IMMUCELL CORP /DE/
Form 10-Q
May 12, 2005
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2005

OR

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

0-15507

Commission file number

IMMUCELL CORPORATION

(Exact name of Registrant as specified in its charter)

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

56 Evergreen Drive

Portland, ME 04103

(Address of principal executive office and zip code)

(207) 878-2770

(Registrant s telephone number, including area code)

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 a check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Class of Securities:	Outstanding at May 11, 2005:
Common Stock, par value $0.10 per share	2,794,650

Table of Contents

IMMUCELL CORPORATION

INDEX TO FORM 10-Q

March 31, 2005

Table of Contents

IMMUCELL CORPORATION

PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BALANCE SHEETS

	December 31, 2004	(Unaudited) March 31, 2005
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,700,567	$ 1,959,423
Short-term investments	2,749,596	2,717,860
Accounts receivable, net of allowance for doubtful accounts of $13,000 and $12,000 at December 31, 2004 and March 31, 2005, respectively	434,591	746,345
Inventories	667,666	554,941
Current portion of deferred tax asset	215,066	215,066
Prepaid expenses	44,913	44,980
Total current assets	5,812,399	6,238,615
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	1,701,583	1,716,385
Building and improvements	1,500,559	1,500,559
Office furniture and equipment	123,289	126,754
Construction in progress	7,356	37,208
Land	50,000	50,000
	3,382,787	3,430,906
Less - accumulated depreciation	1,481,643	1,548,071
Net property, plant and equipment	1,901,144	1,882,835
DEFERRED TAX ASSET	674,240	674,240
PRODUCT RIGHTS AND OTHER ASSETS, net of accumulated amortization of $196,000 and $286,000 at December 31, 2004 and March 31, 2005, respectively	1,141,886	1,053,901
TOTAL ASSETS	$ 9,529,669	$ 9,849,591
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$ 228,609	$ 217,964
Accounts payable	70,143	93,138
Income taxes payable	22,589	156,475

Deferred revenue	493,151	530,651
Total current liabilities	814,492	998,228
Long-term portion of deferred revenue	986,301	863,013
SHAREHOLDERS EQUITY:		
Common stock, Par value-$0.10 per share Authorized-8,000,000 shares, Issued-3,190,148 shares at December 31, 2004 and March 31, 2005	319,015	319,015
Capital in excess of par value	9,160,991	9,160,991
Accumulated deficit	(1,152,128)	(892,654)
Treasury stock, at cost 395,498 shares at December 31, 2004 and March 31, 2005	(599,002)	(599,002)
Total shareholders equity	7,728,876	7,988,350
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 9,529,669	$ 9,849,591

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

Table of Contents

IMMUCELL CORPORATION

STATEMENTS OF OPERATIONS FOR THE THREE

MONTH PERIODS ENDED MARCH 31, 2004 AND 2005

(Unaudited)

	Three Months Ended March 31,	
	2004	**2005**
REVENUES:		
Product sales	$ 1,217,294	$ 1,428,363
Sale of technology rights		123,288
Grant income		37,631
Royalty income	24,256	6,946
Total revenues	1,241,550	1,596,228
COSTS AND EXPENSES:		
Product costs	459,451	561,593
Research and development expenses	221,924	314,186
General and administrative expenses	156,692	168,455
Product selling expenses	124,062	138,887
Total costs and expenses	962,129	1,183,121
Net operating income	279,421	413,107
INTEREST AND OTHER INCOME:		
Interest income	11,425	20,802
Other (expenses) income, net	(355)	441
Net interest and other income	11,070	21,243
INCOME BEFORE INCOME TAXES	290,491	434,350
INCOME TAX EXPENSE	118,350	174,876
NET INCOME	$ 172,141	$ 259,474
NET INCOME PER COMMON SHARE:		
Basic	$ 0.06	$ 0.09
Diluted	$ 0.06	$ 0.09
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic	2,743,455	2,794,650

Diluted	2,932,606	3,033,041

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

Table of Contents

IMMUCELL CORPORATION

STATEMENTS OF CASH FLOWS FOR THE THREE MONTH PERIODS

ENDED MARCH 31, 2004 AND 2005

(Unaudited)

