

IMMUCELL CORP /DE/  
Form 10-K  
March 29, 2010  
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**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, 2009

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

001-12934

(Commission file number)

**IMMUCELL CORPORATION**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of

incorporation or organization)

01-0382980  
(I.R.S. Employer

Identification No.)

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56 Evergreen Drive, Portland, Maine  
(Address of principal executive offices)

04103  
(Zip Code)

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

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

None

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

Common Stock, par value \$0.10 per share

(Title of class)

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates at June 30, 2009 was approximately \$5,467,000, based on the closing sales price on June 30, 2009 of \$2.48 per share.

The number of shares outstanding of the Registrant's common stock outstanding at March 26, 2010 was 2,970,652.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement to be filed in connection with the 2010 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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**Table of Contents****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. 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. After achieving approval from the U.S. Department of Agriculture (USDA) to sell **First Defense**<sup>®</sup> in 1991, we focused most of our efforts in the 1990's developing human product applications of the underlying milk antibody technology. Beginning in 1999, we re-focused on **First Defense**<sup>®</sup> and other products for the dairy industry.

In 2000, we began the development of **Mast Out**<sup>®</sup>, our Nisin-based treatment for subclinical mastitis in lactating dairy cows. This product opportunity was licensed to Pfizer Animal Health, a division of Pfizer, Inc., from December 2004 to July 2007. During that time, Pfizer made significant advances in developing data required for product registration in the areas of effectiveness, manufacturing and pharmacokinetics. Although in 2007 Pfizer elected to discontinue its commercialization efforts for this product, we believe that the sales potential for **Mast Out**<sup>®</sup> justifies the costs of further development of the product. See the discussion under "Sales and Markets" regarding the market estimates for **Mast Out**<sup>®</sup>. Therefore, we decided to pursue this work on our own. We achieved positive results from the pivotal effectiveness study required for product approval by the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine, during the third quarter of 2009. We believe that these results justify continued product development. See the discussion under "Product Development" regarding **Mast Out**

With our shift in focus to animal health products, we were able to record net income for each of the nine years ended from December 31, 1999 through December 31, 2007. We believe that the conservative approach to financial management that is reflected in such results put us in a position to be able to weather a significant financial downturn like the one we are now experiencing, while at the same time allowing us to continue paying for the **Mast Out**<sup>®</sup> product development expenses. This strategy, calling for a significant and controlled investment in the development of **Mast Out**<sup>®</sup>, resulted in net losses during both of the years ended December 31, 2008 and 2009 and is expected to result in another net loss for the year ending December 31, 2010. We believe that we have more than enough cash and short-term investments to fund our projected loss. We have been operating without debt since 2002, and we have not had to dilute our shareholders by raising equity to fund our operations through 2009 and do not expect to do so during 2010. See the discussion under "Product Development" regarding the commercial manufacture of **Mast Out**<sup>®</sup>. This strategy has funded our operations and improved our financial position, as demonstrated in the following table:

	At December 31, 1998		Net \$ increase over eleven-year period		At December 31, 2009		Net % increase over eleven-year period
Cash, cash equivalents and short-term investments	\$ 1,539	+	\$ 3,046	=	\$ 4,585		+198%
Net working capital	1,866	+	4,078	=	5,944		+219%
Total assets	3,145	+	6,840	=	9,985		+217%
Stockholders' equity	\$ 2,248	+	\$ 7,374	=	\$ 9,622		+328%

This growth has been accomplished with only limited dilution from the exercise of stock options. We had approximately 2,429,000 shares of common stock outstanding as of December 31, 1998 in comparison to 2,971,000 as of December 31, 2009. There were approximately 480,000 and 401,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 1998 and 2009, respectively. During the eleven years in the period ended December 31, 2009, we invested an aggregate of \$13,285,000 in product development expenses.

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During 2006, we initiated efforts to become compliant with current Good Manufacturing Practice (cGMP) regulations in our manufacturing operations. Compliance with cGMP regulations will require a sustained investment. We believe that cGMP standards will further increase our products' quality and compliance with current regulations applicable to certain of our products, and this may open access to foreign markets where such standards are imposed. At the same time, we are investigating ways to develop new products utilizing our **First Defense**<sup>®</sup> and Nisin technologies.

### **Animal Health Products for the Dairy and Beef Industries**

Our lead product, **First Defense**<sup>®</sup>, which was approved by the USDA in 1991, is manufactured from cows' colostrum using our proprietary vaccine and milk protein purification technologies. The target disease, bovine enteritis (calf scours), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. **First Defense**<sup>®</sup> is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against *E. coli* K99 and coronavirus (two leading causes of scours). Harsh winter weather and severe temperature fluctuations cause stress to calves, and calves under stress are more susceptible to scours, contributing 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. We have sold over 9,000,000 doses of **First Defense**<sup>®</sup> since receiving USDA approval of this product in 1991. We are a leader in the scours prevention market with this product. During the second quarter of 2006, certain regional organic certifying agencies determined that the ingredients in **First Defense**<sup>®</sup> are in compliance with the National Organic Program (NOP) and may be considered for use on organic farms. **First Defense**<sup>®</sup> should be considered a preventive vaccine as described in USDA-NOP regulations for organic producer consideration when establishing management plans.

**First Defense**<sup>®</sup> provides bovine antibodies that newborn calves need but are unable to produce on their own. Due to natural variability in colostrum, newborn calves do not always get the antibodies they need from maternal colostrum. Newborn calves respond poorly, if at all, to vaccines, and the immune system must be given time to develop a response to vaccines. **First Defense**<sup>®</sup> provides immediate preformed immunity when calves need it most—during the first few critical days of life. A single dose of **First Defense**<sup>®</sup> provides a guaranteed level of protection proven to reduce mortality and morbidity from two major causes of calf scours. Studies have shown that calves that scour are more susceptible to other diseases and under-perform calves that do not contract scours. **First Defense**<sup>®</sup> is convenient. A calf needs to receive only one bolus of **First Defense**<sup>®</sup> 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**<sup>®</sup>.

We also sell three products designed to aid in the management of mastitis (inflammation of the mammary gland) caused by bacterial infections.

In 1999, we acquired **Wipe Out**<sup>®</sup> **Dairy Wipes**, which is our second leading source of product sales, from Nutrition 21, Inc. That transaction included the purchase of certain equipment, trademarks and a license of intellectual property, including several issued patents, covering the product and rights to develop skin and environmental sanitizing applications of the Nisin technology. **Wipe Out**<sup>®</sup> **Dairy Wipes** consist of pre-moistened, biodegradable towelettes that are impregnated with Nisin 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. Milking regulations require that the teat area of cows be cleaned, sanitized and dried for each milking. Some dairy producers wash their cows as they approach the milking parlor. Other 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**<sup>®</sup> **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.

In 2000, we acquired **MASTiK<sup>®</sup>, Mastitis Antibiotic Susceptibility Test Kit**, from an entrepreneurial veterinarian. Once mastitis is detected, there are different treatment options. **MASTiK<sup>®</sup>** helps veterinarians and producers quickly select the antibiotic most likely to be effective in the treatment of individual cases of mastitis. **MASTiK<sup>®</sup>** can usually help make the treatment selection in less than one day, which is faster than other commonly used antibiotic susceptibility tests. Typically, producers will treat mastitis with whatever antibiotics they have on hand while they send samples to a laboratory and wait several days for susceptibility test results to arrive. **MASTiK<sup>®</sup>** allows producers to begin treatment sooner with an antibiotic that is more likely to be effective.

In 1987, we obtained approval from the USDA to sell **rjt** (Rapid Johne's Test). This test can rapidly identify cattle with symptomatic Johne's Disease in a herd with 100% specificity and greater than 85% sensitivity. Our USDA approval is subject to the further approval of each state veterinarian.

## **Product Development**

In 1999, we shifted the primary focus of our product development efforts from applications of our milk antibody technology for humans to products for the dairy and beef industries. This strategy was maintained through 2009 and is expected to continue. We spent approximately \$1,579,000, \$1,746,000 and \$1,645,000 on product development activities during the years ended December 31, 2007, 2008 and 2009, respectively. These expenses included approximately \$439,000 in non-cash amortization expense during the year ended December 31, 2007. We expect higher product development expenses during the year ending December 31, 2010.

In April 2000, we acquired an exclusive license from Nutrition 21, Inc. to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Mast Out<sup>®</sup>**. In November 2004, we paid Nutrition 21 approximately \$965,000 to buy out this royalty and milestone-based license to Nisin, thereby acquiring control of the animal health applications of Nisin. Nisin, the same active ingredient contained in **Wipe Out<sup>®</sup> Dairy Wipes**, is an antibacterial peptide that is commonly used as a preservative in dairy food products. Nisin is known to have activity against most gram positive and some gram negative bacteria. **Mast Out<sup>®</sup>**, an intramammary infusion product containing Nisin, is being developed as an alternative to traditional antibiotics used in the treatment of mastitis in lactating dairy cows.

