

IMMUCELL CORP /DE/
Form 10-K
March 23, 2006
Table of Contents

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, 2005

OR

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

0-15507

(Commission file number)

IMMUCELL CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

Registrant's telephone number, including area code: (207) 878-2770

01-0382980
(I.R.S. Employer
Identification No.)

04103
(Zip Code)

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 Section 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 a check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by a 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 Common Stock held by non-affiliates of the Registrant at June 30, 2005 was approximately \$9,974,000.

The number of shares of the Registrant's Common Stock outstanding at March 21, 2006 was 2,859,813.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement to be filed in connection with the 2006 Annual Meeting of Shareholders are incorporated by reference into Part III hereof.

Table of Contents

TABLE OF CONTENTS

PART I

ITEM 1.	<u>Business</u>	1
ITEM 1A.	<u>Risk Factors; Forward-looking Statements</u>	9
ITEM 1B.	<u>Unresolved Staff Comments</u>	10
ITEM 2.	<u>Properties</u>	11
ITEM 3.	<u>Legal Proceedings</u>	11
ITEM 4.	<u>Submission of Matters to a Vote of Security Holders</u>	11

PART II

ITEM 5.	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	12
ITEM 6.	<u>Selected Financial Data</u>	13
ITEM 7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
ITEM 7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
ITEM 8.	<u>Financial Statements and Supplementary Data</u>	18
ITEM 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	18
ITEM 9A.	<u>Controls and Procedures</u>	18
ITEM 9B.	<u>Other Information</u>	19

PART III

ITEM 10.	<u>Directors and Executive Officers of the Registrant</u>	19
ITEM 11.	<u>Executive Compensation</u>	19
ITEM 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	19
ITEM 13.	<u>Certain Relationships and Related Transactions</u>	19
ITEM 14.	<u>Principal Accountant Fees and Services</u>	19

PART IV

ITEM 15.	<u>Exhibits and Financial Statement Schedules</u>	20
----------	---	----

SIGNATURES

Table of Contents**PART I****ITEM 1 BUSINESS****General**

ImmuCell Corporation is a biotechnology company serving veterinarians and producers in the dairy and beef industries with innovative and proprietary products that improve animal health and productivity. From inception in 1982, we have been engaged in the research and development, manufacture and sales of diagnostic tests and products for therapeutic and preventive use against certain infectious diseases in animals and humans. Prior to 1999, we invested significant funds in the development of products utilizing our core technologies for human health product applications. Since 1999, we have focused our product development efforts on products that improve animal health and productivity for the dairy and beef industries.

Animal health products are generally less expensive to develop than the human health applications that we had pursued during the 1990 s. With our shift in focus, we have been able to record net income for each of the past seven years. During this period, our profitability, together with 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	2005	\$	%
	(In thousands, except for percentages)			
Cash, cash equivalents and short-term investments	\$ 1,539	\$ 5,150	\$ 3,611	235%
Net working capital	1,866	6,091	4,225	226%
Total assets	3,145	9,955	6,810	217%
Shareholders' equity	\$ 2,248	\$ 8,558	\$ 6,310	281%

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 2,850,000 shares as of December 31, 2005.

In December 2004, we entered into a product development and marketing agreement with Pfizer Animal Health, a division of Pfizer Inc., covering **Mast Out**[®], our Nisin-based treatment for mastitis in lactating dairy cows. We granted Pfizer a worldwide, exclusive, long-term license to sell the product. In return, we received an up front payment of \$1,500,000 from Pfizer and are eligible to receive additional, contingent milestone payments, as well as royalties on any future sales, with specified minimum royalties. Subject to the satisfaction of certain designated conditions, we expect to receive an additional \$750,000 in milestone payments in 2006. Further milestone payments may be earned in future years upon attainment of clinical trial objectives, regulatory approvals and patent issuances. During 2005, Pfizer completed an initial efficacy study of **Mast Out**[®] in cows with sub-clinical mastitis and is proceeding with further development of **Mast Out**[®]. Based on the information now available to us, we have extended by one additional year (to December 31, 2008) our original estimate of the product development period over which certain **Mast Out**[®]-related deferred revenue is being recognized and a related license buy out payment to Nutrition 21, Inc. is being amortized. Pfizer is responsible for clinical, regulatory and commercial manufacturing development, and thus the timing of these development efforts is largely outside our control.

Animal Health Products for the Dairy and Beef Industries

Our lead product, **First Defense**[®], which was approved by the U.S. Department of Agriculture (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. Calves under stress are more susceptible to scours. Harsh winter weather and severe temperature fluctuations cause stress to calves. Sales of our product into the beef industry are

Table of Contents

highly seasonal because most beef calves are born between January and April each year. **First Defense**[®] is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against two leading causes of scours (K99+ *E. coli* and coronavirus). We are a leader in the scours prevention market with this product.

Newborn calves respond poorly, if at all, to vaccines, and they do not always get the antibodies they need from maternal colostrum. **First Defense**[®] provides antibodies that newborn calves need but are unable to produce on their own. Vaccines require time for the immune systems to develop a response. **First Defense**[®] provides preformed immunity and immediate protection 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 disease and under-perform calves that never get sick. **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.

We acquired **Wipe Out**[®] **Dairy Wipes**, which is our second leading source of product sales, from Nutrition 21, Inc. in December 1999. 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 a natural 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 strong enough to allow for a vigorous cleaning but still biodegradable for disposal with the manure waste. The wiping process can help promote milk letdown.

In 2000, we acquired **MASTiK**[®], **Mastitis Antibiotic Susceptibility Test Kit**. 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 provide this answer 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 2001, we began to offer our own, internally developed **California Mastitis Test (CMT)**. This test can be performed at cow-side for early detection of mastitis. **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. **CMT** products are also made by other manufacturers and are readily available to the dairy producer. Our product is priced at a discount to the competitive products that were already on the market when we initiated commercial sales.

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. We also sell **rpt** (formerly also sold as **Accufirm**), a milk progesterone test used by dairy producers to monitor the reproductive status of their cows. Sales of these two products have been limited since their commercial introduction.

Table of Contents

Research and Development

Beginning in 1999, we shifted the primary focus of our research and development efforts to products for the dairy and beef industries. This focus has been maintained through 2005 and is expected to continue in 2006 and beyond. We spent approximately \$1,350,000, \$1,092,000, and \$1,270,000 on research and development activities during the years ended December 31, 2003, 2004 and 2005, respectively. These expenditures were supported, in part, by grant income totaling approximately \$112,000, \$67,000, and \$66,000 during the years ended December 31, 2003, 2004 and 2005, respectively.

In April 2000, Nutrition 21, Inc. granted us an exclusive license to develop and market Nisin-based products for animal health applications, and we then initiated development of **Mast Out**[®]. Nisin, the same active ingredient contained in **Wipe Out**[®] **Dairy Wipes**, is a natural antibacterial peptide that is commonly used as a preservative in dairy food products. Nisin is a peptide with 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 safety profile of Nisin and its long history as a food preservative may allow for the sale of this product without a milk discard requirement. Such a product claim could be a significant competitive advantage in comparison to the traditional antibiotic products currently on the market that are sold subject to a requirement to discard milk from treated cows during the course of and for a period following antibiotic treatment. Currently, it is generally common practice to treat only clinical cases (cows producing abnormal milk). Without the milk discard requirement, treatment could be expanded to sub-clinical cases (cows with infected udders but still producing normal milk) as well. 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 need for use of traditional antibiotics in the treatment of mastitis.

In January 2004, we achieved positive results from an experimental field trial of **Mast Out**[®] in 139 cows with sub-clinical 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 optimal treatment demonstrated a 58% efficacy rate in eliminating infection in lactating cows with culture-confirmed mastitis. This efficacy rate represents a blended average of results from cows with mastitis caused by several different pathogens. For example, we achieved a statistically significant 100% efficacy rate in *Streptococcus agalactiae* cases, where antibiotics are commonly used effectively, and a statistically significant 28% against *Staphylococcus aureus* cases, where antibiotics are often not effective. This trial did not investigate clinical mastitis cases.

In November 2004, we paid Nutrition 21 approximately \$965,000 to buy out our royalty and milestone-based license to Nisin, thereby acquiring control of animal health applications of Nisin. In December 2004, we entered into a product development and marketing agreement with Pfizer covering **Mast Out**[®], under which Pfizer agreed to fund future clinical, regulatory and commercial manufacturing development costs in return for global marketing rights. Commercial introduction of **Mast Out**[®] in the United States is subject to approval by the FDA, which approval cannot be assured. Demonstration of efficacy in a pivotal study and the approval of several additional Technical Sections under the FDA's phased review of a New Animal Drug Application (NADA) are required before any U.S. product sales would be allowed. Included among the additional Technical Sections required for NADA final approval are Target Animal Safety, Human Food Safety and several administrative requirements. The Human Food Safety data will affect the milk discard period. The data compiled to-date (which remain subject to review and approval by the FDA) are supportive of arguments for a no discard claim. Commercial-scale manufacturing of **Mast Out**[®] will need to comply with current Good Manufacturing Practice (cGMP) Regulations and will be subject to FDA approval and inspection. We have been working to transfer our Nisin manufacturing process to a Pfizer cGMP facility. Foreign regulatory approvals will be required for sales outside of the United States and will involve some similar and some different requirements.

For other ImmuCell products, we are starting to invest in the process improvements, facility modifications, staffing changes and increased documentation required to become cGMP compliant. We expect that the

Table of Contents

implementation of these increased standards will result in improved overall quality and consistency in our manufacturing operations. Compliance with cGMP regulations may allow us access to additional foreign markets, such as Europe, Australia, and New Zealand, where these standards are required for the sale of **First Defense**[®]. We expect most of these expenses in 2006 to be classified as research and development expenses. At some point in the future, these expenses will need to become part of our recurring manufacturing overhead structure, thereby potentially reducing our reported gross margin.

While we continue our efforts with internally and externally funded product development programs, we also remain interested in acquiring new products and technologies that fit with our sales focus on the dairy and beef industries. We are actively exploring further improvements, extensions or additions to our current product line. For example, we are investigating the potential to prevent scours in calves caused by pathogens in addition to *E. coli* and *coronavirus*, and there may be additional animal disease indications for Nisin that we could pursue using the pharmaceutical-grade Nisin that is being developed for **Mast Out**[®].

