

IMMUCELL CORP /DE/
Form 10-K
March 27, 2009
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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, 2008

.. 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 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, 2008 was approximately \$7,745,571, based on the closing sales price on June 30, 2008 of \$3.47 per share.

The number of shares outstanding of the Registrant's common stock outstanding at March 20, 2009 was 2,970,652.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement to be filed in connection with the 2009 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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ImmuCell Corporation was founded in 1982 and completed an initial public offering of common stock in 1987. We are an animal health biotechnology company serving veterinarians and producers in the dairy and beef industries with innovative and proprietary products that improve animal health and productivity. After achieving approval from the U.S. Department of Agriculture (USDA) to sell **First Defense**[®] 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**[®] and other products for the dairy industry.

With our shift in focus, we were able to record net income for each of the nine years in the period ended December 31, 2007. We feel that our approach to conservative financial management has 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**[®] product development expenses that were previously funded by a former licensee. We have been operating without debt since 2002, and we have not had to dilute our shareholders by raising equity to fund our operations. This approach, together with the divestiture of certain non-core assets, has funded our operations and improved our financial position, as demonstrated in the following table:

	As of December 31,		Increase	
	1998	2008	\$	%
	(In thousands, except for percentages)			
Cash, cash equivalents and short-term investments	\$ 1,539	\$ 5,054	\$ 3,515	228%
Net working capital	1,866	6,245	4,379	235%
Total assets	3,145	10,128	6,983	222%
Stockholders' equity	\$ 2,248	\$ 9,644	\$ 7,396	329%

This growth has been accomplished with only limited dilution to shareholders. We had approximately 2,429,000 shares of common stock outstanding as of December 31, 1998 in comparison to 2,895,000 as of December 31, 2008. There were approximately 480,000 and 416,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 1998 and 2008, respectively. During the ten years in the period ended December 31, 2008, we invested the aggregate of \$11,641,000 in product development expenses.

Over the past three years, we have 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 product quality and compliance with current regulations applicable to certain of our products and 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**[®] and Nisin technologies.

In 2000, we began the development of **Mast Out**[®], our Nisin-based treatment for 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**[®] justifies the costs of further development of the product. Therefore, we decided to pursue this work on our own and expect to complete the pivotal effectiveness study required for FDA approval during the first half of 2009. Upon completion of the treatment phase, it will take approximately two to three months to close out all

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clinical sites, perform statistical analysis of the data and discuss the results with the FDA before a public announcement of the study results can be made. Our increase in product development expenses resulted in a net loss in 2008. Continued development of **Mast Out**[®] will likely result in a net loss in 2009 as well. However, we believe that our current balance of cash and short-term investments is more than sufficient to fund our projected loss.

Animal Health Products for the Dairy and Beef Industries

Our lead product, **First Defense**[®], 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, calf scours, causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. **First Defense**[®] is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against *E. coli* K99 and coronavirus (two leading causes of scours). Harsh winter weather and severe temperature fluctuations cause stress to calves, and calves under stress are more susceptible to scours. Sales of our product into the beef industry are highly seasonal because most beef calves are born between January and April each year. During the first quarter of 2008, we sold our 8,000,000th dose of **First Defense**[®]. We are a leader in the scours prevention market with this product.

First Defense[®] 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**[®] provides immediate preformed immunity when calves need it most—during the first few critical days of life. A single dose of **First Defense**[®] provides a guaranteed level of protection proven to reduce mortality and morbidity from two major causes of scours. Studies have shown that calves that scour are more susceptible to other diseases and under-perform calves that do not contract scours. **First Defense**[®] is convenient. A calf needs to receive only one bolus of **First Defense**[®] within the first twelve hours after birth. The product is stored at room temperature and no mixing is required before it is given to the calf. There is no required slaughter withdrawal period for calves that are given **First Defense**[®].

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

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

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.

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In 2000, we acquired **MASTiK®**, **Mastitis Antibiotic Susceptibility Test Kit** from an entrepreneurial veterinarian. Once mastitis is detected, there are different treatment options. **MASTiK®** helps veterinarians and producers quickly select the antibiotic most likely to be effective in the treatment of individual cases of mastitis. **MASTiK®** 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®** 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. Before sales can be initiated in any state, 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 2008 and is expected to continue. We spent approximately \$966,000, \$1,579,000 and \$1,746,000 on product development activities during the years ended December 31, 2006, 2007 and 2008, respectively. These expenses included approximately \$220,000 and \$439,000 in non-cash amortization expenses during the years ended December 31, 2006 and 2007.

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®**. 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® 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®**, 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. The use of antibiotics in food-producing animals may be a contributing factor to the rising human public health problem of bacterial drug resistance. **Mast Out®** could potentially reduce the use of traditional antibiotics in the treatment of mastitis.

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. The safety profile of Nisin and its long history as a food preservative may allow for the use of **Mast Out®** 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®** could expand the subclinical mastitis treatment market niche. Regulations in the European Union will likely require that **Mast Out®** be sold subject to a milk discard requirement in that territory.

In January 2004, we achieved positive results from an experimental field trial of **Mast Out®** in 139 cows with subclinical mastitis. The placebo-controlled, blinded, multi-farm study was conducted in collaboration with researchers at Cornell University. **Mast Out®** demonstrated a statistically significant overall cure rate in two separate dosage groups as compared to the placebo group. The currently proposed treatment regimen (three doses

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at three consecutive milkings) demonstrated a 58% efficacy rate in eliminating infection in lactating cows with culture-confirmed mastitis (compared to a placebo cure rate of 10%). This efficacy rate represents a blended average of results from cows with mastitis caused by several different pathogens. For example, **Mast Out**[®] achieved a statistically significant 100% efficacy rate in *Streptococcus agalactiae* cases (compared to a placebo cure rate of 25%), where antibiotics are commonly used effectively, and a statistically significant 28% efficacy rate in *Staphylococcus aureus* cases (compared to a placebo cure rate of 0%), where antibiotics are often not effective.

In December 2004, we entered into a product development and marketing agreement with Pfizer Animal Health, a division of Pfizer, Inc. covering **Mast Out**[®]. In July 2007, we received notice from Pfizer that it had elected to terminate the product development and marketing agreement. Since then, Pfizer has 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**[®]. Under that agreement (as amended and supplemented), we received \$2,375,000 in payments from Pfizer. During 2005, Pfizer completed a study further supporting the effectiveness of **Mast Out**[®] in cows with subclinical mastitis. During 2006, Pfizer made significant progress developing data required for product registration in the areas of effectiveness, manufacturing and pharmacokinetics.

