IMMUCELL CORP /DE/
Form 10-K
March 29, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2004

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	**01-0382980**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

56 Evergreen Drive, Portland, Maine **04103**
(Address of principal executive offices) **(Zip Code)**

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

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

None

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

Common Stock, par value $0.10 per share

(Title of class)

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

Indicate by check mark 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). Yes ¨ No x

The aggregate market value of the Common Stock held by non-affiliates of the Registrant at June 30, 2004 was approximately $10,415,000.

The number of shares of the Registrant s Common Stock outstanding at March 21, 2005 was 2,794,650.

Documents incorporated by reference: Portions of the Registrant s definitive Proxy Statement to be filed in connection with the 2005 Annual Meeting of Shareholders are incorporated by reference into Part III hereof.

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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 the majority of our product development efforts on products that improve animal health and productivity for the dairy and beef industries.

One benefit of this shift in strategic focus to animal health products, which are generally less expensive to develop than human health products, is that we have recorded consecutive net income for each of the six years in the period ended December 31, 2004. This profitability, together with the divestiture of certain non-core assets, has improved our financial position and funded our operations. As of December 31, 2004, we had cash, cash equivalents and short-term investments of $4,450,000 (in comparison to $1,539,000 as of December 31, 1998), total assets of $9,530,000 (in comparison to $3,145,000 as of December 31, 1998) and shareholders equity of $7,729,000 (in comparison to $2,248,000 as of December 31, 1998). This growth, a measurable result of our change in strategic focus, has been accomplished with limited dilution to shareholders. We had approximately 2,429,000 shares of common stock outstanding as of December 31, 1998 in comparison to 2,795,000 shares as of December 31, 2004.

In December 2004, we entered into a product development and marketing agreement with Pfizer Animal Health, a division of Pfizer, Inc. for **Mast Out®**, a 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 contingent milestone payments and royalties on sales. Pfizer will be responsible for clinical, regulatory and commercial manufacturing development. We will supply product for efficacy trials that are expected to begin in the first half of 2005.

Primary Animal Health Products for the Dairy and Beef Industries

Scours Prevention

In 1991, we obtained approval from the U.S. Department of Agriculture (USDA) to sell **First Defense®**, which we manufacture from cows colostrum using our proprietary vaccine and milk protein purification technologies. **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 (*E. coli* and coronavirus). The target disease, calf scours , causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. Calf scours is seasonal, with the highest incidence in the winter calving months. We are a leader in the scours prevention market with this product.

Mastitis Management

We are selling and developing several products designed to aid in the management of mastitis (inflammation of the mammary gland) caused by bacterial infections. Mastitis is estimated to cost dairy producers approximately $1.7 to $2 billion dollars per year in the U.S. These losses include the cost of treatment products, reduced milk production, discarded milk and lost cows.

In 1999, we acquired **Wipe Out® Dairy Wipes** from Nutrition 21, Inc. The 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

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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 the cows as they approach the milking parlor. Other producers use a variety of methods including dips with paper or cloth towels. Our wipes are made from a non-woven fabric that is strong enough to allow for a vigorous cleaning but still be biodegradable for disposal with the manure waste. Prepping the cow with **Wipe Out®** is a form of forestripping, which is known to be good for udder health.

In 2000, we acquired the product **MASTiK®, Mastitis Antibiotic Susceptibility Test Kit**. Once mastitis is detected, the dairy producer has 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 the other commonly used antibiotic susceptibility tests. It is common practice for producers using the competitive mastitis antibiotic susceptibility testing technology to treat mastitis based on the availability of antibiotics on-farm while they wait several days for susceptibility test results to arrive from a laboratory. A quicker test result allows producers to begin treatment sooner with an antibiotic that is more likely to be effective.

In 2001, we initiated commercial sales of 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** is made by other manufacturers and is 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.

Other Animal Health Products for the Dairy and Beef Industries

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, the USDA approval is subject to the further approval of each state veterinarian. We also market **rpt** (also formerly sold as **Accufirm**), a milk progesterone test used by dairy producers to monitor the reproductive status of their cows. Sales of these products have been limited since their commercial introduction.

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 continued through 2004 and is expected to continue in 2005 and beyond. In April 2000, we acquired an exclusive license to develop and market Nisin-based products for animal health applications from Nutrition 21, Inc. and initiated the development of **Mast Out®**.

In January 2004, we achieved positive results from an experimental field trial of **Mast Out®** in 139 cows with subclinical mastitis. The placebo-controlled, blinded, multi-farm study was conducted in collaboration with researchers at Cornell University. **Mast Out®** demonstrated a statistically significant overall cure rate in two separate dosage groups as compared to the placebo group. This preliminary study helped us define several important trial parameters relevant to the design of an optimal pivotal efficacy trial. We have selected a strategic treatment that demonstrated a 58% efficacy rate in eliminating infection in lactating cows with high somatic cell counts (a measure of the degree of mastitis infection). This efficacy rate represents a blended average of results from cows with mastitis caused by several different pathogens. For example, we achieved a 100% efficacy rate in *Streptococcus agalactiae* cases, where antibiotics are commonly used, and 28% against *Staphylococcus aureus* cases, where antibiotics are generally not effective. The demonstration of efficacy against clinical mastitis cases is required for FDA approval.

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In November 2004, we paid approximately $965,000 to buy out certain future milestone and royalty payment obligations to Nutrition 21. 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. We will supply product for efficacy trials that are expected to be initiated in the first half of 2005. The 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 Technical Sections required for NADA final approval are Target Animal Safety, Human Food Safety and several administrative requirements. The Human Food Safety data will determine the milk discard period. These studies are presently underway. Commercial-scale manufacturing must comply with cGMP Regulations. The chemistry and manufacturing aspects underlying this commercial production process are also subject to FDA approval. Foreign regulatory approvals will be subject to some similar and some different requirements.

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 products. Nisin is a peptide with activity against most gram positive and some gram negative bacteria. **Mast Out®**, an intramammary infusion product, 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 milk discard period to be eliminated. 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. The use of antibiotics in food-producing animals is 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. 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®**. For example, we are investigating a dry cow application of this technology, meaning treatment during the period that a cow is not lactating.

While we continue our efforts with internally and externally funded product development programs, we also actively seek to acquire 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 other than *E. coli* and *coronavirus*. We are also exploring the potential to use our **First Defense®** technology to produce a colostrum supplement product for newborn calves. Lastly, we are also evaluating new formulations for the preparation and sanitization of udders before and after milking.

We maintain relationships with several scientific advisors who have particular expertise in the areas of strategic interest to us. Our research and development activities are conducted primarily internally and at times through contracts with third parties depending upon the availability of staff, 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. We spent approximately $1,053,000, $1,350,000 and $1,092,000 on research and development activities during the years ended December 31, 2002, 2003 and 2004, respectively. These expenditures were supported, in part, by grant income totaling approximately $303,000, $112,000 and $67,000 during the years ended December 31, 2002, 2003 and 2004, respectively.