Traditional antibiotic products currently on the market for use in the treatment of mastitis are sold subject to a requirement to discard milk from treated cows during the course of and for a period following antibiotic treatment (the milk discard requirement). Currently, mastitis treatment is generally limited to only clinical cases – those cases where cows are producing abnormal milk – since that milk already is unsuitable for commercial sale. Because milk from cows with subclinical mastitis (those with infected udders, but still producing normal milk) can be sold, dairy producers generally do not treat subclinical mastitis – as doing so would give rise to the milk discard requirement and a resulting loss in revenue to the dairy producer. The safety profile of Nisin may allow for the use of **Mast Out<sup>®</sup>** in the U.S. without a milk discard requirement, which would be a significant competitive advantage. We are not aware of any other intramammary mastitis treatment product that has such a zero discard claim. Without the milk discard requirement, we believe **Mast Out<sup>®</sup>** could expand the subclinical mastitis treatment market niche. Regulations in the European Union will likely require that **Mast Out<sup>®</sup>** be sold subject to a milk discard requirement in that territory, although the duration of the milk discard requirement may be shorter than the discard requirement for competitive products on the market.

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In January 2004, we achieved positive results from an experimental field trial of **Mast Out**<sup>®</sup> in 139 cows with subclinical mastitis. The placebo-controlled, blinded, multi-farm study was conducted in collaboration with researchers at Cornell University. **Mast Out**<sup>®</sup> demonstrated a statistically significant overall cure rate in two separate dosage groups in comparison to the placebo group. In December 2004, we entered into a product development and marketing agreement with Pfizer Animal Health, a division of Pfizer, Inc., covering **Mast Out**<sup>®</sup>. Under that agreement (as amended and supplemented and later terminated), we received \$2,375,000 in payments from Pfizer. In July 2007, we received notice from Pfizer that it had elected to terminate the product development and marketing agreement. 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**<sup>®</sup>.

We believe Pfizer's decision was primarily market driven, largely relating to concerns that the use of **Mast Out**<sup>®</sup> may require specific treatment restrictions at the herd level, when used to treat subclinical mastitis with no milk discard. Due to its antibacterial nature, Nisin in bulk tank milk could interfere with the manufacture of certain (but not all) cultured milk products, such as some kinds of cheese and yogurt, if a high enough percentage of animals from a herd is treated at any one time. We believe that this risk can be eliminated by following a herd-level treatment restriction that would require the subclinically mastitic cows in a herd to be treated over a period of weeks rather than all at once, in order to ensure that Nisin levels in bulk tank milk remain below levels that could affect the susceptible starter cultures. Milk that is sold exclusively for fluid milk products would not be subject to this restriction. We believe that the benefits of using **Mast Out**<sup>®</sup> would outweigh the management costs associated with implementing this treatment restriction. Our decision to continue product development efforts reflects our belief that **Mast Out**<sup>®</sup> is approvable by the FDA without a milk discard requirement for sale in the U.S. We believe that such a product has significant sales potential in the U.S. dairy market. See the discussion under Sales and Markets regarding the market estimates for **Mast Out**<sup>®</sup>.

In July 2007, we began preparations for the pivotal effectiveness study required for FDA approval of **Mast Out**<sup>®</sup>. Such preparations included the production of registration batches of drug product at 10% of the scale anticipated for commercial manufacture to fulfill the pivotal regulatory requirements of effectiveness, target animal safety, and stability. In June 2008, we initiated the pivotal effectiveness study. Positive results from the study were announced on September 30, 2009. With enrollment of approximately 300 qualified cows with subclinical mastitis, the **Mast Out**<sup>®</sup> treatment group showed a statistically highly significant ( $p < 0.0001$ ) 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**<sup>®</sup> achieved almost 10-fold higher cure rates than the placebo-treated animals against this pathogen. Further, **Mast Out**<sup>®</sup> treatment was associated with a statistically significant ( $p < 0.005$ ) reduction in milk somatic cell counts (SCC), which are one measure of udder inflammation.

Commercial introduction of **Mast Out**<sup>®</sup> in the United States is subject to approval of our New Animal Drug Application (NADA) by the FDA, which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets outside of the United States and would involve some similar and some different requirements. The NADA is comprised of several Technical Sections under the FDA's phased review of a NADA. 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) *Pivotal Effectiveness*

On September 30, 2009, we announced that we had met the pivotal effectiveness study end point. We accomplished our primary objective, which was to demonstrate effectiveness in the field at a level similar to

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currently marketed intramammary antibiotics. Additionally, we confirmed prior results from two major field studies conducted since 2003. We intend to submit the Effectiveness Technical Section to the FDA for review during the second quarter of 2010.

### 3) *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 intend to submit the Target Animal Safety Technical Section to the FDA for review during the second quarter of 2010.

### 4) *Human Food Safety*

The Human Food Safety data determines if a milk discard period or meat withhold period will be required. This Technical Section includes several subsections such as residue chemistry (we expect to make the pivotal residue chemistry submission during the second quarter of 2010), total metabolism (which is complete), effects of drug residues in food on human intestinal microbiology (which is complete), effects on bacteria of human health concern or antimicrobial resistance (which is complete) and toxicology (which is complete). A zero meat withhold requirement, during the course of and for any period following treatment, has been granted. The Acceptable Daily Intake (ADI) level for humans has been accepted by the FDA, and this ADI continues to support a zero milk discard claim. All of these subsections must be completed before the Human Food Safety Technical Section Complete Letter establishing a zero milk discard (or a milk discard period) can be issued by the FDA.

### 5) *Chemistry, Manufacturing and Controls (CMC)*

We are developing collaborations with three manufacturers to produce inventory for us utilizing our proprietary technology and processes. First, we have entered into a long-term exclusive supply agreement with a plastic packaging manufacturer covering the proprietary syringe that was developed specifically for **Mast Out**<sup>®</sup>. These syringes were used for all pivotal studies of **Mast Out**<sup>®</sup>. Second, we have begun contract development work to produce the Active Pharmaceutical Ingredient (API) with a large-scale, FDA-approved API manufacturer while we are negotiating a long-term commercial contract with this manufacturer. The identified manufacturing site is compliant with cGMP regulations and is subject to continuing FDA approval and inspection. At this preliminary stage of our negotiations, we are estimating that the investment required for full commercial manufacture of API will exceed our available cash. We are exploring opportunities to finance a portion of this investment, including partner, debt and equity funding. Third, we have a manufacturing relationship with an FDA-approved drug product manufacturer to formulate the API into drug product, conduct sterile-fill of syringes and perform final packaging. This manufacturer prepared drug product for all pivotal studies of **Mast Out**<sup>®</sup>. We are negotiating a commercial contract with this manufacturer. We intend to make a first submission of the CMC Technical Section to the FDA for review during the second quarter of 2010. We expect that a second submission will be required by the FDA before a Technical Section Complete Letter could be issued.

### 6) *Several Administrative Requirements*

After we obtain all the Technical Section Complete Letters and we prepare materials responsive to the other administrative requirements, we would assemble the administrative NADA submission for final review by the FDA. The timing of the administrative NADA submission and the timing of a market launch (if the FDA grants approval) will be determined by the FDA's responses to our Technical Section submissions and successful resolution of any identified issues. Assuming no unanticipated delays in this process and subject to our successfully obtaining financing on terms acceptable to us, as described under the CMC Technical Section paragraph above, we believe that a product launch during the latter part of 2011 would be possible.



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In addition to our work on **Mast Out**<sup>®</sup>, we are actively exploring further improvements, extensions or additions to our current product line. For example, we currently are investigating therapies that could prevent scours in calves caused by enteric pathogens other than *E. coli* K99 and bovine coronavirus (the current **First Defense**<sup>®</sup> 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 justify continued product development and conducting a pivotal effectiveness study in 2010. Successful results could position us for USDA approval of a product effective against scours caused by rotavirus in 2011. As additional opportunities arise to commercialize our own technology, or licensable technology, we may begin new development projects. While we continue to pursue internally funded product development programs, we also remain interested in acquiring new products and technologies that fit with our sales focus on the dairy and beef industries.

We believe that market opportunities for growth of **First Defense**<sup>®</sup> sales exist in foreign territories. Regulatory authorities in some foreign territories may require that our manufacturing operations be compliant with cGMP regulations. We are working with in-country consultants in key markets to help us through the process of seeking foreign regulatory approvals. Because of import restrictions, in-country production may be required to gain regulatory approval to sell **First Defense**<sup>®</sup> in Australia and New Zealand. In March 2008, we entered into a license agreement with Immuron, Ltd. of Australia (formerly known as Anadis). Under this agreement, we gained access to relevant production technology and capabilities of Immuron in Australia. We are obligated to pay Immuron a royalty on any sales of **First Defense**<sup>®</sup> manufactured in Australia in collaboration with Immuron.

## **Sales and Markets**

The manner in which we sell and distribute our products depends, in large measure, upon the nature of the particular product, its intended users and the country in which it is sold. The distribution channel selected is intended to address the particular characteristics of the marketplace for a given product. **First Defense**<sup>®</sup> is sold primarily through major veterinarian distributors. We primarily sell **Wipe Out**<sup>®</sup> **Dairy Wipes** directly to dairy producers. **MASTiK**<sup>®</sup> and **CMT** are sold directly to dairy producers as well as to distributors and bovine veterinarians. Sales of **rjt** are made principally to state veterinary laboratories. Product selling expenses amounted to 11%, 12% and 9% of product sales in the years ended December 31, 2007, 2008 and 2009, respectively. Our budget guideline for 2010 is to invest approximately 15% of product sales in selling expenses.