We maintain relationships with several scientific collaborators who have particular expertise in the areas of strategic interest to us. Our research and development activities are conducted primarily internally, but we sometimes rely on contracts with third parties depending upon staff availability, the technical skills required, the nature of the particular project and other considerations. As additional opportunities to commercialize our technology, or technology that we can effectively acquire rights to, become apparent, we may begin new research and development projects. 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.

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 by two of our employees engaged directly in sales. We sell **Wipe Out**[®] **Dairy Wipes** directly to dairy producers. **MASTiK**[®], **CMT**, and **rpt** are sold directly to dairy producers as well as to distributors and bovine veterinarians. Sales of **rjt** are made principally to state veterinary laboratories. We invested 16%, 11% and 10% of product sales in selling expenses in the years ended December 31, 2003, 2004 and 2005, respectively. Going forward, we expect to invest less than 15% of product sales in selling expenses.

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. **First Defense**[®] is generally sold through large, financially strong distributors resulting in minimal bad debt. **Wipe Out**[®] **Dairy Wipes** are generally sold directly to dairy producers, but we have experienced only a minimal problem with uncollectible accounts receivable. We have not used customer rebates or other forms of allowances or purchase incentives as a significant sales promotional tool. We purchase an insignificant amount of promotional merchandise (such as hats, shirts, jackets, pens, note pads, coffee cups and other items) that advertise 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.

We estimate that the potential U.S. market for **Mast Out**[®] in lactating cows with clinical mastitis is approximately \$20,000,000 per year and that a similar market opportunity also exists outside the U.S. If **Mast Out**[®] is approved by the U.S. Food and Drug Administration as the first treatment for mastitis without a milk discard requirement, we believe it could compete effectively against the traditional antibiotic products currently on the market, which are all sold subject to a milk discard. Currently, the loss of milk revenue is a disincentive to the early treatment of disease by dairy producers. The ability to treat without a milk discard could change practices to allow for the treatment of earlier sub-clinical cases, which might increase the market. Pfizer has

Table of Contents

licensed worldwide sales and marketing rights to this product. We would receive royalties on their sales if and when applicable FDA or other regulatory approvals are obtained. A market may also exist for a dry cow application of the product, which would be subject to a separate regulatory approval. Pfizer has a first right to negotiate a license to any such dry cow product that we develop.

Foreign Sales

Foreign product sales represented approximately 7%, 10% and 17% of our total product sales for the years ended December 31, 2003, 2004 and 2005, 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. We have made price adjustments on occasion to mitigate these effects. Conversely, to the extent that the value of the dollar may decline with respect to a foreign currency, our competitive position may be enhanced.

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 research and 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: 1) its capsule form does not require refrigeration and provides ease of administration and 2) 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 another leading cause of the disease (coronavirus). 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.

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 the following: 1) they are convenient to use, 2) they do not irritate the udder or the skin of the milking personnel, 3) they do not adulterate the milk and 4) they are biodegradable.

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

We believe that Novatreat, DMV International Nutritionals and Mucovax have interests in developing immune milk products for use in the treatment or prevention of diseases in humans including *Clostridium difficile*-associated diarrhea. See *Product Opportunities Outside of the Dairy and Beef Industries*, below.

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.

Table of Contents

Patents and Proprietary Information

In connection with the December 1999 acquisition of **Wipe Out® Dairy Wipes** from Nutrition 21, 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 antimicrobial formulations in the veterinary field of use. 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 conjunction with the December 2000 acquisition of **MASTiK®**, we acquired the related U.S. Patent No. 5,026,638 entitled **Antibiotic Sensitivity Test for Pathogenic Organisms Present in Mastitic Milk** covering the test procedure.

In 1998, we were issued U.S. Patent No. 5,747,031 entitled **Process for Isolating Immunoglobulins in Whey** covering certain aspects of our proprietary manufacturing process to separate antibodies from cows' milk. 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 obtained 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.

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.

Product Trademarks

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; **MASTiK®**, our antibiotic susceptibility test; and **Mast Out®**, which we have licensed to Pfizer. In addition, we sell two animal health products under the trademarks, **rjt** and **rpt**.

Government Regulation

The manufacture and sale of animal health biologicals within the United States is generally regulated by the USDA. However, **Mast Out®** is regulated by the FDA, Center for Veterinary Medicine, which regulates veterinary drugs. Pfizer is responsible for the regulatory development of **Mast Out®** under our December 2004 product development and marketing agreement and thus will be making all applicable submissions to the regulatory agencies. The manufacture and sale of disease treatment and prevention products for human health applications and for certain animal health products within the United States is subject to regulation by the FDA. Comparable agencies exist in foreign countries and foreign sales of our products will be subject to regulation by such agencies. Many states (including Maine where our facilities are located) have laws regulating the production, sale, distribution or use of biological products, and we may have to obtain approvals from regulatory

Table of Contents

authorities in states in which we propose to sell our products. Depending upon the product and its applications, obtaining regulatory approvals may be a relatively brief and inexpensive procedure or it may involve extensive clinical tests, incurring significant expenses and an approval process of several years' duration.

We have received USDA approval for **First Defense**[®] (our scours preventive product) and **rjt** (our Johne's Disease diagnostic test). We believe that we are in compliance with current regulatory requirements relating to our business and products.

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) Milk Antibody Products Under Development

During the 1990's, we conducted several trials investigating the use of milk antibodies to prevent gastrointestinal infections caused by *Cryptosporidium parvum*, enterotoxigenic *E. coli* and *Clostridium difficile* in humans. Similar to **First Defense**[®], we immunize cows under contract from commercial dairy herds and source antibodies specific to the pathogens of interest from their milk. After we purify the antibodies from the milk, the product is dried and formulated for oral administration. We discontinued internal funding of the last of these products in 2000.

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 \$67,000 in 2004 and \$66,000 in 2005 and expect to earn an additional \$12,000 in 2006 to complete our work under this grant to supply **TravelGAM** anti-*E. coli* milk immunoglobulins for in vitro and in vivo trials. We also hope to benefit from a long-term supply agreement should the technology be successfully commercialized.

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. While the participation of another partner would be required to pursue FDA approval of a pharmaceutical claim for this product, the available scientific literature and the product's safety profile may be sufficient to allow for sales of **DiffGAM** as a nutritional supplement.

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 a nutritional protein derived from cheese whey, known as lactoferrin. 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. We have no ongoing interest in or obligations to this operation.

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

Table of Contents

\$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 \$81,000, \$85,000 and \$39,000 in royalty income in 2003, 2004 and 2005, respectively, under this agreement.

3) 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 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.

4) 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-Scan®**. 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. TCS has made some modifications to the test kit and obtained the necessary U.K. regulatory approval of the modified test. TCS has initiated commercial sales of this product under their name, Isolate Cryptosporidium. We would benefit from the exclusive supply agreement if TCS achieves and maintains market acceptance of the product.

Employees and Executive Officers

We currently employ 23 full-time employees and 5 part-time employees. Approximately 14 employees (including 2 part-time employees) are engaged in manufacturing operations, 6 employees (including 2 part-time employees) in research and development activities, 6 employees in finance and administration (including 1 part-time employee) and 2 employees in sales. At times, manufacturing personnel are also utilized, as needed, in the production of clinical material for use in research and development. We are not a party to any collective bargaining agreement and consider our employee relations to be excellent. Our executive officers as of March 21, 2006 were as follows:

MICHAEL F. BRIGHAM (Age: 45, Officer since: October 1991, Director since: March 1999) was appointed to serve as President and Chief Executive Officer in February 2000, while maintaining the titles of Treasurer and Secretary, and was appointed to serve as a Director of the Company in March 1999. He previously had been elected Vice President of the Company in December 1998 and served as Chief Financial Officer since October 1991. He has served as Secretary since December 1995 and as Treasurer since October 1991. Prior to that, he served as Director of Finance and Administration since originally joining the Company in September 1989. Mr. Brigham serves on the Board of Directors of the Maine

Table of Contents

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: 51, 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. Effective January 1, 2005, Dr. Crabb reduced the time commitment to his job duties at the Company from full-time to half-time. 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. Dr. Crabb currently serves on advisory committees at the National Institutes of Health and is a reviewer for several peer-reviewed journals. 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.

ITEM 1A 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: 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; anticipated applications for future regulatory approvals; anticipated future research efforts; sources, timing or amounts of possible future milestone payments and other revenue; anticipated availability of materials and supplies; the future adequacy of our working capital; future profitability; future expense ratios; 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 Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized below and uncertainties otherwise referred to in this Annual Report.

Decrease in product sales: 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. Furthermore, if regulatory approval is obtained, there can be no assurance that the market estimates will prove to be accurate or that market acceptance at a profitable price level can be achieved or that the products can be profitably manufactured.

Failure to develop new products: The development of our products is subject to financial, efficacy and regulatory risks. We cannot be sure that we will be able to finance the development of new product opportunities or that, if financed, the new products will be found to be efficacious and gain the appropriate regulatory approval. We are heavily dependent on the successful development of new products for future sales growth.

License arrangement with Pfizer: Our biggest new product development opportunity (**Mast Out**[®]) has been licensed to Pfizer under an exclusive product development and marketing agreement, under which that company will largely control the development and commercialization of the product. Under our agreement, Pfizer retains the right to terminate the license subject to certain conditions.

Table of Contents

Small size: We are a small company with approximately 28 employees. As such, we rely on certain key employees to support different operational functions, with little redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained.

Access to raw materials: Our policy is to maintain more than one source of supply for the components used in our products. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. 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** and for Pfizer are not readily available from other sources. Any disruption in the services at this facility could adversely affect the production of inventory.

Economics of the dairy industry: The dairy industry in the United States has been facing very difficult economic pressures. After declining in 2002 to price levels common in the 1970 s, the price of milk has increased, but the number of small dairy farmers continues to decrease. The financial insecurity of our primary customer base is a risk to our ability to maintain and grow sales at a profitable level.

*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, at any time, the USDA does not approve the requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product.

*Regulatory requirements for **Wipe Out**[®] **Dairy Wipes**:* **Wipe Out**[®] **Dairy Wipes** are permitted to be sold without a New Animal Drug Application approval, in accordance with the FDA s Compliance Policy Guide 7125.30 (Teat Dips and Udder Washes for Dairy Cows and Goats). At some time in the future, this category of products may be required to comply with the NADA approval requirements. The enforcement by the FDA of full drug regulations on this product would likely make it not economical to continue manufacturing it.

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 (especially bovine) origin. **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.