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

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primarily through major veterinarian distributors by two of our employees engaged directly in the selling of our products. We sell **Wipe Out®** **Dairy Wipes** directly to the dairy producer. **MASTiK®** and **CMT** are also sold directly to the dairy producer as well as to bovine veterinarians. Sales of **rjt** are made principally to state veterinary laboratories. We invested 23%, 16% and 11% of product sales in selling expenses in the years ended December 31, 2002, 2003 and 2004, respectively. Going forward, we expect to invest less than 15% of product sales in selling expenses.

Our management estimates that the potential U.S. market for **Mast Out®** in lactating cows is approximately $20,000,000 per year and that similar market opportunities also exist 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 subclinical cases, which might increase the market. Pfizer has 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. We believe that similar potential markets 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 29%, 7% and 10% of our total product sales for the years ended December 31, 2002, 2003 and 2004, respectively. The majority of these foreign sales were to Canada, Australia and New Zealand in 2002 and to Canada in 2003 and 2004. The October 1, 2002 termination of our license to the Kamar Heatmount Detector, which had comprised a significant portion of foreign sales, was the principal cause for the lower ratio of foreign sales after 2002.

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. 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. Many of our competitors may develop technologies and/or products which 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 direct immunity that **First**

Defense® provides to the calf is a competitive advantage over the vaccine products.

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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 easy to use, 2) they do not irritate the udder or the skin of the milking personnel and 3) they do not adulterate the milk.

We would consider any company that sells an antibiotic to treat mastitis, such as Pfizer, Schering and Wyeth, 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.

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. We also have exclusive license rights, in the field of animal vaccines, to certain cloned antigens of *Cryptosporidium parvum* from the Regents of the University of California, for which two U.S. patents have been issued to the Regents. This license covers vaccine product applications for animals, and we sublicensed those rights exclusively to AgriVax Inc. in 1999. These rights were subsequently sublicensed to Agri-Laboratories, Ltd in 2001 in return for a royalty on any related product sales. 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 used in the production of **DiffGAM**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 responsible for colonic delivery used in **DiffGAM** and for other proteins. 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.

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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; **MASTiR®**, 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**. We also own the federal trademark registration **Crypto-Scan®**, for our water diagnostic test.

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. 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 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 received approximately $67,000 in 2004 and expect to receive an additional $72,000 in 2005

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under this grant to supply **TravelGAM** anti-*E. coli* milk immunoglobulins for in vitro and in vivo trials during the two year period ending in December 2005. 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.

In addition to its role in human gastrointestinal disease, *Clostridium difficile* has been implicated as a cause of significant disease in horses and pigs. A preliminary safety study of **DiffGAM** in horses has been completed with no adverse reactions. We remain interested in exploring potential uses of **DiffGAM** in the treatment of these diseases.

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. Agri-Mark funded a capital investment by AgriCell in excess of $1,000,000 principally in working capital, fixed assets and production facility modifications. In August 2001, we entered into an option agreement under which DMV International Nutritionals of the Netherlands paid us $100,000 for an option to buy our interest in this joint venture. DMV principally funded the operations of the joint venture during the option period. In March 2003, DMV exercised this option by paying 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 $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 $41,000, $81,000 and $85,000 in royalty income in 2002, 2003 and 2004, 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.

In February 2002, we were awarded a one-year grant aggregating $191,000 from the National Institutes of Health to investigate, in collaboration with Clemson University, the effectiveness of Nisin alone and in combination with another bacteriocin as a topical skin sanitizer. The principal aims of the grant were focused on manufacturing issues pertaining to both bacteriocins. This work furthered our capability to produce Nisin for **Wipe Out® Dairy Wipes** and **Mast Out®**. The participation of a marketing partner would be required to further develop and commercialize this potential product opportunity.

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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 **Crypto-Scan®** water diagnostic test. This non-animal health product utilizes our immunomagnetic separation technology. Despite gaining U.K. regulatory approval in November 2000, sales of this product have been insignificant.

Former Animal Health Products for the Dairy and Beef Industries

In 1988, we entered into an exclusive worldwide license to purchase from Kamar, Inc. of Steamboat Springs, Colorado and to market and sell an animal health care product known as the Kamar Heatmount Detector. This license, as amended, was set to expire on December 31, 2004, but on October 1, 2002, we accepted $930,000 from Kamar in consideration of the early termination of the product license. The $930,000 approximated our estimate of the net present value of the expected profits from the product over the final 27 months of the license term, had it not been terminated. As a result of the termination of this license, our product sales, costs and selling expenses were reduced beginning October 1, 2002. Sales of this product aggregated 42% of total product sales during the year ended December 31, 2002.

In 1999, we obtained approval from the USDA to sell Tip-Test: Johne s, which is a rapid, on-site immunodiagnostic test for the detection of Johne s Disease. This sensitive product delivered on-site results from a blood or serum sample in about 20 minutes, which could have been a significant advantage to dairy and beef producers in comparison to the existing diagnostic technology that is performed only in veterinary diagnostic laboratories. Sales of this product were limited, in part, due to: 1) regulatory restrictions that significantly limit on-site testing for certain diseases and 2) the state and federal subsidies for serology testing in veterinary diagnostic laboratories. Despite our belief that frequent, rapid, on-site testing could play a useful role in reducing the rate of incidence of this costly disease, we discontinued this product in 2003 due to limited sales.

In 2001, we obtained approval from the USDA to sell Tip-Test: BLV, which is a rapid, on-site immunodiagnostic test for the detection of Bovine Leukemia Virus (BLV) infections. We discontinued this product in 2003 due to limited sales.

Employees and Executive Officers

We currently employ 24 employees, including 3 part-time employees. Approximately 12 employees (including 3 part-time employees) are engaged in manufacturing operations, 6 in research and development activities, 4 in finance and administration and 2 in sales. At times, manufacturing personnel is 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 22, 2005 were as follows:

MICHAEL F. BRIGHAM (Age: 44, 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

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of Treasurer and Secretary, and was appointed to serve as a Director of the Company in March 1999. He previously had been elected Vice President of the Company in December 1998 and served as Chief Financial Officer since October 1991. He has served as Secretary since December 1995 and as Treasurer since October 1991. Prior to that, he served as Director of Finance and Administration since originally joining the Company in September 1989. Mr. Brigham serves on the Board of Directors of the Maine Biotechnology Information Bureau. 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: 50, 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 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

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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 SmallCap Market tier of The Nasdaq Stock Market® under the symbol: ICCC. No dividends have been declared or paid on the common stock since its inception, and we do not contemplate the payment of cash dividends in the foreseeable future. The following table sets forth the high and low sales price information for our common stock as reported by The Nasdaq Stock Market during the period January 1, 2003 through December 31, 2004:

	2003				2004			
	Three Months Ended				Three Months Ended			
	March 31	June 30	September 30	December 31	March 31	June 30	September 30	December 31
High	$ 2.35	$ 2.98	$ 4.86	$ 4.10	$ 4.72	$ 4.89	$ 4.91	$ 9.65
Low	$ 1.69	$ 1.87	$ 2.24	$ 2.45	$ 3.55	$ 3.72	$ 4.11	$ 4.07

As of March 22, 2005, we had 8,000,000 common shares authorized and 2,794,650 common shares outstanding, and there were approximately 1,300 shareholders of record. The last sales price of our common stock on March 21, 2005 was $4.50 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, 2004 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	488,639	$ 2.74	291,167
Equity compensation plans not approved by shareholders			
Total	488,639	$ 2.74	291,167

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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. In particular, see Note 10(d) for an explanation of the difference between the 2003 and 2004 results in comparison to the prior years.