**First Defense**<sup>®</sup> is generally sold through large, financially strong distributors, which we believe has resulted in minimal bad debt with respect to this product. We provide for a 50% account credit for domestic distributors on expired **First Defense**<sup>®</sup> product, which has a two-year shelf life resulting in an immaterial amount of returns. **Wipe Out**<sup>®</sup> **Dairy Wipes** are generally sold directly to dairy producers, but we have experienced only a minimal problem with uncollectible accounts receivable in connection with this product. We purchase a small amount of promotional merchandise (such as hats, shirts, jackets, pens, note pads, coffee cups and other items) that advertises our products. This merchandise is given to certain customers because we believe it enhances brand recognition. There is some general correlation between customer purchase volume and the amount of merchandise received, but not all customers receive merchandise, and there is no contractual obligation relating the distribution of this merchandise to the purchase of our products.

Foreign product sales represented approximately 21%, 16% and 22% of our total product sales for the years ended December 31, 2007, 2008 and 2009, respectively. The majority of these foreign sales were to Canada. We currently price our products in U.S. dollars. An increase in the value of the dollar in any foreign 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 a foreign currency, our competitive position may be enhanced.

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We continue our efforts to grow sales of **First Defense**<sup>®</sup> in North America, where there are approximately 9,000,000 cows in the United States and 1,000,000 cows in Canada. We believe that even greater market opportunities exist in foreign territories. There are estimated to be approximately 24,000,000 dairy cows in the European Union, another 9,000,000 in Russia, another 6,000,000 in Australia and New Zealand and another 900,000 in Japan. These figures do not consider potential sales in the beef markets. Industry practices, economic conditions and cause of disease may differ in these foreign markets from what we experience in the United States. We introduced **First Defense**<sup>®</sup> into South Korea in 2005 and its equivalent into Japan in 2007 through collaborations with in-country distributors.

Mastitis is estimated to cost U.S. dairy producers approximately \$1.7 to \$2 billion dollars per year. These losses include the cost of treatment products, reduced milk production, discarded milk and lost cows. We estimate that the U.S. market for the use of antibiotics to treat clinical mastitis in lactating cows is approximately \$40,000,000 per year and that a similar market opportunity also exists for the treatment of dry (non-lactating) cows and in markets outside the United States. 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 normal milk). The ability to treat such cases without a milk discard could dramatically change the way mastitis is managed in a herd. If **Mast Out**<sup>®</sup> is approved by the FDA as the first treatment for mastitis without a milk discard requirement, we believe it could expand the market for the treatment of subclinical mastitis and could compete effectively against the traditional antibiotic products currently on the market, which are all sold subject to a milk discard. It is difficult to evaluate the potential size of an as-yet undeveloped subclinical mastitis treatment market. A market may also exist for a dry cow application of the product, which would be subject to a separate regulatory approval.

## **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 are 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 believe that **First Defense**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> also competes for market share against vaccine products that are used to increase the mother cow's production of antibodies 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 that **First Defense**<sup>®</sup> provides to the calf is a competitive advantage over the vaccine products. **First Defense**<sup>®</sup> 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**<sup>®</sup> Dairy Wipes. **Wipe Out**<sup>®</sup> Dairy Wipes sell at a premium to most of them. These products include teat dips, teat sprays and other disposable and washable towel products offered by several different companies. Competitive advantages of **Wipe Out**<sup>®</sup> Dairy Wipes include that they are convenient to use, they do not irritate the udder, they do not adulterate the milk and they are biodegradable.

We would consider any company that sells an antibiotic to treat mastitis, such as Pfizer Animal Health (which recently acquired Fort Dodge Animal Health through its acquisition of Wyeth), Merck/Intervet/Schering Plough Animal Health and Boeringher Ingelheim, to be potential competitors for **Mast Out**<sup>®</sup>.

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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.

### **Employees**

We currently employ 31 full-time employees and 2 part-time employees. Approximately 17.25 full-time equivalent employees are engaged in manufacturing operations, 6.25 full-time equivalent employees in product development activities, 5.25 full-time equivalent employees in finance and administration and 3.25 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, 2010 were as follows:

**MICHAEL F. BRIGHAM** (Age: 49, 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 serves on the Board of Directors of the Maine Biotechnology Information Bureau and as the Treasurer of the Board of Trustees of the Kennebunk Free Library. Prior to joining the Company, he was employed as an audit manager for the public accounting firm of Ernst & Young. Mr. Brigham earned his Masters in Business Administration from New York University in 1989.

**JOSEPH H. CRABB, Ph.D.** (Age: 55, 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.

### **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 September 2004, we were issued U.S. Patent No. 6,794,181 entitled

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Method of Purifying Lantibiotics covering a key step in a manufacturing process for pharmaceutical-grade Nisin. We are investigating the merits of filing a new patent application directed toward what we believe to be a novel step in our manufacturing process.

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 **DiffGAM** and other 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 October 2002, we acquired ownership of this patent from the court administering the bankruptcy proceedings of GalaGen. These patents are included in the license we granted to Immuron, Ltd. (formerly known as Anadis) of Australia in March 2008.

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 contractual agreements. Reliance upon trade secret, rather than patent protection, may cause us to be vulnerable to competitors who successfully replicate our manufacturing techniques and processes. Additionally, there can be no assurance that others may not independently develop similar trade secrets or technology or obtain access to our unpatented trade secrets or proprietary technology. Other companies may have filed patent applications and may have been issued patents involving products or technologies potentially useful to us or necessary for us to commercialize our products or achieve our business goals. There can be no assurance that we will be able to obtain licenses to such patents on terms that are acceptable.

We have registered certain trademarks with the U.S. Patent and Trademark Office in connection with the sale of our products. We own federal trademark registrations of the following trademarks: ImmuCell, **First Defense**<sup>®</sup>, our calf scours preventive product; **Wipe Out**<sup>®</sup> **Dairy Wipes** and the related design and the trademark One Step Cow Pre<sup>®</sup>, our pre-milking wipe product; **MASTiR**<sup>®</sup>, our antibiotic susceptibility test; and **Mast Out**<sup>®</sup>. In addition, we sell an animal health product under the trademark, **rjt**.

## **Government Regulation**

We believe that we are in compliance with current regulatory requirements relating to our business and products. The manufacture and sale of animal health biologicals within the United States is generally regulated by the USDA. We have received USDA and Canadian Food Inspection Agency approval for **First Defense**<sup>®</sup> (our scours preventive product) and USDA approval for **rjt** (our Johne's Disease diagnostic test). **Mast Out**<sup>®</sup> is regulated by the FDA, Center for Veterinary Medicine, which regulates veterinary drugs. The manufacture of **Wipe Out**<sup>®</sup> **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.

## **Risk Factors; Forward-Looking Statements**

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;

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the scope and timing of future product development work and commercialization of our products; future costs of product development 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 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; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as "expects", "may", "anticipates", "intends", "would", "could", "should", "will", "plans", "targets" and similar words and expressions. 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, 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. 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 customers and the global economy and the uncertainties surrounding the potential for a prolonged global recession.

*Projections of loss before income taxes and net loss:* After nine consecutive years of reporting net income, we reported a loss before income taxes of \$(961,000) and a net loss of \$(469,000) for the year ended December 31, 2008 and a loss before income taxes of \$(429,000) and a net loss of \$(216,000) for the year ended December 31, 2009, due in large part to our current product development strategy. Continued development of **Mast Out**<sup>®</sup> will likely result in a net loss in 2010 as well. We believe that our current balance of cash and short-term investments is more than sufficient to fund our projected loss in 2010. Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Stronger than expected sales of **First Defense**<sup>®</sup>, for example, could diminish the overall loss. Conversely, weaker than expected sales of **First Defense**<sup>®</sup> could lead to larger losses. Another example of a factor that could increase our loss is if we experience unanticipated costs associated with developing and seeking regulatory approval of **Mast Out**<sup>®</sup>. Historically, we have not publicly disclosed our projections of future profitability. We did so in 2008 and 2009 and have done so again in 2010 to make it clear to our stockholders that the decision to pursue internal development of **Mast Out**<sup>®</sup> entails an important change in our financial model and strategy that, we believe, is in the long-term interests of the company and its stockholders.

*Exposure to risks associated with the current financial downturn and global economic crisis:* The U.S. economy is in a recession caused principally by the housing, credit and financial crises. The credit markets are very turbulent and uncertain. Sales and financial performance are down at most businesses. This extraordinary period of instability facing the U.S. economy and the financial markets has been troubling for nearly all Americans. To survive, companies are eliminating jobs, cutting or freezing pay, trimming hours, suspending matching contributions to 401(k) plans, reducing or doing away with health insurance, bonuses, or perks that were offered during better economic times, among other cost-saving measures. A continued and prolonged economic downturn could have a corresponding negative effect on our business and operations.

