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.

Employees

We currently employ 25 full-time employees and 4 part-time employees. Approximately 14.55 full-time equivalent employees are engaged in manufacturing operations, 3.95 full-time equivalent employees in product development activities, 4.70 full-time equivalent employees in finance and administration and 3.80 full-time equivalent employees in sales. 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 20, 2013 were as follows:

MICHAEL F. BRIGHAM (Age: 52, 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 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 joined the Board of Directors of the United Way of York County in 2011, serving as 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.

JOSEPH H. CRABB, Ph.D. (Age: 58, 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.

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Public Information

As a reporting company, we file quarterly and annual reports with the Securities and Exchange Commission 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 or the availability and cost of alternative manufacturing and/or distribution resources; the future adequacy of our working capital and the availability of third party financing; timing and future costs of a facility to produce API for **Mast Out®**; the timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future expense ratios; 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 API for **Mast Out®**; 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", "intends", "would", "could", "should", "will", "plans", "believes", "estimates", "targets" and s expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate, especially considering the effects the distress in credit and capital markets will have on our current and prospective customers and the global economy and the uncertainties surrounding the potential for a prolonged global recession. 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, manufacturing reliance upon third parties for 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 a net loss for the years ended December 31, 2011, 2010, 2009 and 2008, due in large part to our product development strategy. By reducing our investment in the development of **Mast Out^{O}** and increasing sales of **First Defense®**, we were able to record net operating income of $245,000 and net income of $90,000 during the year ended December 31, 2012. Due principally to an anticipated increase in product development expenses during 2013 (over 2012 levels, but still less than 2011 levels), we expect 2013 results to be near breakeven. 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®**, for example, could increase our net income. Conversely, weaker than expected sales of **First Defense®** could lead to less profits.

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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 either the nine consecutive years in the period ended December 31, 2007 or the year ended December 31, 2012, and our net losses would have been larger during the four years in the period ended December 31, 2011, without the gross margin that we earned from the sale of **First Defense®**.

Economics of the dairy industry: The U.S. dairy industry has been facing very difficult economic pressures. Sales of our products may be influenced by the prices of milk, calves and milking cows. 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. The annual average then declined to 9,203,000 in 2009 and further to 9,119,000 in 2010 before increasing to 9,194,000 in 2011. The average herd size increased to 9,231,000 in 2012. The total cattle inventory in the United States fell to the lowest level in 60 years, largely due to the drought which scorched pastures, causing many ranchers to shrink herds. As of January 1, 2013, dairy and beef farmers held approximately 90.8 million head of cattle, which was down 2.1% from a year earlier and represented the lowest level since 1952. While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk to the market, demand for milk has been 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. For 2010, this price level averaged $14.41, which represents a 27% increase from 2009. This price level averaged $18.37 for 2011, which represents a 27% increase from 2010. This average price level for 2011 was higher than the annual average reached in any of the past 30 years, but then it began to decline in 2012. For 2012, this price level averaged $17.44, which represents a 5% decrease from 2011. The actual level of milk prices may be less important than their level relative to 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. For 2010, this ratio averaged approximately 2.26, representing a 27% increase compared to 2009. For 2011, this ratio averaged approximately 1.88, representing a 17% decrease compared to 2010. For 2012, this ratio averaged approximately 1.52, representing a 19% decrease compared to 2011. The ratio of 1.52 is the lowest recorded since this ratio was first reported in 1985. This means that a dairy producer can buy only 1.52 pounds of feed for every pound of milk sold. 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. Another indication of the economic condition of the dairy industry is the average price for animals sold for dairy herd replacement. This average price (reported as of January, April, July and October) averaged approximately $1,330 in 2010, which represents a 4% decrease in comparison to the same period in 2009. This price averaged approximately $1,420 in 2011, which represents a 7% increase in comparison to the same period in 2010. This price averaged approximately $1,428 in 2012, which represents a 1% increase in comparison to the same period in 2011. The industry data referred to above is compiled from USDA databases. Another factor in the demand for our product is the decline in the value of bull calves. We are trying to maintain and grow our sales for use with heifer calves to offset what we assume is a significant decrease in the use of our product for bull calves. Given our focus on the dairy and beef industries, the financial insecurity of our primary customer base is a risk to our ability to maintain and grow sales at a profitable level. It also heightens the challenge of selling premium-priced animal health products (such as **Mast Out™**) into such a market. Further, the loss of farms from which we buy raw material for **First Defense®** could make it difficult for us

to produce enough inventory until supply agreements are reached with replacement farms on suitable terms.

Regulatory requirements for ***Mast Out***^{Ò}: The commercial introduction of **Mast Out**^{Ò} in the United States will require us to obtain appropriate FDA approval for this product. It presently is uncertain whether or when 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**^{Ò}, 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**^{Ò} in that territory. However, the milk discard period may be shorter for **Mast Out**^{Ò} than it is for other products on the market.

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

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*Risks associated with **Mast Out**Ò funding strategy:* Completing the development of **Mast Out**Ò through to the submission of the administrative NADA to the FDA involves a great deal of risk. We may not be able to obtain financing to fund the completion of this product development effort on terms acceptable to us. We are evaluating alternative financial strategies in order to gain NADA approval and to support the product launch, which may result in our becoming dependent upon the skills and level of effort of a collaborative partner.

Uncertainty of market estimates: Even assuming that **Mast Out**Ò achieves regulatory approval in the United States with a zero milk discard requirement, estimating the size of the market for this product is subject to numerous uncertainties. Some of the uncertainties surrounding our product include the development of the subclinical mastitis

treatment market, coverage of relevant pathogens, selling price and its effect on market penetration, cost of manufacture, integration of milk from treated cows into cheese starter cultures and market acceptance.

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 operations and facility at 56 Evergreen Drive in Portland, Maine for the production of **First Defense**Ò and **Wipe Out**Ò **Dairy Wipes**. The specific antibodies that we purify for **First Defense**Ò and the Nisin we produce by fermentation for **Wipe Out**Ò **Dairy Wipes** are not readily available from other sources. We expect to be dependent on Plas-Pak and Norbrook for the manufacture of **Mast Out**Ò 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.

