

IMMUCELL CORP /DE/  
Form 10-Q  
August 10, 2004  
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 June 30, 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**  
(State or other jurisdiction  
of incorporation)

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

**56 Evergreen Drive**

**Portland, ME 04103**

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

(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  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

<u>Class of Securities:</u>	<u>Outstanding at August 6, 2004:</u>
Common Stock, par value \$0.10 per share	2,757,817

---

---

**Table of Contents**

**IMMUCELL CORPORATION**

INDEX TO FORM 10-Q

June 30, 2004

	<b>Page</b>
<b>PART I: FINANCIAL INFORMATION</b>	
<b>ITEM 1. FINANCIAL STATEMENTS</b>	3
<u>Balance Sheets at December 31, 2003 and June 30, 2004</u>	3-4
<u>Statements of Operations for the three and six month periods ended June 30, 2003 and 2004</u>	5
<u>Statements of Cash Flows for the six month periods ended June 30, 2003 and 2004</u>	6
<u>Notes to Unaudited Financial Statements</u>	7-9
<b>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</b>	9-12
<b>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</b>	13
<b>ITEM 4. CONTROLS AND PROCEDURES</b>	13
<b>PART II: OTHER INFORMATION</b>	
<b><u>ITEMS 1 THROUGH 6</u></b>	13-14
<u>Signatures</u>	14

**Table of Contents****IMMUCELL CORPORATION****PART 1. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****BALANCE SHEETS****ASSETS**

	<b>December 31, 2003</b>	<b>(Unaudited) June 30, 2004</b>
	<u>          </u>	<u>          </u>
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 3,356,742	\$ 1,550,415
Short-term investments	888,320	2,752,571
Accounts receivable, net of allowance for doubtful accounts of \$13,000 and \$12,000 at December 31, 2003 and June 30, 2004, respectively	369,854	345,030
Inventories	674,507	524,062
Current portion of deferred tax asset	45,043	45,043
Prepaid expenses	46,976	96,666
	<u>          </u>	<u>          </u>
Total current assets	5,381,442	5,313,787
<b>PROPERTY, PLANT AND EQUIPMENT, at cost:</b>		
Laboratory and manufacturing equipment	1,456,385	1,461,779
Building and improvements	1,309,781	1,309,781
Construction in progress	210,058	404,646
Office furniture and equipment	91,052	95,771
Land	50,000	50,000
	<u>          </u>	<u>          </u>
	3,117,276	3,321,977
Less - accumulated depreciation	1,322,691	1,414,869
	<u>          </u>	<u>          </u>
Net property, plant and equipment	1,794,585	1,907,108
<b>DEFERRED TAX ASSET</b>	782,145	706,744
<b>PRODUCT RIGHTS AND OTHER ASSETS, net of amortization of \$142,000 and \$162,000 at December 31, 2003 and June 30, 2004, respectively</b>	228,460	208,268
	<u>          </u>	<u>          </u>
<b>TOTAL ASSETS</b>	<b>\$ 8,186,632</b>	<b>\$ 8,135,907</b>
	<u>          </u>	<u>          </u>

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



Table of Contents

## IMMUCELL CORPORATION

## BALANCE SHEETS

LIABILITIES AND SHAREHOLDERS EQUITY

	December 31, 2003	(Unaudited) June 30, 2004
	<u>          </u>	<u>          </u>
<b>CURRENT LIABILITIES:</b>		
Accrued expenses	\$ 354,540	\$ 141,701
Accounts payable	61,640	73,652
	<u>          </u>	<u>          </u>
Total current liabilities	416,180	215,353
<b>LONG-TERM LIABILITIES:</b>		
Long-term portion of deferred revenue	400,000	400,000
	<u>          </u>	<u>          </u>
Total long-term liabilities	400,000	400,000
<b>SHAREHOLDERS EQUITY:</b>		
Common stock, Par value-\$0.10 per share Authorized-8,000,000 shares Issued-3,136,082 and 3,153,315 shares at December 31, 2003 and June 30, 2004, respectively	313,608	315,332
Capital in excess of par value	8,951,493	8,985,735
Accumulated deficit	(1,295,647)	(1,181,511)
Treasury stock, at cost 395,498 shares at December 31, 2003 and June 30, 2004	(599,002)	(599,002)
	<u>          </u>	<u>          </u>
Total shareholders equity	7,370,452	7,520,554
	<u>          </u>	<u>          </u>
<b>TOTAL LIABILITIES AND SHAREHOLDERS EQUITY</b>	<b>\$ 8,186,632</b>	<b>\$ 8,135,907</b>
	<u>          </u>	<u>          </u>

