IMMUCELL CORP /DE/
Form 10-K
March 27, 2012

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, 2011

.. 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 30, 2011 was approximately $17,297,000, based on the closing sales price on June 30, 2011 of $7.90 per share.

The number of shares of the Registrant's common stock outstanding at March 26, 2012 was 3,019,034.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement to be filed in connection with the 2012 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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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 whey 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.

In 2000, we began the development of **Mast Out™**, our Nisin-based treatment for subclinical mastitis in lactating dairy cows. No sales of this product can be made without prior approval from the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA). Because dairy producers are required to discard milk for a period during and after treatment with all currently marketed mastitis treatment products, 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. Because milk from cows treated with **Mast Out™** may be allowed to be sold without a milk discard period, we believe we could revolutionize the way that mastitis is treated by removing the milk discard penalty, which would make earlier treatment of subclinically infected cows economically feasible. No other mastitis treatment product on the market can offer this value proposition. At present, most dairy producers simply do not treat subclinically infected cows or they cull the affected animals from the herd because of the milk discard requirement. **Mast Out™** could be uniquely positioned in the market as both a treatment for subclinical mastitis and as a tool to prevent some cases of clinical mastitis. **Mast Out™** could also be used as a tool to improve milk quality, which could result in higher milk revenue to a producer who could earn milk quality premiums.

During the twelve-year period that began on January 1, 2000 and ended on December 31, 2011, we invested the aggregate of $15,685,000 in product development expenses. Approximately 54% 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 $2,375,000 of this investment was offset by product licensing revenues. We have decided not to completely fund internally the remaining investment principally related to manufacturing scale-up and preparations of full-scale batches of **Mast Out™**. We are engaged in negotiations with potential partners that may fund this investment as well as the marketing expenses for product launch and sales. Our objective from a successful partnership would be to benefit from the gross margin on product that we produce and sell into distribution. We expect that a partner would benefit from a to-be-negotiated

mark-up on the product sold, exclusively by such partner, into distribution. This strategic decision not to fund these large, late-stage development expenses should allow us to return to positive net operating income during 2012.

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 significant financial downturn like the one we have been experiencing, while funding **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 more than enough cash and short-term investments to fund these losses. We expect to return to positive net operating income during 2012 based principally on the sales of **First Defense®**. This strategy, which resulted in nine years of profits followed by four years of losses, has allowed us to fund our operations and improve our net financial position, as demonstrated in the following table (in thousands, except for percentages):

	At December 31, 1998		Net $ increase over thirteen-year period		At December 31, 2011	Net % increase over thirteen-year period	
Cash, cash equivalents and short-term investments	$ 1,539	+	$ 3,421	=	$ 4,960	222	%
Net working capital	1,866	+	4,650	=	6,516	249	
Total assets	3,145	+	7,846	=	10,991	249	
Stockholders’ equity	$ 2,248	+	$ 6,772	=	$ 9,020	301	%

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We had approximately 2,429,000 shares of common stock outstanding as of December 31, 1998 in comparison to 3,004,000 as of December 31, 2011. There were approximately 480,000 and 236,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 1998 and 2011, respectively. During the thirteen-year period that began January 1, 1999 and ended on December 31, 2011, we invested the aggregate of $16,498,000 in product development expenses.

During 2006, we initiated efforts to become compliant with current Good Manufacturing Practice (cGMP) regulations in our manufacturing operations. Compliance with 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 our **First Defense®** and Nisin technologies.

Animal Health Products for the Dairy and Beef Industries

Our lead product, **First Defense®**, is manufactured from cows' colostrum using our proprietary vaccine and whey protein purification technologies. The target disease, bovine enteritis (calf scours), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. **First Defense®** is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against *E. coli* K99 and coronavirus (two leading causes of scours). We are a leader in the scours prevention market with this product. During the fourth quarter of 2011, we sold the 11,000,000th dose of **First Defense®**, since receiving USDA approval of this product in 1991. We believe that this milestone demonstrates the value of our technology and the long-term market acceptance of our product. During the second quarter of 2006, certain regional organic certifying agencies determined that the ingredients in **First Defense®** are in compliance with the National Organic Program (NOP) and may be considered for use on organic farms.

First Defense® provides bovine antibodies that newborn calves need but are unable to produce on their own immediately after birth. Due to natural variability in colostrum, newborn calves do not always get the antibodies they need from maternal colostrum. **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 calf vaccines are used, and it is not 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®**.

In 1999, we acquired **Wipe Out® 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 Out® 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. 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. 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 Out® Dairy Wipes** are manufactured in compliance with cGMP regulations, as required by federal law.

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In 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 sales managers. Effective for 2011 and 2012, and renewable for 2013 and 2014 if certain sales growth objectives are met, we entered into a sales and marketing collaboration with Agri Laboratories Ltd. of St. Joseph, Missouri, (AgriLabs^{Ò}), under which the AgriLabs sales and marketing teams are working with us to expand market demand for **First Defense^{Ò}**. The AgriLabs national marketing network consists of 20 independent distributors operating approximately 125 branch locations with more than 700 sales representatives. AgriLabs has developed and markets more than 750 products through its own branded product lines. The AgriLabs sales team is comprised of approximately 22 well-trained, experienced professionals that cover the United States. 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^{Ò}** 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, which contributes to the seasonality in the sales of this product. 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^{Ò} Dairy Wipes**, and **CMT** to distributors, bovine veterinarians and directly to producers. Sales and marketing expenses amounted to 17%, 15% and 9% of product sales in the years ended December 31, 2011, 2010 and 2009, respectively. Our budget guideline for 2012 is to invest less than 20% of product sales in sales and marketing expenses.

First Defense^{Ò} 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 19%, 18% and 22% of our total product sales for the years ended December 31, 2011, 2010 and 2009, 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 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.

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.

Mastitis is estimated to cost U.S. dairy producers approximately $2 billion per year, making it the leading cause of economic harm to the dairy industry. 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 the use of antibiotics to treat clinical mastitis (those cases where cows are producing abnormal milk) 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.

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Because milk from cows treated with traditional antibiotics must be discarded for a period of time during and after treatment due to concerns about antibiotic residue in the milk, currently it is not common practice to treat subclinical mastitis (those cases where cows have infected udders, but still produce saleable milk). Subclinical mastitis is associated with its own significant economic losses and is recognized as a significant contributor to clinical mastitis cases. Current intervention strategies are considered inadequate and generally not cost-effective due to milk discard requirements. The ability to treat such cases without a milk discard could revolutionize the way mastitis is managed in a herd. Without a milk discard requirement, we believe **Mast Out**Ò could expand the subclinical mastitis treatment market niche. We are not aware of any other FDA-approved intramammary mastitis treatment product that has such a "zero discard" claim. While the benefit of treating clinical mastitis is widely known, 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, increased abortions and increased cull rates. Some industry experts have estimated that subclinical mastitis costs the U.S. dairy industry approximately $1 billion per year. It is difficult to evaluate the potential size of the as-yet undeveloped subclinical mastitis treatment market. The FDA may grant a period of five years of market exclusivity for **Mast Out**Ò (meaning the FDA might 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 could 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 its concern with respect to this important public health issue. Citing concerns about untreatable, life-threatening infections in humans, new FDA regulations proposed to go into effect in April 2012 would further restrict the use of cephalosporins in food animals. Effective January 2012, new USDA regulations are expected to reduce the allowable level of somatic cell counts in milk to 400,000 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. 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

In 1999, we shifted the primary focus of our product development efforts from applications of our whey protein purification technology for humans to scientifically-proven and practical products that result in a measurable economic impact on animal health and productivity in the dairy and beef industries. This strategy was maintained through 2011 and is expected to continue. We spent approximately $1,720,000, $1,493,000 and $1,645,000 on product development activities during the years ended December 31, 2011, 2010 and 2009, respectively. We expect lower product development expenses during the year ending December 31, 2012. If a partner agrees to fund the completion

of the **Mast Out**Ò product development effort, these expenses could increase, but only if they are off set, at least in part, by the funds that we would receive from the potential strategic collaboration.