	Three Months Ended March 31,	
	2004	**2005**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 172,141	$ 259,474
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	49,762	66,428
Amortization	10,131	89,935
Deferred income taxes	115,889	
Loss on disposal of fixed assets	1,260	
Changes in:		
Accounts receivable	(236,935)	(311,754)
Inventories	184,678	112,725
Prepaid expenses and other assets	(4,015)	(2,017)
Accrued expenses	(189,104)	(10,645)
Accounts payable	42,340	22,995
Income taxes payable	(5,450)	133,886
Deferred revenue		(85,788)
Net cash provided by operating activities	140,697	275,239
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(162,772)	(48,119)
Proceeds from disposal of fixed assets	4,000	
Maturities of short-term investments		1,773,375
Purchases of short-term investments	(1,377,895)	(1,741,639)
Net cash used for investing activities	(1,536,667)	(16,383)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	33,546	
Net cash provided by financing activities	33,546	
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,362,424)	258,856
BEGINNING CASH AND CASH EQUIVALENTS	3,356,742	1,700,567
ENDING CASH AND CASH EQUIVALENTS	$ 1,994,318	$ 1,959,423
CASH PAID FOR INCOME TAXES	6,726	40,725

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

Table of Contents

IMMUCELL CORPORATION

Notes to Unaudited Financial Statements

March 31, 2005

1. BASIS OF PRESENTATION

We have prepared the accompanying financial statements without audit and have reflected the adjustments, all of which are of a normal recurring nature, that are, in our opinion, necessary for a fair presentation of the results for the interim periods presented. Certain information and footnote disclosures normally included in the annual financial statements which are prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. Accordingly, we believe that although the disclosures are adequate to make the information presented not misleading, these financial statements should be read in conjunction with the financial statements and the notes to the financial statements as of December 31, 2004, contained in the Company s Annual Report on Form 10-K as filed with the Securities and Exchange Commission.

2. 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. 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 and not more than twelve months from the balance sheet date and are held at different financial institutions that are insured by the Federal Deposit Insurance Corporation (FDIC) within FDIC limits of $100,000 each.

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

	December 31, 2004	March 31, 2005	Increase (Decrease)
Cash and cash equivalents	$ 1,700,567	$ 1,959,423	$ 258,856
Short-term investments	2,749,596	2,717,860	(31,736)
	$ 4,450,163	$ 4,677,283	$ 227,120

3. INVENTORIES

Inventories consist of the following:

	December 31, 2004	March 31, 2005
Raw materials	$ 167,241	$ 144,926
Work-in-process	429,481	330,363
Finished goods	70,944	79,652
	$ 667,666	$ 554,941

4. LICENSING AND SALE OF TECHNOLOGY

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. In December 2004, we received a $1,500,000 up front payment from Pfizer in connection with a 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®**. If the estimate of December 31, 2007 changes, the period during which the then remaining expense and revenue are recognized would be adjusted accordingly. During the three month period ended March 31, 2005, research and development expenses included approximately $80,000 of such amortization expense, and we recognized approximately $123,000 of such deferred revenue. 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 before regulatory approval is obtained 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 achieved. Any future royalty payments will be recognized as earned based on future product sales.

Table of Contents

IMMUCELL CORPORATION

Notes to Unaudited Financial Statements (continued)

March 31, 2005

5. INCOME TAXES

We account for income taxes in accordance with Statement of Financial Accounting Standards (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. Income tax expense aggregated $118,000 (40.7% of income before income taxes) and $175,000 (40.3% of income before income taxes) for the three month periods ended March 31, 2004 and 2005, respectively. We recorded income taxes payable of $156,000 as of March 31, 2005. Income tax expense was comprised principally of non-cash deferred income tax expense of $116,000 during the three month period ended March 31, 2004. In order to accelerate the utilization of available net operating loss carryforwards in advance of their expiration dates, we elected to increase income for federal income tax purposes by capitalizing research and experimentation expenditures aggregating $1,731,000 for our 2000 and 2001 tax returns. As a result, we expect to amortize approximately $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 ended December 31, 2010 for tax return purposes only. 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. We have no remaining net operating loss carryforwards as of December 31, 2004 to offset future taxable income. We believe it is more likely than not that the deferred tax assets will be realized through future tax effects of temporary differences between book income and taxable income. Accordingly, we have not established a valuation allowance for the deferred tax assets, except for the general business credit carryforward of $62,000 as of December 31, 2004 and March 31, 2005.