We do not believe that Pfizer's decision to terminate the product development and marketing agreement was based on any unanticipated efficacy or regulatory issues. Rather, we believe Pfizer's decision was primarily market driven, largely relating to concerns that the use of **Mast Out**[®] 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 guideline, currently estimated at approximately 2% of the herd on **Mast Out**[®] treatment in any given week. This guideline 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**[®] would outweigh the management costs associated with implementing this treatment guideline. Over time and with market acceptance of **Mast Out**[®], Nisin-resistant starter cultures could be developed using starter development and improvement programs that are common in the cheese industry for development of desirable culture characteristics such as phage-resistance and flavor development. These activities could result in relaxation or elimination of the herd-level treatment guidance. Our decision to continue product development efforts reflects our belief that **Mast Out**[®] 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.

In July 2007, we began preparations for the pivotal effectiveness study required for FDA approval of **Mast Out**[®]. Such preparations included the production of registration batches of drug product to fulfill the pivotal regulatory requirements of effectiveness, target animal safety, and stability at no less than 10% of the scale anticipated for commercial manufacture. In June 2008, we initiated the pivotal effectiveness study. We are working with more than a dozen investigators across the U.S. to complete this study. As of March 2009, we had enrolled approximately 67% of the qualified cases required to reach our targeted study size. It has taken longer than we first estimated to achieve the enrollment of the total number of cases meeting our clinical requirements, but we believe the extra time invested at this stage will provide us with more robust results. We expect to complete this study during the first half of 2009. Upon completion of the treatment phase, it will take approximately two to three months to close out all clinical sites, perform statistical analysis of the data and discuss the results with the FDA before a public announcement of study results can be made.

Commercial introduction of **Mast Out**[®] in the United States is subject to approval of our New Animal Drug Application (NADA) by the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine, which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets

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outside of the United States and would involve some similar and some different requirements. While positive results from a pivotal effectiveness study are necessary to support continued development of **Mast Out**[®], the approval of several additional Technical Sections under the FDA's phased review of a NADA is also required. Included among the additional Technical Sections required for NADA final approval are: 1) Environmental Impact, 2) Target Animal Safety, 3) Human Food Safety, 4) Chemistry, Manufacturing and Controls (CMC) and 5) several administrative requirements. During the third quarter of 2008, we received the Environmental Impact Technical Section Complete Letter from the FDA. Work required for the Target Animal Safety Technical Section has been initiated, and critical studies are planned for 2009. The Human Food Safety data will determine if a milk discard period will not be required. The Human Food Safety Technical Section includes several subsections such as residue chemistry (which is in progress), total metabolism (which is complete), effects of drug residues in food on human intestinal microbiology (which is under FDA review), effects on bacteria of human health concern or antimicrobial resistance (which is complete) and toxicology (which is complete). Toxicology studies establish an Acceptable Daily Intake (ADI) level for humans, and the toxicological ADI for Nisin supports a zero milk and meat withhold claim. The toxicology studies were similar to the studies performed by others that affirmed the Generally Regarded As Safe (GRAS) status of Nisin for use as a food preservative. All of these subsections must be completed before the Human Food Safety Technical Section Complete Letter establishing a zero milk discard or a milk withhold period can be issued by the FDA.

Before the CMC Technical Section can be completed, a commercial scale manufacturing site for the Active Pharmaceutical Ingredient (API) that is compliant with current Good Manufacturing Practice (cGMP) regulations must be identified. This site will be subject to FDA approval and inspection. As the result of work we have done with outside companies to examine manufacturing options, we have recently determined that contracting for the manufacture of the API may require investments that could potentially deplete all of our available cash. We are not prepared to take that risk at this time without a licensing partner. We do have a commercial 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. We intend to complete all the Technical Sections pertaining to the safety, effectiveness and zero milk discard claims during 2009. Subject to achieving these critical development milestones, it is our objective to enter into an alliance with a partner that could help underwrite the commercial manufacturing costs and complete the CMC Technical Section and subsequently optimize the launch, distribution and sales of **Mast Out**[®].

In addition to our work on **Mast Out**[®], 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**[®] claims). In connection with that effort, during the second quarter of 2006 we obtained an option to an exclusive license from Baylor College of Medicine covering certain rotavirus vaccine technology. We anticipate converting this option into a license during the second quarter of 2009. Additionally, during the second quarter of 2007, we acquired an option to an exclusive license from Ohio State University covering certain rotavirus technology. Results from recently completed pilot studies justify conducting a pivotal effectiveness study in 2009. This study could position us for USDA approval of a product effective against scours caused by rotavirus in 2010. 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. As additional opportunities arise to commercialize our own technology, or licensable technology, we may begin new development projects.

We believe that market opportunities for growth of **First Defense**[®] 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**[®] in Australia and New Zealand. In March 2008, we entered into a license agreement with Anadis, Ltd. (now known as Immuron) of Australia. Under this agreement, we gained access to

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relevant production technology and capabilities of Immuron in Australia. We are obligated to pay Immuron a royalty on any sales of **First Defense**[®] 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**[®] is sold primarily through major veterinarian distributors. We primarily sell **Wipe Out**[®] **Dairy Wipes** directly to dairy producers. **MASTiK**[®] 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. Selling expenses amounted to 11%, 11% and 12% of product sales in the years ended December 31, 2006, 2007 and 2008, respectively. Our budget guideline has been to invest less than 15% of product sales in selling expenses.

First Defense[®] is generally sold through large, financially strong distributors, which we believe has resulted in minimal bad debt with respect to this product. We provide for a 50% account credit on expired **First Defense**[®] product, which has a two-year shelf life resulting in an immaterial amount of returns. **Wipe Out**[®] **Dairy Wipes** are generally sold directly to dairy producers, but we have experienced only a minimal problem with uncollectible accounts receivable in connection to 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 15%, 21% and 16% of our total product sales for the years ended December 31, 2006, 2007 and 2008, 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 may decline with respect to a foreign currency, our competitive position may be enhanced.

While we continue our efforts to grow sales of **First Defense**[®] in North America, 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 6,000,000 in Australia and New Zealand and another 900,000 in Japan, in comparison to approximately 9,000,000 in the U.S. and 1,000,000 in Canada, without considering 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 U.S. We introduced **First Defense**[®] into South Korea in 2005 and Japan in 2007 through collaborations with in-country distributors.