Concentration of sales: A large portion of our product sales (49%, 52% and 50% for the years ended December 31, 2012, 2011, and 2010, respectively) was made to two large distributors. A large portion of our trade accounts receivable (42% as of December 31, 2012 and 45% as of December 31, 2011) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us. During 2012, 80% of our product sales were made to customers in the U.S. dairy and beef industries. This compares to 81% during of 2011.

Risks associated with USDA and international regulatory oversight: **First Defense®**, and modifications and extensions thereto, 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.

*Regulatory requirements for **First Defense**Ò*: **First Defense**Ò is sold in the United States subject to a product license approval from the USDA, first obtained in 1991. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the "Reference Standard"). Due to the unique nature of the **First Defense**Ò 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.

Product risks generally: The sale of our products is subject to financial, efficacy, regulatory and 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 sufficient gross margin.

Product Liability: The manufacture and sale of certain 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.

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Regulatory requirements for ***Wipe Out® Dairy Wipes***: While the FDA regulates the manufacture and sale of **Wipe Out® Dairy Wipes**, this type of product is permitted to be sold without a NADA approval, in accordance with the FDA's Compliance Policy Guide 7125.30 ("Teat Dips and Udder Washes for Dairy Cows and Goats"). This policy guide could be withdrawn at the FDA's discretion, in which case we would likely discontinue sales of the product. The manufacture of **Wipe Out® Dairy Wipes** is subject to Part 211 of the cGMP regulations. As such, our operations are subject to inspection by the FDA. We continue to invest in personnel, facility improvements and new equipment to sustain compliance with cGMP regulations across our entire product line. In June 2007, we received a Warning Letter from the FDA citing deficiencies in specific areas of the cGMP regulations. We filed a response to the FDA in June 2007, and we responded to a request for additional information in April 2008. We believe we have substantially corrected the deficiencies cited, but have received no further communications from the FDA on this subject. We remain subject to the risk of adverse action by the FDA in this respect.

Small size; dependence on key personnel: We are a small company with 25 full-time and 4 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.

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. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Zoetis, Merck and Boehringer Ingelheim. There is no assurance that **Mast Out®** will compete successfully in this market. We may not be aware of other companies that compete with us or intend to compete with us in the future.

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 that 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 key foreign 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**Ò is considered a veterinary medicine rather than a feed ingredient, and it is manufactured from bovine milk (colostrum), which is not considered a BSE risk material. Future regulatory action to increase protection of the human food supply could affect **First Defense**Ò, although presently we do not anticipate that this will be the case.

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.

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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. 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 results of operations, financial condition, 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: ICCC). Our average daily trading volume is lower than the volume for most other companies and the bid/ask stock price spread can be larger, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire.

Our reporting obligations as a public company are costly: 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 ground level. 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 space, 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 600 square feet to the second floor storage area and 350 square feet of cold storage space connected to our ground floor production area. We funded these investments with available cash. These investments are an integral part of our strategy to increase our production capacity and to be compliant with cGMP regulations in our manufacturing 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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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 ICCC. 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, 2011 through December 31, 2012:

	2012 Three Months Ended				2011 Three Months Ended			
	March 31	June 30	September 30	December 31	March 31	June 30	September 30	December 31
High	$6.08	$ 6.80	$ 7.00	$ 5.50	$3.80	$ 8.50	$ 8.33	$ 6.40
Low	$4.50	$ 4.60	$ 4.84	$ 3.76	$2.91	$ 3.12	$ 4.57	$ 4.49

As of March 20, 2013, we had 8,000,000 common shares authorized and 3,019,034 common shares outstanding, and there were approximately 1,000 shareholders of record. The last sales price of our common stock on March 20, 2013 was $3.53 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, 2012 or that could be granted in the future:

	Number of shares to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of shares remaining available for future issuance under stock-based compensation plans (excluding shares reflected in first column of this table)

Equity compensation plans approved by stockholders	213,000	$ 3.13	250,500
Equity compensation plans not approved by stockholders	—	—	—
Total	213,000	$ 3.13	250,500

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 on Form 10-K (in thousands, except for per share amounts).

	Year Ended December 31,				
	2012	2011	2010	2009	2008
Statement of Operations Data:					
Product sales	$5,390	$5,111	$4,386	$4,506	$4,628
Gross margin	3,054	2,814	2,302	2,398	2,069
Product development expenses	918	1,720	1,493	1,645	1,746
Selling and administrative expenses	1,892	1,726	1,500	1,283	1,496
Net operating income (loss)	245	(633)	(690)	(530)	(1,173)
Other expenses (revenues), net	53	64	(7)	(101)	(212)
Income (loss) before income taxes	192	(697)	(683)	(429)	(961)
Net income (loss)	$90	$(410)	$(385)	$(216)	$(469)

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	Year Ended December 31,				
	2012	2011	2010	2009	2008
Per Common Share:					
Basic net income (loss)	$0.03	$(0.14)	$(0.13)	$(0.07)	$(0.16)
Diluted net income (loss)	$0.03	$(0.14)	$(0.13)	$(0.07)	$(0.16)
Cash dividend	—	—	—	—	—
Statement of Cash Flows Data:					
Net cash provided by (used for) operating activities	$344	$(37)	$(809)	$(110)	$53

	As of December 31,				
	2012	2011	2010	2009	2008
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$4,914	$4,960	$4,626	$4,585	$5,054
Total assets	11,030	10,991	10,751	9,985	10,128
Current liabilities	666	635	525	363	484
Net working capital	6,697	6,516	6,441	5,944	6,245
Long-term liabilities	1,170	1,336	944	—	—
Stockholders' equity	$9,195	$9,020	$9,282	$9,622	$9,644
Per Outstanding Common Share:					
Cash, cash equivalents and short-term investments	$1.63	$1.65	$1.56	$1.54	$1.75
Stockholders' equity	$3.05	$3.00	$3.12	$3.24	$3.33

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

Financial Condition

We had approximately $4,914,000 in available cash and short-term investments as of December 31, 2012. The table below summarizes the changes in selected, key balance sheet items (in thousands, except for percentages):

	As of December 31,		(Decrease) Increase	
	2012	2011	$	%
Cash, cash equivalents and short-term investments	$4,914	$4,960	$(46)	(1)%

Net working capital	6,697	6,516	182	3
Total assets	11,030	10,991	39	0.4
Stockholders’ equity	$9,195	$9,020	$174	2 %

Cash, cash equivalents and short-term investments decreased by 1%, or $46,000, to $4,914,000 at December 31, 2012 from $4,960,000 at December 31, 2011. Net cash provided by operating activities amounted to $344,000 during the year ended December 31, 2012 in contrast to net cash used for operating activities of $37,000 during the year ended December 31, 2011. Capital investments of $275,000 during 2012 compared to capital investments of $244,000 during 2011. Net working capital increased by 3%, or $182,000, to $6,697,000 at December 31, 2012 from $6,516,000 at December 31, 2011. During 2012 we repaid $173,000 in bank debt. Proceeds from bank debt received during 2011 aggregated $455,000, net of debt repayments made during 2011. Total assets increased by less than 1%, or $39,000, to $11,030,000 at December 31, 2012 from $10,991,000 at December 31, 2011. Stockholders' equity increased by 2%, or $174,000, to $9,195,000 at December 31, 2012 from $9,020,000 at December 31, 2011. 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.