ITEM 1B UNRESOLVED STAFF COMMENTS

None

Table of Contents

ITEM 2 PROPERTIES

We own a 15,300 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. In May 2001, we completed a construction project that added approximately 5,300 square feet of new manufacturing space to the original 10,000 square foot building to increase the production capacity of **First Defense**[®] and to provide in-house production capability for **Wipe Out**[®] **Dairy Wipes**. The facility addition also provides a storage mezzanine of approximately 2,000 square feet. In addition, our building has 5,000 square feet of unfinished space available for potential future expansion on the second floor.

We also maintain access to certain animals, primarily cows, through contractual relationships with several 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 REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND 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, 2004 through December 31, 2005:

	2004				2005			
	Three Months Ended				Three Months Ended			
	March 31	June 30	September 30	December 31	March 31	June 30	September 30	December 31
High	\$ 4.72	\$ 4.89	\$ 4.91	\$ 9.65	\$ 7.49	\$ 5.70	\$ 5.50	\$ 6.25
Low	\$ 3.55	\$ 3.72	\$ 4.11	\$ 4.07	\$ 4.14	\$ 3.82	\$ 4.03	\$ 4.72

As of March 21, 2006, we had 8,000,000 common shares authorized and 2,859,813 common shares outstanding, and there were approximately 1,200 shareholders of record. The last sales price of our common stock on March 21, 2006 was \$7.00 as quoted on the NASDAQ Stock Market.

On April 3, 2003, we announced that our Board of Directors had approved a plan to repurchase up to 100,000 shares of our common stock as market conditions warrant. Repurchases under the plan are to be made from time to time at the discretion of management. There is no fixed number of shares to be repurchased and no time limit for the completion of the repurchase plan. Our present intention is to hold repurchased shares as treasury stock to be used for general corporate purposes. During the three months ended June 30, 2003, we repurchased 5,900 shares of our common stock at a total cost of approximately \$12,267 under this plan. We have repurchased no additional shares since then.

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, 2005 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 shareholders	435,638	\$ 2.90	195,501
Equity compensation plans not approved by shareholders			
Total	435,638	\$ 2.90	195,501

Table of Contents**ITEM 6 SELECTED FINANCIAL DATA**

The selected financial data set forth below has been derived from our audited financial statements. The information should be read in conjunction with the audited financial statements and related notes appearing elsewhere in this Form 10-K. The results for the twelve months ended December 31, 2001 and nine months ended September 30, 2002 included product sales, costs and selling expenses related to a product that we sold under a license that was terminated as of October 1, 2002.

	Year Ended December 31,				
	2001	2002	2003	2004	2005
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Product sales	\$ 6,395	\$ 5,301	\$ 3,145	\$ 3,524	\$ 4,233
Total revenues	6,677	6,185	3,357	3,696	4,983
Gross margin from product sales	3,180	2,502	1,797	2,075	2,599
Research & development expenses	849	1,053	1,350	1,092	1,270
Product selling expenses	1,359	1,228	493	401	426
Net interest and other income	26	948	1,145	56	133
Income before income taxes	697	1,481	716	177	1,071
Net income	420	886	411	144	708
Per Common Share:					
Basic net income	0.15	0.32	0.15	0.05	0.25
Diluted net income	0.15	0.32	0.15	0.05	0.24
Cash dividend					
Statement of Cash Flows Data:					
Net cash provided by operating activities	914	1,898	1,404	1,358	765
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	1,883	3,143	4,245	4,450	5,150
Total assets	7,117	7,513	8,187	9,530	9,955
Current liabilities	564	259	416	814	697
Net working capital	2,943	4,228	4,965	4,998	6,091
Long-term liabilities	507	300	400	986	700
Shareholders' equity	\$ 6,046	\$ 6,955	\$ 7,370	\$ 7,729	\$ 8,558

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**Results of Operations***Fiscal 2005 Compared to Fiscal 2004*

Product sales for the year ended December 31, 2005 increased by \$709,000 (20%) to \$4,233,000 from \$3,524,000 in 2004, primarily due to growth in sales of **First Defense**[®]. We believe that sales of our products are influenced by the price of milk sold by our primary customers. After declining in 2002 to price levels common in the 1970s, the price of milk has increased. A common index used in the industry to measure this trend 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 2005 was \$14.05 per 100 pounds, which represents a 9% decrease from the 2004 average, but is still 35% higher than the 2002 price level. The average Class III milk price for 2004 was \$15.39 per 100 pounds, which represents a 35% increase from the \$11.42 average for 2003. The average Class III milk price for 2002 was \$10.42. We have generally held our product selling prices without increase. Sales of **First Defense**[®] increased by 15% during the year ended December 31, 2005 in comparison to the same period in 2004. This increase was principally driven by higher sales volume rather than higher selling prices. Sales of **First Defense**[®] are normally seasonal with highest sales expected in the first quarter and lower sales expected during the summer months. Sales of **Wipe Out**[®] **Dairy Wipes** increased by 16% during 2005 in comparison to 2004.

Table of Contents

During 2005, sales of this product into a new market in South Korea more than offset a 10% decrease in domestic sales. We believe the drop in domestic sales in 2005 was largely due to the continued financial pressures that are forcing many small dairy producers out of business. **Wipe Out® Dairy Wipes** are more often used on small dairies than larger ones. The other products we sell primarily into the dairy industry increased to \$153,000 during the year ended December 31, 2005 compared to \$144,000 during the same period in 2004. The other products we sell outside of dairy and beef industries, principally Isolate (formerly known as **Crypto-Scaff**), increased to \$214,000 during the year ended December 31, 2005 compared to \$19,000 during the same period in 2004.

Total revenues for the year ended December 31, 2005 increased by \$1,287,000 (35%) to \$4,983,000 from \$3,696,000 in 2004. Approximately, \$455,000 and \$21,000, representing 30% and 1% of the \$1,500,000 up front payment that Pfizer made to us under a December 2004 product development and marketing agreement, was recognized as technology licensing revenue during the years ended December 31, 2005 and 2004, respectively. The remaining balance of \$1,024,000 was recorded as deferred revenue at December 31, 2005 and is expected to be recognized over the period ending December 31, 2008. Effective October 1, 2005, this revenue recognition period was extended by one year from December 31, 2007. In 2005, technology licensing revenue also included approximately \$190,000 under a \$225,000 supplemental contract to supply and test additional **Mast Out®** clinical material for Pfizer. Grant income was \$66,000 and \$67,000 for the years ending December 31, 2005 and 2004, respectively, comprising 1% of total revenues in 2005 and 2% of total revenues in 2004. Most of the grant income supported work on the development of **TravelGAM**. Royalty income decreased by \$46,000 (54%) to \$39,000 in 2005 due to lower sales of whey protein isolate by our licensee.

Product costs amounted to 39% of product sales in 2005 as compared to 41% in 2004. The gross margin on product sales increased by \$524,000 (25%) to \$2,599,000 from \$2,075,000 in 2004, primarily due to growth in sales of **First Defense®** and a lower per unit cost of production. Internally developed products such as **First Defense®** tend to have higher gross margin percentages than acquired products. A moderately lower gross margin percentage is anticipated initially as new products are developed and acquired. Over time, as these products are fully integrated into our manufacturing and selling operations, we expect to be able to improve the gross margin percentage. This is the case, for example, with **Wipe Out® Dairy Wipes**, a product that we acquired in December 1999. In 2001, we invested in the necessary facility addition and production equipment required to process the wipe stock and perform the filling operations for this product internally. In 2004, we invested in the necessary facility modifications and production equipment required to produce nonpharmaceutical-grade Nisin internally.

We increased our expenditures for research and development by approximately \$178,000 (16%) to \$1,270,000 in 2005 as compared to \$1,092,000 in 2004. The higher costs in 2005 were due principally to the amortization of the intangible asset pertaining to the November 2004 buy out of our **Mast Out®** royalty obligation from Nutrition 21, Inc. Such non-cash expense amounted to \$293,000 and \$13,000 during the years ended December 31, 2005 and 2004, respectively. The remaining asset balance of \$659,000 as of December 31, 2005 is expected to be amortized to research and development expense over the period ending December 31, 2008. Effective October 1, 2005, this expense amortization period was extended by one year from December 31, 2007. Research and development expenses aggregated 25% and 30% of total revenues in 2005 and 2004, respectively. Research and development expenses exceeded grant income by approximately \$1,204,000 in 2005 and by \$1,025,000 in 2004. These net research and development expenses decreased to 28% of product sales in 2005 from 29% of product sales in 2004. Excluding the non-cash amortization expense, the net research and development expenses were \$912,000 and \$1,012,000 during the years ended December 31, 2005 and 2004, respectively, amounting to 22% and 29% of product sales, respectively. The majority of our research and development budget from 2000 through 2005 has been focused on the development of **Mast Out®**. Pfizer is responsible for most of the **Mast Out®** product development expenses going forward. Going forward, we expect to focus our internally-funded research and development expenses on improvements, extensions or additions to our current product line and an effort to achieve cGMP compliance.

Product selling expenses increased by approximately \$25,000 (6%) to \$426,000 in 2005, aggregating 10% of product sales in 2005, compared to 11% in 2004. We continue to leverage the efforts of our small sales force

Table of Contents

through veterinary distribution channels. General and administrative expenses increased by approximately \$81,000 (13%) to \$715,000 in 2005 as compared to \$634,000 in 2004 due primarily to increased salaries and professional fees associated with being a publicly held company.

Interest income increased by approximately \$72,000 to \$128,000 in 2005 in comparison to 2004 due principally to the increased amount of invested funds and an increase in interest rates in 2005. We have not incurred interest expense since we repaid our outstanding bank debt in May 2002.

Income before income taxes of \$1,071,000 for the year ended December 31, 2005 compares to \$177,000 for the year ended December 31, 2004. We recorded income tax expense at an effective tax rate of 34% and 19% in 2005 and 2004, respectively, resulting in net income of \$708,000 and \$144,000 for the years ended December 31, 2005 and 2004, respectively. The 2005 and 2004 income tax expense includes a tax benefit of approximately \$62,000 and \$35,000, respectively, due to a change in the valuation allowance pertaining to certain deferred tax assets. Income tax expense included deferred taxes of \$140,000 and \$(62,000) for the years ended December 31, 2005 and 2004, respectively.