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

Table of Contents

## IMMUCELL CORPORATION

## STATEMENTS OF OPERATIONS FOR THE THREE AND SIX

MONTH PERIODS ENDED JUNE 30, 2003 AND 2004

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2004	2003	2004
<b>REVENUES:</b>				
Product sales	\$ 589,579	\$ 642,376	\$ 1,605,132	\$ 1,859,669
Grant income	1,500	10,000	82,314	10,000
Royalty income	25,605	13,092	36,531	37,349
Sale of technology rights			20,000	
Total revenues	616,684	665,468	1,743,977	1,907,018
<b>COSTS AND EXPENSES:</b>				
Product costs	284,419	299,768	708,839	759,219
Research and development expenses	288,515	241,309	604,052	463,233
General and administrative expenses	162,535	153,015	312,593	309,707
Product selling expenses	95,247	81,319	262,581	205,381
Total costs and expenses	830,716	775,411	1,888,065	1,737,540
Net operating (loss) income	(214,032)	(109,943)	(144,088)	169,478
<b>INTEREST AND OTHER INCOME:</b>				
Interest income	12,928	13,903	24,558	25,328
Other income, net	314	614	1,098,077	259
Net interest and other income	13,242	14,517	1,122,635	25,587
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(200,790)</b>	<b>(95,426)</b>	<b>978,547</b>	<b>195,065</b>
<b>INCOME TAX (BENEFIT) EXPENSE</b>	<b>(76,292)</b>	<b>(37,422)</b>	<b>401,555</b>	<b>80,929</b>
<b>NET (LOSS) INCOME</b>	<b>\$ (124,498)</b>	<b>\$ (58,004)</b>	<b>\$ 576,992</b>	<b>\$ 114,136</b>
<b>NET (LOSS) INCOME PER COMMON SHARE:</b>				
Basic	\$ (0.05)	\$ (0.02)	\$ 0.21	\$ 0.04
Diluted	\$ (0.05)	\$ (0.02)	\$ 0.21	\$ 0.04
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:</b>				
Basic	2,735,788	2,757,817	2,735,594	2,750,636
Diluted	2,735,788	2,757,817	2,794,045	2,946,913

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



**Table of Contents****IMMUCELL CORPORATION****STATEMENTS OF CASH FLOWS FOR THE SIX MONTH PERIODS**

ENDED JUNE 30, 2003 AND 2004

(Unaudited)

	<b>Six Months Ended June 30,</b>	
	<b>2003</b>	<b>2004</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income	\$ 576,992	\$ 114,136
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	128,479	119,786
Deferred income taxes	390,380	77,821
Loss on disposal of fixed assets	33,695	1,260
Changes in:		
Accounts receivable	148,166	24,824
Inventories	59,790	150,445
Prepaid expenses and other assets	(61,287)	(49,760)
Accounts payable	3,266	12,012
Accrued expenses	(61,396)	(212,839)
Deferred revenue	79,990	
Net cash provided by operating activities	1,298,075	237,685
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property, plant and equipment	(67,006)	(217,307)
Proceeds from disposal of fixed assets		4,000
Maturities of short-term investments	888,697	395,435
Purchases of short-term investments	(497,147)	(2,259,686)
Net cash provided by (used for) investing activities	324,544	(2,077,558)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	14,625	33,546
Acquisition of treasury stock	(12,267)	
Net cash provided by financing activities	2,358	33,546
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>1,624,977</b>	<b>(1,806,327)</b>
<b>BEGINNING CASH AND CASH EQUIVALENTS</b>	<b>2,355,970</b>	<b>3,356,742</b>
<b>ENDING CASH AND CASH EQUIVALENTS</b>	<b>\$ 3,980,947</b>	<b>\$ 1,550,415</b>