ImmuCell Corporation

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, 2012, our outstanding bank debt balance was approximately $1,268,000. The $500,000 line of credit is available as needed. We believe that this debt financing (together with available cash and gross margin from ongoing product sales) provides us with sufficient funding to finance our working capital requirements while completing the first submissions to the FDA of all Technical Sections pertaining to **Mast Out**Ò. 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 very unlikely.

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 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. During this nine years of profitability, our cumulative investment in product development expenses of $9,894,000 was supported, in part, by $3,880,000 in licensing revenue, technology sales and grant income. Our strategic decision to continue developing **Mast Out**Ò 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. After these nine consecutive years of profitability, 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. As anticipated, a reduction in product development expenses during 2012 helped us return to profitability. Due principally to an anticipated increase in product development expenses (for ongoing **Mast Out**Ò expenses and an increased investment in other new product development expenses) above the 2012 investment but still less than the 2011 expense level, we expect 2013 results to be near breakeven. We believe that the two key indicators of our financial performance going forward will be the gross margin on our product sales and our net operating income. The investment of an additional $7,521,000 in product development expenses during 2008 thru 2012 brings our cumulative investment to $17,416,000 during the fourteen-year period ended December 31, 2012. 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.

A significant investment primarily related to the manufacture of the Active Pharmaceutical Ingredient (API) (principally related to manufacturing scale-up and preparations of full-scale batches) remains ahead to complete the **Mast Out**Ò product development initiative. Our initial plan was to have the API 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 were not commercially sustainable. We believe that controlling the manufacture of the API ourselves, rather than hiring a contractor, would improve our competitiveness and increase our opportunity for success. As a result, we developed a plan to build a production facility for the API and, with assistance from prospective builders, we estimated that it would require approximately

$13,000,000 to construct a new manufacturing facility. Because the actual cost could be higher, we have evaluated strategic alternatives to new construction. During the fourth quarter of 2012, we projected that we could reduce this upfront investment by leasing an existing facility rather than constructing a new one, and we engaged an engineering firm to estimate these costs. The resulting engineering report estimated these costs to be in the range of $11,000,000 to $13,000,000. In addition to the use of some of our cash, we are seeking debt issuance, equity financing and/or an investment from a partner as well as possible state and other financial incentives to support the investment required to manufacture the API. Absent such funding, we have not initiated the construction of our own API manufacturing facility or the leasing of an existing facility as of this date. Because we believe that the appropriate development and marketing partner would maximize the commercial sales potential for **Mast Out**Ò, we continue to seek a partnership that would provide guaranteed cash and/or minimum levels of funding and ongoing revenue in return for marketing rights. The information that we have learned during negotiations with potential partners to date has increased our confidence in the likelihood of achieving FDA approval and in the potential value of the market opportunity for **Mast Out®**. We believe that the evolution of our thinking relating to these strategic alternatives demonstrates the flexibility and creativity required to solve this financing challenge.

ImmuCell Corporation

As part of our sustained investment in compliance with cGMP regulations across our product lines and as we make other process improvements, we are investing in personnel, equipment and facility modifications to increase the efficiency and quality of our operations. The size of this investment in capital expenditures for facility modifications and production equipment is subject to review and approval by our Board of Directors. As of January 1, 2013, we had remaining available authorization to spend up to approximately $157,000 on capital expenditures, which authorized amount is net of increases aggregating $200,000 during 2012 that were approved by our Board of Directors.

Off-Balance Sheet Arrangements

None

Results of Operations

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**Ò to new customers. We believe that sales of our products were influenced by the relatively strong prices of milk, cows and calves which values 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**Ò, 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**Ò aggregated 89% of our total product sales during both of the years ended December 31, 2012 and 2011. Sales of **First Defense**Ò increased by 5% during the year ended December 31, 2012 in comparison to 2011. Domestic sales of **First Defense**Ò increased by 4%, and international sales increased by 10%. Sales of **First Defense**Ò 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**Ò 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**Ò 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**Ò 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**Ò.

ImmuCell Corporation

Through our **First Defense Technology™**, we are selling whey concentrate globulin proteins in different formats. During the first quarter of 2011, we initiated sales of our **First Defense Technology™** 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™** in a paste formulation that is delivered through an oral syringe. Through two collaborations, we are working to expand sales of our **First Defense Technology™**. During the first quarter of 2011, AgriLabs launched commercial sales of their product, Colostrx®, a colostrum supplement with **First Defense Technology™ Inside**. During the fourth quarter of 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start® 150 Plus, a colostrum replacer with **First Defense Technology™ Inside**.

Sales of **Wipe Out® 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® 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™ (formerly known as **Crypto-Scan®**). 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®**. 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 December 31,		Increase	
	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**Ò is affected by biological yields from our raw material, which do fluctuate over time. More generally, costs for production of **First Defense**Ò and **Wipe Out**Ò **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**Ò and a lower gross margin on **Wipe Out**Ò **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.

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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**Ò 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.

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**Ò. 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**Ò. Going forward, we expect to maintain a reduced level of product development expenses, which expenses will continue to be focused on **Mast Out**Ò and other improvements, extensions or additions to our **First Defense**Ò product line. The other improvements, extensions, or additions to our current product line include the potential to prevent scours in calves caused by pathogens other than those within the current **First Defense**Ò disease

claims (*E. coli* K99 and coronavirus) such as rotavirus. We also remain interested in acquiring other new products and technologies that fit with our sales focus on the dairy and beef industries. We are currently seeking funding from a partner to complete the development of **Mast Out**Ò and to support the manufacturing, sales and marketing efforts.