Fiscal 2004 Compared to Fiscal 2003

Product sales for the year ended December 31, 2004 increased by \$379,000 (12%) to \$3,524,000 from \$3,145,000 in 2003, primarily due to growth in sales of **First Defense**[®]. We believe sales of our products to the dairy industry benefited from the sharply increased price of milk sold by our primary customers in 2004 as compared to 2003 and 2002. We have generally held our product selling prices without increase. Sales of **First Defense**[®] increased by 17% during the year ended December 31, 2004 in comparison to the same period in 2003. This increase was principally driven by higher sales volume rather than higher selling prices. Sales of **First Defense**[®] are normally seasonal with highest sales expected in the first quarter and lower sales expected during the summer months. Sales of **Wipe Out**[®] **Dairy Wipes** decreased by 8% during the twelve month period ended December 31, 2004 in comparison to the same period in 2003. We believe the drop in sales in 2004 was largely due to the continued financial pressures that are forcing many small dairy producers out of business. **Wipe Out**[®] **Dairy Wipes** are more often used on small dairies than larger ones.

Total revenues for the year ended December 31, 2004 increased by \$339,000 (10%) to \$3,696,000 from \$3,357,000 in 2003. Grant income decreased by \$45,000 (40%) to \$67,000 in 2004, comprising 2% of total revenues in 2004 and 3% of total revenues in 2003. Most of the grant income supported work on the development of **Mast Out**[®]. Royalty income increased by \$4,000 (5%) to \$85,000 in 2004. The \$21,000 in revenue that we recognized from the sale of technology rights in 2004 represents approximately 1% of the \$1,500,000 up front payment that Pfizer made to us under a product development and marketing agreement that we entered into in December 2004. The balance of this payment was recorded as deferred revenue at December 31, 2004. In 2003, we earned \$20,000 in revenue from the sale of technology rights.

Product costs amounted to 41% of product sales in 2004 as compared to 43% in 2003. Internally developed products tend to have higher gross margin percentages than acquired products. A moderately lower gross margin percentage is anticipated initially as new products are developed and acquired. Over time, as these products are fully integrated into our manufacturing and selling operations, we expect to be able to improve the gross margin percentage. This is the case, for example, with **Wipe Out**[®] **Dairy Wipes**, a product that we acquired in December 1999. In 2001, we invested in the necessary facility addition and production equipment required to process the wipe stock and perform the filling operations for this product internally, which has caused an improvement in the gross margin. In 2004, we invested in the necessary facility modifications and production equipment required to produce nonpharmaceutical-grade Nisin internally.

We decreased our expenditures for research and development by approximately \$258,000 (19%) to \$1,092,000 in 2004 as compared to \$1,350,000 in 2003. The higher costs in 2003 were due principally to the expenses incurred in connection with the experimental field trial of **Mast Out**[®] that we completed with positive results in 2003. Research and development expenses aggregated 30% and 40% of total revenues in 2004 and

Table of Contents

2003, respectively. Research and development expenses exceeded grant income by approximately \$1,025,000 in 2004 and by \$1,238,000 in 2003. These net research and development expenses decreased to 29% of product sales in 2004 from 39% of product sales in 2003. The majority of our research and development budget from 2000 through 2004 has been focused on the development of **Mast Out**[®]. We are obligated to supply product for U.S. clinical trials of **Mast Out**[®] in 2005, and Pfizer is responsible for most of the other product development expenses going forward.

Product selling expenses decreased by approximately \$92,000 (19%) to \$401,000 in 2004, aggregating 11% of product sales in 2004, compared to 16% in 2003. We continue to leverage the efforts of our small sales force through veterinary distribution channels. General and administrative expenses increased by approximately \$38,000 (6%) to \$634,000 in 2004 as compared to \$596,000 in 2003. A portion of our general and administrative expenses reflects the necessary expenses associated with being a publicly held company.

Interest income increased by approximately \$10,000 to \$56,000 in 2004 in comparison to 2003 due principally to the increased amount of invested funds and a moderate increase in interest rates in 2004. We have not incurred interest expense since we repaid our outstanding bank debt in May 2002. In 2003, other income included the \$1,100,000 payment earned through the sale of our interest in AgriCell, a non-core joint venture.

Income before income taxes of \$177,000 for the year ended December 31, 2004 compares to \$716,000 for the year ended December 31, 2003 principally due to other income earned in 2003 through the sale of our joint venture interest that was offset by the beneficial effects of increased revenues and decreased expenses in 2004. We recorded tax expense at an effective tax rate of 19.0% and 42.6% in 2004 and 2003, respectively, resulting in net income of \$144,000 and \$411,000 for the years ended December 31, 2004 and 2003, respectively. Income tax expense included deferred taxes of \$(62,000) and \$278,000 for the years ended December 31, 2004 and 2003, respectively, which consisted primarily of the utilization of prior year net operating loss carryforwards. The 2004 income tax expense includes a tax benefit of approximately \$35,000 due to a change in the valuation allowance pertaining to certain deferred tax assets.

Financial Position, Liquidity and Capital Resources

We had approximately \$5,150,000 in available cash and short-term investments as of December 31, 2005. We are using some of this cash to fund product development and to invest in the manufacturing of our commercialized products. 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,		Increase	
	2004	2005	\$	%
	(In thousands, except for percentages)			
Cash, cash equivalents and short-term investments	\$ 4,450	\$ 5,150	\$ 700	16%
Net working capital	4,998	6,091	1,093	22%
Total assets	9,530	9,955	426	4%
Shareholders' equity	\$ 7,729	\$ 8,558	\$ 829	11%

During 2005, operating activities provided approximately \$765,000 in cash. The two largest operating activities that were added back to net income of \$708,000 were: 1) depreciation and amortization expense of \$644,000 and 2) an increase in deferred income taxes of \$140,000. The two largest operating activities that were deducted from net income were: 1) a \$262,000 increase in accounts receivable and 2) a \$420,000 decrease in deferred revenue. Investing activities used \$1,379,000 in cash, comprised of a \$179,000 net investment in fixed assets and a net investment of \$1,200,000 in short-term investments. Financing activities included approximately \$114,000 in proceeds from the issuance of common stock upon the exercise of stock options.

Under our December 2004 product development and marketing agreement with Pfizer, we received an up front payment of \$1,500,000. We are eligible to receive additional performance milestone payments and royalties

Table of Contents

on any sales of **Mast Out**[®] made by Pfizer. During the term of our license agreement, Pfizer is responsible for most of the future product development and all of the marketing expenses pertaining to **Mast Out**[®].

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, which project was completed in 2004 for approximately \$423,000. This manufacturing process was optimized during 2005. This facility was also used to produce clinical material for **Mast Out**[®]. The know-how gained in producing Nisin in our facility is being shared with Pfizer, who is responsible for the production of cGMP Nisin for **Mast Out**[®] for commercial sales.

Since 1999, our strategy has been to focus our research and development efforts on animal health product opportunities, which 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 research and development expenses principally from product sales and have been profitable for each of the seven years in the period ended December 31, 2005.

In March 2001, we received a two year award aggregating up to \$400,000 from the Maine Technology Institute, a non-profit corporation created by the General Assembly of the State of Maine. The award augmented our development of **Mast Out**[®]. The award was subject to a contingent payback obligation unless the product development was terminated. Because of this contingent payback obligation, the funding was recorded as deferred revenue as the cash was received, and no income was recognized to match the development expenses as they were incurred. After Pfizer assumed primary responsibility for the future development of **Mast Out**[®], we repaid this award in full in December 2004.

Our cumulative investment in research and development expenses of \$16,764,000 for the sixteen year period ended December 31, 2005 has been supported, in part, by \$2,758,000 in grant awards since 1990 (not including the \$400,000 award from the Maine Technology Institute, described above). Approximately \$2,680,000 of this grant income was recognized prior to 2005, and \$66,000 was recognized in 2005 and \$12,000 is expected to be recognized in 2006. 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.

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. Significant 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, and the cost of our products to foreign customers could be affected by currency fluctuations.

Critical Accounting Policies

Details regarding the impact of new accounting pronouncements on our financial statements is 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, 2005 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.

Table of Contents

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 a payment of approximately \$965,000 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**[®]. This intangible asset is expected to be amortized over the period from November 15, 2004 to December 31, 2008. We received a \$1,500,000 up front payment from Pfizer in connection with the December 2004 product development and marketing agreement covering **Mast Out**[®]. We expect to recognize this revenue over the period from December 15, 2004 to December 31, 2008. Both of these periods reflect management's estimate of the likely period of development before royalties could be received on sales of **Mast Out**[®]. The Pfizer agreement, among other things, also provides for contingent milestone payments and royalties based on any future sales, subject to certain minimums. We expect that revenue from any future milestone payments that we receive from Pfizer will be recognized from the date that the milestone is achieved through December 31, 2008. Any such milestone payments received for obtaining regulatory approvals, or after a regulatory approval is obtained, are expected to be recognized when the milestone has been reached. Should the December 31, 2008 estimate change, the period during which the then remaining expense and revenue are recognized would be adjusted accordingly. Any future royalty payments will be recognized as earned based on future product sales.

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 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

None

ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements, together with the notes thereto and the report of the independent accountants thereon, are set forth on Pages F-1 through F-19 at the end of this report.

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

None

ITEM 9A 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, 2005. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. 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.

Table of Contents

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 is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

ITEM 9B *OTHER INFORMATION*

None

PART III

ITEM 10 *DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT*

Information with respect to our directors is incorporated herein by reference to the section of our 2006 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, *Employees and Executive Officers*. 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 2006 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 2006 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 2006 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 2006 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.

Table of Contents

PART IV

ITEM 15 EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) 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 (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 1990).
- 3.3 Certificate of Amendment to the Company's Certificate of Incorporation effective August 24, 1992 (incorporated by reference to Exhibit 3.4 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1992).
- 3.4 Bylaws of the Registrant as amended (incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995).
- 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 Amendment to Rights Agreement, dated as of June 30, 2005, between the Registrant and American Stock Transfer & Trust Co., as Rights Agent (incorporated by reference to Exhibit 4.1A to the Registrant's Current Report on Form 8-K filed July 5, 2005).
- 10.1+ 1989 Stock Option and Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1989).
- 10.2+ Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1989).
- 10.3+ Form of Indemnification Agreement entered into with each of the Company's directors and officers (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1989).
- 10.4+ 1995 Stock Option Plan for Outside Directors (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the three months ended June 30, 1995).
- 10.5+ Form of Stock Option Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the three months ended June 30, 1995).
- 10.6(1) License Agreement between the Registrant and Murray Goulburn Co-operative Co., Limited, dated November 14, 1997 (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997).
- 10.7+ Employment Agreement dated April 29, 1999 between the Registrant and Michael F. Brigham (incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999).
- 10.8+ Employment Agreement dated April 29, 1999 between the Registrant and Joseph H. Crabb (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999).
- 10.9 Asset Purchase Agreement between the Registrant and Nutrition 21, Inc. dated December 30, 1999 (incorporated by reference to Exhibit 2 to the Registrant's Current Report on Form 8-K filed January 13, 2000).