In 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, our intramammary infusion product. 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. Nisin has been granted GRAS (Generally Regarded as Safe) status by the FDA for food preservative applications, which may be of some help in obtaining approval for the use of **Mast Out**Ò on organic farms. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes methods to achieve pharmaceutical-grade purity.

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In 2004, we entered into a product development and marketing agreement with 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 from Pfizer. Pfizer elected to terminate the agreement in 2007. Soon thereafter, Pfizer 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 Pfizer's decision to terminate the agreement was not based on any unanticipated efficacy or regulatory issues. Rather, we believe Pfizer's decision was primarily market driven, largely relating to their concern that the use of **Mast Out**Ò might require specific treatment restrictions at the herd level to avoid a problem in the manufacture of cheese.

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 comingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when **Mast Out**Ò is used in accordance with the product label. Milk from treated cows that is sold exclusively for fluid milk products presents no such risk. Another risk is that **Mast Out**Ò likely will be priced at a premium to the traditional antibiotic products currently on the market, which are all sold subject to a milk discard requirement. However, we believe that the product's value proposition demonstrates a return on the investment to the producer that will justify this premium.

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. 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. 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 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) Effectiveness: During the second quarter of 2008, we initiated the pivotal effectiveness study. Positive results from the study were announced during the third quarter of 2009. With enrollment of approximately 300 qualified cows with subclinical mastitis, the **Mast Out**Ò treatment group showed a statistically highly significant overall cure rate in

comparison to the placebo group. We believe that the breakdown of the data by species suggests both the necessary numerical superiority and clinical relevancy to support robust product performance in the field. For example, one of the most important mastitis pathogens, coagulase-negative staphylococci, predominated in our study, and **Mast Out**Ò achieved almost 10-fold higher cure rates than the placebo-treated animals against this pathogen. Further, **Mast Out**Ò treatment was associated with a statistically significant ($p<0.005$) reduction in milk somatic cell count (SCC), which is an important measure of milk quality. During the third quarter of 2010, we made our first submission of the Effectiveness Technical Section. This 65 volume submission contained the results from our pivotal trial conducted from 2008 to 2009 as well as all supporting data related to the effectiveness of Nisin, demonstrating the effectiveness of **Mast Out**Ò in the field at a level similar to currently marketed intramammary antibiotics and confirming prior results from two major field studies conducted since 2003. During the first quarter of 2011, we received an Effectiveness Technical Section Incomplete Letter from the FDA. The FDA requested additional information and clarification in the areas of raw data, subject eligibility and statistical analyses and has requested that certain treatment outcomes be changed or justified. Additional clinical studies were not required. Our response to the FDA, which was submitted during the fourth quarter of 2011, does not materially change our initial conclusions about the product's effectiveness. We expect to receive the FDA's response to this second submission during the second quarter of 2012 after one, six-month review cycle.

3) 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 our pivotal Nisin residue in milk data 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 the FDA laboratory. We anticipate being able to complete this work by the second quarter of 2012, at which point we would be eligible to receive the Technical Section Complete Letter from the FDA.

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4) Target Animal Safety: Under a protocol approved in advance by the FDA, the pivotal Target Animal Safety trial was completed during the first quarter of 2010. We submitted the Target Animal Safety Technical Section to the FDA for review during the third quarter of 2011. We received an end-review amendment (ERA) request from the FDA in response to this submission during the first quarter of 2012 after one, six-month review cycle. An ERA is requested when the FDA has completed its review of a submission and has determined that the submission of additional non-substantial data or information would likely complete the submission. We filed the ERA within the required time frame and expect to receive the FDA's response to this ERA submission during the second quarter of 2012.

5) Chemistry, Manufacturing and Controls (CMC): We have entered into agreements with three manufacturers to produce inventory for us utilizing our proprietary technology 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 current Good Manufacturing Practices (cGMP) regulations and subject to future FDA approval and inspection. Through discussions with partner prospects, we have recently determined that current Lonza contract provisions could result in unfavorable product volumes and costs. Therefore, we are currently seeking contractual amendments while simultaneously investigating a self-sourcing strategy. We are seeking partner funding and exploring state financial incentives for such a plant investment. We are in discussions with multiple prospective partners. When or if a partnership to fund the completion of the development of **Mast Out**Ò will be initiated is not known currently. We will make a public announcement of such a deal if and when it occurs. 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 CMC Technical Section submission requires the identification of all facilities that will be used in the manufacture of the product. We expect to make a first submission of this Technical Section during the second quarter of 2012, and we anticipate that at least two, six-month review cycles by the FDA will be required. Obtaining FDA approval of the CMC Technical Section defines the critical path to the submission of the administrative NADA to the FDA.

6) Several Administrative Requirements: After obtaining the final Technical Section Complete Letter and after preparing materials responsive to other administrative requirements, the administrative NADA submission can be assembled for review by the FDA. This final submission would be subject to a statutory sixty-day review period. Product produced for the validation batches under the CMC Technical Section could be sold upon FDA approval.

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 therapies that could prevent scours in calves caused by enteric pathogens other than *E. coli* K99 and bovine coronavirus (the current **First Defense**Ò claims). 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, three-claim 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 2012.

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We are developing new product applications of our **First Defense Technology™**, which 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. We initiated sales of our **First Defense Technology™** with AgriLabs as a feed ingredient in a colostrum supplement. We also initiated sales of **First Defense Technology™** in a bulk powder format (no capsule), which is delivered with a scoop. Thirdly, we initiated a limited launch of a tube delivery format of our **First Defense Technology™** in a gel solution. Lastly, we initiated sales of our **First Defense Technology™** with Milk Products, LLC of Chilton, Wisconsin as a feed ingredient in a colostrum replacer. As additional opportunities arise to commercialize our own technology, or licensable technology, we 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.

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 Pfizer Animal Health, Merck Animal Health and Boeringher Ingelheim, to be among the potential competitors for **Mast Out®**.

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®** 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®** 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®** 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. The immediate and preformed immunity (Immediate Immunity™) that **First Defense®** provides to the calf is a competitive advantage over the vaccine products. **First Defense®** 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® Dairy Wipes**, and our product sells at a premium to most of them. These products include teat dips, teat sprays and other disposable and washable towel products offered by several different companies. Competitive advantages of **Wipe Out® Dairy Wipes** include that they are convenient to use, they do not irritate the udder, 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.