	Year Ended December 31,				
	2000	2001	2002	2003	2004
Statement of Operations Data:					
Product sales	$ 5,485,003	$ 6,395,140	$ 5,301,313	$ 3,144,512	$ 3,523,982
Total revenues	5,635,985	6,676,766	6,184,704	3,357,342	3,696,280
Research & development expenses	922,347	849,174	1,052,783	1,350,164	1,091,836
Net interest and other income	62,514	26,156	948,243	1,145,408	56,422
Income before income taxes	475,888	697,040	1,481,384	716,377	177,193
Net income	2,222,046	420,435	886,237	411,216	143,519
Per Common Share:					
Basic net income	0.84	0.15	0.32	0.15	0.05
Diluted net income	0.79	0.15	0.32	0.15	0.05
Cash dividend					
Statement of Cash Flows Data:					
Net cash provided by operating activities	81,505	914,347	1,898,385	1,403,933	1,358,036
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	1,895,149	1,883,090	3,143,016	4,245,062	4,450,163
Total assets	6,443,916	7,117,217	7,513,393	8,186,632	9,529,669
Current liabilities	490,745	564,432	258,784	416,180	814,492
Net working capital	2,894,249	2,942,658	4,227,642	4,965,262	4,997,907
Long-term liabilities	414,178	507,131	300,000	400,000	986,301
Shareholders equity	$ 5,538,993	$ 6,045,654	$ 6,954,609	$ 7,370,452	$ 7,728,876

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

Results of Operations

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 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 1970 s, 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 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 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. Sales of **Wipe Out® Dairy Wipes** were first recorded in 2000 following the December 1999 acquisition of the product. We believe the drop in sales in 2004 was largely due to the continued financial

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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 and is expected to be recognized over the period ending December 31, 2007. 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 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 $6,000 and $281,000 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

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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.

Fiscal 2003 Compared to Fiscal 2002

Total product sales decreased by 41% in 2003 in comparison to 2002 due principally to the termination of a product license effective as of October 1, 2002, as further discussed below. The effect of the termination of this product license on the current period-to-period comparison of our performance is now behind us. Going forward as we compare the results for 2004 to 2003, we will be looking at the results of our proprietary products. Sales of our proprietary products (principally **First Defense®** and **Wipe Out® Dairy Wipes**) increased by 2% in 2003 in comparison to 2002. 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 1970 s, the price of milk has recently begun to improve. 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 2003 was $11.42 per 100 pounds, which represents a 10% increase from the $10.42 average for 2002. The average Class III milk price for 2001 was $13.10. This upward trend could have a positive impact on our sales if it continues in the future.

Research and development expenses increased by 28% in 2003 in comparison to 2002 due principally to the expenses incurred in connection with the experimental field trial of **Mast Out®** that we completed with positive results. The $1,100,000 in other income earned from the sale of a non-core joint venture in the first quarter of 2003 enabled us to pay for this study and report a fifth consecutive profitable year in 2003. Given the potential sales levels for **Mast Out®** if it is successfully developed, manufactured and approved for sale by the FDA, we believe the increased level of research and development spending is warranted.

Total revenues for the year ended December 31, 2003 decreased by $2,827,000 (46%) to $3,357,000 from $6,185,000 in 2002. Product sales for the year ended December 31, 2003 decreased by $2,157,000 (41%) to $3,145,000 from $5,301,000 in 2002, primarily due to the termination of the license to market the Kamar Heatmount Detector. We have generally held our product selling prices without increase in consideration of the difficult economic times being experienced by our primary customers, dairy producers. Sales of **First Defense®** increased by 7% during the year ended December 31, 2003 in comparison to the same period in 2002. Sales have benefited from the withdrawal of a competitive product from the market and from a significant increase in the value of calves. However, this positive effect was, in part, offset by negative pressures relating to a decline in milk prices. The 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 16% during the twelve month period ended December 31, 2003 in comparison to the same period in 2002. Sales of **Wipe Out® Dairy Wipes** were first recorded in 2000 following the December 1999 acquisition of the product. We believe the drop in sales in 2003 was largely due to the drop in milk prices which is forcing many small dairy producers out of business. **Wipe Out® Dairy Wipes** are more often used on small dairies than larger ones.

Grant income decreased by $191,000 (63%) to $112,000 in 2003, comprising 3% of total revenues in 2003 and 5% of total revenues in 2002. Most of the grant income supported work on the development of **Mast Out®** and new approaches to the diagnosis of Johne s Disease. Royalty income increased by $40,000 (100%) to $81,000 in 2003. In 2003, we earned $20,000 in revenue from the sale of technology rights. In 2002, revenue from the sale of technology rights included $400,000 earned upon the termination of a license covering certain of the **DiffGAM** technology rights, $55,000 earned under this license before it was cancelled, $60,000 from an option to the lactoferrin technology and $25,000 from a different license to the **DiffGAM** technology.

On October 1, 2002, we accepted a payment of $930,000 from Kamar, Inc. of Steamboat Springs, Colorado in consideration of the early termination of our rights to market the Kamar Heatmount Detector. Since 1988, the Company had marketed Kamar s product under an exclusive license that was set to expire on December 31, 2004 when we negotiated the receipt of $930,000 in return for its termination twenty-seven months ahead of schedule.

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The $930,000 approximated the net present value of the expected net contribution from the product over the final twenty-seven months of the license term, had it not been terminated. As this license had no book value, the full amount of the proceeds was recorded as a pre-tax gain of $930,000. The $930,000 was recorded as other income in the fourth quarter of 2002. As a result of the termination of this license, the Company s product sales, product costs and sales and marketing expenses were reduced beginning October 1, 2002.

The following unaudited, pro forma, condensed financial information gives effect to this transaction as if it had occurred as of the beginning of the twelve month periods ended December 31, 2002 and 2003:

	2002			2003		
	Year Ended December 31, 2002	Adjustments	Pro forma Adjusted	Year Ended December 31, 2003	Adjustments	Pro forma Adjusted
Product sales	$ 5,301,313	$ (2,204,077)	$ 3,097,236	$ 3,144,512		$ 3,144,512
Product costs	2,799,429	(1,347,861)	1,451,568	1,347,289		1,347,289
Product selling expenses	1,227,598	(566,922)	660,676	493,151		493,151
Net operating income (loss)	533,141	(289,294)	243,847	(429,031)		(429,031)
Net interest and other income	948,243	(930,000)	18,243	1,145,408		1,145,408
Income before income taxes	1,481,384	(1,219,294)	262,090	716,377		716,377
Tax expense	595,147	(489,865)	105,282	305,161		305,161
Net income	$ 886,237	$ (729,429)	$ 156,808	$ 411,216		$ 411,216
Diluted net income per common share	$ 0.32	$ (0.26)	$ 0.06	$ 0.15		$ 0.15

Product costs amounted to 43% of product sales in 2003 as compared to 53% in 2002. Internally developed products tend to have higher gross margin percentages than licensed-in products. A moderately lower gross margin percentage is anticipated as new products initially 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. We are now investing in the necessary facility modifications and production equipment required to produce Nisin internally. At this stage in our development, management is focusing on growing the absolute dollar value of the gross margin from the products that we continue to sell.