Table of Contents

10.10+	2000 Stock Option and Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 2000).
10.11+	Form of Incentive Stock Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 2000).
10.12+	2000 Stock Option Plan for Outside Directors of the Registrant (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 2000).
10.13+	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the three month period ended June 30, 2000).
10.14	License and Sublicense Agreement between the Registrant and Nutrition 21, Inc. (f/k/a AMBI Inc.) dated as of April 12, 2000, as amended through November 17, 2004 (conformed copy) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed November 19, 2004).
10.15(1)	License Agreement between the Registrant and Pfizer Inc. dated as of December 21, 2004 (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004).
10.16+	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).
10.17+	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, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

-
- (1) Confidential treatment previously granted as to certain portions.
 + Management contract or compensatory plan or arrangement.

Table of Contents

(b) Index to Financial Statements

<u>Report of Baker Newman & Noyes, LLC, Independent Auditors</u>	F-1
<u>Balance Sheets as of December 31, 2004 and 2005</u>	F-2
<u>Statements of Operations for the years ended December 31, 2003, 2004 and 2005</u>	F-3
<u>Statements of Shareholders' Equity for the years ended December 31, 2003, 2004 and 2005</u>	F-4
<u>Statements of Cash Flows for the years ended December 31, 2003, 2004 and 2005</u>	F-5
<u>Notes to Financial Statements</u>	F-6 to F-18
<i><u>(c) Schedule 2 Supplemental Valuation and Qualifying Accounts</u></i>	F-19

Table of Contents

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, 2005 and 2004, and the related statements of operations, shareholders' equity and cash flows for each of the three years in the three year period ended December 31, 2005. Our audits also included the financial statement schedule. These financial statements and financial statement schedule 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 provided a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of ImmuCell Corporation as of December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the three year period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

Portland, Maine

February 3, 2006

/s/ BAKER NEWMAN & NOYES
Baker Newman & Noyes, LLC

Table of Contents**IMMUCELL CORPORATION****BALANCE SHEETS****AS OF DECEMBER 31, 2004 and 2005**

	2004	2005
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,700,567	\$ 1,200,341
Short-term investments	2,749,596	3,949,742
Trade accounts receivable, net of allowance for doubtful accounts of \$13,000 and \$11,000 at December 31, 2004 and 2005, respectively	312,988	565,468
Other receivables	121,603	131,293
Inventories	667,666	704,085
Current portion of deferred tax asset	215,066	164,066
Prepaid expenses	44,913	73,057
Total current assets	5,812,399	6,788,052
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	1,701,583	1,792,237
Building and improvements	1,500,559	1,556,569
Office furniture and equipment	123,289	133,875
Construction in progress	7,356	
Land	50,000	50,000
	3,382,787	3,532,681
Less-accumulated depreciation	1,481,643	1,761,277
Net property, plant and equipment	1,901,144	1,771,404
DEFERRED TAX ASSET	674,240	585,240
PRODUCT RIGHTS AND OTHER ASSETS, net of accumulated amortization of \$196,000 and \$529,000 at December 31, 2004 and 2005, respectively	1,141,886	810,530
TOTAL ASSETS	\$ 9,529,669	\$ 9,955,226
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Deferred revenue	\$ 493,151	\$ 359,012
Accrued expenses	228,609	212,776
Accounts payable	70,143	81,198
Income taxes payable	22,589	44,304
Total current liabilities	814,492	697,290
Long-term portion of deferred revenue	986,301	700,424
SHAREHOLDERS EQUITY:		
Common stock, Par value \$0.10 per share, Authorized 8,000,000 shares, Issued 3,190,148 and 3,261,148 shares at December 31, 2004 and 2005, respectively	319,015	326,115
Capital in excess of par value	9,160,991	9,345,896
Accumulated deficit	(1,152,128)	(444,346)

Edgar Filing: IMMUCELL CORP /DE/ - Form 10-K

Treasury stock, at cost 395,498 and 411,335 shares at December 31, 2004 and 2005, respectively	(599,002)	(670,153)
Total shareholders equity	7,728,876	8,557,512
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 9,529,669	\$ 9,955,226

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

F-2

Table of Contents**IMMUCELL CORPORATION****STATEMENTS OF OPERATIONS****FOR THE YEARS ENDED DECEMBER 31, 2003, 2004 and 2005**

	2003	2004	2005
REVENUES:			
Product sales	\$ 3,144,512	\$ 3,523,982	\$ 4,233,282
Technology licensing revenue	20,000	20,548	645,016
Grant income	111,724	66,900	65,515
Royalty income	81,106	84,850	39,329
Total revenues	3,357,342	3,696,280	4,983,142
COSTS AND EXPENSES:			
Product costs	1,347,289	1,449,016	1,633,932
Research and development expenses	1,350,164	1,091,836	1,269,950
General and administrative expenses	595,769	633,728	714,943
Product selling expenses	493,151	400,929	426,283
Total costs and expenses	3,786,373	3,575,509	4,045,108
Net operating (loss) income	(429,031)	120,771	938,034
Interest income	46,181	56,221	127,786
Other income, net	1,099,227	201	5,268
Net interest and other income	1,145,408	56,422	133,054
INCOME BEFORE INCOME TAXES	716,377	177,193	1,071,088
INCOME TAX EXPENSE	305,161	33,674	363,306
NET INCOME	\$ 411,216	\$ 143,519	\$ 707,782
NET INCOME PER COMMON SHARE:			
Basic	\$ 0.15	\$ 0.05	\$ 0.25
Diluted	\$ 0.15	\$ 0.05	\$ 0.24
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:			
Basic	2,738,193	2,755,070	2,823,599
Diluted	2,823,696	2,966,923	3,003,002

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

Table of Contents**IMMUCELL CORPORATION****STATEMENTS OF SHAREHOLDERS EQUITY****FOR THE YEARS ENDED DECEMBER 31, 2003, 2004 and 2005**

	Common Stock		Capital in		Treasury Stock		Total
	\$.10 Par Value		Excess of	Accumulated			Shareholders
	Shares	Amount	Par Value	Deficit	Shares	Amount	Equity
BALANCE,							
December 31, 2002	3,125,582	\$ 312,558	\$ 8,935,649	\$ (1,706,863)	389,598	\$ (586,735)	\$ 6,954,609
Net income				411,216			411,216
Exercise of stock options	10,500	1,050	13,575				14,625
Tax benefits related to stock options			2,269				2,269
Acquisition of treasury stock					5,900	(12,267)	(12,267)
BALANCE,							
December 31, 2003	3,136,082	313,608	8,951,493	(1,295,647)	395,498	(599,002)	7,370,452
Net income				143,519			143,519
Exercise of stock options	54,066	5,407	140,887				146,294
Tax benefits related to stock options			68,611				68,611
BALANCE,							
December 31, 2004	3,190,148	319,015	9,160,991	(1,152,128)	395,498	(599,002)	7,728,876
Net Income				707,782			707,782
Exercise of stock options	71,000	7,100	178,323		15,837	(71,151)	114,272
Tax benefits related to stock options			6,582				6,582
BALANCE,							
December 31, 2005	3,261,148	\$ 326,115	\$ 9,345,896	\$ (444,346)	411,335	\$ (670,153)	\$ 8,557,512

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

Table of Contents**IMMUCELL CORPORATION****STATEMENTS OF CASH FLOWS****FOR THE YEARS ENDED DECEMBER 31, 2003, 2004 and 2005**

	2003	2004	2005
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	\$ 411,216	\$ 143,519	\$ 707,782
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	215,745	224,778	310,241
Amortization	40,525	53,744	333,381
Deferred income taxes	278,398	(62,118)	140,000
Tax benefits related to stock options	2,269	68,611	6,582
Loss (gain) on disposal of fixed assets	33,695	2,892	(1,372)
Changes in:			
Receivables	54,889	(64,737)	(262,170)
Inventories	115,687	6,841	(36,419)
Prepaid expenses and other assets	(5,887)	(107)	(30,169)
Accounts payable	(25,160)	17,831	11,055
Accrued expenses	193,238	(125,931)	(15,833)
Income taxes receivable/payable	9,328	13,261	21,715
Deferred revenue	79,990	1,079,452	(420,016)
Net cash provided by operating activities	1,403,933	1,358,036	764,777
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(304,245)	(338,229)	(185,129)
Proceeds from disposal of fixed assets		4,000	6,000
Maturities of short-term investments	1,781,702	1,879,413	3,436,934
Purchases of short-term investments	(1,882,976)	(3,740,689)	(4,637,080)
Acquisition of product rights		(965,000)	
Net cash used for investing activities	(405,519)	(3,160,505)	(1,379,275)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	14,625	146,294	114,272
Acquisition of treasury stock	(12,267)		
Net cash provided by financing activities	2,358	146,294	114,272
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,000,772	(1,656,175)	(500,226)
BEGINNING CASH AND CASH EQUIVALENTS	2,355,970	3,356,742	1,700,567
ENDING CASH AND CASH EQUIVALENTS	\$ 3,356,742	\$ 1,700,567	\$ 1,200,341
CASH PAID FOR INCOME TAXES	\$ 17,150	\$ 13,893	\$ 195,009
NON-CASH FINANCING ACTIVITIES:			
Treasury stock acquired upon exercise of stock options			\$ (75,496)

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

Table of Contents**IMMUCELL CORPORATION****NOTES TO FINANCIAL STATEMENTS****1. BUSINESS OPERATIONS**

ImmuCell Corporation (the Company) is a biotechnology company primarily engaged in the development, manufacture and sales of products that improve the health and productivity of cows for the dairy and beef industry. The Company was originally incorporated in Maine in 1982 and reincorporated in Delaware in 1987, in conjunction with its initial public offering of common stock. The Company is subject to certain risks associated with its stage of development including dependence on key individuals, competition from other larger companies, the successful sales of existing products and the development and acquisition of additional commercially viable products with appropriate regulatory approvals, where applicable.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**(a) Cash, Cash Equivalents and Short-Term Investments**

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits of \$100,000 per financial institution are maintained in money market accounts at financial institutions that are secured, in part, by the Securities Investor Protection Corporation. Amounts in excess of the FDIC limit of \$100,000 per bank that are not invested in securities backed by the U.S. government aggregated \$1,491,000 and \$978,000 at December 31, 2004 and 2005, respectively. Short-term investments are classified as held to maturity and are comprised principally of certificates of deposits that mature in more than three months from their purchase dates and not more than twelve months from the balance sheet date and are held at different financial institutions that are insured by the FDIC within FDIC limits of \$100,000 each.