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

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In the future, we may file additional patent applications for certain products under development. There can be no assurance that patents will be issued with respect to any pending or future applications.

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

We have registered certain trademarks with the U.S. Patent and Trademark Office in connection with the sale of our products. We own federal trademark registrations of the following trademarks: ImmuCell, **First Defense®**, our calf scours preventive product; **Wipe Out® Dairy Wipes** and the related design and the trademark "One Step Cow Prep®", our pre-milking wipe product; **MASTiK®**, our antibiotic susceptibility test; and **Mast Out®**.

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®** (our scours preventive product). **Mast Out®** is regulated by the FDA, Center for Veterinary Medicine, which regulates veterinary drugs. The manufacture of **Wipe Out® 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 26 full-time employees and 3 part-time employees. Approximately 15.05 full-time equivalent employees are engaged in manufacturing operations, 3.95 full-time equivalent employees in product development activities, 4.75 full-time equivalent employees in finance and administration and 3.75 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 26, 2012 were as follows:

MICHAEL F. BRIGHAM (Age: 51, Officer since October 1991, Director since March 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. Prior to joining the Company, he was employed as an audit manager for the public accounting firm of Ernst & Young. Mr. Brigham earned his Masters in Business Administration from New York University in 1989.

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JOSEPH H. CRABB, Ph.D. (Age: 57, Officer since March 1996, Director since March 2001) was appointed to serve as Chairman of the Board of Directors in June 2009. 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. He is currently a reviewer for several peer-reviewed journals. Concurrent with his employment, he has served on five study sections at the National Institutes of Health and held three adjunct faculty positions. Prior to joining the Company in 1988, Dr. Crabb earned his Ph.D. in Biochemistry from Dartmouth Medical School and completed postdoctoral studies in microbial pathogenesis at Harvard Medical School, where he also served on the faculty.

Public Information

As a reporting company, we file quarterly and annual reports with the Securities and Exchange Commission 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; future compliance with bank debt covenants; 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 timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future realization of deferred tax assets; factors that may affect the dairy industry and future demand for our products; the accuracy of our understanding of our distributors' ordering patterns; anticipated changes in our manufacturing capabilities and efficiencies; 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; future expense ratios; costs and timing associated with sustaining compliance with cGMP regulations;

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” “plans”, “believes”, “estimates”, “targets” and similar words and 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.

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Economics of the dairy industry: The U.S. dairy industry has been facing very difficult economic pressures, which are forcing many dairy producers out of business. 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 size of the milking herd affects the price of milk. Over time, the impact on the milk supply from a decrease in cows has been offset, in part, by an increase in milk production per cow. 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 largely influenced by very volatile international demand for milk products. Sales of our products may be influenced by the prices of milk, milking cows and calves. 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. The average Class III milk price for 2009 was $11.36, which represented a 35% decrease from 2008. The average price for 2009 was 36% lower than the average experienced during the two-year period ended December 31, 2008. For 2010, this price level averaged $14.41, which represented a 27% increase from 2009 but was well below the 2007 and 2008 levels. This price level averaged $18.37 for 2011, which represents a 27% increase from 2010. This average price level is higher than the annual average reached in any of the past 30 years. The actual level of milk prices may be less important than their level relative to costs because recent improvement in milk prices has been offset, in part, by higher feed costs. One measure of this relationship is known as the milk-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 2009, this ratio averaged 1.78, representing a 12% decrease compared to 2008. For 2010, this ratio averaged 2.26, representing a 27% increase compared to 2009. For 2011, this ratio averaged approximately 1.88 representing a 17% decrease compared to 2010. This means that a dairy producer can buy only 1.88 pounds of feed for every pound of milk sold. An increase in feed costs also has a negative impact on the beef industry. Another indication of the economic condition of the dairy industry is the average price for animals sold for dairy herd replacement. In 2009, this average price (reported as of January, April, July and October) was estimated to be approximately $1,385, which was a 29% decrease in comparison to the same period in 2008. This price averaged approximately $1,330 in 2010, which represented 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. The dairy industry data referred to above is compiled from USDA databases. Another factor in the demand for our product is the value of bull calves. A decline in the price of bull calves reduces the return on investment from a dose of **First Defense®** for 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. 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.

*Risks associated with **Mast Out**Ò funding strategy:* There are risks associated with our decision not to internally fully fund the completion of the development of **Mast Out**Ò through to the submission of the administrative NADA to the FDA. A partner may not be willing to step in and fund the completion of this product development effort on terms acceptable to us. If a partner is not willing to agree to acceptable terms on this collaboration with us, we will need to re-evaluate alternative strategies in order to gain NADA approval and to support the product launch. If we do

complete the submission, the FDA may not grant approval of this product.

Projections of loss before income taxes and net loss: After nine consecutive years of reporting net income, we reported a loss before income taxes and a net loss for the years ended December 31, 2011, 2010, 2009 and 2008, due in large part to our current product development strategy. Our decision not to fund, with internally generated or borrowed funds, the majority of the remaining expenses to complete the development of **Mast Out**Ò may allow us to return to positive net operating income (before other (expenses) revenues, net and before income taxes). 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 diminish the overall loss. Conversely, weaker than expected sales of **First Defense®** could lead to less profits or larger losses. Prior to 2008, we had not publicly disclosed our projections of future profitability. We did so in 2011, 2010, 2009 and 2008 and have done so again for 2012 to make it clear to our stockholders that the decision to pursue internal development of **Mast Out®** entails an important change in our financial model and strategy that, we believe, is in the long-term interests of the Company and our stockholders.

Concentration of sales: A large portion of our product sales (52%, 50% and 50% for the years ended December 31, 2011, 2010, and 2009, respectively) was made to two large distributors. A large portion of our trade accounts receivable (45% as of December 31, 2011 and 48% as of December 31, 2010) was due from these two distributors. These calculations give effect to acquisitions made during the period retroactively to the beginning of the period. 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 2011, 81% of our product sales were made to customers in the U.S. dairy and beef industries. This compares to 82% during of 2010.

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Product development risks: Our current business growth strategy relies heavily on the development of new products, the most important of which is **Mast Out**Ò. The development of new products is subject to financial, scientific, regulatory and market risks. In particular, the development of **Mast Out**Ò requires (and will continue to require) substantial investments by us and by a potential partner, and there is no assurance whether or when we will obtain all of the clinical and other data necessary to support regulatory approval for this product or secure a partner on acceptable terms. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Pfizer, Merck and Boehringer Ingelheim. There is no assurance that **Mast Out**Ò will compete successfully in this market.

*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.

Risks associated with USDA 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.

*Reliance on sales of **First Defense®**:* We are heavily reliant on the market acceptance of **First Defense®** to generate product sales and fund our operations. Our business would not have been profitable during the nine consecutive years in the period ended December 31, 2007, 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®**.

*Regulatory requirements for **Wipe Out**Ò **Dairy Wipes***: While the FDA regulates the manufacture and sale of **Wipe Out**Ò, 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**Ò 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.

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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.

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 do we, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. We may not be aware of other companies that compete with us or intend to compete with us in the future. 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 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.