We increased our expenditures for research and development by approximately $297,000 (28%) to $1,350,000 in 2003 as compared to $1,053,000 in 2002. Research and development expenses aggregated 40% and 17% of total revenues in 2003 and 2002, respectively. Research and development expenses exceeded grant income by approximately $1,238,000 in 2003 and by $750,000 in 2002. These net research and development expenses increased to 39% of product sales in 2003 from 14% of product sales in 2002. Since 1999, we have shifted the primary focus of our research and development efforts to products for the animal health industry. The majority of our research and development budget is focused on the development of **Mast Out®**.

Product selling expenses decreased by approximately $734,000 (60%) to $493,000 in 2003, aggregating 16% of product sales in 2003, compared to 23% in 2002. The decrease in the aggregate dollar amount of these expenses results principally from the October 1, 2002 termination of the license to market the Kamar Heatmount Detector, a product that had comprised a significant percentage of total sales. We continue to leverage the efforts of our small sales force through veterinary distribution channels. General and administrative expenses increased by approximately $24,000 (4%) to $596,000 in 2003 as compared to $572,000 in 2002. We continue our efforts

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to control general and administrative expenses while incurring all the necessary expenses associated with being a publicly held company.

Interest income increased by approximately $14,000 to $46,000 in 2003 in comparison to 2002 due principally to the increased amount of invested funds despite the low interest rate environment. We did not incur interest expense after 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 a lactoferrin-producing joint venture. Other income in 2002 included a one-time payment of $930,000 that we accepted in consideration of the October 1, 2002 termination of a product license.

The income before taxes of $716,000 for the year ended December 31, 2003 compares to $1,481,000 for the year ended December 31, 2002. We recorded tax expense at an effective tax rate of 42.6% and 40.2% in 2003 and 2002, respectively, resulting in net income of $411,000 and $886,000 for the years ended December 31, 2003 and 2002, respectively. Income tax expense included deferred taxes of $281,000 and $589,000 for the years ended December 31, 2003 and 2002, respectively, which consisted primarily of the utilization of prior year net operating loss carryforwards.

Financial Position, Liquidity and Capital Resources

We had approximately $4,450,000 in available cash and short-term investments as of December 31, 2004. 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.

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 on any sales of **Mast Out®** made by Pfizer. 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. As of December 31, 2003, approximately $227,000 had been paid to vendors on this project. We completed this investment in July 2004 for a total cost of approximately $423,000. This facility is also being used to produce clinical material for **Mast Out®**. The know-how gained in producing Nisin in our facility is being transferred to Pfizer, who is responsible for the production of cGMP Nisin for **Mast Out®**.

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

	Balance at December 31,		Increase	
	2003	2004	$	%
Cash, cash equivalents and short-term investments	$ 4,245,000	$ 4,450,000	$ 205,000	5%
Net working capital	4,965,000	4,998,000	33,000	1%
Total assets	8,187,000	9,530,000	1,343,000	16%

Shareholders equity	$ 7,370,000	$ 7,729,000	$ 358,000	5%

During 2004, operating activities provided approximately $1,358,000 in cash. The two largest operating activities that were added back to net income were: 1) depreciation and amortization expense of $279,000 and 2) an increase in deferred revenue of $1,079,000. Investing activities used $3,161,000 in cash, comprised of a $334,000 net investment in fixed assets, a net investment of $1,861,000 in short-term investments and a $965,000 acquisition of product rights. Financing activities included approximately $146,000 in proceeds from the issuance of common stock upon the exercise of stock options.

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We funded our 2004 research and development expenses principally from product sales. During the year ended December 31, 2004, gross margin of $2,075,000 from product sales was sufficient to fund the aggregate of $2,060,000 in research and development expenses net of grant income (net R&D) and selling, general and administrative (S,G&A) expenses, resulting in our sixth consecutive year of profitability. In 2003, the $1,797,000 in gross margin was not sufficient to fund the aggregate of $2,327,000 in net R&D and S,G&A expenses. The resulting deficit was more than funded by the $1,100,000 in other income received from the sale of our interest in a lactoferrin-producing joint venture, and as a result, we were able to record our fifth consecutive year of profitability. In 2002, the $2,502,000 in gross margin almost funded the aggregate of $2,549,000 in net R&D and S,G&A expenses. In 2001, the $3,180,000 gross margin more than funded the aggregate of $2,658,000 in net R&D and S,G&A expenses. In 2000, the $2,684,000 gross margin more than funded the aggregate of $2,325,000 in net R&D and S,G&A expenses. In 1999, the $2,569,000 gross margin more than funded the aggregate of $1,954,000 in net R&D and S,G&A expenses. 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 human health products.

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 $15,494,000 for the fifteen year period ended December 31, 2004 has been supported, in part, by $3,152,000 in grant awards since 1990. We have been awarded seven Phase I and three Phase II Small Business Innovation Research (SBIR) grants from the National Institutes of Health aggregating $2,378,000. In addition, we have received three awards from the State of Maine aggregating $455,000, two Phase I SBIR grants from the USDA aggregating $140,000 and one $139,000 grant from the Department of Defense. In addition to the $2,030,000 that supported the development of the Company s milk antibody products for humans, approximately $666,000 was awarded in support of the **Mast Out®** development program, $191,000 was awarded in support of skin sanitizing applications of Nisin, $140,000 was awarded in support of **Crypto-Scan®** and $70,000 was awarded in support of new approaches to the diagnosis of Johne s Disease. Approximately $2,613,000 of this grant income was recognized prior to 2004, and $67,000 was recognized in 2004 (not including the $400,000 award from the Maine Technology Institute, described above) and $72,000 is expected to be recognized in 2005. 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.

Forward-Looking Statements

This Annual Report 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 our objectives concerning future product sales, research and development expenses and anticipated timelines, profitability, 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 and our Quarterly Reports on Form 10-Q. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this Annual Report.

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Risk Factors

The sale and development 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 or 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. 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. We are heavily dependent on the successful development of new products for future growth. One such major effort is our arrangement with Pfizer which will control the development and commercialization of **Mast Out®**. Under our agreement, Pfizer has broad discretion over the development efforts and retains the right to terminate the license subject to certain conditions.

We believe that supplies and raw materials for the production of our products are available from more than one source. 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**. Any disruption in the services at this facility could negatively effect the production of inventory.

The dairy industry has been facing very difficult economic pressures. Many small farmers have been forced out of business. During 2003, milk prices declined to levels last experienced in the 1970 s. While these conditions have recently improved, the financial insecurity of our primary customer base is a risk to our ability to maintain and grow sales at a profitable level.

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.