Other 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.

ImmuCell Corporation

2011 Compared to 2010

Product Sales

Product sales for the year ended December 31, 2011 increased by 17%, or $725,000, to $5,111,000 from $4,386,000 in 2010. Domestic product sales increased by 16%, or $560,000, during the year ended December 31, 2011, and international sales increased by 21%, or $165,000, in comparison to 2010. For the three-month period ended December 31, 2011, product sales increased by 16%, or $181,000, in comparison to the three-month period ended December 31, 2010. We believe that sales of our products were influenced by the increased price of milk, cows and calves and 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**Ò, continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent bovine enteritis (scours) in newborn calves. During the fourth quarter of 2011, we sold our 11,000,000th dose of **First Defense**Ò . The third quarter of 2011 marked the 20th anniversary of the original USDA approval of this product in 1991. We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product. 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**Ò increased by 21% during the year ended December 31, 2011 in comparison to 2010. Domestic sales of **First Defense**Ò increased by 20%, and international sales increased by 25%. Sales of **First Defense**Ò are normally seasonal, with higher sales expected during the first quarter. We have been experiencing consistently positive sales growth of **First Defense**Ò since the fourth quarter of 2010, as demonstrated below:

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**Ò may reflect, at least in part, the success of our strategic decision 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**Ò 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 are working with us to expand market demand for **First Defense**Ò.

We are investigating additional opportunities to commercialize our whey protein purification technologies in the nutritional and feed supplement markets in different formats not regulated by the USDA. **First Defense Technology**™ is a unique whey protein concentrate that is purified utilizing our proprietary whey protein processing methods. It does not carry the claims of our USDA-licensed product. Through our **First Defense Technology**™, we are selling whey concentrate globulin proteins in different formats. During the first quarter of 2011, we initiated sales of our **First Defense Technology**™ in a bulk powder format (no capsule), which is delivered with a scoop. During the first quarter of 2012, we initiated a limited launch of a tube delivery format of our **First Defense Technology**™ in a gel solution. Through two collaborations, we are working to expand sales of our **First Defense Technology**™ by accessing the U.S. feed market. During the first quarter of 2011, AgriLabs launched commercial sales of their product, Colostrx®, a colostrum supplement with **First Defense Technology**™ **Inside**. During the fourth quarter of 2011, Milk Products, LLC launched commercial sales of their product, Ultra Start® 150 Plus, a colostrum replacer with **First Defense Technology**™ **Inside**.

Sales of **Wipe Out**Ò **Dairy Wipes** decreased by 18% during the year ended December 31, 2011 in comparison to 2010. We believe that sales growth potential for **Wipe Out**Ò **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.

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The other products we sell primarily into the dairy industry aggregated approximately 3% of product sales during 2011 and 2010. Sales of these products were 28% higher in 2011 than the level of sales achieved in 2010. The other products we sell outside of the dairy and beef industries, principally Isolate™ (formerly known as **Crypto-Scan®**), aggregated 2% and 3% of product sales during the years ended December 31, 2011 and 2010, respectively. Sales of our bulk reagents for use in a drinking water test sold by others decreased by 21% during the year ended December 31, 2011 in comparison to 2010. During 2011, these sales were recorded during the fourth quarter. During 2010, these sales were recorded during the second quarter. Our animal health sales (total product sales less sales of the water diagnostic reagents) increased by 18% during the year ended December 31, 2011 in comparison to 2010. This comparison more accurately reflects 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®**. 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 December 31,		Increase	
	2011	2010	Amount	%
Gross margin	$2,814	$2,302	$511	22%
Percent of product sales	55 %	52 %	3 %	5 %

The gross margin as a percentage of product sales was 55% and 52% during the years ended December 31, 2011 and 2010, respectively. This compares to gross margin percentages of 53% and 45% for the years ended December 31, 2009 and 2008, respectively. Our current annual target is to maintain the gross margin percentage at approximately 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®** is affected by biological yields from our raw material, which do fluctuate over time. More generally, costs for production of **First Defense®** and **Wipe Out® 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**Ò and a lower gross margin on **Wipe Out**Ò **Dairy Wipes**. Our inventory balance increased by 4%, or $65,000, to $1,666,000 at December 31, 2011 from $1,601,000 at December 31, 2010. This level of investment was made in both periods to help prevent a potential back log of orders. We have not experienced a back log of orders since the third quarter of 2009.

Sales and Marketing Expenses

Sales and marketing expenses increased by approximately 34%, or $219,000, to $870,000 in 2011, increasing to 17% of product sales in 2011 from 15% in 2010. 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**Ò sales and to prepare for a market launch of **Mast Out**Ò. This investment may have created, at least in part, our recent increase in product sales. Our budgetary objective in 2012 was 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 1%, or $8,000, to $857,000 during the year ended December 31, 2011 as compared to $849,000 during 2010. 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**Ò. 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 increased by 15%, or $227,000, to $1,720,000 during the year ended December 31, 2011, as compared to $1,493,000 during 2010. We expected higher product development expenses during the year ended December 31, 2011. Product development expenses aggregated 34% of product sales in 2011 and 2010. The majority of our product development budget from 2000 through 2011 has been focused on the development of **Mast Out**Ò. Going forward, we expect to reduce our product development expenses, which expenses will continue to be focused on **Mast Out**Ò and other improvements, extensions or additions to our **First Defense**Ò product line. The other improvements, extensions, or additions to our current product line include the potential to prevent scours in calves caused by pathogens other than those within the current **First Defense**Ò disease claims (*E. coli* K99 and coronavirus) such as rotavirus. We also remain interested in acquiring other new products and technologies that fit with our sales focus on the dairy and beef industries. We are currently seeking funding from a partner to complete the development of **Mast Out**Ò and to support the manufacturing, sales and marketing efforts.

Other Expenses, Net

Interest income decreased by approximately 38%, or $10,000, to $15,000 in 2011 in comparison to 2010 due principally to a decrease in interest rates. Interest expense aggregated $81,000 and $22,000 during 2011 and 2010, respectively.