Small size; dependence on key employees: We are a small company with 26 full-time and 3 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.

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. 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 U.S. 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.

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.

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.

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. 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.

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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 U.S. 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 and 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 to our ability to economically acquire and collect good quality raw material from our contract farms. Any act of widespread bioterrorism against the dairy industry could adversely affect our operations.

No expectation to pay any dividends for the foreseeable future: We do not anticipate paying any dividends to our stockholders for the foreseeable future, instead using cash to fund product development costs. Also, 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, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire.

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 a storage mezzanine of approximately 4,100 square feet 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 mezzanine storage space in the second floor. During 2009, we added 600 square feet to the mezzanine storage area and 350 square feet of cold storage space. 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 State 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 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, 2010 through December 31, 2011:

	2011 Three Months Ended				2010 Three Months Ended			
	March 31	June 30	September 30	December 31	March 31	June 30	September 30	December 31
High	$3.80	$ 8.50	$ 8.33	$ 6.40	$4.40	$ 4.10	$ 3.59	$ 3.49
Low	$2.91	$ 3.12	$ 4.57	$ 4.49	$3.45	$ 2.90	$ 2.78	$ 2.47

As of March 26, 2012, 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 21, 2012 was $4.70 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, 2011 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)
236,000	$ 3.19	250,500

Equity compensation plans approved by stockholders			
Equity compensation plans not approved by stockholders	—	—	—
Total	236,000	$ 3.19	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-KSB or 10-K (in thousands, except for per share amounts).

	Year Ended December 31,				
	2011	2010	2009	2008	2007
Statement of Operations Data:					
Product sales	$5,111	$4,386	$4,506	$4,628	$4,772
Gross margin	2,814	2,302	2,398	2,069	2,504
Product development expenses	1,720	1,493	1,645	1,746	1,579
Selling and administrative expenses	1,726	1,500	1,283	1,496	1,349
Net operating (loss) income	(633)	(690)	(530)	(1,173)	(425)
Other (expenses) revenues, net	(64)	7	101	212	1,568
(Loss) income before income taxes	(697)	(683)	(429)	(961)	1,144
Net (loss) income	$(410)	$(385)	$(216)	$(469)	$662

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	Year Ended December 31,				
	2011	2010	2009	2008	2007
Per Common Share:					
Basic net (loss) income	$(0.14)	$(0.13)	$(0.07)	$(0.16)	$0.23
Diluted net (loss) income	$(0.14)	$(0.13)	$(0.07)	$(0.16)	$0.22
Cash dividend	—	—	—	—	—
Statement of Cash Flows Data:					
Net cash (used for) provided by operating activities	$(37)	$(809)	$(110)	$53	$350

	As of December 31,				
	2011	2010	2009	2008	2007
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$4,960	$4,626	$4,585	$5,054	$5,412
Total assets	10,991	10,751	9,985	10,128	10,412
Current liabilities	635	525	363	484	356
Net working capital	6,516	6,441	5,944	6,245	6,710
Long-term liabilities	1,336	944	—	—	—
Stockholders' equity	$9,020	$9,282	$9,622	$9,644	$10,057
Per Outstanding Common share:					
Cash, cash equivalents and short-term investments	$1.65	$1.56	$1.54	$1.75	$1.87
Stockholders' equity	$3.00	$3.12	$3.24	$3.33	$3.48

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

Results of Operations

Fiscal Year 2011 Compared to Fiscal Year 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:

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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, and renewable for 2013 and 2014 if certain sales growth objectives are met, 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.

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.

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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. We experienced an unusually low gross margin percentage during 2008 in comparison to those achieved in other periods. 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**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 manufacturers in the U.S., 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.

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.

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 current budgetary objective in 2012 is to maintain the ratio of product selling expenses to product sales below 20% on an annual basis.

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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.

Other (Expenses) Revenues, 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.

Fiscal Year 2010 Compared to Fiscal Year 2009

Product Sales

Product sales for the year ended December 31, 2010 decreased by 3%, or $120,000, to $4,386,000 from $4,506,000 in 2009. Domestic product sales increased by 2%, or $76,000, during the year ended December 31, 2010, while international sales decreased by 20%, or $196,000, in comparison to 2009. For the three-month period ended December 31, 2010, product sales increased by 9%, or $89,000, in comparison to the three-month period ended December 31, 2009. We expect some sales volatility in our international sales. We believe that sales of our products were influenced by the price of milk, cows and calves and by the cost of feed.

Sales of **First Defense**Ò decreased by 2% during the year ended December 31, 2010 in comparison to 2009. Domestic sales of **First Defense**Ò increased by 2%, but international sales decreased by 18%. Sales of **First Defense**Ò increased by 13% during the three-month period ended December 31, 2010 in comparison to the three-month period ended December 31, 2009. Sales of **First Defense**Ò are normally seasonal, with higher sales expected during the first quarter. **First Defense**Ò continued to benefit in 2010 from wide acceptance by dairy and beef producers as an effective tool to prevent bovine enteritis (calf scours).

Sales of **Wipe Out**Ò **Dairy Wipes** increased by 10% during the year ended December 31, 2010 in comparison to 2009. 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 that are forcing many small dairy producers out of business and because, while our product is a high quality tool, there are less expensive ways to sanitize a cow prior to milking.

The other products we sell primarily into the dairy industry decreased to 3% of product sales during the year ended December 31, 2010 compared to 4% of product sales during 2009. The other products we sell outside of the dairy and beef industries, principally Isolate™ (formerly known as **Crypto-Scan**®), aggregated 3% of product sales during the years ended December 31, 2010 and 2009.

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.

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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,		Decrease	
	2010	2009	Amount	%
Gross margin	$2,302	$2,398	$96	4%
Percent of product sales	52 %	53 %	1 %	2%

The gross margin as a percentage of product sales was 52% and 53% during the years ended December 31, 2010 and 2009, respectively. This compares to gross margin percentages of 45% and 52% for the years ended December 31, 2008 and 2007, respectively. We experienced an unusually low gross margin percentage during 2008 in comparison to those achieved in other periods. 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**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 manufacturers in the U.S., 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 47%, or $514,000, to $1,601,000 at December 31, 2010 from $1,087,000 at December 31, 2009. This investment was made to help prevent a potential back log of orders. We have not experienced a back log of orders since the third quarter of 2009. We have not implemented significant increases to our selling prices, believing that we could benefit more from higher unit sales volume than through a higher average selling price per unit.

Product Development Expenses

Product development expenses decreased by 9%, or $152,000, to $1,493,000 during the year ended December 31, 2010, as compared to $1,645,000 during 2009. We expect higher product development expenses during the year ending December 31, 2011. If a partner agrees to fund the completion of the **Mast Out**Ò product development effort, these expenses would be expected to increase even higher, but only if they are off set, in part, by the funds expected to be received from a potential strategic collaboration. Product development expenses aggregated 34% and 37% of

product sales in 2010 and 2009, respectively. The majority of our product development budget from 2000 through 2010 has been focused on the development of **Mast Out**Ò. Going forward, we expect to focus our product development expenses 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.