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

	December 31, 2004	December 31, 2005	(Decrease) Increase
Cash and cash equivalents	\$ 1,700,567	\$ 1,200,341	\$ (500,226)
Short-term investments	2,749,596	3,949,742	1,200,146
	\$ 4,450,163	\$ 5,150,083	\$ 699,920

(b) Inventories

Inventories include raw materials, work-in-process and finished goods and are recorded at the lower of cost, on the first-in, first-out method, or market (net realizable value). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. Inventories consist of the following:

	As of December 31,	
	2004	2005
Raw materials	\$ 167,241	\$ 112,469
Work-in-process	429,481	424,492
Finished goods	70,944	167,124
	\$ 667,666	\$ 704,085

Table of Contents**IMMUCELL CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)*****(c) Property, Plant and Equipment***

We depreciate property, plant and equipment on the straight-line method by charges to operations in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The cost of the building, acquired in 1993, and the subsequent addition thereto, completed in 2001, are being depreciated through 2023. Related building improvements are depreciated over ten year periods. Large and durable fixed assets are depreciated over their useful lives that are generally estimated to be ten years. Other fixed assets and computer equipment are depreciated over their useful lives that are generally estimated to be five and three years, respectively.

(d) Intangible Assets

We amortize intangible assets on the straight-line method by charges to operations in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The \$250,000 acquisition of product rights related to **Wipe Out® Dairy Wipes** in December 1999 is being amortized to cost of sales over the ten year period ending in December 2009, and the related manufacturing rights acquired in 2001 for \$45,000 are being amortized to cost of sales through December 2009. The \$75,000 acquisition of product rights related to **MASTiK®** is being amortized to cost of sales through June 2008. Amortization expense relating to these intangible assets is expected to amount to approximately \$41,000 per year in both of the years 2006 and 2007, \$35,000 in 2008 and the remaining \$30,000 in 2009. No material changes are anticipated in the remaining useful lives of intangible assets.

In November 2004, we capitalized a payment of approximately \$965,000 made to Nutrition 21, Inc. to buy out certain future milestone and royalty payment obligations relating principally to **Mast Out®**. This intangible asset is expected to be amortized over the period from November 15, 2004 to December 31, 2008. Accordingly, we expect amortization expense of approximately \$220,000 annually from 2006 through 2008. See Note 10(a).

We continually assess the realizability of these assets in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets . If an impairment review is triggered, we evaluate the carrying value of long-lived assets by determining if impairment exists based on estimated undiscounted future cash flows over the remaining useful life of the assets and comparing that value to the carrying value of the assets. If the carrying value of the asset is greater than the estimated future cash flows, the asset is written down to its estimated fair value. The cash flow estimates that are used contain our best estimates, using appropriate and customary assumptions and projections at the time. We also review the estimated useful life of intangible assets at the end of each reporting period, making any necessary adjustments. Management believes that none of these assets was impaired as of December 31, 2005.

(e) Disclosure of Fair Value of Financial Instruments and Concentration of Risk

Financial instruments consist mainly of cash and cash equivalents, short-term investments, accounts receivable and accounts payable. Financial instruments that potentially subject the Company to concentrations of credit risk are principally cash, cash equivalents, short-term investments and accounts receivable. We invest our short-term investments in financial instruments that are insured by the FDIC. Concentration of credit risk with respect to accounts receivable is principally limited to certain customers to whom we make substantial sales. To reduce risk, we routinely assess the financial strength of our customers and, as a consequence, believe that our accounts receivable credit risk exposure is limited. We maintain an allowance for potential credit losses, but historically we have not experienced significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area. The carrying amounts of our financial instruments approximate fair market value.

Table of Contents

IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

We believe that supplies and raw materials for the production of our products are available from more than one vendor or farm. Our policy is to maintain more than one source of supply for the components used in our products. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies.

(f) Revenue Recognition

Revenues related to the sale of manufactured products are recorded when title and risk of loss have passed to the customer, which is at the time of shipment and when collectibility is reasonably assured. Non-refundable grant income is recognized as reimbursable expenses are incurred. Indirect costs which are billed to the government are subject to their review. Royalty income is recorded on the accrual basis based on sales as reported to us by our licensee pursuant to the terms of the agreement. Revenues from non-refundable upfront payments are deferred and recognized ratably over the period during which the earning process is completed.

We received a \$1,500,000 up front payment from Pfizer in connection with the December 2004 product development and marketing agreement covering **Mast Out**[®]. We expect to recognize this revenue over the period from December 15, 2004 to December 31, 2008. Accordingly, we recognized \$21,000 and \$455,000 during the years ended December 31, 2004 and 2005, respectively, and we expect to recognize another \$341,000 in each of the three years ended December 31, 2008 pertaining to this payment. The provisions of the Financial Accounting Standards Board's (FASB's) Emerging Issues Task Force No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, were considered in connection with this transaction. See Note 10(a).

We were awarded a grant in 2001 for \$400,000 that carried a contingent payback obligation upon commercialization of **Mast Out**[®]. Because of this contingent payback obligation, the funding was recorded as deferred revenue as the cash was received, and no income was recognized to match the development expenses as they were incurred. After Pfizer assumed primary responsibility for the future development of **Mast Out**[®], we repaid this award in full in December 2004.

(g) Expense Recognition

Advertising expenses are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to \$163,000, \$172,000 and \$189,000 during the years ended December 31, 2003, 2004 and 2005, respectively. All research and development costs are expensed as incurred, as are all related patent costs.

(h) Income Taxes

We account for income taxes in accordance with SFAS No. 109, Accounting for Income Taxes. This statement requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. See Note 4.

Table of Contents**IMMUCELL CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****(i) Net Income Per Common Share**

The basic net income per common share has been computed in accordance with Financial Accounting Standards Board (FASB) Statement No. 128, Earnings Per Share , by dividing net income by the weighted average number of common shares outstanding during the year. The diluted net income per common share reflects the potential dilution from outstanding stock options as shown below:

	Year Ended December 31,		
	2003	2004	2005
Weighted average number of shares outstanding during the period	2,738,193	2,755,070	2,823,599
Dilutive stock options	261,811	542,889	435,638
Shares that could have been repurchased with the proceeds from the dilutive stock options	(176,308)	(331,036)	(256,235)
Diluted number of shares outstanding during the period	2,823,696	2,966,923	3,003,002
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	337,936	2,500	

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

(j) Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual amounts could differ from those estimates.

(k) Employee Stock-Based Compensation

We measure compensation related to employee stock-based compensation plans in accordance with the intrinsic value method of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees , and we elect to disclose the pro forma impact of accounting for stock-based compensation plans under the provisions of SFAS No. 123, Accounting for Stock-Based Compensation and SFAS No. 148,

Accounting for Stock-Based Compensation-Transition and Disclosure . Accordingly, no stock-based employee compensation cost has been recognized for these plans. Had compensation cost for our stock plans been determined consistent with the provisions of these statements, our net income and basic and diluted net income per share would have been reduced to the pro forma amounts indicated below:

	Year Ended December 31,		
	2003	2004	2005
Net income, as reported	\$ 411,216	\$ 143,519	\$ 707,782
Pro forma stock-based employee compensation expense determined under the fair value based method, net of related tax effects	40,358	27,768	21,883
Pro forma net income	\$ 370,858	\$ 115,751	\$ 685,899
Net income per share:			
Basic: as reported	\$ 0.15	\$ 0.05	\$ 0.25
Basic: pro forma	0.14	0.04	0.24
Diluted: as reported	0.15	0.05	0.24
Diluted: pro forma	\$ 0.13	\$ 0.04	\$ 0.23

Table of Contents

IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

See Note 2(l) for new accounting requirements in 2006 and Note 5(a) and (b) for discussion of our stock-based compensation plans and assumptions used in determining the pro forma stock-based employee compensation above.

(l) New Accounting Pronouncements

In November 2004, the FASB issued, Statement of Financial Accounting Standards No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4. This Statement amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal as to require treatment as current period charges. This Statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Earlier application is permitted for inventory costs incurred during fiscal years beginning after the date this Statement is issued. The provisions of this Statement shall be applied prospectively. We do not expect the adoption of this Statement to have a material impact on our financial condition, results of operations, earnings per share or cash flows.

In December 2004, the FASB issued, Statement of Financial Accounting Standards No. 153, *Exchange of Nonmonetary Assets*, an amendment of APB Opinion No. 29. The guidance in APB Opinion No. 29, *Accounting for Nonmonetary Transactions*, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. This Statement amends Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions of this Statement shall be effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges occurring in fiscal periods beginning after the date this Statement is issued. The provisions of this Statement shall be applied prospectively. We do not expect the adoption of this Statement to have a material impact on our financial condition, results of operations, earnings per share or cash flows.

In December 2004, the FASB issued Revised Statement of Financial Accounting Standards No. 123, *Share-Based Payments (FAS 123R)*, revising FASB Statements No. 123 and 95. FAS 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. FAS 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and generally requires that such transactions be accounted for using the fair-value-based method. This requires us to recognize compensation costs for share-based payments. The provisions of this Statement shall be effective for the quarter ending March 31, 2006. We expect the adoption of this Statement to have an impact of less than \$50,000 on our financial condition, results of operations and cash flows in 2006.

(m) Reclassifications

Certain prior year accounts have been reclassified to conform with the 2005 financial statement presentation.