The potential for epidemics of bovine diseases such as Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) present a risk to us and our customers. A documented case of BSE in the U.S. in 2003 has led to an overall tightening of regulations pertaining to ingredients of animal (especially bovine) origin. For example, the FDA has amended its animal feed rule to eliminate the exemption allowing mammalian blood and blood products to be fed to other ruminants as a protein source. These actions, together with actions by the USDA, to increase the levels of protection of the human food supply do not currently, and are not anticipated to, affect **First Defense®**. **First Defense®** is considered a veterinary medicine rather than a feed ingredient, and it is manufactured from bovine milk and colostrums, which is not considered a BSE risk material. However, future regulations to minimize risk against the spread of disease could affect the regulatory status of **First Defense®**.

The threat of biological terrorism is a risk to both our ability to economically acquire and collect good quality raw material from our contract farms as well as to the economical health of our customers. Any act of widespread bioterrorism against the dairy industry could have a negative impact on our operations.

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

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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(m) to our financial statements. The financial statements are presented on the basis of accounting principles that are generally accepted in the U.S. All professional accounting standards that were effective and applicable to us as of December 31, 2004 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, investments, intangible and long lived assets, income taxes and contingencies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have chosen to highlight certain policies that we consider critical to the operations of the business and understanding our financial statements.

We recognize revenue in accordance with Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition , which supersedes SAB No. 101, Revenue Recognition in Financial Statements . SAB No. 104 requires that four criteria are met before revenue is recognized. These include i) persuasive evidence that an arrangement exists, ii) delivery has occurred or services have been rendered, iii) the seller s price is fixed and determinable and iv) collectibility is reasonably assured. We recognize revenue at the time of shipment (including to distributors) for substantially all products, as title and risk of loss pass to the customer on delivery to the common carrier after concluding that collectibility is reasonably assured. We recognize service revenue at the time the service is performed. Royalty income is recorded on the accrual basis based on sales as reported to us by our licensee pursuant to the terms of the agreement. 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, 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 expect to recognize this revenue over the period from December 15, 2004 to December 31, 2007. 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, 2007. 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, 2007 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.

We record estimated reductions to revenue in connection with customer programs and incentive offerings that allow customers to earn cash rebates or future rights to free or discounted product. We record product selling expenses for customer programs and incentive offerings that allow customers to earn promotional merchandise. We estimate these expenses based on our experience with similar customer programs in prior years. Distributors of **First Defense®** have the right to return expired product for a 50% credit on future orders. As the product has a two year shelf life, we have not experienced significant product returns historically.

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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.

We utilized approximately $1,264,000, $495,000 and $540,000 of net operating loss carryforwards to offset taxable income in fiscal years 2002, 2003 and 2004, respectively. We have no remaining net operating loss carryforwards as of December 31, 2004 to offset future taxable income. As a result of two consecutive years of profitable results in 1999 and 2000 and the expectation of continued profitability, we recorded a tax benefit of approximately $1,967,000 in fiscal 2000 as a result of the release of the valuation allowance on the deferred tax asset related to net operating loss carryforwards. The remaining valuation allowance related to the general business credit carryforward of approximately $97,000 and $62,000 as of December 31, 2003 and 2004, respectively, has not been released due to the uncertainty of its use before expiration. This credit expires in the years 2005 through 2010.

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 reports of the independent accountants thereon, are set forth on Pages F-1 through F-20 at the end of this report.

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

Our Board of Directors decided to change our independent accountants effective April 1, 2003. On that date, the Board dismissed PricewaterhouseCoopers LLP and engaged Baker Newman & Noyes LLC as principal accountants to audit our financial statements. In each case, the decision was recommended by the Audit Committee of the Board of Directors and then approved by the Board.

PricewaterhouseCoopers LLP s report on the financial statements for the year ended December 31, 2002 contained no adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles. In addition, in connection with its audit for the year ended December 31, 2002 and through April 1, 2003, there were no disagreements with PricewaterhouseCoopers LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope and procedures, which disagreements, if not resolved to the satisfaction of PricewaterhouseCoopers LLP, would have caused PricewaterhouseCoopers LLP to make reference to the subject matter of the disagreements in their reports on the financial statements for such years.

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, 2004. 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.

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

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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***

(A) Information with respect to our directors is incorporated herein by reference to the section of our 2005 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 2005 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 2005 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 2005 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 2005 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.

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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).
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+	Amendment, dated April 1992, to Employment Agreement dated November 1991, between the Registrant and Michael F. Brigham (incorporated by reference to Exhibit 10.26 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1992).
10.5+	Amendment, dated April 1992, to Employment Agreement dated November 1991, between the Registrant and Joseph H. Crabb (incorporated by reference to Exhibit 10.32 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1995).
10.6+	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).
10.7+	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).
10.8(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).
10.9+	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).

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10.10	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).
10.11+	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).
10.12+	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).
10.13+	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).
10.14+	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).
10.15	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).
10.16(2)	License Agreement between the Registrant and Pfizer Inc. dated as of December 21, 2004.
10.17+	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).
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).
16	Letter re Change in Certifying Accountant (incorporated by reference to Exhibit 16 to the Registrant s Current Report on Form 8-K/A filed April 15, 2003).
23.1	Consent of Baker Newman & Noyes, LLC.
23.2	Consent of PricewaterhouseCoopers LLP.
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.
(2) Confidential treatment as to certain portions has been requested, which portions have been omitted and filed separately with the Securities and Exchange Commission.
+ Management contract or compensatory plan or arrangement.

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(b) Index to Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ImmuCell Corporation

Portland, Maine

We have audited the balance sheets of ImmuCell Corporation as of December 31, 2004 and 2003, and the related statements of operations, shareholders equity and cash flows for each of the two years in the two year period ended December 31, 2004. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits 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, 2004 and 2003, and the results of its operations and its cash flows for each of the two years in the two year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

Our audits were conducted in accordance with the standards of the Public Company Accounting Oversight Board (United States) and were made for the purpose of forming an opinion on the basic financial statements taken as a whole. The financial statement schedule is presented for purposes of complying with the Securities and Exchange Commission s rules and is not a required part of the basic financial statements. The financial statement schedule for the years ended December 31, 2004 and 2003, has been subjected to the auditing procedures applied in the audits of the basic financial statements and, in our opinion, is fairly stated in all material respects in relation to the basic financial statements taken as a whole.