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



**Table of Contents****IMMUCELL CORPORATION**

## Notes to Unaudited Financial Statements

June 30, 2004

**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, 2003, 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:

	<u>December 31, 2003</u>	<u>June 30, 2004</u>	<u>(Decrease) Increase</u>
Cash and cash equivalents	\$ 3,356,742	\$ 1,550,415	\$ (1,806,327)
Short-term investments	888,320	2,752,571	1,864,251
	<u>\$ 4,245,062</u>	<u>\$ 4,302,986</u>	<u>\$ 57,924</u>

**3. INVENTORIES**

Inventories consist of the following:

December 31, 2003

June 30, 2004

Raw materials	\$ 86,304	\$ 95,488
Work-in-process	405,004	335,867
Finished goods	183,199	92,707
	<u>\$ 674,507</u>	<u>\$ 524,062</u>

#### 4. OTHER INCOME

In the first quarter of 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. The \$1,100,000 in proceeds from the sale was recorded as other income in the first quarter of 2003. This joint venture and the related technology had no book value.

#### 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. We recorded non-cash deferred income tax expense of \$388,000 and \$75,000 during the six month periods ended June 30, 2003 and 2004, respectively. The total income tax expense aggregated \$402,000 and \$81,000 for the six month periods ended June 30, 2003 and 2004, respectively. For federal and state income tax purposes, we have remaining net operating loss carryforwards of approximately \$527,000 as of December 31, 2003, which expire if they are not utilized to offset taxable income earned during or before the following years: 2009 (\$334,000), 2011 (\$132,000), 2013 (\$57,000) and 2015 (\$4,000). In order to accelerate the utilization of available net operating loss carryforwards in advance of their expiration dates,

**Table of Contents****IMMUCELL CORPORATION**

## Notes to Unaudited Financial Statements

June 30, 2004

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 six years ending December 31, 2004 to December 31, 2009 as well as \$84,000 for the year ended December 31, 2010 for tax return purposes only. Repayment of the \$400,000 Development Award from the Maine Technology Institute would result in a \$400,000 deduction for tax return purposes only. We believe it is more likely than not that the deferred tax assets will be realized through taxable income generated in future years. Accordingly, we have not established a valuation allowance for the deferred tax assets, except for the general business credit carryforward of \$97,000 as of December 31, 2003.

**6. NET INCOME (LOSS) PER COMMON SHARE**

The basic net income (loss) per common share has been computed in accordance with SFAS No. 128, Earnings Per Share, by dividing the net income (loss) 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. Outstanding stock options have not been included in the calculation of the diluted net loss per share for the three month periods ended June 30, 2003 and 2004 as the effect would be antidilutive, thereby decreasing the diluted net loss per share.

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2003</b>	<b>2004</b>	<b>2003</b>	<b>2004</b>
Weighted average number of shares outstanding during the period	2,735,788	2,757,817	2,735,594	2,750,636
Dilutive stock options			208,750	554,889
Shares that could have been repurchased with the proceeds from the dilutive stock options			(150,299)	(358,612)
Diluted number of shares outstanding during the period	2,735,788	2,757,817	2,794,045	2,946,913
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	595,872	568,139	394,872	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 elect to disclose the pro forma impact of accounting for