*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. A significant decrease in the herd size was expected in 2009, but the average only declined to 9,200,000. The herd size peaked at 9,334,000 in December 2008 and did decline to 9,082,000 in

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December 2009. As of February 2010, the herd size is estimated to be approximately 9,088,000 cows. The size of the milking herd affects the price of milk. The impact on the milk supply from this decrease in cows is offset, in part, by an increase in milk production per cow. Sales of our products may be influenced by the prices of milk, milking cows and calves. A common index used in the industry to measure the price of milk is known as the Class III milk price, which indicates the value of 100 pounds of milk sold into the cheese market. The average Class III milk price for 2008 was \$17.44 per 100 pounds, which represented a 3% decrease from the 2007 average of \$18.04. For 2009, this price level averaged \$11.36 which represents 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. 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. 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 foreign demand for milk products. However, the actual level of milk prices may be less important than their level relative to costs. Costs to produce milk are significant and to some extent can be managed by dairy producers. 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 2008, this ratio averaged 2.01. For 2009, this ratio averaged 1.77, representing a 12% decrease compared to 2008. This means that a dairy producer can buy only 1.77 pounds of feed for every pound of milk sold. Before the milk-feed ratio dropped to these very low levels beginning in early 2008, the ratio had not been this low since the 1970s. The 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 price received by producers for milking cows. In 2008, this average price is estimated to have increased to approximately \$1,953, which is a 6% increase over 2007. This price (reported as of January, April, July and October 2009) averaged approximately \$1,385, which represents a 29% decrease in comparison to the same period in 2008. 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. The decline in the price of bull calves has reduced the return on investment from a dose of **First Defense**<sup>®</sup> 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 loss in our sales 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**<sup>®</sup> could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms on suitable terms.

*Product risks generally:* The sale of our products is subject to financial, efficacy, regulatory and 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**<sup>®</sup>:* We are heavily reliant on the market acceptance of **First Defense**<sup>®</sup> to generate product sales and fund our operations. Our business would not have been profitable during the nine consecutive years in the period ended December 31, 2007, and our net losses would have been larger during the years ended December 31, 2008 and 2009, without the gross margin that we earned from the sale of **First Defense**<sup>®</sup>.

*Concentration of sales:* A large portion of our product sales (47% and 49% for the years ended December 31, 2008 and 2009, respectively) was made to three large distributors. A large portion of our trade accounts receivable (62% as of December 31, 2009) was due from these three distributors. We have a good

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history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us.

*Product development risks:* Our current strategy relies heavily on the development of new products, the most important of which is **Mast Out**<sup>®</sup>. The development of new products is subject to financial, scientific, regulatory and market risks. In particular, the development of **Mast Out**<sup>®</sup> requires (and will continue to require) substantial investments by us, and there is no assurance that we will obtain all of the clinical and other data necessary to support regulatory approval for this product. There is also no assurance that we will be able to obtain amounts of financing on terms acceptable to us, which together with our cash and short-term investments, will be sufficient to cover the costs associated with regulatory approvals, commercial manufacture and market launch of **Mast Out**<sup>®</sup> or any other new products. The capital markets for both debt and equity financing are challenging at present, and we are unsure as to whether, when, to what extent or on what terms such financing will be available to us. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Pfizer, Merck/Intervet/Schering Plough and Boehringer Ingelheim. There is no assurance that **Mast Out**<sup>®</sup> will compete successfully in this market.

*Regulatory requirements for Mast Out*<sup>®</sup>: The commercial introduction of **Mast Out**<sup>®</sup> in the United States will require us to obtain appropriate FDA approval for this product. Approval of a zero milk discard claim is an important competitive feature of this product. It presently is uncertain whether and when this approval will be achieved. Such approval will also require a successful inspection under cGMP standards by the FDA of the facilities used to manufacture the product. We have identified at least one potential commercial manufacturer for Nisin and have a preliminary evaluation of the potential costs, but we have not made a final determination of the cost or location of the commercial manufacturing facilities at this time. Foreign regulatory approvals would be required for sales outside of the United States. European regulatory authorities are not expected to approve a product with a zero milk discard claim, which would remove a significant competitive advantage of **Mast Out**<sup>®</sup> in that territory.

*Risks associated with USDA regulatory oversight:* Two of our products, and modifications and extensions thereto, are subject to the jurisdiction of the Center for Veterinary Biologics, USDA. Recent budgetary constraints at the USDA have caused significant delays in rulings and responses to submissions, according to the Association of Veterinary Biologics Companies, of which we are a member. Similar regulatory oversight risks exist in territories outside of the United States where we sell our products.

*Regulatory requirements for First Defense*<sup>®</sup>: **First Defense**<sup>®</sup> 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**<sup>®</sup> label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product.

*Regulatory requirements for Wipe Out*<sup>®</sup> *Dairy Wipes:* While the FDA regulates the manufacture and sale of **Wipe Out**<sup>®</sup>, this type of product is permitted to be sold without a NADA approval, in accordance with the FDA's Compliance Policy Guide 7125.30 ( Teat Dips and Udder Washes for Dairy Cows and Goats ). This policy guide could be withdrawn at the FDA's discretion, in which case we would likely discontinue sales of the product. The manufacture of **Wipe Out**<sup>®</sup> 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

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believe we have substantially corrected the deficiencies cited, but we remain subject to the risk of adverse action by the FDA in this respect.

*Uncertainty of market estimates:* Even assuming that **Mast Out**<sup>®</sup> achieves regulatory approval in the United States with a zero milk discard requirement, estimating the size of the market for this product is subject to numerous uncertainties. Some of the uncertainties surrounding our product include the development of the subclinical mastitis treatment market, coverage of relevant pathogens, selling price, 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 better established 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. 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.

*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 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.

*Small size:* We are a small company with approximately 32 full-time equivalent employees. As such, we rely on certain key employees to support different operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained.

*Our reporting obligations as a public company are costly:* Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws that are continuing to increase as provisions of the Sarbanes-Oxley Act of 2002 are implemented. As a smaller reporting company, the requirement that we comply with the provisions of Section 404(b) of the Sarbanes-Oxley Act has been deferred until fiscal year 2010. These reporting obligations will increase our operating costs.

*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**<sup>®</sup> and **Wipe Out**<sup>®</sup> **Dairy Wipes**. The specific antibodies that we purify for **First Defense**<sup>®</sup> and the Nisin we produce by fermentation for **Wipe Out**<sup>®</sup> **Dairy Wipes** are not readily available from other sources. Any significant damage to or other disruption in the services at this facility 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**<sup>®</sup> 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**<sup>®</sup>, although presently we do not anticipate that this will be the case.

*Biological terrorism:* The threat of biological terrorism is a risk to both the economic health of our customers and 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 shareholders 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. Shareholders 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: ICCG). Our average daily trading volume is lower than the volume for many other companies, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire.

## **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 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 May 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 May 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.

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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 RESERVED**

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Our common stock trades on the NASDAQ Capital Market tier of the NASDAQ Stock Market under the symbol ICCG. No dividends have been declared or paid on the common stock since its inception, and we do not 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, 2008 through December 31, 2009:

	2009				2008			
	March 31	Three Months Ended		December 31	March 31	Three Months Ended		December 31
		June 30	September 30			June 30	September 30	
High	\$ 2.25	\$ 2.97	\$ 4.75	\$ 4.50	\$ 4.08	\$ 3.99	\$ 3.87	\$ 3.20
Low	\$ 1.33	\$ 1.71	\$ 2.21	\$ 3.01	\$ 2.54	\$ 2.91	\$ 2.75	\$ 1.65

As of March 26, 2010, we had 8,000,000 common shares authorized and 2,970,652 common shares outstanding, and there were approximately 1,100 shareholders of record. The last sales price of our common stock on March 26, 2010 was \$3.52 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, 2009 or that could be granted in the future:

	Number of shares to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of shares remaining available for future issuance under stock-based compensation plans (excluding shares reflected in first column of this table)
Equity compensation plans approved by stockholders	401,000	\$ 3.54	6,667
Equity compensation plans not approved by stockholders	--	--	--
<b>Total</b>	<b>401,000</b>	<b>\$ 3.54</b>	<b>6,667</b>

**ITEM 6 SELECTED FINANCIAL DATA**

Not applicable

**ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Results of Operations***Fiscal Year 2009 Compared to Fiscal Year 2008**Product Sales*

Product sales for the year ended December 31, 2009 decreased by 3%, or \$123,000, to \$4,506,000 from \$4,628,000 in 2008. Domestic product sales decreased by 10%, or \$374,000, during the year ended December 31, 2009, while foreign sales increased by 34%, or \$252,000, in comparison to 2008. As we introduce our products



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(principally **First Defense**<sup>®</sup>) to markets outside of the United States, we expect some sales volatility in those territories. For example, foreign sales in 2008 decreased by 26% in comparison to 2007. The 2009 level of foreign sales was 58% higher than 2006 but 1% lower than 2007. We believe that sales of our products were influenced by the price of milk, cows and calves and by the cost of feed as well as by the number of cows in the U.S. dairy herd.

Sales of **First Defense**<sup>®</sup> decreased by 4% during the year ended December 31, 2009 in comparison to 2008. Sales of **First Defense**<sup>®</sup> are normally seasonal, with higher sales expected during the first and fourth quarters and lower sales expected during the second and third quarters. **First Defense**<sup>®</sup> continued to benefit in 2009 from wide acceptance by dairy and beef producers as an effective tool to prevent calf scours.

Sales of **Wipe Out**<sup>®</sup> **Dairy Wipes** decreased by 9% during the year ended December 31, 2009 in comparison to 2008. We believe that sales growth potential for **Wipe Out**<sup>®</sup> **Dairy Wipes** is limited because most of our sales of this product tend to be to smaller dairies that are under continued financial pressures that are forcing many small dairy producers out of business.