Baker Newman & Noyes, LLC

Portland, Maine

January 21, 2005

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To Board of Directors and Shareholders of

ImmuCell Corporation:

In our opinion, the consolidated financial statements listed in the accompanying index appearing under Item 15(b) present fairly, in all material respects, the results of operations and cash flows of ImmuCell Corporation for the year ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index appearing under Item 15(c) presents fairly, in all material respects, the information set forth therein for the period ended December 31, 2002 when read in conjunction with the related consolidated financial statements. 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 audit. We conducted our audit of these statements in accordance with the standards of the Public Company Accounting Oversight Board, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

Boston, Massachusetts

January 24, 2003

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IMMUCELL CORPORATION

BALANCE SHEETS

AS OF DECEMBER 31, 2003 and 2004

	2003	2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,356,742	$ 1,700,567
Short-term investments	888,320	2,749,596
Accounts receivable, net of allowance for doubtful accounts of $13,000 at December 31, 2003 and 2004	369,854	434,591
Inventories	674,507	667,666
Current portion of deferred tax asset	45,043	215,066
Prepaid expenses	46,976	44,913
Total current assets	5,381,442	5,812,399
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	1,456,385	1,701,583
Building and improvements	1,309,781	1,500,559
Office furniture and equipment	91,052	123,289
Construction in progress	210,058	7,356
Land	50,000	50,000
	3,117,276	3,382,787
Less-accumulated depreciation	1,322,691	1,481,643
Net property, plant and equipment	1,794,585	1,901,144
DEFERRED TAX ASSET	782,145	674,240
PRODUCT RIGHTS AND OTHER ASSETS, net of accumulated amortization of $142,000 and $196,000 at December 31, 2003 and 2004, respectively	228,460	1,141,886
TOTAL ASSETS	$ 8,186,632	$ 9,529,669
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$ 354,540	$ 228,609
Accounts payable	61,640	92,732
Deferred revenue		493,151
Total current liabilities	416,180	814,492
Long-term portion of deferred revenue	400,000	986,301
COMMITMENTS AND CONTINGENT LIABILITIES (NOTES 5 AND 6)		
SHAREHOLDERS EQUITY:		
Common stock, Par value $0.10 per share,		
Authorized 8,000,000 shares, Issued 3,136,082 and 3,190,148 shares at December 31, 2003 and 2004, respectively	313,608	319,015
Capital in excess of par value	8,951,493	9,160,991
Accumulated deficit	(1,295,647)	(1,152,128)
Treasury stock, at cost 395,498 shares at December 31, 2003 and 2004	(599,002)	(599,002)

Total shareholders equity	7,370,452	7,728,876
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 8,186,632	$ 9,529,669

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

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IMMUCELL CORPORATION

STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31, 2002, 2003 and 2004

	2002	2003	2004
REVENUES:			
Product sales	$ 5,301,313	$ 3,144,512	$ 3,523,982
Grant income	303,207	111,724	66,900
Royalty income	40,644	81,106	84,850
Sale of technology rights	539,540	20,000	20,548
Total revenues	6,184,704	3,357,342	3,696,280
COSTS AND EXPENSES:			
Product costs	2,799,429	1,347,289	1,449,016
Research and development expenses	1,052,783	1,350,164	1,091,836
Product selling expenses	1,227,598	493,151	400,929
General and administrative expenses	571,753	595,769	633,728
Total costs and expenses	5,651,563	3,786,373	3,575,509
Net operating income (loss)	533,141	(429,031)	120,771
Interest income	32,227	46,181	56,221
Interest expense	(19,708)		
Other income, net	935,724	1,099,227	201
Net interest and other income	948,243	1,145,408	56,422
INCOME BEFORE INCOME TAXES	1,481,384	716,377	177,193
INCOME TAX EXPENSE	595,147	305,161	33,674
NET INCOME	$ 886,237	$ 411,216	$ 143,519
NET INCOME PER COMMON SHARE:			
Basic	$ 0.32	$ 0.15	$ 0.05
Diluted	$ 0.32	$ 0.15	$ 0.05
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:			
Basic	2,735,495	2,738,193	2,755,070
Diluted	2,797,660	2,823,696	2,966,923

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

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IMMUCELL CORPORATION

STATEMENTS OF SHAREHOLDERS EQUITY

FOR THE YEARS ENDED DECEMBER 31, 2002, 2003 and 2004

	Common Stock $.10 Par Value		Capital in Excess of Par Value	Accumulated Deficit	Treasury Stock		Total Shareholders Equity
	Shares	Amount			Shares	Amount	
BALANCE, December 31, 2001	3,115,082	$ 311,508	$ 8,913,981	$ (2,593,100)	389,598	$ (586,735)	$ 6,045,654
Net income				886,237			886,237
Exercise of stock Options	10,500	1,050	21,668				22,718
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

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

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IMMUCELL CORPORATION

STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2002, 2003 and 2004

	2002	2003	2004
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 886,237	$ 411,216	$ 143,519
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	236,771	256,270	278,522
Deferred income taxes	589,480	280,667	6,493
(Gain) loss on disposal of fixed assets	(4,786)	33,695	2,892
Changes in:			
Accounts receivable	549,640	54,889	(64,737)
Inventories	(256,330)	115,687	6,841
Prepaid expenses and other assets	(4,026)	(5,887)	(107)
Accounts payable	(84,460)	(25,160)	31,092
Accrued expenses	(104,601)	202,566	(125,931)
Deferred revenue	90,460	79,990	1,079,452
Net cash provided by operating activities	1,898,385	1,403,933	1,358,036
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(250,004)	(304,245)	(338,229)
Proceeds from disposal of fixed assets	3,005		4,000
Maturities of short-term investments	392,145	1,781,702	1,879,413
Purchases of short-term investments	(1,179,191)	(1,882,976)	(3,740,689)
Acquisition of product rights			(965,000)
Net cash used for investing activities	(1,034,045)	(405,519)	(3,160,505)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payments of debt obligations	(414,178)		
Proceeds from exercise of stock options	22,718	14,625	146,294
Acquisition of treasury stock		(12,267)	
Net cash (used for) provided by financing activities	(391,460)	2,358	146,294
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	472,880	1,000,772	(1,656,175)
BEGINNING CASH AND CASH EQUIVALENTS	1,883,090	2,355,970	3,356,742
ENDING CASH AND CASH EQUIVALENTS	$ 2,355,970	$ 3,356,742	$ 1,700,567
CASH PAID FOR INTEREST	$ 22,739	$	$

CASH PAID FOR INCOME TAXES	$ 8,617	$ 17,150	$ 13,893

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

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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) Consolidation Principles

Prior to 2003, the consolidated financial statements of the Company included the accounts of the Company and its wholly-owned subsidiary, the Kamar Marketing Group, Inc. All intercompany accounts and transactions were eliminated in consolidation. In connection with the termination of a license to a product that had been marketed by this subsidiary, the subsidiary was merged into the Company at December 31, 2002.

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

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits 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 $2,068,000 and $1,491,000 at December 31, 2003 and 2004, 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, 2003	December 31, 2004	(Decrease) Increase
Cash and cash equivalents	$ 3,356,742	$ 1,700,567	$ (1,656,175)
Short-term investments	888,320	2,749,596	1,861,276
	$ 4,245,062	$ 4,450,163	$ 205,101

(c) Inventories

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

	As of December 31,	
	2003	2004
Raw materials	$ 86,304	$ 167,241
Work-in-process	405,004	429,481
Finished goods	183,199	70,944
	$ 674,507	$ 667,666

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IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

(d) Property, Plant and Equipment

We depreciate property, plant and equipment on the straight-line method by charges to operations in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The cost of the building, acquired in 1993, and the subsequent 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.

(e) Intangible Assets

We amortize intangible assets on the straight-line method by charges to operations in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The $250,000 acquisition of product rights related to **Wipe Out® Dairy Wipes** in December 1999 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®**, that was paid for in two installments in December 2000 and July 2001, 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 each of the years from 2005 to 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, 2007. Accordingly, we expect amortization expense of approximately $317,000 annually from 2005 through 2007. 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, 2004.