Table of Contents**IMMUCELL CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****3. ACCRUED EXPENSES**

Accrued expenses consisted of the following:

	As of December 31,	
	2004	2005
Professional fees	\$ 56,697	\$ 48,186
Payroll	109,196	92,231
Other	62,716	72,359
	\$ 228,609	\$ 212,776

4. INCOME TAXES

The income tax provision consists of the following:

	Year Ended December 31,		
	2003	2004	2005
Current			
Federal	\$ 11,392	\$ 70,449	\$ 161,340
State	9,500	21,100	60,000
Foreign	5,871	4,243	1,966
	26,763	95,792	223,306
Deferred			
Federal	214,426	(47,784)	116,000
State	63,972	(14,334)	24,000
	278,398	(62,118)	140,000
Total	\$ 305,161	\$ 33,674	\$ 363,306

Total currently payable income taxes were reduced by the benefits related to stock options of \$2,269, \$68,611 and \$6,582 in 2003, 2004 and 2005, respectively.

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

	Year Ended December 31,		
	2003	2004	2005
Computed expected tax expense	\$ 243,568	\$ 60,245	\$ 364,170
State income taxes, net of federal benefit	48,492	4,465	55,676

Edgar Filing: IMMUCELL CORP /DE/ - Form 10-K

Foreign tax on royalty income	5,871	4,243	1,966
Change in valuation allowance		(35,000)	(62,419)
Other	7,230	(279)	3,913
Total income tax expense	\$ 305,161	\$ 33,674	\$ 363,306

F-11

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

The significant components of our deferred tax assets and liabilities are as follows:

	As of December 31,	
	2004	2005
Deferred tax assets (liabilities):		
Deferred revenue and other reserves	\$ 626,457	\$ 568,360
Depreciation	(97,534)	(99,976)
Capitalized research and experimentation	378,301	309,285
Prepaid expenses	(17,918)	(28,363)
General business credit carryforward	62,419	
Deferred tax assets before valuation allowance	951,725	749,306
Valuation allowance	(62,419)	
Net deferred tax assets	\$ 889,306	\$ 749,306

We utilized approximately \$495,000 and \$540,000 of net operating loss carryforwards to offset taxable income in fiscal years 2003 and 2004, respectively, and \$35,000 and \$62,000 of general business tax credits in 2004 and 2005, respectively. We had no remaining net operating loss carryforwards as of December 31, 2004. The \$1,500,000 payment from Pfizer received in December 2004 was treated as taxable income, for tax return purposes only. The \$965,000 payment made to Nutrition 21 in November 2004 was treated as an intangible asset and is being amortized over 15 years, for tax return purposes only.

In order to accelerate the utilization of available net operating loss carryforwards in advance of their expiration dates, we elected to increase income for federal tax purposes by capitalizing research and experimentation expenditures aggregating \$900,000 and \$831,000 for the years ended December 31, 2000 and 2001, respectively, for tax return purposes only in accordance with the Internal Revenue Code. We do not intend to capitalize additional research and experimentation expenditures. Accordingly, we recorded amortization of these capitalized expenditures aggregating \$90,000 for the year ended December 31, 2000 and \$173,000 for the subsequent five years through December 31, 2005 for tax return purposes only. We expect to amortize an additional \$173,000 of these capitalized expenditures for each of the four years ending December 31, 2006 to December 31, 2009 as well as \$84,000 for the year ending December 31, 2010 for tax return purposes only.

5. STOCKHOLDERS EQUITY**(a) Non-qualified Stock Options**

In April 1999, a total of 93,300 non-qualified stock options were issued to the three then-serving executive officers at an exercise price of \$1.31 per share, the then current market price of our common stock. These options were granted outside of the stock option plans described below. In March 2000, 31,098 of these options became exercisable. In 2000, 20,734 of these options terminated when one of the officers separated from the Company. In September 2001, that former officer exercised 10,300 of these options and 66 of these options expired without being exercised. An additional 20,734 options became exercisable in March 2001, and the remaining 20,734 options became exercisable in March 2002. If not exercised, the 62,200 remaining outstanding options expire in April 2009.

Table of Contents

IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

(b) Stock Option Plans

In May 1989, the shareholders approved the 1989 Stock Option and Incentive Plan (the 1989 Plan) pursuant to the provisions of the Internal Revenue Code of 1986, under which employees may be granted options to purchase shares of the Company s common stock at i) no less than fair market value on the date of grant in the case of incentive stock options and ii) no less than 85% of fair market value on the date of grant in the case of non-qualified stock options. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. All options granted under the 1989 Plan expire no later than ten years from the date of grant. The 1989 Plan expired in March 1999, and no further options may be granted under the 1989 Plan. However, outstanding options under the 1989 Plan may be exercised in accordance with their terms.

In June 2000, the shareholders approved the 2000 Stock Option and Incentive Plan (the 2000 Plan) pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company s common stock at i) no less than fair market value on the date of grant in the case of incentive stock options and ii) no less than 85% of fair market value on the date of grant in the case of non-qualified stock options. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. Originally, 250,000 shares of common stock were reserved for issuance under the 2000 Plan. The shareholders of the Company approved an increase in this number to 500,000 shares in June 2001. All options granted under the 2000 Plan expire no later than ten years from the date of grant. The 2000 Plan expires in June 2010, after which date no further options may be granted under the 2000 Plan. However, any outstanding options under the 2000 Plan may be exercised in accordance with their terms.

In June 2000, the shareholders approved the 2000 Stock Option Plan for Outside Directors (the 2000 Outside Director Plan) pursuant to the provisions of the Internal Revenue Code of 1986, under which each of the five, then-serving outside directors of the Company was automatically granted a non-qualified stock option to purchase 15,000 shares of common stock at its fair market value on the date the 2000 Outside Director Plan was approved by the shareholders. Directors who are newly elected to the Board subsequent to June 2000 receive an automatic grant of an option to purchase 15,000 shares, at fair market value on the date when such directors are first elected to the Board by the shareholders. One-third of the options subject to the grant vest on the date that the director is re-elected to the Board by the shareholders; an additional 5,000 options vest on the second date that the director is re-elected to the Board by the shareholders; and the remaining 5,000 options vest on the third date that the director is re-elected to the Board by the shareholders. Directors of the Company are elected at each Annual Meeting of Shareholders for one-year terms. There are 120,000 shares of common stock reserved for issuance under the 2000 Outside Director Plan. All options granted under the 2000 Outside Director Plan expire no later than five years from the date of grant. The 2000 Outside Director Plan expired in June 2005, after which date no further options may be granted under the 2000 Outside Director Plan. However, any outstanding options under the 2000 Outside Director Plan may be exercised in accordance with their terms.

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

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

			2000	
			Outside	Weighted
			Director	Average
	1989 Plan	2000 Plan	Plan	Exercise Price
Balance at December 31, 2002	175,672	327,000	60,000	\$ 2.78
Grants		34,000		3.10
Terminations	(13,500)	(39,000)		2.36
Exercises	(10,500)			1.39
Balance at December 31, 2003	151,672	322,000	60,000	2.87
Grants		28,500		4.10
Terminations		(81,667)		3.01
Exercises	(19,000)	(35,066)		2.71
Balance at December 31, 2004	132,672	233,767	60,000	2.94
Grants		51,000		4.52
Terminations		(15,334)	(15,000)	3.80
Exercises	(43,000)	(667)	(30,000)	2.58
Balance at December 31, 2005	89,672	268,766	15,000	3.16
Exercisable at December 31, 2005	89,672	189,265	15,000	\$ 2.91
Reserved for future grants		195,501		

At December 31, 2005, 435,638 common shares were reserved for future issuance under all outstanding stock options described above, and an additional 195,501 common shares were reserved for the potential issuance of stock options in the future under the 2000 Plan. The weighted average remaining life of the options outstanding under the 1989 Plan, the 2000 Plan and the 2000 Outside Director Plan as of December 31, 2005 was approximately five years and one month. The exercise price of the options outstanding and of the options exercisable as of December 31, 2005 ranged from \$1.31 to \$4.90 per share. The weighted-average grant date fair values of options granted during 2003, 2004 and 2005 were \$0.23, \$0.92 and \$1.03 per share, respectively. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, for the purpose discussed in Note 2(k), with the following weighted-average assumptions:

	2003	2004	2005
Risk-free interest rate	2.2%	3.0%	4.2%
Dividend yield	0	0	0
Expected volatility	26%	27.8%	25.7%
Expected life	3 years	3 years	3 years

(c) *Common Stock Rights Plan*

Edgar Filing: IMMUCELL CORP /DE/ - Form 10-K

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

F-14

Table of Contents

IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

The Rights become exercisable and transferable apart from the common stock upon the earlier of i) 10 days following a public announcement that a person or group (acquiring person) has, without the prior consent of the Continuing Directors (as such term is defined in the Rights Agreement), acquired beneficial ownership of 15% or more of the outstanding common stock, or ii) 10 days following commencement of a tender offer or exchange offer the consummation of which would result in ownership by a person or group of 20% or more of the outstanding common stock (the earlier of such dates being called the Distribution Date).

Upon the acquisition of 15% or more of the Company's common stock by an acquiring person, the holder of each Right not owned by the acquiring person would be entitled to purchase common stock having a market value equal to two times the exercise price of the Right (i.e., at a 50% discount). If, after the Distribution Date, the Company should consolidate or merge with any other entity and the Company were not the surviving company, or, if the Company were the surviving company, all or part of the Company's common stock were changed or exchanged into the securities of any other entity, or if more than 50% of the Company's assets or earning power were sold, each Right would entitle its holder to purchase, at the Rights' then-current purchase price, a number of shares of the acquiring company's common stock having a market value at that time equal to twice the Right's exercise price.

At any time after a person or group becomes an acquiring person and prior to the acquisition by such person or group of 50% or more of the outstanding common stock, the Board of Directors of the Company may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of common stock per Right (subject to adjustment). At any time prior to 14 days following the date that any person or group becomes an acquiring person (subject to extension by the Board of Directors), the Board of Directors of the Company may redeem the then outstanding Rights in whole, but not in part, at a price of \$.005 per Right, subject to adjustment.

On June 8, 2005, our Board voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years, to September 19, 2008. As of June 30, 2005, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. No other changes were made to the terms of the Rights or the Rights Agreement. The Rights will expire on the earlier of i) the close of business on September 19, 2008, or ii) the time at which the Rights are redeemed by the Company.

6. COMMITMENTS AND CONTINGENT LIABILITIES

In March 2003, we entered into an agreement with a vendor that has offered to perform certain manufacturing services for us relating to **Mast Out®**. Under the December 2004 product development and marketing agreement with Pfizer, Pfizer has the right to approve or disapprove the contract manufacturer. In the event that Pfizer elects to not approve our existing vendor, we would be responsible for any termination payment owing to that vendor. The agreement with the vendor provides for a termination payment of \$100,000 in certain circumstances. Pfizer is presently evaluating its options and has not elected to terminate the agreement with this contract manufacturer at this time, and thus we have accrued no liability for any such termination in the future.