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

stock-based compensation plans under the provisions of SFAS No. 123, Accounting for Stock-Based Compensation as amended by SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure. Accordingly, no SFAS No. 123 or No. 148 based employee compensation cost has been recognized for these plans. The following table illustrates the effect on net income and net income per share as if the fair value based method had been applied to all outstanding and unvested stock options in both periods:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2004	2003	2004
Net (loss) income, as reported	\$ (124,498)	\$ (58,004)	\$ 576,992	\$ 114,136
Less: Pro forma stock-based employee compensation expense determined under the fair value based method, net of related tax effects	14,741	12,221	29,669	22,244
Pro forma net (loss) income	\$ (139,239)	\$ (70,225)	\$ 547,323	\$ 91,892
Net (loss) income per share:				
Basic: as reported	\$ (0.05)	\$ (0.02)	\$ 0.21	\$ 0.04
Basic: pro forma	\$ (0.05)	\$ (0.03)	\$ 0.20	\$ 0.03
Diluted: as reported	\$ (0.05)	\$ (0.02)	\$ 0.21	\$ 0.04
Diluted: pro forma	\$ (0.05)	\$ (0.03)	\$ 0.20	\$ 0.03

---

**Table of Contents**

**IMMUCELL CORPORATION**

Notes to Unaudited Financial Statements

June 30, 2004

**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 industry. 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, 2003. 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 industry.

Our primary customers for the majority (91% and 96% for the three month periods ended June 30, 2003 and 2004, respectively, and 93% and 90% for the six month periods ended June 30, 2003 and 2004, respectively) of our product sales are in the United States dairy and beef industry. Sales to foreign customers, who are in the dairy and beef industry, aggregated 8% and 4% of product sales for the three month periods ended June 30, 2003 and 2004, respectively, and 4% and 10% of product sales for the six month periods ended June 30, 2003 and 2004, respectively. Sales made to one distributor aggregated 17% and 23% of total product sales during the three month periods ended June 30, 2003 and 2004, respectively, and 21% and 19% of total product sales during the six month periods ended June 30, 2003 and 2004, respectively. This customer accounted for 21% and 10% of the Company's outstanding accounts receivable as of December 31, 2003 and June 30, 2004, 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 under this plan. As of August 6, 2004, 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 the repurchase plan was adopted.

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

**RESULTS OF OPERATIONS FOR THE THREE AND SIX MONTH PERIODS ENDED JUNE 30, 2004**

Product sales increased by 9%, or \$53,000, to \$642,000 during the three month period ended June 30, 2004 in comparison to \$590,000 during the three month period ended June 30, 2003. Product sales increased by 16%, or \$255,000, to \$1,860,000 during the six month period ended June 30, 2004 in comparison to \$1,605,000 during the six month period ended June 30, 2003. Sales of **First Defense**<sup>®</sup> are normally seasonal

## Edgar Filing: IMMUCELL CORP /DE/ - Form 10-Q

with highest sales expected in the first quarter and lower sales expected during the summer months. Sales of **First Defense** increased by 24% during the six month period ended June 30, 2004 in comparison to the same period in 2003. Sales of **Wipe Out® Dairy Wipes** decreased by 2% during the six month period ended June 30, 2004 in comparison to the same period in 2003. Sales have been positively effected by the recent increase in the price that dairy producers are paid for the milk that they produce and sell.

Total revenues increased by 8%, or \$49,000, to \$665,000 during the three month period ended June 30, 2004 in comparison to the same period in 2003. Total revenues increased by 9%, or \$163,000, to \$1,907,000 during the six month period ended June 30, 2004 in comparison to the same period in 2003. Grant income of \$82,000 and \$10,000 was earned during the six month period ended June 30, 2003 and 2004, respectively. Royalty income increased by less than \$1,000 to \$37,000 during the six month period ended June 30, 2004 in comparison to the same period in 2003. Royalty income is earned on the sale of whey protein isolate by a licensee to certain rights to our milk protein purification technology.



---

**Table of Contents****IMMUCELL CORPORATION**

Gross margin as a percentage of product sales was 52% and 53% during the three month periods ended June 30, 2003 and 2004, respectively. The total gross margin increased by 12%, or \$37,000, to \$343,000 during the three month period ended June 30, 2004, as compared to the same period in 2003. Gross margin as a percentage of product sales was 56% and 59% during the six month periods ended June 30, 2003 and 2004, respectively. The total gross margin increased by 23%, or \$204,000, to \$1,100,000 during the six month period ended June 30, 2004, as compared to the same period in 2003. Changes in the gross margin percentage principally reflect changes in the product sales mix. The Company experiences a better gross margin from products that it has developed, such as **First Defense**<sup>®</sup>, and a lower gross margin from acquired products, such as **Wipe Out**<sup>®</sup> Dairy Wipes.