6. NET INCOME PER COMMON SHARE

The basic net income per common share has been computed in accordance with SFAS No. 128, *Earnings Per Share*, by dividing the net income by the weighted average number of common shares outstanding during the period. The diluted net income per share reflects the potential dilution from outstanding stock options as shown below.

	Three Months Ended March 31,	
	2004	**2005**
Weighted average number of shares outstanding during the period	2,743,455	2,794,650
Dilutive stock options	546,639	506,305
Shares that could have been repurchased with the proceeds from the dilutive stock options	(357,488)	(267,914)
Diluted number of shares outstanding during the period	2,932,606	3,033,041

Outstanding stock options not included in the calculation because the effect would be anti-dilutive	5,000

7. 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. 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 eliminates the ability to account for stock-based compensation transactions using APB Option No. 25 and generally requires us to recognize compensation costs for stock-based payments using the fair-value-based method. Implementation of the provisions of FAS 123R has been deferred and shall be effective beginning January 1, 2006. Had compensation cost for our stock plans been determined consistent with the provisions of FAS 123R, our net income and basic and diluted net income per share would have been reduced to the pro forma amounts indicated below:

Table of Contents

IMMUCELL CORPORATION

Notes to Unaudited Financial Statements (continued)

March 31, 2005

	Three Months Ended March 31,	
	2004	**2005**
Net income, as reported	$ 172,141	$ 259,474
Less: Pro forma stock-based employee compensation expense determined under the fair value based method, net of related tax effects	(10,023)	(3,173)
Pro forma net income	$ 162,118	$ 256,301
Net income per share:		
Basic: as reported	$ 0.06	$ 0.09
Basic: pro forma	$ 0.06	$ 0.09
Diluted: as reported	$ 0.06	$ 0.09
Diluted: pro forma	$ 0.06	$ 0.08

8. SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

Pursuant to SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, we operate in one reportable business segment, that being the development, acquisition, manufacture and sales of products that improve the health and productivity of cows for the dairy and beef industries. Almost all of the Company s internally funded research and development expenses are in support of products that improve the health and productivity of cows for the dairy and beef industries. The significant accounting policies of this segment are the same as those described in Note 2 to the Company s Annual Report on Form 10-K for the year ended December 31, 2004.

Our primary customers for the majority (87% and 85% for the three month periods ended March 31, 2004 and 2005, respectively) of our product sales are in the United States dairy and beef industries. Sales to foreign customers, who are in the dairy and beef industries, aggregated 13% and 15% of product sales for the three month periods ended March 31, 2004 and 2005, respectively. Sales made to Walco International, Inc. aggregated 17% and 18% of total product sales during the three month periods ended March 31, 2004 and 2005, respectively. This customer accounted for 16% and 17% of our outstanding accounts receivable as of December 31, 2004 and March 31, 2005, respectively.

9. 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 because of our belief that the stock had been trading at undervalued levels at that time and thus represented a good investment. Repurchases under the plan may be made from time to time at the discretion of management. There is no guarantee as to the exact number of shares to be repurchased, and no time limit was set 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 (an average purchase price of $2.08 per share) under this plan. As of May 11, 2005, no additional shares had been repurchased. The repurchase of shares under this plan has been limited to date because the share price has generally traded above the level experienced around the time that we adopted the repurchase plan.

Table of Contents

IMMUCELL CORPORATION

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

RESULTS OF OPERATIONS FOR THE THREE MONTH PERIOD ENDED MARCH 31, 2005

Product sales increased by 17%, or $211,000, to $1,428,000 during the three month period ended March 31, 2005 in comparison to $1,217,000 during the three month period ended March 31, 2004. 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 **First Defense** increased by 16% during the three month period ended March 31, 2005 in comparison to the same period in 2004. Sales have been positively affected by the upward trend in the price that dairy producers are paid for the milk that they produce and sell. Sales of **Wipe Out® Dairy Wipes** increased by 54% during the three month period ended March 31, 2005 in comparison to the same period in 2004. A decrease in the domestic sales of this product was more than offset by new foreign sales in the first quarter of 2005. Domestic sales of this premium product have been challenged by less expensive competitive products and by the continuing economic pressure in the U.S. dairy industry that is forcing many small producers out of business.