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 outside the U.S. 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**[®] 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.

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Competition

Our competition in the animal health market includes other biotechnology companies and major animal health companies. Many of these competitors have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do. Many 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**[®] 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, competitive products currently on the market provide protection only against one leading cause of calf scours (*E. coli*), while **First Defense**[®] provides this protection and additional protection against coronavirus, another leading cause of the disease. In addition to direct competition from oral antibody products, **First Defense**[®] also competes for market share against vaccine products that are used to increase the 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**[®] provides to the calf is a competitive advantage over the vaccine products. **First Defense**[®] also competes against scours preventives that are not licensed by the USDA.

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

We would consider any company that sells an antibiotic to treat mastitis, such as Pfizer Animal Health, Intervet/Schering Plough Animal Health and Wyeth (Fort Dodge Animal Health), to be potential competitors for **Mast Out**[®].

We may not be aware of competition that we face from other companies. Our competitive position will be highly influenced by our ability to attract and retain key scientific and managerial personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products 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 30 full-time employees and 2 part-time employees. Approximately 16.5 full-time equivalent employees are engaged in manufacturing operations, 6.5 full-time equivalent employees in product development activities, 6 full-time equivalent employees in finance and administration and 2 full-time equivalent employees in sales. Approximately 25 of these employees joined the Company since January 1, 2006. 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 Registrant

Our executive officers as of March 20, 2009 were as follows:

MICHAEL F. BRIGHAM (Age: 48, 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

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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: 54, Officer since March 1996, Director since March 2001) was appointed to serve as a Director of the Company in March 2001, having previously served in that capacity during the period from March 1999 until February 2000, and 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** from Nutrition 21, Inc., we acquired a license to several patents covering the use of Nisin in antibacterial wipes as well as certain proprietary know-how used in the production of Nisin. In April 2000, we acquired from Nutrition 21 an additional license to several patents covering the use of Nisin in specific antibacterial formulations in the veterinary field of use. In November 2004, we bought out certain future milestone and royalty obligations under this license, which principally resulted in a fully paid, perpetual license related to the animal health applications of Nisin. In September 2004, we were issued U.S. Patent No. 6,794,181 entitled **Method of Purifying Lantibiotics** covering a key step in the manufacturing process for pharmaceutical-grade Nisin.

In 2000, we were issued U.S. Patent No. 6,074,689 entitled **Colonic Delivery of Protein or Peptide Compositions** covering the method of formulation that can be used to deliver **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 Anadis, Ltd. (now known as Immuron) 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.

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We have registered certain trademarks with the U.S. Patent and Trademark Office in connection with the sale of our products. We own federal trademark registrations of the following trademarks: **First Defense**[®], our calf scours preventive product; **Wipe Out**[®] **Dairy Wipes** and the related design and the trademark **One Step Cow Prep**[®], our pre-milking wipe product; **MASTi**[®], our antibiotic susceptibility test; and **Mast Out**[®]. 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 approval for **First Defense**[®] (our scours preventive product) and **rjt** (our Johne's Disease diagnostic test). **Mast Out** is regulated by the FDA, Center for Veterinary Medicine, which regulates veterinary drugs. The manufacture of **Wipe Out**[®] **Dairy Wipes** also is regulated by the FDA, Center for Veterinary Medicine. Comparable agencies exist in foreign countries and foreign sales of our products will be subject to regulation by such agencies. Many states have laws regulating the production, sale, distribution or use of biological products, and we may have to obtain approvals from regulatory authorities in states in which we propose to sell our products. Depending upon the product and its applications, obtaining regulatory approvals may be a relatively brief and inexpensive procedure or it may involve extensive clinical tests, incurring significant expenses and an approval process of several years' duration.

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.

Product Opportunities Outside of the Dairy and Beef Industries

1) Product to Detect Cryptosporidium in Drinking Water

Capitalizing on certain scientific knowledge gained while working on a milk antibody product to prevent *Cryptosporidium parvum* infections in humans during the early 1990's, we developed the water diagnostic test, Crypto-Scaff. This non-animal health product utilizes our immunomagnetic separation technology. Despite gaining U.K. regulatory approval in November 2000, our sales of this product had been insignificant. In April 2005, we entered into an exclusive distribution agreement with TCS Biosciences Ltd. of England covering sales of this product in the European Union, Japan, and Australia, under which we are the exclusive manufacturer and supplier of the product to TCS. TCS has made some modifications to the test kit and obtained the necessary U.K. regulatory approval of the modified test. TCS sells this product under its trade name, Isolate Cryptosporidium.

2) Milk Protein Purification Technology for Nutritional Applications

In 1996, we formed a joint venture with Agri-Mark Inc. of Methuen, Massachusetts known as AgriCell Company, LLC to produce and sell lactoferrin, a nutritional protein derived from cheese whey. We licensed certain rights to a patented purification system to AgriCell for use in the production of lactoferrin. In March 2003, DMV International Nutritionals paid us \$1,100,000 for our interest in the joint venture, which payment was in addition to \$100,000 paid by DMV in August 2001 for an option to buy our interest. We have no ongoing interest in or obligations to this operation.

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In 1997, we licensed certain rights to the same patented protein purification system described above to Murray Goulburn Co-operative Co., Limited of Australia for the production of whey protein isolate and certain other milk proteins (excluding high purity lactoferrin). In consideration for the license, we received a \$250,000 payment in 1997 and are entitled to a royalty on the sales of whey protein isolate and any other milk proteins manufactured under this license. In early 2000, Murray Goulburn launched commercial sales of whey protein isolate. We earned approximately \$21,000, \$49,000 and \$5,000 in royalty income in 2006, 2007 and 2008, respectively, under this agreement.

3) *Milk Antibody Products for Humans*

During the 1990 s, we conducted several trials investigating the use of milk antibodies produced utilizing our **First Defense**® technology to prevent gastrointestinal infections caused by *Cryptosporidium parvum*, enterotoxigenic *E. coli* (Traveler s Diarrhea) and *Clostridium difficile* in humans. We discontinued internal funding of the last of these products in 2000. In March 2008, we granted Anadis, Ltd. of Australia an exclusive, worldwide license to the human and environmental applications of our milk antibody technology. In 2008, Anadis changed its name to Immuron. Under this agreement, we are not obligated to fund further product development and are entitled to a royalty on any sales achieved by Immuron utilizing our technology.