Loss Before Income Taxes and Net Loss

Our loss before income taxes of $697,000 during the year ended December 31, 2011 compares to a loss before income taxes of $683,000 during 2010. We recorded income tax benefits of 41% and 44% of the losses before income taxes during the years ended December 31, 2011 and 2010, respectively. Our net loss of $410,000, or $0.14 per share, during the year ended December 31, 2011 compares to a net loss of $385,000, or $0.13 per share, during 2010.

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, 2012 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.

ImmuCell Corporation

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) collectibility 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 collectibility is reasonably assured. We recognize service revenue at the time the service is performed. Royalty income is recorded on the accrual basis based on sales as reported to us by our licensee pursuant to the terms of the relevant agreement. All research and development costs and patent costs are expensed as incurred.

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

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We believe that neither inflation nor interest rates nor currency exchange rates have had a significant effect on our revenues and expenses. However, future increases in inflation or interest rates or the value of the U.S. dollar could affect our customers and the demand for our products. We 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. 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.

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:

ImmuCell Corporation

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, 2012. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (ii) is accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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

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

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2012. Based on management's assessment and those criteria, management believes that the internal control over financial reporting as of December 31, 2012 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 2013 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, 2012. 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 2013 Proxy Statement titled “Executive Officer Compensation”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2012.

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 2013 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, 2012.

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 2013 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, 2012.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

Information regarding our principal accountant fees and services is incorporated by reference to the section of our 2013 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, 2012.

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	Second Amendment to Rights Agreement dated as of June 30, 2008 (incorporated by reference to Exhibit 4.1A of the Company’s Annual Report on Form 10-K for the year ended December 31, 2008).

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4.1B	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).
10.1+	Form of Indemnification Agreement (updated) entered into with each of the Company's Directors and Officers (incorporated by reference to Exhibit 10.3A to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2006).
10.2+	2000 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
10.3+	Form of Incentive Stock Agreement (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
10.4+	Amendment to Employment Agreement between the Company and Michael F. Brigham dated March 26, 2010 (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2009).
10.5+	Amendment to Employment Agreement between the Company and Joseph H. Crabb dated March 26, 2010 (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2009).
10.6+	2010 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2010).
10.7+	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2010).
10.8(1)	Development and Manufacturing Agreement between the Company and Lonza Sales, Ltd. dated July 15, 2010 (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).
10.9	Commercial Promissory Note for $1,000,000 between the Company and TD Bank, N.A. dated August 13, 2010 (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).
10.10	Commercial Promissory Note for $600,000 between the Company and TD Bank, N.A. dated August 13, 2010 (incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).
10.11	Line of Credit Agreement and Promissory Note for up to $500,000 between the Company and TD Bank, N.A. dated August 13, 2010 (incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).
10.12(1)	Loan Agreement between the Company and TD Bank, N.A. dated August 13, 2010 (incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2010).
10.13(1)	Contract Manufacture Agreement between the Company and Norbrook Laboratories Limited dated as of September 27, 2010 (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended September 30, 2010).
14	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
23	Consent of Baker Newman & Noyes, LLC.
31	Certifications required by Rule 13a-14(a).
32	Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.

101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

+ Management contract or compensatory plan or arrangement.

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ImmuCell Corporation

Portland, Maine

We have audited the accompanying balance sheets of ImmuCell Corporation (the Company) as of December 31, 2012 and 2011, 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, 2012. 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, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

Portland, Maine /s/ Baker Newman & Noyes
March 28, 2013 Limited Liability Company

ImmuCell Corporation

BALANCE SHEETS

	As of December 31, 2012	2011
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$2,673,719	$781,516
Short-term investments	2,240,000	4,178,000
Trade accounts receivable, net of allowance for doubtful accounts of $15,111 and $16,359 at December 31, 2012 and 2011, respectively	574,146	346,447
Income taxes receivable	348	648
Other receivables	36,860	36,701
Inventory	1,649,002	1,666,465
Current portion of deferred tax asset	31,177	59,016
Prepaid expenses	157,930	81,807
Total current assets	7,363,182	7,150,600
NET PROPERTY, PLANT AND EQUIPMENT, at cost	2,357,609	2,515,331
LONG-TERM PORTION OF DEFERRED TAX ASSET	1,245,982	1,306,335
OTHER ASSETS, net	63,634	19,006
TOTAL ASSETS	$11,030,407	$10,991,272
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$255,568	$303,900
Accounts payable	228,711	149,877
Current portion of bank debt	181,491	172,973
Deferred revenue	—	8,250
Total current liabilities	665,770	635,000
LONG-TERM LIABILITIES:		
Long-term portion of bank debt	1,086,568	1,267,939
Interest rate swap	83,386	67,900
Total long-term liabilities	1,169,954	1,335,839
TOTAL LIABILITIES	1,835,724	1,970,839
STOCKHOLDERS' EQUITY:		
	326,115	326,115

Common stock, $0.10 par value per share, 8,000,000 shares authorized, 3,261,148 shares issued at December 31, 2012 and 2011		
Capital in excess of par value	9,973,146	9,911,914
Accumulated deficit	(524,803)	(614,315)
Treasury stock, at cost, 242,114 and 257,114 shares at December 31, 2012 and 2011, respectively	(529,655)	(562,469)
Accumulated other comprehensive loss	(50,120)	(40,812)
Total stockholders' equity	9,194,683	9,020,433
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$11,030,407	$10,991,272

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

ImmuCell Corporation

STATEMENTS OF OPERATIONS

	For the Years Ended December 31,		
	2012	2011	2010
Product sales	$5,389,935	$5,111,143	$4,386,196
Costs of goods sold	2,335,676	2,297,339	2,083,718
Gross margin	3,054,259	2,813,804	2,302,478
Sales and marketing expenses	973,217	869,869	650,889
Administrative expenses	918,441	856,606	849,064
Product development expenses	917,600	1,720,055	1,492,806
Operating expenses	2,809,258	3,446,530	2,992,759
NET OPERATING INCOME (LOSS)	245,001	(632,726)	(690,281)
Other expenses, net	52,849	63,955	(6,869)
INCOME (LOSS) BEFORE INCOME TAXES	192,152	(696,681)	(683,412)
Income tax expense (benefit)	102,640	(287,171)	(298,728)
NET INCOME (LOSS)	$89,512	$(409,510)	$(384,684)
Weighted average common shares outstanding:			
Basic	3,018,296	2,984,749	2,970,833
Diluted	3,108,419	2,984,749	2,970,833
NET INCOME (LOSS) PER SHARE:			
Basic	$0.03	$(0.14)	$(0.13)
Diluted	$0.03	$(0.14)	$(0.13)