Total revenues increased by 29%, or $355,000, to $1,596,000 during the three month period ended March 31, 2005 in comparison to the same period in 2004. We recognized $123,000 in deferred revenue during the first quarter of 2005 related to the $1,500,000 up front payment received from Pfizer in December 2004, which deferred revenue is being recognized over the period from December 15, 2004 to December 31, 2007. Grant income of $38,000 was earned during the three month period ended March 31, 2005 which supported the development of a bovine milk immunoglobulin supplement to prevent diarrhea in humans. No revenue from the sale of technology rights or grant income was earned during the same period in 2004. Royalty income decreased by $17,000 to $7,000 during the three month period ended March 31, 2005 in comparison to the same period in 2004. Royalty income is earned on the sale of whey protein isolate by a licensee to certain rights to our milk protein purification technology.

Gross margin as a percentage of product sales was 61% and 62% during the three month periods ended March 31, 2005 and 2004, respectively. The total gross margin increased by 14%, or $109,000, to $867,000 during the three month period ended March 31, 2005, as compared to the same period in 2004. Changes in the gross margin percentage principally reflect changes in the product sales mix. We earn a higher gross margin on products that we have developed, such as **First Defense®**, and a lower gross margin on acquired products, such as **Wipe Out® Dairy Wipes**.

During the three month period ended March 31, 2005, research and development expenses increased by 42%, or $92,000, to $314,000, as compared to the same period in 2004. This 2005 expense included $80,000 in amortization of the intangible asset pertaining to the November 2004 buy out of certain future milestone and royalty payment obligations under our **Mast Out®** license from Nutrition 21, which intangible asset is being amortized over the period from November 15, 2004 to December 31, 2007. Research and development expenses aggregated 20% and 18% of total revenues during the three month periods ended March 31, 2005 and 2004, respectively. Research and development expenses exceeded grant income and revenue from the sale of technology rights by $153,000 (which net amount equaled 11% of product sales) during the three month period ended March 31, 2005. No grant income or revenue from the sale of technology rights was earned during the three month period ended March 31, 2004, and research and development expenses of $222,000 equaled 18% of product sales during this period.

During 2000, we initiated the development of **Mast Out®**, a Nisin-based treatment for mastitis in lactating dairy cows. Nisin, a natural anti-bacterial peptide, is also the active ingredient in our product, **Wipe Out® Dairy Wipes**. This product development program has become the primary focus of our research and development investment. We are supplying product for efficacy trials that are expected to begin in the first

half of 2005. This activity comprised most of our research and development expenses during the first quarter of 2005. In December 2004, we entered into a product development and marketing agreement with Pfizer Animal Health, a division of Pfizer, Inc. for **Mast Out®**. 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 is responsible for clinical, regulatory and commercial manufacturing development.

While we continue our efforts with internally and externally funded product development programs, we also seek to acquire new products and technologies that fit with our sales focus on the dairy and beef industries. We are 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 exploring the potential to use our **First Defense®** technology to produce a colostrum supplement product for newborn calves. We are also evaluating new formulations for the preparation and sanitization of udders before and after milking. Lastly, there are other applications of our Nisin technology that may lead to potential product applications, including a treatment for mastitis in dry (non-lactating) cows.

Table of Contents

IMMUCELL CORPORATION

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. In April 2005, we entered into an exclusive distribution agreement with TCS Biosciences Ltd. of England covering sales of this product in the European Union, Japan, and Australia. TCS has made some modifications to the test kit and placed an initial order with us for product. TCS intends to launch commercial sales of this product under their name, Isolate Cryptosporidium, this summer, and we hope to benefit from the related supply agreement.

General and administrative expenses were $168,000 during the three month period ended March 31, 2005 compared to $157,000 during the same period in 2004. During the three month period ended March 31, 2005, product selling expenses increased by 12%, or $15,000, to $139,000, as compared to the same period in 2004, aggregating 10% of product sales during the three month periods ended March 31, 2005 and 2004. Our objective is to maintain the ratio of product selling expenses to product sales below 15% on an annual basis.