Under an Investigational New Drug application filed with the FDA in March 1997, we conducted a clinical trial in mid-1997 demonstrating the safety of DiffGAM anti-*Clostridium difficile* milk immunoglobulins and the colonic bioavailability of our patented oral formulation. We completed a multi-site, open label Phase I/II clinical trial of this product in 2000. The results of this trial demonstrated the preliminary safety and efficacy of DiffGAM in the treatment of *Clostridium difficile* associated diarrhea, a debilitating gastrointestinal disease that can be precipitated by the use of broad-spectrum antibiotics. The available scientific literature and the product s safety profile may be sufficient to allow for sales of DiffGAM as a nutritional supplement.

In 2003, we became part of a consortium with the Naval Medical Research Center and John Hopkins University which received funding under the Department of Defense Peer Reviewed Medical Research Program to study the development of a bovine milk immunoglobulins supplement to prevent diarrhea in humans. We earned approximately \$66,000 and \$12,000 during the years ended December 31, 2005 and 2006, respectively, to complete our work under this grant to supply TravelGAM anti-E. coli milk immunoglobulins for in vitro and in vivo trials. During 2006, our collaborators demonstrated preliminary efficacy of TravelGAM in a challenge/protection study in humans. This work was presented at the 41st Joint Conference on Cholera and other Bacterial Infections in Japan on November 7, 2006.

4) *Skin and Environment Sanitizing Products*

In connection with the December 1999 acquisition of **Wipe Out**® **Dairy Wipes**, we acquired certain exclusive rights to develop Nisin as a skin and environment sanitizer. These rights do not cover drug claims for specific indications or food preservation. There is significant published scientific literature that supports the broad-spectrum, antibacterial activity of Nisin. The expertise being developed in the manufacture of Nisin for our animal health products, **Wipe Out**® **Dairy Wipes** and **Mast Out**®, may benefit us in developing and selling Nisin formulations for additional animal disease indications or for skin and environment sanitizing applications.

During 2002, we collaborated with the U.S. Army s Edgewood Chemical Biological Center to investigate the effectiveness of Nisin against *Bacillus anthracis*. The major conclusions of this work were that: 1) Nisin formulations containing excipients selected from certain classes of detergents and chelators, kill vegetative cells and germinating spores of *B. anthracis*, *megaterium* and *cereus*, 2) Nisin alone has potent killing activity against *B. cereus* and *megaterium*, but not *B. anthracis* and 3) Nisin in the formulations tested does not kill spores of any species of *Bacillus*. This work was accepted and presented at the Biodefense Research Meeting of the American Society for Microbiology in March 2003. The participation of a marketing partner would be required to further develop and commercialize this potential product opportunity.

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During 2006, we completed a collaborative study of Nisin susceptibility in methicillin-resistant canine staphylococcal isolates with investigators at University of Pennsylvania School of Veterinary Medicine. One hundred isolates of methicillin-resistant canine *Staphylococcus aureus* (MRSA), *intermedius* and *schleiferi* were tested and found to be highly susceptible to Nisin's antibacterial activity. These data were presented at the 2007 North American Veterinary Dermatology Forum in Kauai, Hawaii. During the second quarter of 2008, we completed a study in collaboration with the University of Tennessee evaluating the effectiveness of Nisin impregnated wipes used to treat skin infections in dogs. The study consisted of two separate clinical feasibility studies, each of which was defined by the severity of canine skin infections. In the first study, 10 dogs with localized surface skin infections were treated with Nisin impregnated wipes as a stand alone therapy for 2 weeks. The second study consisted of treating 20 dogs that had more severe skin infections generally located in multiple sites on the body. The skin infections in the second study were treated with Nisin impregnated wipes in conjunction with systemic antibiotics. While this study was not designed to show statistical significance, the results do suggest that Nisin could be effective against pyoderma caused by common bacteria, such as methicillin-resistant canine *staphylococcus aureus* (MRSA). The results confirmed our expectation that Nisin is not as effective against fungal and gram negative causes of pyoderma. We continue to evaluate whether further development of this or other Nisin formulations is warranted, and we remain open to out-licensing this product opportunity to a partner more focused on the companion animal market than we are.

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; future costs of development-related efforts; future realization of deferred tax assets; future regulatory requirements relating to our products; factors that may affect the dairy industry and future demand for our products; the scope and timing of future development work and commercialization of our products; anticipated changes in our manufacturing capabilities; the timing of anticipated applications for future regulatory approvals; anticipated future product development efforts; the future adequacy of our working capital; future expense ratios; costs and timing associated with achieving compliance with cGMP regulations; and any other statements that are not historical facts. 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 Quarterly 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, due in large part to our current product development strategy. In our Annual Report on Form 10-KSB for the year ended December 31, 2007, we projected that loss before income taxes would be approximately \$500,000 to \$750,000. In our Quarterly Report on Form 10-Q for the three months ended September 30, 2008, we revised the amount of the projected loss before income taxes to approximately \$600,000 to \$750,000. We exceeded this estimated amount by \$211,000 principally due to an unexpected decrease in gross margin on product sales. Continued development of **Mast Out**[®] will likely result in a net loss in 2009 as well. We believe that our current balance of cash and short-term investments is more than sufficient to fund our projected loss. Generally speaking, our financial performance can differ significantly from the management projections, due to numerous factors that are difficult to predict or that are beyond our control. Stronger than

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expected sales of **First Defense**[®], for example, could diminish the overall loss. Conversely, weaker than expected sales of **First Defense**[®] could lead to larger losses. Another example of a factor that could increase our loss beyond the current projection is if we experience unanticipated costs associated with developing and seeking regulatory approval of **Mast Out**[®]. Historically, we have not publicly disclosed our projections of future profitability. We did so in 2008 and have done so again in 2009 to make it clear to our stockholders that the decision to pursue internal development of **Mast Out**[®] entails an important change in our financial model and strategy, but one that we believe we have sufficient cash reserves to fund.

We are exposed 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, doing away with health care, 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 dairy industry in the United States has been facing very difficult economic pressures. The number of small dairy producers continues to decrease. The milk price strengthened significantly in 2007 and held approximately at the 2007 average level during the first nine months of 2008. Then during the fourth quarter of 2008, milk prices began to deteriorate and are expected to decline significantly in 2009. While any decrease in the sales value of milk is not good for our customers, dairy producers are also facing increases in the costs to produce milk. The size of the U.S. dairy herd has remained consistently in the range of approximately 9,000,000 to 9,300,000 cows over the last ten years, but a significant decrease in the herd size is expected in 2009. 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 that we buy raw material from could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms.