During the three month period ended June 30, 2004, research and development expenses decreased by 16%, or \$47,000, to \$241,000, as compared to the same period in 2003. Research and development expenses aggregated 47% and 36% of total revenues during the three month periods ended June 30, 2003 and 2004, respectively. Research and development expenses exceeded grant income by \$287,000 (which net amount equals 49% of product sales) during the three month period ended June 30, 2003. Research and development expenses exceeded grant income by \$231,000 (which net amount equals 36% of product sales) during the three month period ended June 30, 2004. During the six month period ended June 30, 2004, research and development expenses decreased by 23%, or \$141,000, to \$463,000, as compared to the same period in 2003. Research and development expenses aggregated 35% and 24% of total revenues during the six month periods ended June 30, 2003 and 2004, respectively. Research and development expenses exceeded grant income by \$522,000 (which net amount equals 33% of product sales) during the six month period ended June 30, 2003. Research and development expenses exceeded grant income by \$453,000 (which net amount equals 24% of product sales) during the six month period ended June 30, 2004.

Beginning in 1999, we increased our development of new animal health products that fit our objective of commercializing our proprietary technologies and developing innovative and proprietary products that improve animal health and productivity in the dairy and beef industry. At that time, we also decreased our internally funded research and development investment in products targeted towards the human healthcare markets. Funding requirements for animal health programs are generally less than the requirements for human health programs. As a result, we have been able to achieve continued profitable operations on an annual basis since 1999.

During 2000, we initiated the development of **Mast Out**<sup>®</sup>, a new product utilizing Nisin (the same natural, antibacterial peptide that is the active ingredient in **Wipe Out Dairy Wipes**) as an alternative to antibiotics in the treatment of mastitis in dairy cows. This product development program has become the primary focus of our research and development investment. The costs associated with developing **Mast Out**, which is subject to the approval of the U.S. Food and Drug Administration, are significantly higher than for the other animal health products that we have developed. We anticipated an increase in research and development expenses beginning in the fourth quarter of 2002 and continuing through 2003, 2004 and 2005 to fund 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 defined several important trial design parameters that should help us conduct the pivotal efficacy trial. It is our intention to initiate a pivotal efficacy trial of this product during 2004. We anticipate higher research and development expenditures to be incurred later in the year in connection with this trial. The necessary level of research and development expenses required to fund this investment may result in net losses for 2004 and 2005. We believe that the market potential for **Mast Out** justifies such an investment. Our objective is to file for final FDA approval during the first half of 2006. In June 2004, we obtained Notice of Allowance from the U.S. Patent and Trademark Office for patent application #10/268,037 entitled **Method of Purifying Lantibiotics** covering a key step in the manufacturing process for pharmaceutical-grade Nisin. This patent, together with several issued patents that we licensed from Nutrition 21, Inc. in 2000 and additional patent application(s) to be filed, comprise the principal intellectual property protection covering **Mast Out**.

We also conduct early stage product development research. Among these smaller projects are: the evaluation of new approaches to better diagnosis of Johne's Disease, an effort to expand the **First Defense** claims to cover infection by rotavirus, the development of an oral colostrum supplement for calves and the evaluation of new formulations for the preparation and sanitization of udders before and after milking.

General and administrative expenses of \$153,000 during the three month period ended June 30, 2004 compared to \$163,000 during the same period in 2003. General and administrative expenses of \$310,000 during the six month period ended June 30, 2004 compare to \$313,000 during the same period in 2003. We continue our efforts to control these expenses while incurring all the necessary costs associated with being a publicly held company. During the three month period ended June 30, 2004, product selling expenses decreased by 15%, or \$14,000, to \$81,000, as compared to the same period in 2003, aggregating 16% and 13% of product sales during the three month periods ended June 30, 2003 and 2004, respectively. During the six month period ended June 30, 2004, product selling expenses decreased by 22%, or \$57,000 to \$205,000, as compared to the same period in 2003, aggregating 16% and 11% of product sales during the six month periods ended June 30, 2003 and 2004, respectively. Our objective is to maintain the ratio of sales and marketing expenses to product sales below 20% on an annual basis.