The other products we sell primarily into the dairy industry increased to 4% of product sales during the year ended December 31, 2009 compared to 3% of product sales during 2008. The other products we sell outside of the dairy and beef industries, principally Isolate (formerly known as **Crypto-Scan**<sup>®</sup>), aggregated 3% of product sales during the years ended December 31, 2009 and 2008.

We generally held our product selling prices without increase during the seven year period ended December 31, 2007. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense**<sup>®</sup>. We have implemented no significant price increases since then.

*Other Revenues*

Royalty income decreased by \$2,000 to just \$3,000 during the year ended December 31, 2009 in comparison to 2008, as the result of less sales reported by the firm that has licensed our milk protein purification technology. No product development grants or contracts have been applied-for or awarded since the first quarter of 2006.

*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	
	2009	2008	Amount	%
Gross margin	\$ 2,398	\$ 2,069	\$ 329	16%
Percent of product sales	53%	45%	8%	18%

We experienced an unusually low gross margin percentage during 2008 in comparison to those achieved in prior years. The gross margin as a percentage of product sales was 53% and 45% during the years ended December 31, 2009 and 2008, respectively. This compares to gross margin percentages of 52% and 56% for the years ended December 31, 2007 and 2006, respectively. Our current annual target is to maintain the gross margin percentage at around 50%. A number of factors account for the variability in our costs. We expect some fluctuations in gross margin percentages from quarter to quarter. The gross margin on **First Defense**<sup>®</sup> is affected by biological yields from our raw material, which do fluctuate over time. More generally, we are beginning to experience higher costs for production of **First Defense**<sup>®</sup> and **Wipe Out**<sup>®</sup> **Dairy Wipes** due to increased labor costs and expenses associated with our efforts to sustain compliance with cGMP regulations in our production

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processes. Like most manufacturers in the U.S., we have been experiencing increases in the cost of raw materials that we purchase. Product mix also affects gross margin in that we earn a higher gross margin on **First Defense**<sup>®</sup> and a lower gross margin on **Wipe Out**<sup>®</sup> **Dairy Wipes**. Because **First Defense**<sup>®</sup> customers are price sensitive, we had held its selling price without significant increase for about seven years, believing that we could benefit more from higher unit sales volume than through a higher average selling price per unit. However, during the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense**<sup>®</sup> reflecting a part of the increase we have experienced in our labor and raw material costs.

### *Product Development and Licensing*

Product development expenses decreased by 6%, or \$102,000, to \$1,645,000 during the year ended December 31, 2009, as compared to \$1,746,000 during 2008. Product development expenses aggregated 36% and 38% of total revenues in 2009 and 2008, respectively. The majority of our product development budget from 2000 through 2009 has been focused on the development of **Mast Out**<sup>®</sup>. Going forward, we expect to focus our internally-funded product development expenses on **Mast Out**<sup>®</sup> and other improvements, extensions or additions to our **First Defense**<sup>®</sup> product line and a sustained effort to maintain cGMP compliance in our manufacturing operations. The other improvements, extensions, or additions to our current product line include the potential to prevent scours in calves caused by pathogens other than those within the current **First Defense**<sup>®</sup> disease claims (*E. coli* K99 and coronavirus) such as rotavirus. We also remain interested in acquiring other new products and technologies that fit with our sales focus on the dairy and beef industries.

### *Administrative Expenses*

Administrative expenses decreased by approximately 6%, or \$54,000, to \$873,000 during the year ended December 31, 2009 as compared to \$926,000 during 2008. 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.

### *Product Selling Expenses*

Product selling expenses decreased by approximately 28%, or \$159,000, to \$411,000 in 2009, decreasing to 9% of product sales in 2009 from 12% in 2008. We continue to leverage the efforts of our small sales force through veterinary distributors. As we invest more to support **First Defense**<sup>®</sup> sales and begin to prepare for a market launch of **Mast Out**<sup>®</sup>, we anticipate an increase in these expenses. Our objective in 2010 is to maintain the ratio of product selling expenses to product sales at approximately 15% on an annual basis.

### *Interest Income*

Interest income decreased by approximately 53%, or \$108,000, to \$96,000 in 2009 in comparison to 2008 due principally to a decrease in interest rates and a reduction in funds invested during 2009. We have not incurred interest expense since we repaid our outstanding bank debt in May 2002.

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

Our loss before income taxes of \$(429,000) during the year ended December 31, 2009 compares to a loss before income taxes of \$(961,000) during the year ended December 31, 2008. We recorded income tax benefits of 49% and 51% of the losses before income taxes during the years ended December 31, 2009 and 2008, respectively. Our net loss of \$(216,000), or \$(0.07) per share, during the year ended December 31, 2009 compares to a net loss of \$(469,000), or \$(0.16) per share, during the year ended December 31, 2008.

**Table of Contents***Fiscal Year 2008 Compared to Fiscal Year 2007**Product Sales*

Product sales for the year ended December 31, 2008 decreased by 3%, or \$144,000, to \$4,628,000 from \$4,772,000 in 2007. Domestic product sales increased by 3% during the year ended December 31, 2008, while foreign sales decreased by 26%, in comparison to 2007. As we introduce our products (principally **First Defense**<sup>®</sup>) to markets outside of the United States, we expect some sales volatility in those territories. Despite the decline in 2008 in comparison to 2007, foreign sales in 2008 were 18% greater than foreign sales in 2006. We believe that sales of our products were influenced by the price of milk, cows and calves.

Sales of **First Defense**<sup>®</sup> decreased by 3% during the year ended December 31, 2008 in comparison to 2007. A 2% increase in our average selling price was more than offset by a 6% decrease in unit sales volume. Sales of **First Defense**<sup>®</sup> are normally seasonal, with higher sales expected during the first and fourth quarters and lower sales expected during the second and third quarters. **First Defense**<sup>®</sup> continued to benefit in 2008 from wide acceptance by dairy and beef producers as an effective tool to prevent calf scours.

Sales of **Wipe Out**<sup>®</sup> **Dairy Wipes** decreased by 2% during the year ended December 31, 2008 in comparison to 2007. Domestic sales were essentially unchanged in 2008. We believe that domestic sales growth potential 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.

The other products we sell primarily into the dairy industry increased to 3% of product sales during the year ended December 31, 2008 compared to 2% of product sales during 2007. The other products we sell outside of dairy and beef industries, principally Isolate (formerly known as **Crypto-Scan**<sup>®</sup>), increased to 3% of product sales during the year ended December 31, 2008 compared to 2% of product sales during 2007.

We generally held our product selling prices without increase during the seven-year period ended December 31, 2007. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense**<sup>®</sup>.

*Other Revenues*

Technology licensing revenue decreased by 100%, or \$1,248,000, during the year ended December 31, 2008 in comparison to 2007, due to the recognition during the third quarter of 2007 of all remaining deferred revenue from milestone payments under a product development and marketing agreement with Pfizer, which terminated during the third quarter of 2007. Royalty income decreased by \$44,000 to just \$5,000 during the year ended December 31, 2008 in comparison to 2007, as the result of less sales reported by the firm that has licensed our milk protein purification technology. No product development grants or contracts have been applied-for or awarded since the first quarter of 2006.

*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):

	Twelve Month Periods Ended December 31,		(Decrease)	
	2008	2007	Amount	%
Gross margin	\$ 2,069	\$ 2,504	\$ (435)	(17%)
Percent of product sales	45%	52%	(7%)	(13%)

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We experienced lower gross margin percentages in 2008 in comparison to those achieved in the past. The gross margin as a percentage of product sales was 45% and 52% during the years ended December 31, 2008 and 2007, respectively. This compares to gross margin percentages of 56% and 61% for the years ended December 31, 2006 and 2005, respectively. The gross margin percentage was unusually low during 2008. At the end of 2008, our target was to improve the gross margin percentage from 45% to closer to 50%. A number of factors accounted for the relative increase in costs and for their variability. We expect some fluctuations in gross margin percentages from quarter to quarter. The gross margin on **First Defense**<sup>®</sup> was adversely affected by biological yields from our raw material, which do fluctuate over time. More generally, we began in 2008 to experience higher costs for production of **First Defense**<sup>®</sup> and **Wipe Out**<sup>®</sup> **Dairy Wipes** due to increased labor costs and expenses associated with our efforts to implement compliance with cGMP regulations in our production processes. Like most manufacturers in the United States, in 2008, we experienced increases in the cost of raw materials that we purchase. Product mix also affects gross margin in that we earn a higher gross margin on **First Defense**<sup>®</sup> and a lower gross margin on **Wipe Out**<sup>®</sup> **Dairy Wipes**. Because **First Defense**<sup>®</sup> customers are price sensitive, we had held its selling price without significant increase for about seven years, believing that we could benefit more from higher unit sales volume than through a higher average selling price per unit. However, during the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense**<sup>®</sup> reflecting a part of the increase we have experienced in our labor and raw material costs.

### *Product Development and Licensing*

Product development expenses increased by 11%, or \$167,000, to \$1,746,000 during the year ended December 31, 2008, as compared to \$1,579,000 during 2007. Product development expenses aggregated 38% and 26% of total revenues in 2008 and 2007, respectively. During the year ended December 31, 2007, product development expenses included \$439,000, in amortization of the intangible asset pertaining to our November 2004 buy-out of certain future milestone and royalty payment obligations under our license to the animal health applications of Nisin. Net of these amortization expenses in 2007, product development expenses of \$1,746,000 and \$1,140,000, amounted to 38% and 24% of product sales during the years ended December 31, 2008 and 2007, respectively. The majority of our product development budget from 2000 through 2008 has been focused on the development of **Mast Out**.