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

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.

*Reliance on sales of **First Defense**[®]:* We are heavily reliant on the market acceptance of **First Defense**[®] to generate product sales and fund our operations. Our business would not have been profitable during the nine consecutive years in the period ended December 31, 2007, and our net loss would have been larger during the year ended December 31, 2008, without the gross margin that we earned from the sale of **First Defense**[®].

Product development risks: Our current strategy relies heavily on the development of new products, the most important of which is **Mast Out**[®]. The development of new products is subject to financial, scientific, regulatory and market risks. In particular, the development of **Mast Out**[®] requires substantial investments by us, and there is no assurance that we will obtain the necessary clinical and other data necessary to support regulatory approval for this product. There is also no assurance that our capital resources will prove to be sufficient to cover the costs associated with regulatory approvals, commercial manufacture or market launch of **Mast Out**[®] or any other new products. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Pfizer, Fort Dodge and Intervet/Schering Plough. There is no assurance that **Mast Out**[®] will compete successfully in this market.

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Competition from others: 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 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.

Small size: We are a small company with approximately 31 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, we need to implement additional provisions of the Sarbanes Oxley Act during fiscal year 2009. 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**[®] and **Wipe Out**[®] **Dairy Wipes**. The specific antibodies that we purify for **First Defense**[®] and the Nisin we produce by fermentation for **Wipe Out**[®] **Dairy Wipes** are not readily available from other sources. Any disruption in the services at this facility could adversely affect the production of inventory.

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.

*Regulatory requirements for **First Defense**[®]:* **First Defense**[®] 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**[®] 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 declined to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product.

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Regulatory requirements for Wipe Out® Dairy Wipes: While the FDA regulates the manufacture and sale of **Wipe Out®**, 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. The manufacture of **Wipe Out®** is subject to Part 211 of the cGMP regulations. As such, our operations are subject to inspection by the FDA. We are investing in personnel, facility improvements and new equipment to bring our manufacturing operations into compliance with cGMP regulations across our entire product line. In June 2007, we received a Warning Letter from the FDA citing deficiencies in specific areas of the cGMP regulations. We filed a response to the FDA in June 2007, and we responded to a request for additional information in April 2008. We believe we have substantially corrected the deficiencies, but we remain subject to the risk of adverse action by the FDA in this respect.

Regulatory requirements for Mast Out®: The commercial introduction of **Mast Out®** in the United States will require us to obtain appropriate FDA approval for this product. 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 U.S. European regulatory authorities are not likely to approve a product with a zero milk discard claim, which would remove a significant competitive advantage of **Mast Out®** in that territory.

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®** 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®**, 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. 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 conditions, conditions, contractual restrictions, restrictions imposed by applicable laws and other factors our Board deems relevant.

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>.

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ITEM 2 DESCRIPTION OF PROPERTY

We own a 26,800 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 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 this project, we also added approximately 2,500 square feet of mezzanine storage space in the second floor. This investment is an integral part of our strategy to become compliant with cGMP regulations in our manufacturing operations. We funded this project from available cash.

We rent approximately 550 square feet of office and warehouse space in New York State on a short-term basis to support our farm operations.

We maintain property insurance in amounts that approximate replacement cost. We also maintain access to certain animals, primarily cows, through contractual relationships with several commercial dairy farms.

ITEM 3 LEGAL PROCEEDINGS

None

ITEM 4 SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

Table of Contents**PART II****ITEM 5 MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock trades on the NASDAQ Capital Market tier of the NASDAQ Stock Market under the symbol ICCG. No dividends have been declared or paid on the common stock since 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, 2007 through December 31, 2008:

	2007				2008			
	March 31	June 30	September 30	December 31	March 31	June 30	September 30	December 31
High	\$ 6.44	\$ 6.12	\$ 6.23	\$ 4.88	\$ 4.08	\$ 3.99	\$ 3.87	\$ 3.20
Low	\$ 5.03	\$ 5.16	\$ 3.56	\$ 3.27	\$ 2.54	\$ 2.91	\$ 2.75	\$ 1.65

As of March 20, 2009, 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 20, 2009 was \$2.00 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, 2008 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	416,000	\$ 3.42	95,667
Equity compensation plans not approved by stockholders	--	--	--
Total	416,000	\$ 3.42	95,667

ITEM 6 SELECTED FINANCIAL DATA

Not applicable

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION**Results of Operations***Fiscal Year 2008 Compared to Fiscal Year 2007**Product Sales*

Product sales for the year ended December 31, 2008 decreased by \$144,000 (3%) 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**[®]) 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

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believe that sales of our products may be influenced by the price of milk, 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 represents a 3% decrease from the 2007 average of \$18.04. However, this price has declined in 2009. The average for the months of January and February 2009 was \$10.05 in comparison to \$18.18 for the same period in 2008. For a point of reference, the average for all of 2002 was \$10.42, which approximates the price levels experienced during the 1970 s. While any decrease in the sales value of milk is not good for our customers, dairy producers are also facing increases in the costs to produce milk. One measure of this relationship is known as the milk-to-feed ratio. The milk-to-feed ratio measures the amount of feed that can be purchased with one pound of milk. In January 2009, the milk-to-feed ratio of 1.69 was the worst it has ever been since the USDA began using the profitability measure in 1985. A ratio of 1.69 means that a dairy producer can buy 1.69 pounds of feed for every pound of milk sold. Whenever the ratio meets or exceeds 3.0, it is considered profitable to buy feed and produce milk. Another indication of the economic condition of the dairy industry is the price received by producers for milk cows. In 2008, this price is estimated to have increased by approximately 6% to \$1,953 in comparison to \$1,840 per cow in 2007, but this value is declining in 2009. During 2008, the value of bull calves in the dairy industry declined materially making it less economical to treat bull calves with **First Defense**[®]. The size of the U.S. dairy herd has remained consistently in the range of approximately 9,000,000 to 9,300,000 cows over the last ten years, but a significant decrease in the herd size is expected in 2009.

Sales of **First Defense**[®] decreased by 3% during the year ended December 31, 2008 in comparison to the same period in 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**[®] 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**[®] continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent calf scours. During the second quarter of 2006, certain regional organic certifying agencies determined that the ingredients in **First Defense**[®] are in compliance with the National Organic Program (NOP) and may be considered for use on organic farms. **First Defense**[®] should be considered a preventive vaccine as described in USDA-NOP regulations for organic producer consideration when establishing management plans.