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

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

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IMMUCELL CORPORATION

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

(g) Revenue Recognition

Revenues related to the sale of manufactured products are recorded when title and risk of loss have passed to the customer, which is at the time of shipment and when collectibility is reasonably assured. 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 the Company 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, 2007. Accordingly, we expect to recognize revenue of approximately $493,000 annually from 2005 through 2007 pertaining to this payment. See Notes 2(m) and 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.

(h) Expense Recognition

Advertising expenses are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to $242,000, $163,000 and $172,000 during the years ended December 31, 2002, 2003 and 2004, respectively. All research and development costs are expensed as incurred, as are all related patent costs.

(i) 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.

(j) 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

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IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

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,		
	2002	2003	2004
Weighted average number of shares outstanding during the period	2,735,495	2,738,193	2,755,070
Dilutive stock options	210,201	261,811	542,889
Shares that could have been repurchased with the proceeds from the dilutive stock options	(148,036)	(176,308)	(331,036)
Diluted number of shares outstanding during the period	2,797,660	2,823,696	2,966,923
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	346,000	337,936	2,500

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

(k) Use of Estimates

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

(l) Employee Stock-Based Compensation

We 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,		
	2002	2003	2004
Net income, as reported	$ 886,237	$ 411,216	$ 143,519
Pro forma stock-based employee compensation expense determined under the fair value based method, net of related tax effects	12,865	40,358	27,768
Pro forma net income	$ 873,372	$ 370,858	$ 115,751
Net income per share:			
Basic: as reported	$ 0.32	$ 0.15	$ 0.05
Basic: pro forma	0.32	0.14	0.04
Diluted: as reported	0.32	0.15	0.05
Diluted: pro forma	$ 0.31	$ 0.13	$ 0.04

See 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.

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NOTES TO FINANCIAL STATEMENTS (Continued)

(m) New Accounting Pronouncements

In November 2002, the Financial Accounting Standards Board s (FASB s) Emerging Issues Task Force reached consensus on EITF No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF No. 00-21). EITF No. 00-21 addresses the accounting treatment for arrangements that provide for the delivery or performance of multiple products or services where the delivery of a product, system or performance of services may occur at different points in time or over different periods of time. EITF No. 00-21 requires the separation of the multiple deliverables that meet certain requirements into individual units of accounting that are accounted for separately under the appropriate authoritative accounting literature. EITF No. 00-21 is applicable to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The provisions of EITF No. 00-21 were considered in 2004 in implementing our revenue recognition method to account for the transaction with Pfizer. See Note 10(a).

Statement on Financial Accounting Standards (SFAS) No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities* was effective for contracts entered into or modified after June 30, 2003 and will be applied prospectively. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivatives instruments embedded in other contracts and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities,* resulting in more consistent reporting of contracts as either derivatives or hybrid instruments. The adoption of this standard did not have a material impact on our financial condition, results of operations, earnings per share or cash flows.

FASB Interpretation No. 46, *Consolidation of Variable Interest Entities, an interpretation of Accounting Review Board (ARB) No. 51,* was effective immediately for variable interest entities (VIEs) created after January 31, 2003 and was effective beginning July 1, 2003 for VIEs created prior to the issuance of the interpretation. Interpretation No. 46 provides a new framework for identifying VIEs and determining when a company should include the assets, liabilities, non-controlling interests, and results of activities of a VIE in its financial statements. FASB Interpretation No. 46, *Consolidation of Variable Interest Entities, an interpretation of ARB No. 51,* was revised by FASB Interpretation No. 46 (Revised December 2003), *Consolidation of Variable Interest Entities.* Application of FIN 46R (or FIN 46) is required in financial statements of public entities for periods ending after December 15, 2003, which have interests in special-purpose entities. Application by public entities, other than small business issuers, for all other types of VIEs is required in financial statements for periods ending after March 15, 2004. This pronouncement did not have a material effect on our financial condition, results of operations, earnings per share or cash flows.

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*

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NOTES TO FINANCIAL STATEMENTS (Continued)

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 September 30, 2005. We have not yet determined the possible impact of this Statement on our financial condition, results of operations, earnings per share or cash flows in the years 2005 and after.

3. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2003	**2004**
Royalties	$ 1,673	$
Professional fees	48,817	56,697
Payroll	84,007	109,196
Other	220,043	62,716
	$ 354,540	$ 228,609

The accrued other category as of December 31, 2003 included approximately $164,000 for services performed by outside contractors in connection with the preliminary field trial of **Mast Out®** that were completed but not billed as of December 31, 2003.

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NOTES TO FINANCIAL STATEMENTS (Continued)

4. INCOME TAXES

The income tax provision consists of the following:

	Year Ended December 31,		
	2002	**2003**	**2004**
Current			
Federal	$	$ 9,123	$ 11,996
State	1,603	9,500	10,942
Foreign	4,064	5,871	4,243
	5,667	24,494	27,181
Deferred			
Federal	457,528	216,695	2,670
State	131,952	63,972	3,823
	589,480	280,667	6,493
Total	$ 595,147	$ 305,161	$ 33,674

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,		
	2002	**2003**	**2004**
Computed expected tax expense	$ 503,671	$ 243,568	$ 60,245
State income taxes, net of federal benefit	87,310	48,492	9,745
Foreign tax on royalty income	4,064	5,871	4,243
Change in valuation allowance			(35,000)
Other	102	7,230	(5,559)
Total income tax expense	$ 595,147	$ 305,161	$ 33,674

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

	As of December 31,	
	2003	2004
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 210,097	$
Deferred revenue and other reserves	204,660	626,457
Depreciation	(34,903)	(97,534)
Capitalized research and experimentation	447,334	378,301
Prepaid expenses		(17,918)
General business credit carryforward	97,419	62,419
Deferred tax assets before valuation allowance	924,607	951,725
Valuation allowance	(97,419)	(62,419)
Net deferred tax assets	$ 827,188	$ 889,306

We utilized approximately $1,264,000, $495,000 and $540,000 of net operating loss carryforwards to offset taxable income in fiscal years 2002, 2003 and 2004, respectively, and $35,000 of general business tax credits in

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NOTES TO FINANCIAL STATEMENTS (Continued)

2004. We have no remaining net operating loss carryforwards as of December 31, 2004 to offset future taxable income. 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. The valuation allowance related to the general business credit carryforward of approximately $97,000 and $62,000 as of December 31, 2003 and 2004, respectively, is due to the uncertainty of its use before expiration. This credit expires in the years 2005 through 2010 if not utilized.

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 four years through December 31, 2004 for tax return purposes only. We expect to amortize an additional $173,000 of these capitalized expenditures for each of the five years ending December 31, 2005 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.

(b) Stock Option Plans

In May 1989, the shareholders approved the 1989 Stock Option and Incentive Plan (the 1989 Employee 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 Employee Plan expire no later than ten years from the date of grant. The 1989 Employee Plan expired in March 1999, and no further options may be granted under the 1989 Employee Plan. However, outstanding options under the 1989 Employee Plan may be exercised in accordance with their terms.