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

ImmuCell Corporation

STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	For the Years Ended December 31,		
	2012	2011	2010
Net income (loss)	$89,512	$(409,510)	$(384,684)
Other comprehensive (loss) income:			
Interest rate swap, before taxes	(15,486)	(77,531)	9,631
Income tax applicable to interest rate swap	6,178	27,088	—
Other comprehensive (loss) income, net of taxes	(9,308)	(50,443)	9,631
Total comprehensive income (loss)	$80,204	$(459,953)	$(375,053)

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

ImmuCell Corporation

STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock $0.10 Par Value		Capital in Excess of	Accumulated Surplus	Treasury Stock		Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Par Value	(Deficit)	Shares	Amount	Income (Loss)	Equity
BALANCE, December 31, 2009	3,261,148	$326,115	$9,751,442	$179,879	290,496	$(635,495)	$—	$9,621,941
Net loss	—	—	—	(384,684)	—	—	—	(384,684)
Other comprehensive income, net of taxes	—	—	—	—	—	—	9,631	9,631
Exercise of stock options	—	—	(563)	—	(3,000)	6,563	—	6,000
Stock-based compensation	—	—	29,513	—	—	—	—	29,513
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

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

ImmuCell Corporation

STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,		
	2012	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$89,512	$(409,510)	$(384,684)
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:			
Depreciation	399,640	413,132	416,918
Amortization	2,876	5,240	2,593
Deferred income taxes	94,370	(302,500)	(299,171)
Stock-based compensation	35,985	38,172	29,513
Loss on disposal of fixed assets	12,265	10,822	575
Changes in:			
Receivables	(227,858)	113,417	(82,301)
Income taxes receivable/payable	300	300	300
Inventory	17,463	(65,449)	(513,625)
Prepaid expenses and other assets	(123,628)	159,484	(60,913)
Accounts payable	100,047	59,479	(26,811)
Accrued expenses	(48,332)	(68,152)	108,993
Deferred revenue	(8,250)	8,250	—
Net cash provided by (used for) operating activities	344,390	(37,315)	(808,613)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(275,395)	(243,735)	(116,547)
Maturities of short-term investments	4,178,000	3,227,000	4,108,000
Purchases of short-term investments	(2,240,000)	(4,178,000)	(3,725,000)
Net cash provided by (used for) investing activities	1,662,605	(1,194,735)	266,453
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from debt issuance	—	600,000	1,000,000
Debt principal repayments	(172,853)	(145,232)	(13,856)
Debt issuance costs	—	—	(26,489)
Proceeds from exercise of stock options	50,800	145,295	6,000
Tax benefits related to stock options	7,261	14,518	—
Net cash (used for) provided by financing activities	(114,792)	614,581	965,655
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,892,203	(617,469)	423,495
BEGINNING CASH AND CASH EQUIVALENTS	781,516	1,398,985	975,490
ENDING CASH AND CASH EQUIVALENTS	$2,673,719	$781,516	$1,398,985

INCOME TAXES PAID	$(708)	$(510)	$(144)
INTEREST EXPENSE PAID	$(75,681)	$(78,737)	$(20,000)
NON-CASH ACTIVITIES:			
Change in capital expenditures included in accounts payable and accrued expenses	$(21,212)	$(15,341)	$32,839
Net change in fair value of interest rate swap	$9,308	$50,443	$(9,631)

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*™ (Codification). The FASB finalized the Codification effective for periods ending on or after September 15, 2009. Certain prior year accounts have been reclassified to conform with the 2012 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 the Federal Deposit Insurance Corporation (FDIC) limit 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 $2,173,000 and $281,000 at December 31, 2012 and 2011, 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. We are required by bank debt covenant to maintain at least $1,000,000 of otherwise unrestricted cash, cash equivalents and short-term investments. Cash, cash equivalents and short-term investments consist of the following:

	As of December 31,		Increase
	2012	2011	(Decrease)
Cash and cash equivalents	$2,673,719	$781,516	$ 1,892,203
Short-term investments	2,240,000	4,178,000	(1,938,000)
Total	$4,913,719	$4,959,516	($45,797)

(c) 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.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

(d) 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. Inventory consists of the following:

	As of December 31,		(Decrease)
	2012	2011	Increase
Raw materials	$198,441	$218,104	$ (19,663)
Work-in-process	986,243	1,000,037	(13,794)
Finished goods	464,318	448,324	15,994
Inventory	$1,649,002	$1,666,465	$ (17,463)

(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 the building, acquired in 1993, and the 2001 and 2007 additions thereto, are being depreciated through 2023. 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 3.

(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 Note 6.

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, 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. Codification Topic 820 applies to fair value measurements that are already required or permitted by other accounting standards, except for measurements of share-based payments and measurements that are similar to, but not intended to be, fair value and does not change existing guidance as to whether or not an instrument is carried at fair value. The adoption of this Statement did not have a material impact on our financial condition, results of operations, earnings per share, cash flows or financial statement disclosures.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

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 did incur a net loss of $13,986 during 2010 as the result of the bankruptcy of a former distributor. The carrying amounts of our financial instruments approximate fair market value.

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.

(h) Interest Rate Swap Agreement

As described in Note 6, we entered into an interest rate swap agreement in 2010. All derivatives are recognized on the balance sheet at their fair value. 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 the long-term debt described in Note 6. 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 in other comprehensive income, until earnings are affected by the variability of cash flows (e.g. when periodic settlements on a variable-rate asset or liability are recorded in earnings). We formally documented the relationship between the interest rate swap agreement and the related hedged items. We also formally assess, both at this interest rate swap agreement’s inception and on an ongoing basis, whether the agreement is highly effective in offsetting changes in cash flow of hedged items.

(i) Revenue Recognition

Revenues related to the sale of manufactured products are recorded when title and risk of loss have passed to the customer, which is at the time of shipment and when collectability is reasonably assured. Royalty income is recognized on the accrual basis based on sales as reported to us by our licensee and is recorded as other expenses, net.