Sales of **Wipe Out**[®] **Dairy Wipes** decreased by 2% during the year ended December 31, 2008 in comparison to the same period in 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 \$116,000 during the year ended December 31, 2008 compared to \$108,000 during the same period in 2007. The other products we sell outside of dairy and beef industries, principally Isolate (formerly known as **Crypto-Scan**[®]), increased slightly to \$119,000 during the year ended December 31, 2008 compared to \$116,000 during the same period in 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**[®].

Other Revenues

Technology licensing revenue decreased by 100%, or \$1,248,000, during the year ended December 31, 2008 in comparison to the same period in 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 the same period in 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.

Table of Contents*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%)

We now experience lower gross margin percentages 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 30, 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. Our current annual target is to improve the gross margin percentage from 45% to closer to 50%. A number of factors account 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**[®] was adversely 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**[®] and **Wipe Out**[®] 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 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**[®] and a lower gross margin on **Wipe Out**[®] Dairy Wipes. Because **First Defense**[®] 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**[®] 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 the same period in 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**[®]. Going forward, we expect to focus our internally-funded product development expenses on **Mast Out**[®] and other improvements, extensions or additions to our current product line and an effort to achieve 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**[®] 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.

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 result, 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.

Table of Contents*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. We continue to leverage the efforts of our small sales force through veterinary distributors. Our objective is to maintain the ratio of product selling expenses to product sales below 15% on an annual basis.

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.

Loss Before Income Taxes and Net 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 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 (\$0.16 per share) during the year ended December 31, 2008 is in contrast to net income of \$662,000 (\$0.22 per diluted share) during the year ended December 31, 2007.

*Fiscal Year 2007 Compared to Fiscal Year 2006**Product Sales*

Product sales for the year ended December 31, 2007 increased by \$466,000 (11%) to \$4,772,000 from \$4,306,000 in 2006, primarily due to growth in sales of **First Defense**[®]. We believe that sales of our products may be influenced by the price of milk, heifers 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 2007 was \$18.04 per 100 pounds, which represents a 52% increase over the 2006 average of \$11.89. The average for 2006 decreased by 15% from the 2005 average of \$14.05. For a point of reference, this price level was \$10.42 in 2002, which approximates the price level experienced during the 1970 s. While an increase in the sales value of milk is good for our customers, some of this benefit has been offset by an increase in the cost to produce milk. One measure of this relationship is known as the milk-to-feed ratio. The milk-to-feed ratio measures the amount of feed that can be purchased with one pound of milk. In December 2007, this ratio dropped below the 3.0 level for the first time since June 2007, but this level is still above levels experienced in 2006. Another indication of the economic condition of the dairy industry is the price received by producers for milk cows. In 2007, this price is estimated to have increased by approximately 6% to \$1,840 in comparison to \$1,735 per cow in 2006. This 2006 price is estimated to have held relatively flat in comparison to \$1,773 in 2005.

Sales of **First Defense**[®] increased by 16% during the year ended December 31, 2007 in comparison to the same period in 2006. This increase was principally driven by higher sales volume rather than higher selling prices. Sales of **First Defense**[®] 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**[®] continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent calf scours. During the second quarter of 2006, certain regional organic certifying agencies determined that the ingredients in **First Defense**[®] are in compliance with the National Organic Program (NOP) and may be considered for use on organic farms. **First Defense**[®] should be considered a preventive vaccine as described in USDA-NOP regulations for organic producer consideration when establishing management plans.

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Sales of **Wipe Out® Dairy Wipes** decreased by 24% during the year ended December 31, 2007 in comparison to the same period in 2006. Domestic sales were essentially unchanged in 2007, and sales of this product into South Korea of approximately \$90,000 during the year ended December 31, 2006 were not repeated in 2007. We believe that domestic sales growth potential is limited because most of our sales of this product tend to be to smaller farms 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 \$108,000 during the year ended December 31, 2007 compared to \$88,000 during the same period in 2006. The other products we sell outside of dairy and beef industries, principally Isolate (formerly known as **Crypto-Scan®**), decreased to \$116,000 during the year ended December 31, 2007 compared to \$121,000 during the same period in 2006.

We have generally held our product selling prices without increase for the past seven years. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense®**.

Other Revenues

Due primarily to the recognition of all remaining non-cash deferred technology licensing revenue during the third quarter of 2007, other revenues increased by 162%, or \$801,000, to \$1,297,000 during the year ended December 31, 2007 in comparison to the same period in 2006. Technology licensing revenue increased by 170%, or \$786,000 to \$1,248,000 during the year ended December 31, 2007 in comparison to the same period in 2006, 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 increased by \$28,000 during the year ended December 31, 2007 in comparison to the same period in 2006, as the result of higher 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,		Increase (Decrease)	
	2007	2006	Amount	%
Gross margin	\$ 2,504	\$ 2,424	\$ 80	3%
Percent of product sales	52%	56%	(4%)	(7%)

Product costs amounted to 48% of product sales in 2007 as compared to 44% in 2006. Driven primarily by increased sales of **First Defense®**, the gross margin on product sales increased by \$80,000 (3%) to \$2,504,000 from \$2,424,000 in 2006. Internally developed products such as **First Defense®** tend to have higher gross margin percentages than acquired products. We anticipate a moderately lower gross margin percentage initially as new products are developed and acquired. Our gross margin percentage during 2007 was somewhat lower than normally expected during the nine month period ended September 30, 2007. We experienced some temporary inefficiencies during the renovation of our facility, which generally resulted in decreased output with no decline in labor and overhead costs. During the nine month period ended September 30, 2007, the gross margin on **First Defense®** also was adversely affected by biological yields from our raw material, which do fluctuate over time. Product mix also affects gross margin in that we earn a higher gross margin on **First Defense®** and a lower gross margin on **Wipe Out® Dairy Wipes**. More generally, we are beginning to experience higher costs for production of **First Defense®** and **Wipe Out® Dairy Wipes** due to increased labor costs and expenses associated with our efforts to implement compliance with cGMP regulations in our production processes.