### *General and Administrative Expenses*

General and administrative expenses increased by approximately \$83,000 (10%) to \$926,000 in 2008 as compared to \$843,000 in 2007. These increases resulted, in large part, from costs associated with complying with the Sarbanes-Oxley Act of 2002 and other costs associated with being a publicly-held company.

### *Product Selling Expenses*

Product selling expenses increased by approximately \$64,000 (13%) to \$570,000 in 2008, increasing to 12% of product sales in 2008 from 11% in 2007.

### *Interest Income*

Interest income decreased by approximately \$72,000 (26%) to \$204,000 in 2008 in comparison to 2007 due principally to a decrease in interest rates and a reduction in funds invested during 2008. We have not incurred interest expense since we repaid our outstanding bank debt in May 2002.

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

Our loss before income taxes of \$(961,000) during the year ended December 31, 2008 is in contrast to income before income taxes of \$1,144,000 during the year ended December 31, 2007. We recorded a 51% income tax benefit during the year ended December 31, 2008 and income tax expense at an effective tax rate of



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42% during the year ended December 31, 2007. Our income tax (benefit) expense included a deferred tax (benefit) expense of (\$108,000) and \$435,000 during the years ended December 31, 2008 and 2007, respectively. Our net loss of \$(469,000), or \$(0.16) per share, during the year ended December 31, 2008 is in contrast to net income of \$662,000, or \$0.22 per diluted share, during the year ended December 31, 2007.

**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.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
	(In thousands, except for per share amounts)				
<b>Statement of Operations Data:</b>					
Product sales	\$ 4,506	\$ 4,628	\$ 4,772	\$ 4,306	\$ 4,233
Total revenues	4,509	4,634	6,069	4,801	4,983
Gross margin from product sales	2,398	2,069	2,504	2,424	2,599
Product development expenses	1,645	1,746	1,579	966	1,270
Selling and administrative expenses	1,283	1,496	1,349	1,182	1,141
Net interest and other income	99	207	272	263	133
Income (loss) before income taxes	(429)	(961)	1,144	1,034	1,071
Net income (loss)	(216)	(469)	662	647	708

**Statement of Cash Flows Data:**

Net cash provided by (used for) operating activities	\$ (110)	\$ 53	\$ 350	\$ 1,583	\$ 765
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**Per Common Share:**

Basic net income (loss)	\$ (0.07)	\$ (0.16)	\$ 0.23	\$ 0.22	\$ 0.25
Diluted net income (loss)	\$ (0.07)	\$ (0.16)	\$ 0.22	\$ 0.21	\$ 0.24
Cash dividend	--	--	--	--	--

	As of December 31,				
	2009	2008	2007	2006	2005
	(In thousands, except for per share amounts)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 4,585	\$ 5,054	\$ 5,412	\$ 6,614	\$ 5,150
Total assets	9,985	10,128	10,412	11,364	9,955
Current liabilities	363	484	356	1,417	697
Net working capital	5,944	6,245	6,710	6,934	6,091
Long-term liabilities	--	--	--	615	700
Stockholders' equity	\$ 9,622	\$ 9,644	\$ 10,057	\$ 9,332	\$ 8,558

**Per Outstanding Common share:**

Cash, cash equivalents and short-term investments	\$ 1.54	\$ 1.75	\$ 1.87	\$ 2.28	\$ 1.81
Stockholders' equity	\$ 3.24	\$ 3.33	\$ 3.48	\$ 3.22	\$ 3.00

**Financial Condition, Liquidity and Capital Resources**

We had approximately \$4,585,000 in available cash and short-term investments as of December 31, 2009. We are using some of this cash to fund product development, principally **Mast Out**<sup>®</sup>, and to continue a sustained investment in compliance with cGMP regulations in our manufacturing operations. We continue to look for new product acquisition opportunities that would have a strategic fit with the products that we currently sell.

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The table below summarizes the changes in selected, key balance sheet items:

	Balance at December 31,		(Decrease)	
	2009	2008	\$	%
	(In thousands, except for percentages)			
Cash, cash equivalents and short-term investments	\$ 4,585	\$ 5,054	\$ (469)	(9)%
Net working capital	5,944	6,245	(301)	(5)%
Total Assets	9,985	10,128	(143)	(1)%
Stockholders' equity	\$ 9,622	\$ 9,644	\$ (22)	(0.2)%

Cash, cash equivalents and short-term investments decreased by 9%, or \$469,000, to \$4,585,000 at December 31, 2009 from \$5,054,000 at December 31, 2008. Net cash used for operating activities amounted to \$110,000 during the year ended December 31, 2009 as compared to net cash provided by operating activities of \$53,000 during the year ended December 31, 2008. After adding back \$424,000 in depreciation and amortization to and deducting deferred income taxes of \$(213,000) from the net loss incurred during the year ended December 31, 2009, the most significant use of cash for operating activities was due to an increase in inventories. Capital investments of \$460,000 were funded principally by cash and maturities of short-term investments. Net working capital decreased by 5%, or \$301,000, to \$5,944,000 at December 31, 2009 from \$6,245,000 at December 31, 2008. Total assets decreased by 1%, or \$143,000, to \$9,985,000 at December 31, 2009 from \$10,128,000 at December 31, 2008. We have no outstanding bank debt. Stockholders' equity decreased by less than 1%, or \$22,000, to \$9,622,000 at December 31, 2009 from \$9,644,000 at December 31, 2008.

As we implement process improvements, we are investing in personnel, equipment and facility improvements to increase the efficiency and quality of our operations. In June 2008, our Board of Directors authorized the investment of approximately \$775,000 for facility modifications and more production equipment to increase our production capacity. This authorization was in addition to \$254,000 that was included in the original 2008 budget for fixed asset investments. As of December 31, 2009, we had remaining Board authorization to spend up to \$158,000 under this capital expenditure budget net of the \$460,000 and \$411,000 we invested in capital expenditures during 2009 and 2008, respectively.

We believe that we have sufficient capital resources to meet our working capital requirements and to finance our ongoing business operations during at least the next twelve months. The return of the **Mast Out**<sup>®</sup> product rights to us has caused us to increase our spending on product development expenses that had been funded by Pfizer from 2005 to mid 2007. As expected, the expenditures on this program of product development resulted in net losses in 2009 and 2008 ending the nine consecutive years of profitability that we recorded through the year ended December 31, 2007. Continued development towards regulatory approval of **Mast Out**<sup>®</sup> will likely result in a net loss in 2010 as well. We believe that our current balance of cash and short-term investments is more than sufficient to fund our projected loss. We believe that the commercial prospects for **Mast Out**<sup>®</sup> warrant this level of investment. At this preliminary stage of our negotiations with a contract manufacturer, we are estimating that the investment required for full commercial manufacture of Nisin for **Mast Out**<sup>®</sup> for a possible product launch in 2011 will exceed our available cash. We are exploring opportunities to finance a portion of this investment including partner, debt and equity funding.

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 \$3,391,000 in product development expenses during 2008 and 2009 brings our cumulative investment to \$13,285,000 during the eleven-year period ended December 31, 2009. 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.

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### **Off-Balance Sheet Arrangements**

None

### **Effects of Inflation and Interest Rates; Currency Fluctuations**

We believe that neither inflation nor interest rates have had a significant effect on our revenues and expenses. Future increases in inflation or interest rates, however, could affect our customers and the demand for our products. We hope to increase the level of our future sales of products outside the United States. The cost of our products to foreign customers could be affected by currency fluctuations. The decline of the U.S. dollar against other currencies could make our products less expensive to foreign customers. Overall, however, we do not anticipate that currency fluctuations will significantly affect our sales or the cost of operations.

### **Critical Accounting Policies**

Details regarding the impact of new accounting pronouncements on our financial statements are provided in Note 2(m) to our financial statements. 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, 2009 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, except as described in the next paragraph.

In November 2004, we capitalized the \$965,000 payment we made to Nutrition 21, Inc. to buy out certain future milestone and royalty payment obligations, which principally resulted in a fully paid, perpetual license related to **Mast Out**<sup>®</sup>. We deferred the revenue from the \$2,150,000 in milestone payments that were received from Pfizer from December 2004 to September 2006 in connection with a product development and marketing agreement covering **Mast Out**<sup>®</sup>. Upon termination of this agreement in 2007, we wrote-off the remaining unamortized cost of technology rights and recognized the remaining deferred income from non-refundable milestone payments. This resulted in a net increase to income before income taxes of approximately \$602,000 during the third quarter of 2007.

Inventories include 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.