In June 2000, the shareholders approved the 2000 Stock Option and Incentive Plan (the 2000 Employee 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. Originally, 250,000 shares of common stock were reserved for issuance under the 2000 Employee Plan. The shareholders of the Company approved an

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increase in this number to 500,000 shares in June 2001. All options granted under the 2000 Employee Plan expire no later than ten years from the date of grant. The 2000 Employee Plan expires in June 2010, after which date no further options may be granted under the 2000 Employee Plan. However, any outstanding options under the 2000 Employee 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 expires 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.

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

	1989 Employee Plan	2000 Employee Plan	2000 Outside Director Plan	Weighted Average Exercise Price
Balance at December 31, 2001	186,672	357,000	75,000	$ 2.81
Grants		30,000		2.37
Terminations	(500)	(60,000)	(15,000)	2.92
Exercises	(10,500)			2.16
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

Exercisable at December 31, 2004	132,672	159,266	60,000	$ 2.89
Reserved for future grants		231,167	60,000	

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At December 31, 2004, 488,639 common shares were reserved for future issuance under all outstanding stock options described above. An additional 291,167 common shares were reserved for potential issuance under future stock option grants. The weighted average remaining life of the options outstanding under the 1989 Employee Plan, the 2000 Employee Plan and the 2000 Outside Director Plan as of December 31, 2004 was approximately four years and six months. The exercise price of the options outstanding and of the options exercisable as of December 31, 2004 ranged from $1.31 to $4.36 per share. The weighted-average grant date fair values of options granted during 2002, 2003 and 2004 were $0.43, $0.23 and $0.92 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(l), with the following weighted-average assumptions:

	2002	2003	2004
Risk-free interest rate	2.9%	2.2%	3.0%
Dividend yield	0	0	0
Expected volatility	45.6%	26%	27.8%
Expected life	3 years	3 years	3 years

(c) Common Stock Rights Plan

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.

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

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NOTES TO FINANCIAL STATEMENTS (Continued)

outstanding Rights in whole, but not in part, at a price of $.005 per Right, subject to adjustment. The Rights will expire on the earlier of i) the close of business on September 19, 2005, 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, 2004. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

We enter into agreements with third parties in the ordinary course of business under which we are obligated to indemnify such third parties for and against various risks and losses. The precise terms of such indemnities vary with the nature of the agreement. In many cases, 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, 2004.

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. Depending upon the circumstances of any termination of employment of this key employee, we could be required to pay this salary through December 31, 2005.

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

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NOTES TO FINANCIAL STATEMENTS (Continued)

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 (70%, 92% and 89% for the years ended December 31, 2002, 2003 and 2004, 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 29%, 7% and 10% of our total product sales for the years ended December 31, 2002, 2003 and 2004, respectively. The changes in the domestic and foreign components of the product sales mix is principally the result of the license termination discussed in Note 10(d). Sales made to Walco International aggregated 8%, 19% and 17% of total product sales during the years ended December 31, 2002, 2003 and 2004, respectively. This customer accounted for 21% and 16% of the Company s outstanding accounts receivable as of December 31, 2003 and 2004, respectively.

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 $33,000, $35,000 and $35,000 to the plan for the years ended December 31, 2002, 2003 and 2004, respectively.

9. UNAUDITED QUARTERLY FINANCIAL DATA

The following tables present the quarterly information for fiscal years 2003 and 2004 (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 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 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

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IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

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 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, 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 expect to recognize this revenue over the period from December 15, 2004 to December 31, 2007. 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, 2007. 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, 2007 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.

(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.

(c) We received a payment of $100,000 in March 2001 under a license agreement covering certain rights to the Company s **DiffGAM**echnology which was recognized as revenue from the sale of technology rights over the twenty-two month period ended in December 2002, representing the period during which we had agreed to provide clinical material to the licensee at a discount. In December 2002, we received a $400,000 payment upon the termination of this license in accordance with the terms of the agreement. The full amount of the proceeds was recorded as revenue from the sale of technology rights in the fourth quarter of 2002.

(d) In October 2002, we accepted a payment of $930,000 in consideration of the early termination of our rights to market the Kamar Heatmount Detector. As this license had no book value, the full amount of the proceeds represented a pre-tax gain and was recorded as other income in the fourth quarter of 2002. The license was scheduled to expire after an additional twenty-seven months on December 31, 2004, had it not been terminated. As a result of the termination of this license, our product sales, product costs and sales and marketing expenses were reduced beginning October 1, 2002. The following unaudited, pro forma, condensed financial

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IMMUCELL CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

information gives effect to this transaction as if it had occurred as of January 1, 2002 and then compares those figures to the results obtained for the twelve month periods ended December 31, 2003 and 2004.

	Year Ended December 31, 2002	2002 Adjustments	2002 Pro forma Adjusted	Year Ended December 31, 2003	Year Ended December 31, 2004
Product sales	$ 5,301,313	$ (2,204,077)	$ 3,097,236	$ 3,144,512	$ 3,523,982
Product costs	2,799,429	(1,347,861)	1,451,568	1,347,289	1,449,016
Product selling expenses	1,227,598	(566,922)	660,676	493,151	400,929
Net operating income (loss)	533,141	(289,294)	243,847	(429,031)	120,771
Net interest and other income	948,243	(930,000)	18,243	1,145,408	56,422
Income before income taxes	1,481,384	(1,219,294)	262,090	716,377	177,193
Tax expense	595,147	(489,865)	105,282	305,161	33,674
Net income	$ 886,237	$ (729,429)	$ 156,808	$ 411,216	$ 143,519
Diluted net income per common share	$ 0.32	$ (0.26)	$ 0.06	$ 0.15	$ 0.05

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.

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SCHEDULE 2 SUPPLEMENTAL VALUATION AND QUALIFYING ACCOUNTS

Allowance for Doubtful Accounts:	
Balance at December 31, 2001	$ 38,000
Amount charged to costs and expenses	
Write-offs and returns	(1,000)
Reversal of accrual	(18,000)
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

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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, 2005 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, 2005 By: /s/ MICHAEL F. BRIGHAM
Michael F. Brigham

President, Chief Executive Officer,

Treasurer and Director

Date: March 21, 2005 By: /s/ ANTHONY B. CASHEN
Anthony B. Cashen, Director

Date: March 21, 2005 By: /s/ JOSEPH H. CRABB
Joseph H. Crabb, Ph.D., Director

Date: March 21, 2005 By: /s/ WILLIAM H. MAXWELL
William H. Maxwell, M.D., Director

Date: March 21, 2005 By: /s/ JONATHAN E. ROTHSCHILD
Jonathan E. Rothschild, Director

Date: March 21, 2005 By: /s/ MITCHEL SAYARE
Mitchel Sayare, Ph.D., Director

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IMMUCELL CORPORATION

EXHIBIT INDEX

Exhibit 10.16*	License Agreement between the Registrant and Pfizer Inc. dated as of December 21, 2004.
Exhibit 23.1	Consent of Baker Newman & Noyes, LLC.
Exhibit 23.2	Consent of PricewaterhouseCoopers LLP.
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.

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