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Because **First Defense**[®] customers tend to be price sensitive, we have held its selling price without significant increase for approximately the past seven years, believing that we can benefit more from higher unit sales volume than through a higher average selling price per unit. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense**[®] 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 64%, or \$613,000, to \$1,579,000 during the year ended December 31, 2007, as compared to \$966,000 during the same period in 2006. Product development expenses aggregated 26% and 20% of total revenues in 2007 and 2006, respectively. During the years ended December 31, 2007 and 2006, product development expenses included \$439,000 and \$220,000, respectively, 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, product development expenses of \$1,140,000 and \$746,000, amounted to 24% and 17% of product sales during the years ended December 31, 2007 and 2006, respectively. The majority of our product development budget from 2000 through 2007 has been focused on the development of **Mast Out**[®]. Going forward, we expect to focus our internally-funded product development expenses on **Mast Out**[®] and other improvements, extensions or additions to our current product line and an effort to achieve cGMP compliance in our manufacturing operations.

In addition to the development efforts on **Mast Out**[®], we are actively exploring further improvements, extensions, or additions to our current product line. We are investigating the potential to prevent scours in calves caused by pathogens other than those within the current **First Defense**[®] disease claims (*E. coli* K99 and coronavirus). We also remain interested in acquiring other new products and technologies that fit with our sales focus on the dairy and beef industries.

General and Administrative Expenses

General and administrative expenses increased by approximately \$132,000 (18%) to \$843,000 in 2007 as compared to \$712,000 in 2006. These increases result, in large part, from increased stock-based compensation expense (approximately \$44,000 during 2007 compared to \$18,000 during 2006), 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 \$35,000 (7%) to \$506,000 in 2007, aggregating 11% of product sales in 2007 and 2006. We continue to leverage the efforts of our small sales force through veterinary distributors. Our objective is to maintain the ratio of product selling expenses to product sales below 15% on an annual basis.

Interest Income

Interest income increased by approximately \$8,000 (3%) to \$276,000 in 2007 in comparison to 2006 due principally to an increase in interest rates in 2007 that was offset, in part, by a reduction in funds invested during 2007. We have not incurred interest expense since we repaid our outstanding bank debt in May 2002.

Income Before Income Taxes and Net Income

Upon termination of the product development and marketing agreement with Pfizer, we recognized \$931,000 in related deferred revenue and amortized \$329,000 of an associated intangible technology asset, resulting in a \$602,000 net increase to income before income taxes during the third quarter of 2007. During the year ended December 31, 2007, we recognized \$1,248,000 in deferred revenue related to the product

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development and marketing agreement, and we recorded \$439,000 in amortization expense pertaining to the associated intangible technology asset, resulting in a net increase to income before income taxes of \$808,000.

Income before income taxes of \$1,144,000 for the year ended December 31, 2007 compares to \$1,034,000 for the year ended December 31, 2006. We recorded income tax expense at an effective tax rate of 42% and 37% in 2007 and 2006, respectively, resulting in net income of \$662,000 and \$647,000 for the years ended December 31, 2007 and 2006, respectively. Income tax expense included a deferred tax expense (benefit) of \$435,000 and (\$101,000) for the years ended December 31, 2007 and 2006, respectively. The increase in the effective tax rate was largely due to an increase in non tax deductible stock-based compensation expense. Our net income during the years ended December 31, 2007 and 2006 was \$662,000 (\$0.22 per diluted share) and \$647,000 (\$0.21 per diluted share), respectively.

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,				
	2004	2005	2006	2007	2008
	(In thousands, except for per share amounts)				
Statement of Operations Data:					
Product sales	\$ 3,524	\$ 4,233	\$ 4,306	\$ 4,772	\$ 4,628
Total revenues	3,696	4,983	4,801	6,069	4,634
Gross margin from product sales	2,075	2,599	2,424	2,504	2,069
Product development expenses	1,092	1,270	966	1,579	1,746
Selling and administrative expenses	1,035	1,141	1,182	1,349	1,496
Net interest and other income	56	133	263	272	207
Income (loss) before income taxes	177	1,071	1,034	1,144	(961)
Net income (loss)	144	708	647	662	(469)
Statement of Cash Flows Data:					
Net cash provided by operating activities	\$ 1,358	\$ 765	\$ 1,583	\$ 350	\$ 53
Per Common Share:					
Basic net income (loss)	\$ 0.05	\$ 0.25	\$ 0.22	\$ 0.23	\$ (0.16)
Diluted net income (loss)	\$ 0.05	\$ 0.24	\$ 0.21	\$ 0.22	\$ (0.16)
Cash dividend	--	--	--	--	--
	As of December 31,				
	2004	2005	2006	2007	2008
	(In thousands, except for per share amounts)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 4,450	\$ 5,150	\$ 6,614	\$ 5,412	\$ 5,054
Total assets	9,530	9,955	11,364	10,412	10,128
Current liabilities	814	697	1,417	356	484
Net working capital	4,998	6,091	6,934	6,710	6,245
Long-term liabilities	986	700	615	--	--
Stockholders' equity	\$ 7,729	\$ 8,558	\$ 9,332	\$ 10,057	\$ 9,644
Per Outstanding Common share:					
Cash, cash equivalents and short-term investments	\$ 1.59	\$ 1.81	\$ 2.28	\$ 1.87	\$ 1.75
Stockholders' equity	\$ 2.77	\$ 3.00	\$ 3.22	\$ 3.48	\$ 3.33

Table of Contents**Financial Condition, Liquidity and Capital Resources**

We had approximately \$5,054,000 in available cash and short-term investments as of December 31, 2008. We are using some of this cash to fund product development, principally **Mast Out**[®], and to invest in our efforts to become compliant 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.

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

	Balance at December 31,		(Decrease)	
	2007	2008	\$	%
	(In thousands, except for percentages)			
Cash, cash equivalents and short-term investments	\$ 5,412	\$ 5,054	\$ (358)	(7%)
Total assets	10,412	10,128	(284)	(3%)
Net working capital	6,710	6,245	(465)	(7%)
Stockholders' equity	\$ 10,057	\$ 9,644	\$ (413)	(4%)

Cash, cash equivalents and short-term investments decreased by 7%, or \$358,000, to \$5,054,000 at December 31, 2008 from \$5,412,000 at December 31, 2007. Net cash provided by operating activities amounted to \$53,000 during the year ended December 31, 2008 as compared to \$350,000 during the year ended December 31, 2007. After adding back \$399,000 in depreciation and amortization to the net loss incurred during the year ended December 31, 2008, the most significant uses of cash for operating activities were due to the timing of income tax payments and deferred income taxes. Capital investments of \$411,000 were funded principally by maturities of short-term investments. Total assets decreased by 3%, or \$284,000, to \$10,128,000 at December 31, 2008 from \$10,412,000 at December 31, 2007. We have no outstanding bank debt. Net working capital decreased by 7%, or \$465,000, to \$6,245,000 at December 31, 2008 from \$6,710,000 at December 31, 2007. Stockholders' equity decreased by 4%, or \$413,000, to \$9,644,000 at December 31, 2008 from \$10,057,000 at December 31, 2007, primarily as a result of loss incurred during 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 a facility addition and more production equipment to increase our production capacity by providing more production and warehouse space, a more efficient loading dock and significantly more on-site cold storage. This authorization was in addition to \$254,000 that was included in the original 2008 budget for fixed asset investments. In September 2008, we decided to postpone most of this project until at least the spring of 2009 to avoid the added costs of winter construction. We also wanted to use the additional time to finalize the design and permitting, solicit more competitive construction bids and monitor the status of the economy and our business. As of December 31, 2008, we have Board authorization to spend up to \$904,000 on this project and other fixed asset investments.