Income before income taxes for the three month periods ended March 31, 2005 and 2004 was $434,000 and $290,000, respectively. The net profit for the three months ended March 31, 2005 of $259,000 ($0.09 per diluted share) compares to a net profit of $172,000 ($0.06 per diluted share) for the three months ended March 31, 2004. The effective income tax rate was 40% and 41% for the three month periods ended March 31, 2005 and 2004, respectively.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and short-term investments increased by $227,000 to $4,677,000 at March 31, 2005 from $4,450,000 at December 31, 2004. Net cash provided by operating activities amounted to $275,000 during the three months ended March 31, 2005 as compared to $141,000 during the three months ended March 31, 2004. Accounts receivable increased by $312,000 and $237,000 during the three month periods ended March 31, 2005 and 2004, respectively. Inventories decreased by $113,000 and $185,000 during the three month periods ended March 31, 2005 and 2004, respectively. These changes resulted principally from the increased level of product sales during the first quarter of both years due to the seasonality of our sales. Total assets increased by $320,000 to $9,850,000 at March 31, 2005 from $9,530,000 at December 31, 2004. The Company has no outstanding bank debt. Net working capital increased by $242,000 to $5,240,000 at March 31, 2005 from $4,998,000 at December 31, 2004. Shareholders equity increased by $259,000 to $7,988,000 at March 31, 2005 from $7,729,000 at December 31, 2004.

Under the December 2004 product development and marketing agreement with Pfizer for **Mast Out®**, we are eligible to earn milestone payments as development objectives are achieved. For instance, we received $1,500,000 upon signing of the agreement. We are eligible to receive an additional $250,000 during the second half of 2005 in connection with a patent filing milestone and an additional $500,000 during the first half of 2006 in connection with the transfer of the manufacturing process to Pfizer. Additional milestone payments may be earned in the future in connection with certain clinical trial objectives, regulatory approvals and patent issuances.

We believe that we have sufficient capital resources to meet our working capital requirements and to finance our ongoing business operations during at least the next twelve months.

FORWARD-LOOKING STATEMENTS

This Quarterly 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 factors that may affect the dairy industry and future demand for our products, the estimated timing of future development work and commercialization of our products, anticipated future research efforts, sources of possible future revenue, the future adequacy of our working capital, future profitability, future expense ratios and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, the uncertainties associated with product development, and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Annual Report on Form 10-K 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 Quarterly Report.

Table of Contents

IMMUCELL CORPORATION

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 product development and marketing agreement with Pfizer, under which that company will largely 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 are a small company with approximately 24 employees. As such, we rely on certain key employees to support different operational functions, with little redundancy in capacity. The loss of any of these key employees could adversely effect our operations until a qualified replacement is hired and trained.

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**. The specific antibodies that we purify for **First Defense®** and the Nisin we produce by fermentation for **Wipe Out® Dairy Wipes** are not readily available from other sources. Any disruption in the services at this facility could adversely affect the production of inventory.

The dairy industry in the United States has been facing very difficult economic pressures. Many small farmers have been forced out of business. After declining in 2002 to price levels common in the 1970 s, the price of milk has increased. 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. **First Defense®** is considered a veterinary medicine rather than a feed ingredient, and it is manufactured from bovine milk and colostrum, which is not considered a BSE risk material. Any regulatory action to increase protection of the human food supply may in the future, but does not currently, and is not anticipated to, affect **First Defense®**.

The threat of biological terrorism is a risk to both the economic health of our customers and to our ability to economically acquire and collect good quality raw material from our contract farms. Any act of widespread bioterrorism against the dairy industry could adversely affect our operations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable

ITEM 4. 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 March 31, 2005. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. There was no change in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

IMMUCELL CORPORATION

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable

ITEM 5. OTHER INFORMATION

Not applicable

ITEM 6. EXHIBITS

Exhibit 31 Certifications required by Rule 13a-14(a).

Exhibit 32 Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ImmuCell Corporation
Registrant

Date: May 11, 2005

By: /s/ Michael F. Brigham

Michael F. Brigham
President, Chief Executive Officer
and Principal Financial Officer