Administrative Expenses

Administrative expenses decreased by approximately 3%, or $23,000, to $849,000 during the year ended December 31, 2010 as compared to $873,000 during 2009. 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.

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Product Selling Expenses

Product selling expenses increased by approximately 58%, or $240,000, to $651,000 in 2010, increasing to 15% of product sales in 2010 from 9% in 2009. 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. Our objective in 2011 was to maintain the ratio of product selling expenses to product sales below 20% on an annual basis.

Other Revenues (Expenses), Net

Interest income decreased by approximately 74%, or $71,000, to $25,000 in 2010 in comparison to 2009 due principally to a decrease in interest rates. We did not incur interest expense during 2009 or 2008. Interest expense during 2010 aggregated $22,000.

Loss Before Income Taxes and Net Loss

Our loss before income taxes of $683,000 during the year ended December 31, 2010 compares to a loss before income taxes of $429,000 during the year ended December 31, 2009. We recorded income tax benefits of 44% and 49% of the losses before income taxes during the years ended December 31, 2010 and 2009, respectively. Our net loss of $385,000, or $0.13 per share, during the year ended December 31, 2010 compares to a net loss of $216,000, or $0.07 per share, during the year ended December 31, 2009.

Liquidity and Capital Resources

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 the nine years of profitability from 1999 through 2007, our cumulative investment in product development expenses of $9,894,000 was supported, in small part, by $975,000 in grant awards. The

investment of an additional $6,604,000 in product development expenses during 2011, 2010, 2009 and 2008 brings our cumulative investment to $16,498,000 during the thirteen-year period ended December 31, 2011. 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.

Our strategic decision to continue developing **Mast Out**Ò after the product rights were returned to us in 2007 has caused us to increase our spending on product development expenses that were previously funded by Pfizer from late 2004 to mid-2007. After the nine consecutive years of profitability that we recorded during the years ended December 31, 1999 to December 31, 2007, we incurred net losses of $410,000, $385,000, $216,000, and $469,000 during the years ended December 31, 2011, 2010, 2009, and 2008, respectively. As we reduce product development spending on **Mast Out**Ò, we expect to return to profitable operations. We have not invested the time and resources to carefully make an exact projection about the timing or extent of our anticipated return to profitability. We believe that the three key indicators that investors should watch going forward will be the gross margin on our product sales, our net operating income (loss) and our net income (loss).

We estimate that it will require approximately $13,000,000 to complete the development of **Mast Out**Ò and bring the product to market, sales of which are subject to FDA approval. This budget is comprised of costs primarily related to the manufacture of commercial inventory. We are seeking to finance this investment with a combination of available cash, partner funding and debt. Outside funding is required to pay for the larger financial commitments required for manufacturing scale-up and preparation of full-scale validation batches of **Mast Out**Ò. By the second quarter of 2011, we had advanced the product development effort internally to the point where we could begin earnest negotiations with prospective partners. All anticipated initial discussions are now complete, and some prospective partners are conducting their due diligence. It is difficult to predict when or if this partnering effort will be successful. Although these partnering discussions are taking longer than we would like or had initially anticipated, we believe that the commercial prospects for **Mast Out**Ò warrant our continued efforts and patience with the process.

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We had approximately $4,960,000 in available cash and short-term investments as of December 31, 2011. We are using some of this cash to fund product development, principally **Mast Out®**. We continue to look for new product acquisition opportunities that would have a strategic fit with the products that we currently sell. The table below summarizes the changes in selected, key balance sheet items (in thousands, except for percentages):

	Balance at December 31,		Increase (Decrease)	
	2011	2010	$	%
Cash, cash equivalents and short-term investments	$ 4,960	$ 4,626	$ 334	7 %
Net working capital	6,516	6,441	75	1
Total Assets	10,991	10,751	240	2
Stockholders' equity	$ 9,020	$ 9,282	$ (262)	(3)%

Cash, cash equivalents and short-term investments increased by 7%, or $334,000, to $4,960,000 at December 31, 2011 from $4,626,000 at December 31, 2010. Net cash used for operating activities amounted to $37,000 during the year ended December 31, 2011 as compared to net cash used for operating activities of $809,000 during the year ended December 31, 2010. Capital investments of $244,000 during 2011 compared to capital investments of $117,000 during 2010. Net working capital increased by 1%, or $75,000, to $6,516,000 at December 31, 2011 from $6,441,000 at December 31, 2010. Proceeds from bank debt received during 2011 aggregated $455,000, net of debt repayments made during 2011. Proceeds from bank debt received during 2010 aggregated $986,000, net of debt repayments made during 2010. Total assets increased by 2%, or $240,000, to $10,991,000 at December 31, 2011 from $10,751,000 at December 31, 2010. Stockholders' equity decreased by 3%, or $262,000, to $9,020,000 at December 31, 2011 from $9,282,000 at December 31, 2010. We believe that we have sufficient capital resources to meet our working capital requirements and to finance our ongoing business operators during at least the next twelve months. We expect to return to positive net operating income (before other revenues (expenses), net and income taxes) during 2012.

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. 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.

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. In 2008, our Board of Directors authorized an investment of approximately $1,314,000 for capital expenditures (facility modifications and production equipment). As of January 1, 2012, we had remaining available authorization to spend up to $234,000 on capital expenditures, net of $1,230,000 in investments made from January 1, 2008 through December 31, 2011, which amount includes a $150,000 increase to this authorized limit that was approved by our Board of Directors during the fourth quarter of 2011.

Off-Balance Sheet Arrangements

None

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Critical Accounting Policies

The financial statements are presented on the basis of accounting principles that are generally accepted in the U.S. All professional accounting standards that were effective and applicable to us as of December 31, 2011 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 the business and understanding our financial statements.

We recognize revenue in accordance with Staff Accounting Bulletin (SAB) No. 104, “Revenue Recognition”, which supersedes SAB No. 101, “Revenue Recognition in Financial Statements”. SAB No. 104 requires that four criteria are met before revenue is recognized. These include i) persuasive evidence that an arrangement exists, ii) delivery has occurred or services have been rendered, iii) the seller’s price is fixed and determinable and iv) 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 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-18 at the end of this report. The index to these financial statements is as follows:

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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, 2011. 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, 2011. Based on management's assessment and those criteria, management believes that the internal control over financial reporting as of December 31, 2011 was effective.

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

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

ITEM 9B – OTHER INFORMATION

None

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PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information with respect to our directors is incorporated herein by reference to the section of our 2012 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, 2011. 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 2012 Proxy Statement titled “Executive Officer Compensation”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2011.

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 2012 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, 2011.

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 2012 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, 2011.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

Information regarding our principal accountant fees and services is incorporated by reference to the section of our 2012 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, 2011.

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.

+ 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.