Our By-Laws, as amended, in effect provide that the Company will indemnify its officers and directors to the maximum extent permitted by Delaware law. The maximum payment that we may be required to make under such provisions is theoretically unlimited and is impossible to determine. We maintain directors' and officers' liability insurance, which may provide reimbursement to the Company for payments made to, or on behalf of, officers and directors pursuant to the indemnification provisions. Our indemnification obligations were grandfathered under the provisions of FIN No. 45 as they were in effect prior to December 31, 2002. Accordingly, we have recorded no liability for such obligations as of December 31, 2005. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

Table of Contents

IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

We enter into agreements with third parties in the ordinary course of business under which we are obligated to indemnify such third parties for and against various risks and losses. The precise terms of such indemnities vary with the nature of the agreement. In many cases, the Company limits the maximum amount of its indemnification obligations, but in some cases those obligations may be theoretically unlimited. We have not incurred material expenses in discharging any of these indemnification obligations, and based on our analysis of the nature of the risks involved, we believe that the fair value of these agreements is minimal. Accordingly, we have recorded no liabilities for these obligations as of December 31, 2005.

We entered into an employment contract with our president and chief executive officer, which could require us to pay three months' salary as severance pay depending upon the circumstances of any termination of employment of this key employee. We also entered into an employment contract with our vice president and chief scientific officer, requiring us to pay him a reduced annual salary for the one year period ending December 31, 2005 in exchange for a half-time commitment to his job duties. Effective July 28, 2005, we entered into an amended Employment Agreement with this key employee covering the term through December 31, 2007. Depending upon the circumstances of any termination of employment of this key employee, we could be required to pay this salary through December 31, 2007.

The research, manufacturing and marketing of human and animal health care products entails an inherent risk that liability claims will be asserted against us. We feel that we have reasonable levels of liability insurance to support our operations.

7. SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

We principally operate in the business segment described in Note 1. Pursuant to SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information", we operate in one reportable business segment, that being the development, acquisition, manufacture and sales of products that improve the health and productivity of cows for the dairy and beef industries. The significant accounting policies of this segment are described in Note 2.

Our primary customers for the majority of our product sales (92%, 89% and 83% for the years ended December 31, 2003, 2004 and 2005, respectively) are in the U.S. dairy and beef industry. Revenues derived from foreign customers, who are also in the dairy and beef industry, aggregated 7%, 10% and 12% of our total product sales for the years ended December 31, 2003, 2004 and 2005, respectively. Sales made to Walco International aggregated 19%, 17% and 18% of total product sales during the years ended December 31, 2003, 2004 and 2005, respectively. This customer accounted for 16% and 12% of our outstanding accounts receivable as of December 31, 2004 and 2005, respectively. Another customer, TCS Biosciences Ltd, accounted for 18% of our outstanding accounts receivable as of December 31, 2005.

8. EMPLOYEE BENEFITS

We have a 401(k) savings plan in which all employees completing one year of service with the Company (working at least 1,000 hours) are eligible to participate. Participants may contribute up to the maximum amount allowed by the Internal Revenue Service. We match 50% of each employee's contribution to the plan up to a maximum match of 4% of each employee's base compensation. Under this matching contribution program, we paid approximately \$35,000, \$35,000 and \$32,000 to the plan for the years ended December 31, 2003, 2004 and 2005, respectively.

Table of Contents**IMMUCELL CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****9. UNAUDITED QUARTERLY FINANCIAL DATA**

The following tables present the quarterly information for fiscal years 2003, 2004 and 2005 (in thousands, except per share amounts):

	Three Months Ended			
	March 31	June 30	September 30	December 31
Fiscal 2003:				
Product sales	\$ 1,016	\$ 590	\$ 745	\$ 794
Total revenues	1,127	617	789	825
Gross margin	591	305	410	491
Research and development expenses	316	289	270	476
Income (loss) before income taxes	1,179	(201)	(58)	(204)
Net income (loss)	701	(124)	(38)	(128)
Net income (loss) per common share:				
Basic	\$ 0.26	\$ (0.05)	\$ (0.01)	\$ (0.05)
Diluted	\$ 0.25	\$ (0.05)	\$ (0.01)	\$ (0.05)
Fiscal 2004:				
Product sales	\$ 1,217	\$ 642	\$ 808	\$ 856
Total revenues	1,242	665	846	944
Gross margin	758	343	465	510
Research and development expenses	222	241	272	356
Income (loss) before income taxes	290	(95)	(5)	(13)
Net income (loss)	172	(58)	(5)	35
Net income (loss) per common share:				
Basic	\$ 0.06	\$ (0.02)	\$ (0.00)	\$ 0.01
Diluted	\$ 0.06	\$ (0.02)	\$ (0.00)	\$ 0.01
Fiscal 2005:				
Product sales	\$ 1,428	\$ 848	\$ 783	\$ 1,174
Total revenues	1,596	984	1,035	1,368
Gross margin	867	499	516	718
Research and development expenses	314	253	358	345
Income before income taxes	434	135	185	317
Net income	259	79	109	260
Net income per common share:				
Basic	\$ 0.09	\$ 0.03	\$ 0.04	\$ 0.09
Diluted	\$ 0.09	\$ 0.03	\$ 0.04	\$ 0.09

10. LICENSING AND SALE OF TECHNOLOGY

(a) In November 2004, we capitalized a payment of approximately \$965,000 made to Nutrition 21, Inc. to buy out certain future royalty and milestone payment obligations, which principally resulted in a fully paid, perpetual license related to **Mast Out**[®]. Since the benefit of this license is closely associated with our Pfizer agreement, we originally expected to amortize this intangible asset over the period from November 15, 2004 to December 31, 2007. We received a \$1,500,000 up front payment from Pfizer in connection with the December 2004 product development and marketing agreement covering **Mast Out**[®]. We originally expected to recognize this revenue over the period from December 15, 2004 to December 31, 2007. Both of these periods reflected our original estimate of the likely period of development before royalties could be received on sales of **Mast Out**[®]. Based on the information now available to us, effective October 1, 2005 we have extended by one additional year

Table of Contents

IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

(to December 31, 2008) our original estimate of the product development period. Therefore, the \$1,110,000 in deferred revenue recorded as of September 30, 2005 from the \$1,500,000 up front milestone payment now is being recognized over the revised period from October 1, 2005 to December 31, 2008, and the \$714,000 intangible asset recorded as of September 30, 2005 is now being amortized over the same revised period. The estimate of this product development period, during which revenue from milestone payments is being recognized, is subject to further change in either direction based on future developments. Pfizer is responsible for clinical, regulatory and commercial manufacturing development, and thus the timing of these developments is largely outside of our control. The Pfizer agreement, among other things, also provides for contingent milestone payments and royalties based on any future sales, with specified minimum royalties. We expect that revenue from any future milestone payments that we receive from Pfizer before regulatory approval is obtained will be recognized from the date that the milestone is achieved through December 31, 2008. Any such milestone payments received for obtaining regulatory approvals, or after a regulatory approval is obtained, are expected to be recognized when the milestone has been reached. Any future royalty payments will be recognized as earned based on future product sales.

(b) In March 2003, we sold our 50% interest in the joint venture, AgriCell Company, LLC, to DMV International Nutritionals, an operating division of DMV USA LP of the Netherlands, for \$1,100,000. As this joint venture and the related technology had no book value, the full amount of the proceeds was recorded as other income in the first quarter of 2003. In August 2001, DMV paid us \$100,000 for an option to purchase our interest, which income was recognized as revenue from the sale of technology rights over the twenty month option period ended in March 2003.

11. COMMON STOCK REPURCHASE PLAN

On April 3, 2003, we announced that our Board of Directors had approved a plan to repurchase up to 100,000 shares of our common stock as market conditions warrant. Repurchases under the plan are to be made from time to time at the discretion of management. There is no fixed number of shares to be repurchased and no time limit for the completion of the repurchase plan. Our present intention is to hold repurchased shares as treasury stock to be used for general corporate purposes. The maximum of 100,000 shares represented approximately 3.7% of our outstanding common stock as of March 31, 2003. During the three months ended June 30, 2003, we repurchased 5,900 shares of our common stock at a total cost of approximately \$12,267 under this plan. We have repurchased no additional shares since then.

Table of Contents

SCHEDULE 2 SUPPLEMENTAL VALUATION AND QUALIFYING ACCOUNTS

Allowance for Doubtful Accounts:	
Balance at December 31, 2002	\$ 19,000
Amount charged to costs and expenses	
Write-offs and returns	(6,000)
Balance at December 31, 2003	13,000
Amount charged to costs and expenses	5,000
Write-offs and returns	(5,000)
Balance at December 31, 2004	13,000
Amount charged to costs and expenses	3,000
Write-offs and returns	(5,000)
Balance at December 31, 2005	\$ 11,000

F-19

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IMMUCELL CORPORATION

Date: March 21, 2006

By: /s/ **MICHAEL F. BRIGHAM**
Michael F. Brigham

President, Chief Executive Officer and Treasurer

POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Date: March 21, 2006

By: /s/ **MICHAEL F. BRIGHAM**
Michael F. Brigham

President, Chief Executive Officer,

Treasurer and Director

Date: March 21, 2006

By: /s/ **ANTHONY B. CASHEN**
Anthony B. Cashen, Director

Date: March 21, 2006

By: /s/ **JOSEPH H. CRABB**
Joseph H. Crabb, Ph.D., Director

Date: March 21, 2006

By: /s/ **WILLIAM H. MAXWELL**
William H. Maxwell, M.D., Director

Date: March 21, 2006

By: /s/ **LINDA RHODES**
Linda Rhodes, VMD, Ph.D., Director

Date: March 21, 2006

By: /s/ **JONATHAN E. ROTHSCHILD**
Jonathan E. Rothschild, Director

Date: March 21, 2006

By: /s/ **MITCHEL SAYARE**
Mitchel Sayare, Ph.D., Director

Table of Contents

IMMUCELL CORPORATION

EXHIBIT INDEX

Exhibit 23	Consent of Baker Newman & Noyes, LLC.
Exhibit 31	Rule 13a-14(a) Certifications.
Exhibit 32	Section 1350 Certifications, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.