---

**Table of Contents****IMMUCELL CORPORATION**

The net loss for the three months ended June 30, 2003 of \$124,000 (\$0.05 per share) compares to a net loss of \$58,000 (\$0.02 per share) for the three months ended June 30, 2004. Income before income taxes for the six months ended June 30, 2003 of \$979,000 included \$1,100,000 in other income earned from the sale of our 50% interest in a non-core joint venture. Income before income taxes for the six months ended June 30, 2004 was \$195,000. The net income for the six months ended June 30, 2003 of \$577,000 (\$0.21 per diluted share) compares to net income of \$114,000 (\$0.04 per diluted share) for the six months ended June 30, 2004. The effective income tax rate was 41% for both the six month periods ended June 30, 2003 and 2004.

**LIQUIDITY AND CAPITAL RESOURCES**

Cash, cash equivalents and short-term investments increased by \$58,000 to \$4,303,000 at June 30, 2004 from \$4,245,000 at December 31, 2003. Net cash provided by operating activities amounted to \$238,000 during the six months ended June 30, 2004 as compared to \$1,298,000 during the six months ended June 30, 2003. This difference was principally due to the \$1,100,000 sale of our 50% interest in a non-core joint venture during the 2003 period. Accrued expenses decreased by \$213,000 during the first six months of 2004 as expenses accrued at the end of 2003 in connection with the completion of the experimental field trial of **Mast Out**<sup>®</sup> were paid, and inventories decreased by \$150,000 during this period primarily as the result of increased sales. Total assets decreased by \$51,000 to \$8,136,000 at June 30, 2004 from \$8,187,000 at December 31, 2003. The Company has no outstanding bank debt. Net working capital increased by \$133,000 to \$5,098,000 at June 30, 2004 from \$4,965,000 at December 31, 2003. Shareholders' equity increased by \$150,000 to \$7,521,000 at June 30, 2004 from \$7,370,000 at December 31, 2003 as the result of the \$114,000 in net income earned and the \$36,000 raised from the issuance of common stock upon the exercise of 17,233 stock options during the first quarter of 2004.

During the third quarter of 2003, we initiated an investment in facility modifications and processing equipment required to produce Nisin in-house. This project was completed for a total cost of approximately \$425,000 in July 2004 eliminating our prior reliance on a subcontractor to perform this function. It is our plan to use the Nisin to be produced in this plant for clinical trial material for **Mast Out** and for commercial sale in **Wipe Out**<sup>®</sup> **Dairy Wipes**. We believe this investment will result in better control over product quality and a reduction in the cost to produce inventory. We will have production capacity available should we be able to develop and commercialize additional product applications of Nisin.

In March 2001, we received a two year Development Award aggregating \$400,000 from the Maine Technology Institute augmenting the development of **Mast Out**. Because of a contingent pay back obligation in connection with this grant, 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. There is no pay back obligation in the event that a product is not commercialized. In such event, the deferred revenue would be recognized at the time the product development effort is discontinued. Should the product be commercialized, we would have the choice of paying back either: 1) the grant amount in a lump sum payment within two years of commercialization or 2) two times the grant amount through a 2% royalty on sales. In June 2004, we received notice of approval of a second two year Development Award aggregating up to \$500,000 from the Maine Technology Institute further supporting the development of **Mast Out**. None of this funding has yet been received. Acceptance and final documentation of the award is pending resolution of certain budget and repayment issues currently under negotiation.