The return of the **Mast Out**[®] 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 a net loss in 2008 ending the nine consecutive years of profitability that we recorded during the period ended December 31, 2007. Continued development towards regulatory approval of **Mast Out**[®] will likely result in a net loss in 2009 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**[®] warrant this level of investment.

With approximately \$5,054,000 in cash and short-term investments as of December 31, 2008, 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. Although we also believe that these cash reserves should be sufficient to fund our development of **Mast Out**[®], we have decided that the cost of a cGMP

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manufacturing facility is too high for us to undertake with current resources. Therefore, we plan to seek a partner to help share the anticipated costs and risks associated with developing the required manufacturing capacity to achieve FDA approval and to help launch, distribute and sell the product.

Nisin for **Wipe Out® Dairy Wipes** had been produced for us under subcontract since the product's acquisition in 1999. During 2003, we began making building modifications and fixed asset acquisitions necessary to bring the production process in-house. This project was completed in 2004 for approximately \$423,000. This manufacturing process was further improved during 2005 and 2006. This facility was also used during 2005 to produce clinical material for **Mast Out®** studies.

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 have been 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 part, by \$975,000 in grant awards. The investment of an additional \$1,746,000 in product development expenses during 2008 brings our cumulative investment to \$11,641,000 during the ten year period ended December 31, 2008. 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.

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(l) 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, 2008 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.

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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. Non-refundable grant income is recognized as reimbursable expenses are incurred. Indirect costs which are billed to the government are subject to their review. 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**[®]. 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**[®]. Upon termination of this agreement in 2007, we recognized the remaining deferred income from non-refundable milestone payments and wrote-off the remaining unamortized cost of technology license rights. 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.

ITEM 8 FINANCIAL STATEMENTS

Our financial statements, together with the notes thereto and the report of the independent registered public accounting firm thereon, are set forth on Pages F-1 through F-18 at the end of this report. The index to these financial statements is as follows:

<u>Report of Baker Newman & Noyes, LLC, Independent Registered Public Accounting Firm</u>	F-1
<u>Balance Sheets as of December 31, 2007 and 2008</u>	F-2
<u>Statements of Operations for the years ended December 31, 2006, 2007 and 2008</u>	F-3
<u>Statements of Stockholders' Equity for the years ended December 31, 2006, 2007 and 2008</u>	F-4
<u>Statements of Cash Flows for the years ended December 31, 2006, 2007 and 2008</u>	F-5
<u>Notes to Financial Statements</u>	F-6 to F-18

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

None

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ITEM 9A(T) 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, 2008. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (ii) is accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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

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

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. Based on management's assessment and those criteria, management believes that the internal control over financial reporting as of December 31, 2008 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, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

Information with respect to our directors is incorporated herein by reference to the section of our 2009 Proxy Statement titled "Election of the Board of Directors", which we intend to file with the Securities and Exchange Commission within 120 days after the end of our fiscal year. 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 Registrant*. 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 2009 Proxy Statement titled "Executive Compensation", which we intend to file with the Securities and Exchange Commission within 120 days after the end of our fiscal year.

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 2009 Proxy Statement titled "Security Ownership of Certain Beneficial Owners and Management", which we intend to file with the Securities and Exchange Commission within 120 days after the end of our fiscal year.

ITEM 13 CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Information regarding certain relationships and related transactions is incorporated herein by reference to the section of our 2009 Proxy Statement titled "Certain Relationships and Related Transactions", which we intend to file with the Securities and Exchange Commission within 120 days after the end of our fiscal year.

ITEM 14 PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information regarding our principal accountant fees and services is incorporated by reference to the section of our 2009 Proxy Statement titled "Principal Accountant Fees and Services", which we intend to file with the Securities and Exchange Commission within 120 days after the end of our fiscal year.

ITEM 15 EXHIBITS

- 3.1 Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's 1987 Registration Statement Number 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.
- 3.3 Certificate of Amendment to the Company's Certificate of Incorporation effective August 24, 1992.
- 3.4 Bylaws of the Registrant as amended.
- 4.1 Rights Agreement dated as of September 5, 1995, between the Registrant 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 Registrant's Current Report on Form 8-K dated September 5, 1995).
- 4.1A Second Amendment to Rights Agreement dated as of June 30, 2008.
- 10.1+ 1989 Stock Option and Incentive Plan of the Registrant.

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10.2+	Form of Incentive Stock Option Agreement.
10.3+	Form of Indemnification Agreement (updated) entered into with each of the Registrant's Directors and Officers (incorporated by reference to Exhibit 10.3A to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006).
10.4+	Employment Agreement dated April 29, 1999 between the Registrant and Michael F. Brigham.
10.5+	Employment Agreement dated April 29, 1999 between the Registrant and Joseph H. Crabb.
10.6+	2000 Stock Option and Incentive Plan of the Registrant.
10.7+	Form of Incentive Stock Agreement.
10.8+	Amended Employment Agreement dated as of January 1, 2005 between the Registrant and Joseph H. Crabb (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 4, 2005).
10.9+	Amended and restated Employment Agreement between the Registrant and Joseph H. Crabb, effective July 28, 2005 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 28, 2005).
14	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003).
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 as of December 31, 2008 and 2007, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2008. 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.

As discussed in note 2(k) to the financial statements, in 2006 ImmuCell Corporation changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123R, *Share-Based Payments*.

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, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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, 2008 included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting (Item 9A(T)) and, accordingly, we do not express an opinion thereon.

Portland, Maine
March 25, 2009

/s/ Baker Newman & Noyes
Baker Newman & Noyes, LLC