(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 $174,314, $4,658 and $16,108 during the years ended December 31, 2012, 2011 and 2010, 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, 2012. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 9.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

(l) 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 10(a). Accordingly, we recorded $35,985, $38,172 and $29,513 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, 2012, 2011 and 2010, 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, but there were no significant tax deductions during the three years in the period ended December 31, 2012.

(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,		
	2012	2011	2010
Weighted average number of shares outstanding during the period	3,018,296	2,984,749	2,970,833
Dilutive stock options	172,750	—	—
Shares that could have been repurchased with the proceeds from the dilutive stock options	(82,627)	—	—

Diluted number of shares outstanding during the period	3,108,419	2,984,749	2,970,833
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	43,000	236,000	273,500

For additional disclosures regarding the outstanding common stock options, see Note 10(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.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

(o) New Accounting Pronouncements

We adopted Accounting Standards Update (ASU) No. 2011-05, *Presentation of Comprehensive Income (Loss)* (Topic 220) during the quarter 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 a single continuous statement. 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. PROPERTY, PLANT AND EQUIPMENT

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

	As of December 31,	
	2012	2011
Laboratory and manufacturing equipment	$3,029,559	$2,978,716
Building and improvements	2,785,698	2,667,220
Office furniture and equipment	312,979	252,737
Construction in progress	—	1,331
Land	50,000	50,000
Property, plant and equipment, gross	6,178,236	5,950,004
Less: accumulated depreciation	3,820,627	3,434,673
Property, plant and equipment, net	$2,357,609	$2,515,331

4. OTHER ASSETS

Other assets consisted of the following:

	As of December 31,	
	2012	2011
Security deposits	$ 250	$ 350
Debt issue costs	26,489	26,489
Other	47,604	—
Other assets, gross	74,343	26,839
Less: accumulated amortization of debt issue costs	10,709	7,833
Other assets, net	$ 63,634	$ 19,006

5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2012	2011
Professional fees	$48,378	$40,100
Payroll	131,524	128,091
Other	75,666	135,709
Accrued expenses	$255,568	$303,900

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

6. 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 to the fixed rate of 6.04%. All derivatives are recognized on the balance sheet at their fair value. The agreement has been determined to be highly effective in hedging the variability of the identified cash flows and has been designated as a cash flow hedge of the variability in the hedged interest payments. Changes in the fair value of the interest rate swap agreement are recorded in other comprehensive (loss) income, net of taxes. The original notional amount of the interest rate swap agreement of $1,000,000 amortizes in accordance with the amortization of the mortgage. As the result of our decision to hedge this interest rate risk, we recorded other comprehensive (loss) income, net of taxes, in the amount of ($9,308), ($50,443) and $9,631 during the years ended December 31, 2012, 2011 and 2010, 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 one month London Interbank Offered Rate (LIBOR) plus 3.25% per annum. The $500,000 line of credit is available as needed and has been extended through May 31, 2013 and is renewable annually thereafter. Interest on any borrowings against the line of credit will be variable at the higher of 4.25% per annum or the one month LIBOR plus 3.5% per annum. These credit facilities are subject to certain financial covenants. Principal payments due under debt outstanding as of December 31, 2012 are reflected in the following table by the year that payments are due:

Period	$1,000,000 mortgage	$600,000 note	Total
Twelve months ending December 31, 2013	$ 47,908	$ 133,583	$181,491
Twelve months ending December 31, 2014	50,900	139,490	190,390
Twelve months ending December 31, 2015	54,044	96,213	150,257
Twelve months ending December 31, 2016	57,384	—	57,384
Twelve months ending December 31, 2017	61,056	—	61,056
After December 31, 2017	627,481	—	627,481
Total	$ 898,773	$ 369,286	$1,268,059

7. PRODUCT DEVELOPMENT EXPENSES

In 1999, we shifted the primary focus of our product development efforts from human applications of our whey protein purification technology to 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. As anticipated, we reduced product development expenses during the year ended December 31, 2012 primarily because we are spending less money on the development of **Mast Out**Ò with the significant clinical studies now largely complete. We decreased product development expenses by 47%, or $802,455, to $917,600 during the year ended December 31, 2012 in comparison to $1,720,055 during the same period in 2011.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

8. OTHER EXPENSES, NET

Other expenses, net, consisted of the following:

	Year Ended December 31,		
	2012	2011	2010
Royalty income	$(15,166)	$(11,190)	$(3,385)
Interest income	(17,202)	(15,499)	(25,185)
Interest expense	75,274	81,397	21,610
Debt issuance amortization	2,876	5,240	2,593
Other losses (gains)	7,067	4,007	(2,502)
Other expenses, net	$52,849	$63,955	$(6,869)

9. INCOME TAXES

Our income tax expense (benefit) aggregated $102,640, ($287,171) and ($298,728) (amounting to 53%, (41%) and (44%) of the income (loss) before income taxes, respectively) for the years ended December 31, 2012, 2011 and 2010, respectively. The income tax provision consists of the following:

	Year Ended December 31,		
	2012	2011	2010
Federal	$—	$—	$—
State	—	—	—
International	708	510	144
Current	708	510	144
Federal	89,788	(250,899)	(262,985)
State	12,144	(36,782)	(35,887)
International	—	—	—
Deferred	101,932	(287,681)	(298,872)
Total	$102,640	$(287,171)	$(298,728)

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,		
	2012	2011	2010
Computed expected tax expense (benefit)	$65,332	$(236,871)	$(232,360)
State income taxes, net of federal expense (benefit)	12,144	(36,782)	(35,887)
Share-based compensation	9,766	8,042	10,034
Research and development tax credit	(10,813)	(23,796)	(22,357)
Other	26,211	2,236	(18,158)
Total income tax expense (benefit)	$102,640	$(287,171)	$(298,728)

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Notes to Audited Financial Statements (continued)

The significant components of our deferred tax asset are as follows:

	As of December 31,	
	2012	2011
Deferred revenue and other reserves	$6,028	$9,817
Product rights	201,000	236,509
Depreciation	8,355	(32,781)
Research and development tax credit	207,529	180,192
Federal net operating loss carryforward	592,774	651,465
State net operating loss carryforward	238,536	275,226
Interest rate swap	33,263	27,088
Prepaid expenses and other	(10,326)	17,835
Deferred tax asset	$1,277,159	$1,365,351

In order to accelerate the utilization of available net operating loss carryforwards in advance of their expiration dates, we elected to increase income for federal income tax purposes by capitalizing research and experimentation expenditures aggregating approximately $1,731,000 for our 2000 and 2001 tax returns. Accordingly, we recorded amortization of these capitalized expenditures of approximately $90,000 in 2000 and $173,000 in each of the nine years ended December 31, 2009 and $83,000 for the year ending December 31, 2010 for tax return purposes only. We carried back our 2008 federal net operating loss of approximately $1,151,000 to previous years for tax return purposes, and we have a state net operating loss carryforward of approximately $2,671,000 that expires in 2028, 2029, 2030 and 2031, if not utilized before then, and a federal net operating loss carryforward of approximately $1,743,000 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.