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**ITEM 8 FINANCIAL STATEMENTS**

Our financial statements, together with the notes thereto and the report of the independent registered public accounting firm thereon, are set forth on Pages F-1 through F-19 at the end of this report. The index to these financial statements is as follows:

<u>Report of Baker Newman &amp; Noyes, LLC, Independent Registered Public Accounting Firm</u>	F-1
<u>Balance Sheets as of December 31, 2008 and 2009</u>	F-2
<u>Statements of Operations for the years ended December 31, 2007, 2008 and 2009</u>	F-3
<u>Statements of Stockholders' Equity for the years ended December 31, 2007, 2008 and 2009</u>	F-4
<u>Statements of Cash Flows for the years ended December 31, 2007, 2008 and 2009</u>	F-5
<u>Notes to Financial Statements</u>	F-6 to F-19

**ITEM 9 CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND**

**FINANCIAL DISCLOSURE**

None

**ITEM 9A CONTROLS AND PROCEDURES**

*Disclosure Controls and Procedures.* Our management, with the participation of the individual who serves as our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2009. 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.

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Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2009. Based on management's assessment and those criteria, management believes that the internal control over financial reporting as of December 31, 2009 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 temporary 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 2010 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, 2009. 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 2010 Proxy Statement titled "Executive Officer Compensation", which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2009.

**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 2010 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, 2009.

**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 2010 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, 2009.

**ITEM 14 PRINCIPAL ACCOUNTING FEES AND SERVICES**

Information regarding our principal accountant fees and services is incorporated by reference to the section of our 2010 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, 2009.

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**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).
- 10.1+ 1989 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.1 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
- 10.2+ Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.2 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
- 10.3+ 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).
- 10.4+ 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).
- 10.5+ 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).
- 10.6+ Amendment to Employment Agreement between the Company and Michael F. Brigham dated March 26, 2010.
- 10.7+ Amendment to Employment Agreement between the Company and Joseph H. Crabb dated March 26, 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 Rule 13a-14(a) Certifications.
- 32 Section 1350 Certifications.

+ Management contract or compensatory plan or arrangement.

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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 balance sheets of ImmuCell Corporation (the Company) as of December 31, 2009 and 2008, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2009. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

We were not engaged to examine management's assessment of the effectiveness of ImmuCell Corporation's internal control over financial reporting as of December 31, 2009 included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting (Item 9A) and, accordingly, we do not express an opinion thereon.

Portland, Maine  
March 29, 2010

/s/ Baker Newman & Noyes  
Limited Liability Company

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**Table of Contents****IMMUCELL CORPORATION****BALANCE SHEETS****AS OF DECEMBER 31, 2008 and 2009**

	2008	2009
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,199,929	\$ 975,490
Short-term investments	3,854,103	3,610,000
Trade accounts receivable, net of allowance for doubtful accounts of \$8,000 and \$10,000 at December 31, 2008 and 2009, respectively	480,752	390,242
Income taxes receivable	362,474	1,248
Other receivables	51,378	24,022
Inventories	596,404	1,087,391
Current portion of deferred tax asset	91,537	38,507
Prepaid expenses	92,622	179,828
<b>Total current assets</b>	<b>6,729,199</b>	<b>6,306,728</b>
<b>PROPERTY, PLANT AND EQUIPMENT, at cost:</b>		
Laboratory and manufacturing equipment	2,480,400	2,820,425
Building and improvements	2,402,979	2,537,602
Office furniture and equipment	190,799	190,799
Construction in progress	84,827	--
Land	50,000	50,000
	5,209,005	5,598,826
Less-accumulated depreciation	2,273,663	2,619,828
Net property, plant and equipment	2,935,342	2,978,998
<b>LONG-TERM PORTION OF DEFERRED TAX ASSET</b>	<b>431,707</b>	<b>698,085</b>
<b>PRODUCT RIGHTS AND OTHER ASSETS, net of accumulated amortization of \$1,304,000 and \$1,335,000 at December 31, 2008 and 2009, respectively</b>	<b>31,945</b>	<b>900</b>
<b>TOTAL ASSETS</b>	<b>\$ 10,128,193</b>	<b>\$ 9,984,711</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accrued expenses	\$ 382,855	\$ 222,885
Accounts payable	101,637	139,885
<b>Total current liabilities</b>	<b>484,492</b>	<b>362,770</b>
<b>STOCKHOLDERS EQUITY:</b>		
Common stock, Par value-\$0.10 per share, Authorized-8,000,000 shares, Issued- 3,261,148 shares at December 31, 2008 and 2009	326,115	326,115
Capital in excess of par value	9,722,967	9,751,442
Accumulated surplus	396,372	179,879
Treasury stock, at cost- 366,496 and 290,496 shares at December 31, 2008 and 2009, respectively	(801,753)	(635,495)

Total stockholders' equity	9,643,701	9,621,941
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 10,128,193</b>	<b>\$ 9,984,711</b>

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

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**Table of Contents****IMMUCELL CORPORATION****STATEMENTS OF OPERATIONS****FOR THE YEARS ENDED DECEMBER 31, 2007, 2008 and 2009**

	2007	2008	2009
<b>REVENUES:</b>			
Product sales	\$ 4,772,331	\$ 4,628,308	\$ 4,505,759
Royalty income	49,306	5,382	2,887
Technology licensing revenue	1,247,550	--	--
<b>Total revenues</b>	<b>6,069,187</b>	<b>4,633,690</b>	<b>4,508,646</b>
<b>COSTS AND EXPENSES:</b>			
Product costs	2,268,817	2,559,053	2,107,678
Product development expenses	1,579,352	1,746,233	1,644,725
Administrative expenses	843,341	926,287	872,526
Product selling expenses	505,574	569,714	410,744
<b>Total costs and expenses</b>	<b>5,197,084</b>	<b>5,801,287</b>	<b>5,035,673</b>
Net operating income (loss)	872,103	(1,167,597)	(527,027)
Interest income	276,370	204,479	96,292
Other (expense) income, net	(4,830)	2,465	2,234
<b>Net interest and other income</b>	<b>271,540</b>	<b>206,944</b>	<b>98,526</b>
<b>INCOME (LOSS) BEFORE INCOME TAXES</b>	<b>1,143,643</b>	<b>(960,653)</b>	<b>(428,501)</b>
<b>INCOME TAX EXPENSE (BENEFIT)</b>	<b>481,505</b>	<b>(492,096)</b>	<b>(212,008)</b>
<b>NET INCOME (LOSS)</b>	<b>\$ 662,138</b>	<b>\$ (468,557)</b>	<b>\$ (216,493)</b>
<b>NET INCOME (LOSS) PER COMMON SHARE:</b>			
Basic	\$ 0.23	\$ (0.16)	\$ (0.07)
Diluted	\$ 0.22	\$ (0.16)	\$ (0.07)
<b>WEIGHTED AVERAGE COMMON SHARES</b>			
<b>OUTSTANDING:</b>			
Basic	2,897,488	2,893,597	2,958,784
Diluted	3,033,797	2,893,597	2,958,784

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

**Table of Contents****IMMUCELL CORPORATION****STATEMENTS OF STOCKHOLDERS EQUITY****FOR THE YEARS ENDED DECEMBER 31, 2007, 2008 and 2009**

	Common Stock \$0.10 Par Value		Capital in Excess of Par Value	Accumulated Surplus	Treasury Stock		Total Stockholders Equity
	Shares	Amount			Shares	Amount	
<b>BALANCE,</b>							
December 31, 2006	3,261,148	\$ 326,115	\$ 9,565,738	\$ 202,791	365,454	\$ (762,630)	\$ 9,332,014
Net income	--	--	--	662,138	--	--	662,138
Exercise of stock options	--	--	13,077	--	(12,000)	25,135	38,212
Stock-based compensation	--	--	87,224	--	--	--	87,224
Tax benefits related to stock options	--	--	2,833	--	--	--	2,833
Acquisition of treasury stock	--	--	--	--	15,218	(65,450)	(65,450)
<b>BALANCE,</b>							
December 31, 2007	3,261,148	326,115	9,668,872	864,929	368,672	(802,945)	10,056,971
Net loss	--	--	--	(468,557)	--	--	(468,557)
Exercise of stock Options, net	--	--	(1,190)	--	(2,176)	1,192	2
Stock-based compensation	--	--	55,285	--	--	--	55,285
<b>BALANCE,</b>							
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
<b>BALANCE,</b>							
December 31, 2009	3,261,148	\$ 326,115	\$ 9,751,442	\$ 179,879	290,496	\$ (635,495)	\$ 9,621,941

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

**Table of Contents****IMMUCELL CORPORATION****STATEMENTS OF CASH FLOWS****FOR THE YEARS ENDED DECEMBER 31, 2007, 2008 and 2009**

	2007	2008	2009
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income (loss)	\$ 662,138	\$ (468,557)	\$ (216,493)
Adjustments to reconcile net income to net cash provided by (used for) operating activities:			
Depreciation	309,087	363,770	394,295
Amortization	479,809	35,334	30,145
Deferred income taxes	435,203	(108,141)	(213,348)
Stock-based compensation	87,224	55,285	94,062
Loss on disposal of fixed assets	6,594	51,898	29,860
Changes in:			
Receivables	(172,369)	260,952	117,866
Income taxes receivable/payable	(367,199)	(235,602)	361,226
Inventories	200,569	(7,795)	(490,987)
Prepaid expenses and other assets	(10,613)	(22,982)	(86,306)
Accounts payable	23,853	(16,699)	29,985
Accrued expenses	(57,189)	145,674	(159,970)
Deferred revenue	(1,247,550)	--	--
Net cash provided by (used for) operating activities	349,557	53,137	(109,665)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property, plant and equipment	(1,527,825)	(410,624)	(459,548)
Maturities of short-term investments	5,850,341	4,903,880	3,854,103
Purchases of short-term investments	(4,803,885)	(4,539,103)	(3,610,000)
Net cash used for investing activities	(481,369)	(45,847)	(215,445)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Tax benefits related to stock options	2,833	--	921
Proceeds from exercise of stock options	38,212	2	99,750
Acquisition of treasury stock	(65,450)	--	--
Net cash (used for) provided by financing activities	(24,405)	2	100,671
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	(156,217)	7,292	(224,439)
<b>BEGINNING CASH AND CASH EQUIVALENTS</b>	1,348,854	1,192,637	1,199,929
<b>ENDING CASH AND CASH EQUIVALENTS</b>	\$ 1,192,637	\$ 1,199,929	\$ 975,490
<b>INCOME TAXES (PAID) REFUNDED, NET</b>	\$ (410,039)	\$ 147,730	\$ 360,777
<b>NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>			
Change in capital expenditures included in accounts payable	\$ (155,042)	\$ --	\$ 8,263

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



**Table of Contents****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, commonly referred to as the 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 2009 financial statement presentation.