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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, 2011 and 2010, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

Portland, Maine /s/ Baker Newman & Noyes
March 27, 2012 Limited Liability Company

ImmuCell Corporation

BALANCE SHEETS

AS OF DECEMBER 31, 2011 AND 2010

	2011	2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$781,516	$1,398,985
Short-term investments	4,178,000	3,227,000
Trade accounts receivable, net of allowance for doubtful accounts of $16,000 and $13,000 at December 31, 2011 and 2010, respectively	346,447	465,278
Income taxes receivable	648	948
Other receivables	36,701	31,287
Inventory	1,666,465	1,601,016
Current portion of deferred tax asset	59,016	—
Prepaid expenses	81,807	241,191
Total current assets	7,150,600	6,965,705
NET PROPERTY, PLANT AND EQUIPMENT, at cost	2,515,331	2,710,891
LONG-TERM PORTION OF DEFERRED TAX ASSET	1,306,335	1,040,606
OTHER ASSETS, net	19,006	33,977
TOTAL ASSETS	$10,991,272	$10,751,179
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$303,900	$372,052
Accounts payable	149,877	105,739
Current portion of bank debt	172,973	42,384
Deferred revenue	8,250	—
Current portion of deferred tax liability	—	4,843
Total current liabilities	635,000	525,018
LONG-TERM LIABILITIES:		
Long-term portion of bank debt	1,267,939	943,760
Interest rate swap	67,900	—
Total long-term liabilities	1,335,839	943,760
TOTAL LIABILITIES	1,970,839	1,468,778

STOCKHOLDERS' EQUITY:		
Common stock, $0.10 par value per share, 8,000,000 shares authorized, 3,261,148 shares issued at December 31, 2011 and 2010	326,115	326,115
Capital in excess of par value	9,911,914	9,780,392
Accumulated deficit	(614,315)	(204,805)
Treasury stock, at cost, 257,114 and 287,496 shares at December 31, 2011 and 2010, respectively and 2008, respectively	(562,469)	(628,932)
Accumulated other comprehensive (loss) income: interest rate swap	(40,812)	9,631
Total stockholders' equity	9,020,433	9,282,401
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$10,991,272	$10,751,179

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

ImmuCell Corporation

STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

	2011	2010	2009
Product sales	$5,111,143	$4,386,196	$4,505,759
Costs of goods sold	2,297,339	2,083,718	2,107,678
Gross margin	2,813,804	2,302,478	2,398,081
Product development expenses	1,720,055	1,492,806	1,644,725
Sales and marketing expenses	869,869	650,889	410,744
Administrative expenses	856,606	849,064	872,526
Other operating expenses	3,446,530	2,992,759	2,927,995
NET OPERATING INCOME (LOSS)	(632,726)	(690,281)	(529,914)
Other (expenses) revenues, net	(63,955)	6,869	101,413
INCOME (LOSS) BEFORE INCOME TAXES	(696,681)	(683,412)	(428,501)
Income tax benefit	287,171	298,728	212,008
NET INCOME (LOSS)	$(409,510)	$(384,684)	$(216,493)
Weighted average common shares outstanding:			
Basic	2,984,749	2,970,833	2,958,784
Diluted	2,984,749	2,970,833	2,958,784
NET INCOME (LOSS) PER SHARE:			
Basic	$(0.14)	$(0.13)	$(0.07)
Diluted	$(0.14)	$(0.13)	$(0.07)

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

ImmuCell Corporation

STATEMENTS OF STOCKHOLDERS' EQUITY

FOR THE YEARS ENDED DECEMBER 31, 2009, 2010 AND 2011

	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	Equity
BALANCE, December 31, 2008	3,261,148	$326,115	$9,722,967	$396,372	366,496	$(801,753)	—	$9,643,701
Net loss	—	—	—	(216,493)	—	—	—	(216,493)
Exercise of stock options	—	—	(66,508)	—	(76,000)	166,258	—	99,750
Stock-based compensation	—	—	94,062	—	—	—	—	94,062
Tax benefits related to stock options	—	—	921	—	—	—	—	921
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: interest rate swap	—	—	—	—	—	—	9,631	9,631
Total comprehensive loss	—	—	—	—	—	—	—	(375,053)
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: interest rate swap	—	—	—	—	—	—	(50,443)	(50,443)
Total comprehensive loss	—	—	—	—	—	—	—	(459,953)
Exercise of stock options, net	—	—	78,832	—	(30,382)	66,463	—	145,295
Stock-based compensation	—	—	38,172	—	—	—	—	38,172
Tax benefits related to stock options	—	—	14,518	—	—	—	—	14,518
BALANCE, December 31, 2011	3,261,148	$326,115	$9,911,914	$(614,315)	257,114	$(562,469)	$ (40,812)	$9,020,433

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

ImmuCell Corporation

STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

	2011	2010	2009
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$(409,510)	$(384,684)	$(216,493)
Adjustments to reconcile net income (loss) to net cash used for operating activities:			
Depreciation	413,132	416,918	394,295
Amortization	5,240	2,593	30,145
Deferred income taxes	(302,500)	(299,171)	(213,348)
Stock-based compensation	38,172	29,513	94,062
Loss on disposal of fixed assets	10,822	575	29,860
Changes in:			
Receivables	113,417	(82,301)	117,866
Income taxes receivable/payable	300	300	361,226
Inventory	(65,449)	(513,625)	(490,987)
Prepaid expenses and other assets	159,484	(60,913)	(86,306)
Accounts payable	59,479	(26,811)	29,985
Accrued expenses	(68,152)	108,993	(159,970)
Deferred revenue	8,250	—	—
Net cash used for operating activities	(37,315)	(808,613)	(109,665)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(243,735)	(116,547)	(459,548)
Maturities of short-term investments	3,227,000	4,108,000	3,854,103
Purchases of short-term investments	(4,178,000)	(3,725,000)	(3,610,000)
Net cash (used for) provided by investing activities	(1,194,735)	266,453	(215,445)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from debt issuance	600,000	1,000,000	—
Debt principal repayments	(145,232)	(13,856)	—
Debt issuance costs	—	(26,489)	—
Tax benefits related to stock options	14,518	—	921
Proceeds from exercise of stock options	145,295	6,000	99,750
Net cash provided by financing activities	614,581	965,655	100,671
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(617,469)	423,495	(224,439)
BEGINNING CASH AND CASH EQUIVALENTS	1,398,985	975,490	1,199,929

ENDING CASH AND CASH EQUIVALENTS	$781,516	$1,398,985	$975,490
INCOME TAXES (PAID) REFUNDED, NET	$(510)	$(144)	$360,777
INTEREST EXPENSE PAID	$(78,737)	$(20,000)	$—
NON-CASH ACTIVITIES:			
Change in capital expenditures included in accounts payable and accrued expenses	$(15,341)	$32,839	$8,263
Net change in fair value of interest rate swap	$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 issued by the FASB 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 2011 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. Amounts in excess of these FDIC limits per bank that are not invested in securities backed by the U.S. government aggregated $281,000 and $899,000 at December 31, 2011 and 2010, respectively. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits per financial institution are maintained in money market accounts at financial institutions that are secured, in part, by the Securities Investor Protection Corporation. Short-term investments are classified as held to maturity and are comprised principally of certificates of deposits that mature in

more than three months from their purchase dates and not more than twelve months from the balance sheet date and are held at different financial institutions that are insured by the FDIC within the FDIC insurance limit of $250,000 per institution per depositor. 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 (in thousands):

	As of December 31,		(Decrease)
	2011	2010	Increase
Cash and cash equivalents	$ 782	$ 1,399	$ (617)
Short-term investments	4,178	3,227	951
	$ 4,960	$ 4,626	$ 334

(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 (in thousands):

	As of December 31,		(Decrease)
	2011	2010	Increase
Raw materials	$ 218	$ 237	$ (19)
Work-in-process	1,000	977	23
Finished goods	448	387	61
	$ 1,666	$ 1,601	$ 65

(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. The $250,000 acquisition of product rights related to **Wipe Out® Dairy Wipes** in December 1999 was amortized to cost of sales over the ten-year period ended in December 2009, and the related manufacturing rights acquired in 2001 for $45,000 were amortized to cost of sales through December 2009. In connection with certain credit facilities entered into during the third quarter of 2010, we incurred debt issue costs of approximately $26,000, which costs are being amortized to other revenues (expenses), net over the terms of the credit facilities.