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 2009. 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.

10. 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.

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.

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Notes to Audited Financial Statements (continued)

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

	2000 Plan	2010 Plan	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2009	401,000	—	$ 3.54	$ 69,000
Grants	20,000	25,500	$ 3.48	
Terminations	(169,000)	(1,000)	$ 3.84	
Exercises	(3,000)	—	$ 2.00	
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
Exercisable at December 31, 2012	149,000	—	$ 2.60	$ 208,000
Reserved for future grants	—	250,500		

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. During the year ended December 31, 2010, three employees exercised 1,000 stock options each, covering the aggregate of 3,000 shares. These options were exercised for cash, resulting in total proceeds of $6,000. At December 31, 2012, 213,000 shares of common stock were reserved for future issuance under all outstanding stock options described above, and an additional 250,500 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, 2012 was approximately six years. The exercise price of the options outstanding as of December 31, 2012 ranged from $1.70 to $7.00 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 45,500 stock options granted during 2010 had exercise prices between $3.15 and $3.99 per share. The aggregate intrinsic value of options exercised during 2012, 2011 and 2010 approximated $25,000, $49,000 and $3,000, respectively. The weighted-average grant date fair values of options granted during 2012, 2011 and 2010 were $2.86, $2.40 and $1.45 per share, respectively. As of December 31, 2012, total unrecognized stock-based compensation related to non-vested stock options aggregated approximately $49,000. That cost is expected to be recognized at a declining rate through June 2015, which represents the remaining vesting period of the outstanding non-vested stock options. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, for the purpose discussed in Note 2(l), with the following weighted-average assumptions:

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Notes to Audited Financial Statements (continued)

	2012		2011		2010	
Risk-free interest rate	0.97	%	1.1	%	2.4	%
Dividend yield	0	%	0	%	0	%
Expected volatility	48.7	%	47.6	%	44.2	%
Expected life	6.5 years		5 years		5 years	

(b) Common Stock Rights Plan

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

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

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

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

On June 8, 2005, our Board of Directors voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years, to September 19, 2008. As of June 30, 2005, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. No other changes were made to the terms of the Rights or the Rights Agreement at that time. 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. No other changes were made to the terms of the Rights or the Rights Agreement at that time. 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.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

Our Board of Directors believes that there is some risk that the potential value of the **Mast Out**® product development initiative may not be 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.

11. COMMITMENTS AND CONTINGENT LIABILITIES

Our By-Laws, 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, 2012. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

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 these obligations as of December 31, 2012.

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.

12. 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 (80%, 81% and 82% for the years ended December 31, 2012, 2011 and 2010, 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 16%, 17% and 15% of our total product sales for the years ended December 31, 2012, 2011 and 2010, respectively. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

	Year Ended December 31,		
	2012	2011	2010
Animal Health International, Inc.[1]	35 %	38 %	36 %
MWI Veterinary Supply Company[2]	14 %	14 %	13 %

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

(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 March 2011 acquisition of Nelson Laboratories and the October 2011 acquisition of Micro Beef Technologies by MWI had 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,			
	2012		2011	
Animal Health International, Inc.[(1)]	28	%	23	%
TCS BioSciences, Ltd.	15	%	*	
MWI Veterinary Supply Company[(2)]	14	%	21	%
Leedstone Inc. (formerly Stearns Veterinary Outlet, Inc.)	*		18	%

*Amount is less than 10%.

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

(2) Assumes that the March 2011 acquisition of Nelson Laboratories and the October 2011 acquisition of Micro Beef Technologies by MWI had occurred as of the dates being reported.

13. 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**Ò, **Wipe Out**Ò **Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased $326,513, $295,164 and $288,243 of products from ImmuCell during the years ended December 31, 2012, 2011 and 2010, respectively, on

terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated $27,348 and $60,831 as of December 31, 2012 and 2011, respectively.

14. 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 $51,145, $48,038 and $40,792 into the plan for the years ended December 31, 2012, 2011 and 2010, respectively.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

15. UNAUDITED QUARTERLY FINANCIAL DATA

The following tables present the quarterly information for fiscal years 2012, 2011 and 2010:

	Three Months Ended			
	March 31	June 30	September 30	December 31
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)
Fiscal 2010:				
Product sales	$1,311,748	$1,077,672	$ 873,722	$ 1,123,054
Gross margin	739,159	618,617	357,269	587,433
Product development expenses	405,462	333,320	312,158	441,866
Net operating loss	(74,398)	(47,630)	(347,542)	(220,711)
Net loss	(53,266)	(6,439)	(197,116)	(127,863)
Net loss per common share:				
Basic	$(0.02)	$(0.00)	$ (0.07)	$ (0.04)
Diluted	$(0.02)	$(0.00)	$ (0.07)	$ (0.04)

16. 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 28, 2013, the date we have issued this Annual Report on Form 10-K.

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 28, 2013 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 28, 2013 By: /s/ Michael F. Brigham
Michael F. Brigham

President, Chief Executive Officer,

Principal Financial Officer and Director

Date: March 28, 2013 By: /s/ Joseph H. Crabb
Joseph H. Crabb, Ph.D., Director

Date: March 28, 2013 By: /s/ David S. Cunningham
David S. Cunningham, Director

Date: March 28, 2013 By: /s/ William H. Maxwell
William H. Maxwell, M.D., Director

Date: March 28, 2013 By: /s/ Linda Rhodes
Linda Rhodes, VMD, Ph.D., Director

Date: March 28, 2013 By: /s/ Jonathan E. Rothschild
Jonathan E. Rothschild, Director

Date: March 28, 2013 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.