**(b) Cash, Cash Equivalents and Short-Term Investments**

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits per financial institution are maintained in money market accounts at financial institutions that are secured, in part, by the Securities Investor Protection Corporation. Amounts in excess of these FDIC limits per bank that are not invested in securities backed by the U.S. government aggregated \$928,000 and \$704,000 at December 31, 2008 and 2009, respectively. Short-term investments are classified as held to maturity and are comprised principally of certificates of deposits that mature in more than three months from their purchase dates and not more than twelve months from the balance sheet date and are held at different financial institutions that are insured by the FDIC within FDIC limits. The Emergency Economic Stabilization Act of 2008 increased these insurance limits from \$100,000 each to \$250,000 per institution per depositor for the period from October 3, 2008 to December 31, 2009. During the second quarter of 2009, this period of increased insurance limits was extended through December 31, 2013.

Cash, cash equivalents and short-term investments consist of the following (in thousands):

	As of December 31,		
	2008	2009	(Decrease)
Cash and cash equivalents	\$ 1,200	\$ 975	\$ (225)
Short-term investments	3,854	3,610	(244)
	\$ 5,054	\$ 4,585	\$ (469)





**Table of Contents****IMMUCELL CORPORATION****NOTES TO AUDITED FINANCIAL STATEMENTS (Continued)****(c) Inventories**

Inventories include raw materials, work-in-process and finished goods and are 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. Inventories consist of the following (in thousands):

	As of December 31,		(Decrease)
	2008	2009	Increase
Raw materials	\$ 180	\$ 176	\$ (4)
Work-in-process	292	630	338
Finished goods	124	281	157
	\$ 596	\$ 1,087	\$ 491

**(d) 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 subsequent additions thereto completed in 2001 and 2007, 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.

**(e) 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. The \$75,000 acquisition of product rights related to **MASTiK®** in July 2000 was amortized to cost of sales through June 2008.

In November 2004, we capitalized a payment of approximately \$965,000 made to Nutrition 21, Inc. to buy out certain future milestone and royalty payment obligations relating principally to **Mast Out®**. In connection with Pfizer's termination of a product development and marketing agreement covering **Mast Out®**, we amortized the remaining balance of this asset during the third quarter of 2007. Product development expenses included such amortization expense amounting to approximately \$439,000 during the year ended December 31, 2007.

We continually assess the realizability of these assets in accordance with the impairment provisions of Codification Topic 360 (formerly known as Statement of Financial Accounting Standards (SFAS) No. 144, *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

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**IMMUCELL CORPORATION**

**NOTES TO AUDITED FINANCIAL STATEMENTS (Continued)**

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. There were no significant unamortized intangible assets remaining at December 31, 2009.

**(f) 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 and accounts payable. 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. 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. 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.

**(g) 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 collectibility is reasonably assured. 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. Revenues from non-refundable upfront payments are deferred and recognized ratably over the period during which the earning process is completed.

We received a \$1,500,000 up front payment from Pfizer in connection with the December 2004 product development and marketing agreement covering **Mast Out**<sup>®</sup>. During 2006, we received additional milestone payments aggregating \$650,000. We had been recognizing this revenue from the dates of receipt through December 31, 2008. In connection with Pfizer's termination of the agreement, the remaining deferred revenue was recognized during the third quarter of 2007. Accordingly, we recognized \$1,230,000 during the year ended December 31, 2007. The provisions of Codification Topic 605, *Revenue Recognition*, were considered in connection with these transactions. See Note 11.

**(h) Expense Recognition**

Advertising costs are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to \$202,000, \$140,000 and \$33,000 during the years ended December 31, 2007, 2008 and 2009, respectively. All product development expenses are expensed as incurred, as are all related patent costs.

**(i) Income Taxes**

We account for income taxes in accordance with Codification Topic 740, *Income Taxes* (formerly known as SFAS No. 109, *Accounting for Income Taxes*). This topic requires that we recognize a current tax



**Table of Contents****IMMUCELL CORPORATION****NOTES TO AUDITED FINANCIAL STATEMENTS (Continued)**

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 tax effects of temporary differences between book income and taxable income. Accordingly, we have not established a valuation allowance for the deferred tax assets. Effective January 1, 2007, we implemented the provisions of Codification Topic 740-10, which clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax provision must meet before being recognized in the financial statements. Adoption of this Topic did not have an impact on our financial condition, results of operations, earnings per share or cash flows. 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. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 4.

**(j) Net Income (Loss) Per Common Share**

The net income (loss) per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share* (formerly known as SFAS No. 128, *Earnings Per Share*). The basic net income per common share has been computed by dividing net income by the weighted average number of common shares outstanding during the period. The diluted net income per common share reflects the potential dilution from outstanding stock options as shown below. The net loss per common share has been computed by dividing the net loss by the weighted average number of common shares outstanding during the period, without giving consideration to outstanding stock options because the impact would be anti-dilutive.

	Year Ended December 31,		
	2007	2008	2009
Weighted average number of shares outstanding during the period	2,897,487	2,893,597	2,958,784
Dilutive stock options	338,654	--	--
Shares that could have been repurchased with the proceeds from the dilutive stock options	(202,344)	--	--
Diluted number of shares outstanding during the period	3,033,797	2,893,597	2,958,784
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	149,555	416,000	401,000

For additional disclosures regarding the outstanding common stock options, see Note 5(a) and (b).

**(k) 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.

**(l) Employee Stock-Based Compensation**

We account for the stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation* (formerly known as Revised SFAS No. 123, *Share-Based Payments*), which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-



**Table of Contents****IMMUCELL CORPORATION****NOTES TO AUDITED FINANCIAL STATEMENTS (Continued)**

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 5(b). Accordingly, we recorded \$87,000, \$55,000 and \$94,000 of compensation expense pertaining to stock-based compensation, which resulted in a reduction in income (or increase in loss) before income taxes of approximately \$0.03, \$0.02 and \$0.03 per share (before the effect of income taxes), during the years ended December 31, 2007, 2008 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 such tax deductions during the three years in the period ended December 31, 2009.

**(m) New Accounting Pronouncements**

Effective January 1, 2008, we implemented Codification Topic 820, *Fair Value Measurements and Disclosures* (formerly known as SFAS No. 157, *Fair Value Measures*). Codification Topic 820 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.

**3. ACCRUED EXPENSES**

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2008	2009
Professional fees	\$ 49	\$ 46
Payroll	124	133
Product development expenses	76	--
Other	134	44
	\$ 383	\$ 223

**Table of Contents****IMMUCELL CORPORATION****NOTES TO AUDITED FINANCIAL STATEMENTS (Continued)****4. INCOME TAXES**

We account for income taxes in accordance with Codification Topic 740, *Income Taxes* (formerly known as SFAS No. 109, *Accounting for Income Taxes*). This statement requires that we recognize a current tax liability or asset for current taxes payable or receivable 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 tax effects of temporary differences between book income and taxable income. Accordingly, we have not established a valuation allowance for the deferred tax assets. Our income tax expense aggregated \$482,000 (42% of income before income taxes) for the year ended December 31, 2007. Our income tax benefit aggregated \$(492,000) and \$(212,000) (51% and 50% of the loss before income taxes, respectively) for the years ended December 31, 2008 and 2009, respectively. The income tax provision consists of the following (in thousands):

	Year Ended December 31,		
	2007	2008	2009
Current			
Federal	\$ 34	\$ (384)	\$ --
State	11	--	1
Foreign	2	--	--
	47	(384)	1
Deferred			
Federal	340	(30)	(112)
State	95	(78)	(101)
	435	(108)	(213)
Total	\$ 482	\$ (492)	\$ (212)

Total currently payable income taxes were reduced by the benefits related to stock options of approximately \$3,000, \$0 and \$1,000 in 2007, 2008 and 2009, respectively. 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,		
	2007	2008	2009
Computed expected tax expense	\$ 389	\$ (327)	\$ (146)
State income taxes, net of federal benefit	70	(51)	(38)
Foreign tax on royalty income	2	--	--
Tax exclusion foreign sales and manufacturing activities	(3)	--	--
Share-based compensation	28	19	32
Research and development tax credit	--	(75)	(58)
Other	(4)	(58)	(2)
Total income tax expense (benefit)	\$ 482	\$ (492)	