Since our initial public offering of common stock in 1987, we have largely avoided using the issuance of additional equity as a primary source of funding for our operations in order to minimize the resulting dilution to existing shareholders. Our shareholders' equity has increased by \$2,140,000 to \$7,521,000 at June 30, 2004 from \$5,381,000 at December 31, 1987. During this period, we invested the aggregate of approximately \$15,922,000 in research and development expenses. This investment was funded, in part, by approximately \$2,623,000 in grant income earned since 1990. From 1988 through June 30, 2004, we have issued 394,747 shares pursuant to the exercise of stock options for the aggregate of \$552,000 (average price = \$1.40 per share). In 1992, we issued 342,857 shares to an unrelated biotechnology company for

## Edgar Filing: IMMUCELL CORP /DE/ - Form 10-Q

\$600,000 (\$1.75 per share); we subsequently repurchased these shares for \$309,000 (\$0.90 per share) in 1994. In 1993, we issued 300,000 shares to a microcap investment fund for \$520,000 (\$1.73 per share). In 1997, we issued 80,820 shares in a private placement for \$183,000 (\$2.26 per share). In the second quarter of 2003 we repurchased 5,900 shares for \$12,267 under our open market stock repurchase plan. The net result of the transactions described above is that during the past 16.5 years, we have issued 769,667 shares raising \$1,534,000 (average price = \$1.99 per share) in equity. Since 1999, we have focused on using our profitability and the proceeds from the sale of non-core assets to fund our operations and build shareholders' equity.

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.

## Table of Contents

### IMMUCELL CORPORATION

#### 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 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 Quarterly Report.

#### 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.

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 heavily dependent on our manufacturing operations and facility at 56 Evergreen Drive in Portland, Maine for the production of **First Defense**<sup>®</sup> and **Wipe Out**<sup>®</sup> **Dairy Wipes**. 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.

## Edgar Filing: IMMUCELL CORP /DE/ - Form 10-Q

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 intends to amend 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, effect **First Defense**, which is manufactured from bovine milk and colostrum and is considered a veterinary medicine rather than a feed ingredient. However, future regulations to minimize risk against the spread of disease could effect 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.

**Table of Contents**

**IMMUCELL CORPORATION**

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable

**ITEM 4. CONTROLS AND PROCEDURES**

*(a) Evaluation of Disclosure Controls and Procedures.* Under the supervision of our principal executive and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act )) as of June 30, 2004. Based on this evaluation, we have concluded that, as of June 30, 2004, our disclosure controls and procedures were (1) designed to ensure that material information is made known to our principal executive and principal financial officer by others, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed 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 SEC's rules and forms.

*(b) Changes in Internal Controls.* No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the period ended June 30, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

None

**ITEM 2. CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES**

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 are to 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. 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 at an average purchase price of \$2.08 per share. Since that time and as of August 6, 2004, no additional shares had been repurchased. As of August 6, 2004, management is authorized to repurchase the remaining 94,100 shares at its discretion under the plan. 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 the repurchase plan was adopted.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

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

At the Annual Meeting of Shareholders held on June 8, 2004, the shareholders voted on one matter, the election of the Board of Directors for the next ensuing year. Each of the six nominees recommended by management to the shareholders was elected to the Board. The following list by name of director shows how the votes were cast for each director:

Michael F. Brigham (for: 2,459,625; withhold: 24,208), Anthony B. Cashen (for: 2,458,980; withhold: 24,853), Joseph H. Crabb (for: 2,458,584; withhold: 25,249), William H. Maxwell (for: 2,459,045; withhold: 24,788), Jonathan E. Rothschild (for: 2,460,045; withhold: 23,788) and Mitchel Sayare (for: 2,459,008; withhold: 24,825).

**ITEM 5. OTHER INFORMATION**

None



**Table of Contents**

**IMMUCELL CORPORATION**

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

(a) Exhibits

Exhibit 31 Certifications required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit 32 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

The Company furnished a Current Report on Form 8-K dated as of April 20, 2004 with the Commission under Item 12, Results of Operations and Financial Condition , containing the press release relating to its financial results for the quarterly period ended March 31, 2004.

**SIGNATURES**

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: August 6, 2004

By: /s/ Michael F. Brigham  
Michael F. Brigham

President, Chief Executive Officer

and Principal Financial Officer