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 $14,000 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 revenues (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 $5,000, $16,000 and $33,000 during the years ended December 31, 2011, 2010 and 2009, 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 IRS 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, 2011. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 8.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

(l) Net Income (Loss) Per Common Share

The net loss per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share,* 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,		
	2011	2010	2009
Weighted average number of shares outstanding during the period	2,984,749	2,970,833	2,958,784
Dilutive stock options	—	—	—
Shares that could have been repurchased with the proceeds from the dilutive stock options	—	—	—
Diluted number of shares outstanding during the period	2,984,749	2,970,833	2,958,784
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	236,000	273,500	401,000

For additional disclosures regarding the outstanding common stock options, see Notes 9(a) and 9(b).

(m) Employee 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 9(b). Accordingly, we recorded $38,000, $30,000 and $94,000 of compensation expense pertaining to stock-based compensation, which resulted in an increase in loss before income taxes of approximately $0.01, $0.01 and $0.03 per share (before the effect of income taxes), during the years ended December 31, 2011, 2010 and 2009, 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, 2011.

(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 to be Adopted

Accounting Standards Update (ASU) No. 2011-05, *Presentation of Comprehensive Income (Loss)* (Topic 220) will be adopted during the first quarter of 2012. 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. This guidance eliminates the option to report components of other comprehensive income (loss) as part of the statement of changes in stockholders' equity. Under either option, we are required to present each component of net income (loss) along with total net income (loss), each component of other comprehensive income (loss) along with a total for other comprehensive income (loss), and a total amount for comprehensive income (loss). In a single continuous statement, we are required to present the components of net income (loss) and total net income (loss), the components of other comprehensive income (loss) and a total for other comprehensive income (loss), along with the total of comprehensive income (loss) in that statement. In the two statement approach, we are required to present components of net income (loss) and total net income (loss) in our statement of operations. The statement of other comprehensive income (loss) should immediately follow the statement 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). ASU 2011-05 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, and retrospective application is required. The guidance is effective for our first quarter ending March 31, 2012. The Company believes the adoption will impact only the presentation of the financial statements.

3. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following, at cost (in thousands):

	As of December 31,	
	2011	2010
Laboratory and manufacturing equipment	$ 2,979	$ 2,870
Building and improvements	2,667	2,553
Office furniture and equipment	253	225
Construction in progress	1	40
Land	50	50
Property, plant and equipment, gross	5,950	5,738
Less-accumulated depreciation	3,435	3,027

Property, plant and equipment, net	$ 2,515	$ 2,711

4. OTHER ASSETS

Other assets consisted of the following (in thousands):

	As of December 31,	
	2011	2010
Security deposits	$ 1	$ 1
Debt issue costs	26	26
Interest rate swap[(1)]	—	10
Other assets, gross	27	37
Less-Accumulated amortization of debt issue costs	8	3
Other assets, net	$ 19	$ 34

(1) Amount included in long-term liabilities as of December 31, 2011.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

5. ACCRUED EXPENSES

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2011	2010
Professional fees	$ 40	$ 42
Payroll	128	136
Other	136	194
	$ 304	$ 372

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 approximately $452,000 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 in the amount of approximately $(50,000) as of December 31, 2011 and other comprehensive income in the amount of approximately $10,000 as of December 31, 2010, 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 rate of 4.25% or the one month London Interbank Offered Rate (LIBOR) plus 3.25%. The $500,000 line of credit is available as needed and has been extended through May 31, 2012 and is renewable annually thereafter. Interest on any borrowings against the line of credit will be variable at the higher rate of 4.25% or the one month LIBOR plus 3.5%. These credit facilities are subject to certain financial covenants.

Principal payments due under debt outstanding as of December 31, 2011 are reflected in the following table by the year that payments are due (in thousands):

	Year ending December 31,					
	2012	2013	2014	2015	2016	Thereafter
$1,000,000 mortgage	$45	$48	$51	$54	$ 57	$ 689
$600,000 note	128	134	139	96	—	—
Total	$173	$182	$190	$150	$ 57	$ 689

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

7. OTHER (EXPENSES) REVENUES, NET

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

	Year Ended December 31,		
	2011	2010	2009
Royalty income	$ 11	$ 3	$ 3
Interest income	15	26	96
Interest expense	(81)	(22)	—
Debt issuance amortization	(5)	(3)	—
Other gains (losses)	(4)	3	2
	$ (64)	$ 7	$ 101

8. INCOME TAXES

Our income tax benefit aggregated $287,000, $299,000 and $212,000 (41%, 44% and 49% of the loss before income taxes, respectively) for the years ended December 31, 2011, 2010 and 2009, respectively. The income tax provision consists of the following (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Current			
Federal	$ —	$ —	$ —
State	(1)	(1)	(1)
Foreign	—	—	—
	(1)	(1)	(1)
Deferred			
Federal	260	260	112
State	28	40	101
	288	300	213
Total	$ 287	$ 299	$ 212

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

	Year Ended December 31,		
	2011	2010	2009
Computed expected tax benefit	$ 237	$ 233	$ 146
State income taxes, net of federal benefit	36	39	38
Share-based compensation	(8)	(10)	(32)
Research and development tax credit	24	22	58
Other	(2)	15	2
Total income tax benefit	$ 287	$ 299	$ 212

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

The significant components of our deferred tax assets and liabilities are as follows (in thousands):

	As of December 31,	
	2011	2010
Deferred tax assets (liabilities):		
Deferred revenue and other reserves	$ 10	$ 5
Product rights	237	272
Depreciation	(33)	(56)
Research and development tax credit	180	157
Federal net operating loss carryforward	652	474
State net operating loss carryforward	275	229
Interest rate swap	27	—
Prepaid expenses and other	17	(45)
Deferred tax assets	$ 1,365	$ 1,036

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 $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 $84,000 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 $3,082,000 that expires in 2028, 2029, 2030 and 2031, if not utilized before then, and a federal net operating loss carryforward of approximately $1,916,000 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 2008. 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.

9. STOCKHOLDERS' EQUITY

(a) Stock Option Grants Outside of Stock Option Plans

On March 1, 1999, 31,100 non-qualified stock options were issued to each of the three then-serving executive officers at an exercise price of $1.31 per share, the then current market price of our common stock, vesting as to one-third in each of March 2000, 2001 and 2002. These options were granted outside of the stock option plans described below. In 2000, 20,734 of these options terminated when one of the officers separated from the Company. In September 2001, that former officer exercised 10,300 of these options and 66 of these options expired without being exercised. In February 2009, the aggregate of 34,200 of the outstanding options were exercised by two current executive officers and the remaining 28,000 of these options expired without being exercised. The aggregate intrinsic value of these outstanding options approximated $22,000 as of December 31, 2008.

(b) Stock Option Plans

In May 1989, the stockholders approved the 1989 Stock Option and Incentive Plan (the “1989 Plan”) pursuant to the provisions of the Internal Revenue Code of 1986, under which employees 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. All options granted under the 1989 Plan expire no later than ten years from the date of grant. The 1989 Plan expired in March 1999, and no further options may be granted under the 1989 Plan. The last 41,800 options under the 1989 plan were exercised in February 2009 in accordance with their terms.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

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.

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

	1989 Plan	2000 Plan	2010 Plan	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2008	41,800	312,000	—	$ 3.79	None
Grants	—	115,000	—	$ 1.94	
Terminations	—	(26,000)	—	$ 3.43	
Exercises	(41,800)	—	—	$ 1.31	
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
Exercisable at December 31, 2011	—	64,000	—	$ 4.28	$ 24,000
Reserved for future grants	—	—	250,500		

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

At December 31, 2011, 236,000 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, 2011 was approximately six years and six months. The exercise price of the options outstanding as of December 31, 2011 ranged from $1.70 to $7.00 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 115,000 stock options granted during 2009 had exercise prices between $1.70 and $3.99 per share. The aggregate intrinsic value of options exercised during 2011, 2010 and 2009 approximated $49,000, $3,000 and $5,000, respectively. The weighted-average grant date fair values of options granted during 2011, 2010 and 2009 were $2.40, $1.45 and $0.81 per share, respectively. 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(m), with the following weighted-average assumptions:

	2011		2010		2009	
Risk-free interest rate	1.1	%	2.4	%	1.7	%
Dividend yield	0	%	0	%	0	%
Expected volatility	47.6	%	44.2	%	44.9	%
Expected life	5 years		5 years		5 years	

As of December 31, 2011, total unrecognized stock-based compensation related to non-vested stock options aggregated approximately $84,000. That cost is expected to be recognized at a declining rate through December 31, 2014 which represents the remaining vesting period of the outstanding non-vested stock options.

(c) Stock Option Exercises

During the year ended December 31, 2009, four employees exercised stock options covering the aggregate of 76,000 shares. These options were exercised for cash, resulting in total proceeds of $99,750. 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. During the year ended December 31, 2011, eight employees exercised stock options covering the aggregate of 31,000 shares. 30,000 of these options were exercised for cash, resulting in total proceeds of $145,000, and 1,000 of these options were exercised by the surrender of 618 shares of common stock with a fair market value of $3,200 at the time of exercise.

(d) Common Stock Rights Plan

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

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

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

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

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

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

Our Board of Directors believes that there is 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 feels that the Rights Plan could enhance stockholder value by providing management with negotiating leverage.

10. 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, 2011. 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 for 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, 2011.

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.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

11. 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 (81%, 82% and 78% for the years ended December 31, 2011, 2010 and 2009, 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 17%, 15% and 19% of our total product sales for the years ended December 31, 2011, 2010 and 2009, 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,		
	2011	2010	2009
Animal Health International, Inc.[1]	38 %	36 %	40 %
MWI Veterinary Supply Company[2]	14 %	13 %	10 %

(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,	
	2011	2010

Animal Health International, Inc.[1]	23	%	35	%
MWI Veterinary Supply Company[2]	21	%	12	%
Stearns Veterinary Outlet, Inc.	18	%	10	%
Robert J. Matthews Company	*		15	%

*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.

12. RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (a member of our Board of Directors) is a controlling owner of 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 approximately $295,000, $288,000 and $283,000 of products from ImmuCell during the years ended December 31, 2011, 2010 and 2009, 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 approximately $61,000 and $45,000 as of December 31, 2011 and 2010, respectively.

ImmuCell Corporation

Notes to Audited Financial Statements (continued)

13. EMPLOYEE BENEFITS

We have a 401(k) savings plan in which all employees completing one year of service with the Company (working at least 1,000 hours) are eligible to participate. Participants may contribute up to the maximum amount allowed by the Internal Revenue Service. We match 50% of each employee's contribution to the plan up to a maximum match of 4% of each employee's base compensation. Under this matching plan, we paid approximately $48,000, $41,000 and $40,000 to the plan for the years ended December 31, 2011, 2010 and 2009, respectively.

14. UNAUDITED QUARTERLY FINANCIAL DATA

The following tables present the quarterly information for fiscal years 2011, 2010 and 2009 (in thousands, except per share amounts):

	Three Months Ended			
	March 31	June 30	September 30	December 31
Fiscal 2011:				
Product sales	$1,556	$1,247	$ 1,003	$ 1,305
Gross margin	868	695	526	725
Product development expenses	472	673	304	271
Net operating income (loss)	(17)	(433)	(192)	9
Income (loss) before income taxes	(31)	(457)	(211)	2
Net income (loss)	(23)	(258)	(128)	(1)
Net income (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	$1,078	$ 874	$ 1,123
Gross margin	739	619	357	587
Product development expenses	405	333	312	443
Net operating loss	(74)	(48)	(347)	(221)
Loss before income taxes	(65)	(37)	(350)	(231)
Net loss	(53)	(6)	(197)	(129)
Net loss per common share:				

Basic	$(0.02)	$(0.00)	$ (0.07)	$ (0.04)
Diluted	$(0.02)	$(0.00)	$ (0.07)	$ (0.04)
Fiscal 2009:				
Product Sales	$1,460	$1,001	$ 1,011	$ 1,034
Gross margin	721	488	598	591
Product development expenses	432	490	328	395
Net operating loss	(74)	(316)	(40)	(100)
Loss before income taxes	(36)	(284)	(20)	(89)
Net loss	(35)	(147)	(19)	(15)
Net loss per common share:				
Basic	$(0.01)	$(0.04)	$ (0.01)	$ (0.01)
Diluted	$(0.01)	$(0.04)	$ (0.01)	$ (0.01)

15. 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 27, 2012, the date we have issued this Annual Report on Form 10-K.

ImmuCell Corporation

Signatures

In accordance with Section 13 or 15(d) of the Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IMMUCELL CORPORATION

Date: March 27, 2012 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer and
Treasurer

POWER OF ATTORNEY

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

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

Date: March 21, 2012 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer,
Treasurer and Director

Date: March 21, 2012 By: /s/ Joseph H. Crabb
Joseph H. Crabb, Ph.D., Director

Date: March 21, 2012 By: /s/ David S. Cunningham
David S. Cunningham, Director

Date: March 21, 2012 By: /s/ William H. Maxwell
William H. Maxwell, M.D., Director

Date: March 21, 2012 By: /s/ Linda Rhodes
Linda Rhodes, VMD, Ph.D., Director

Date: March 21, 2012 By: /s/ Jonathan E. Rothschild
Jonathan E. Rothschild, Director

Date: March 21, 2012 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