

IMMUCELL CORP /DE/
Form 10-Q
July 29, 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 June 30, 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)

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

DELAWARE
(State or other jurisdiction
of incorporation)

01-0382980
(I.R.S. Employer
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 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

Class of Securities:

Outstanding at July 28, 2005:

Common Stock, par value \$0.10 per share

2,847,146

Table of Contents

IMMUCELL CORPORATION

INDEX TO FORM 10-Q

June 30, 2005

	<u>Page</u>
PART I: <u>FINANCIAL INFORMATION</u>	
ITEM 1. <u>FINANCIAL STATEMENTS</u>	
<u>Balance Sheets at December 31, 2004 and June 30, 2005</u>	3
<u>Statements of Operations for the three and six month periods ended June 30, 2004 and 2005</u>	4
<u>Statements of Cash Flows for the six month periods ended June 30, 2004 and 2005</u>	5
<u>Notes to Unaudited Financial Statements</u>	6-9
ITEM 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	9-12
ITEM 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	12
ITEM 4. <u>CONTROLS AND PROCEDURES</u>	12
PART II: <u>OTHER INFORMATION</u>	
<u>ITEMS 1 THROUGH 6</u>	12-13
<u>SIGNATURE</u>	13

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

	(Unaudited)	
	<u>December 31, 2004</u>	<u>June 30, 2005</u>
<u>ASSETS</u>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,700,567	\$ 1,335,167
Short-term investments	2,749,596	3,590,038
Accounts receivable, net of allowance for doubtful accounts of \$13,000 and \$11,000 at December 31, 2004 and June 30, 2005, respectively	434,591	426,735
Income taxes receivable		33,270
Inventories	667,666	617,262
Current portion of deferred tax asset	215,066	215,066
Prepaid expenses	44,913	177,125
	<u>5,812,399</u>	<u>6,394,663</u>
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	1,701,583	1,736,085
Building and improvements	1,500,559	1,545,200
Office furniture and equipment	123,289	128,106
Construction in progress	7,356	
Land	50,000	50,000
	<u>3,382,787</u>	<u>3,459,391</u>
Less - accumulated depreciation	1,481,643	1,616,444
	<u>1,901,144</u>	<u>1,842,947</u>
DEFERRED TAX ASSET	674,240	584,240
PRODUCT RIGHTS AND OTHER ASSETS, net of accumulated amortization of \$196,000 and \$375,000 at December 31, 2004 and June 30, 2005, respectively	1,141,886	963,043
	<u>9,529,669</u>	<u>9,784,893</u>
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
CURRENT LIABILITIES:		
Accrued expenses	\$ 228,609	\$ 170,558
Accounts payable	70,143	123,342

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

Income taxes payable	22,589	
Deferred revenue	493,151	568,151
	<u> </u>	<u> </u>
Total current liabilities	814,492	862,051
Long-term portion of deferred revenue	986,301	739,726
SHAREHOLDERS EQUITY:		
Common stock, Par value-\$0.10 per share		
Authorized-8,000,000 shares, Issued-3,190,148 and 3,261,148 shares at December 31, 2004 and June 30, 2005, respectively	319,015	326,115
Capital in excess of par value	9,160,991	9,344,911
Accumulated deficit	(1,152,128)	(813,412)
Treasury stock, at cost 395,498 and 414,002 shares at December 31, 2004 and June 30, 2005, respectively	(599,002)	(674,498)
	<u> </u>	<u> </u>
Total shareholders equity	7,728,876	8,183,116
	<u> </u>	<u> </u>
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 9,529,669	\$ 9,784,893
	<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, 2004 AND 2005

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2004	2005	2004	2005
REVENUES:				
Product sales	\$ 642,376	\$ 848,059	\$ 1,859,669	\$ 2,276,423
Sale of technology rights		123,288		246,575
Grant income	10,000		10,000	37,632
Royalty income	13,092	12,443	37,349	19,388
Total revenues	665,468	983,790	1,907,018	2,580,018
COSTS AND EXPENSES:				
Product costs	299,768	348,992	759,219	910,583
Research and development expenses	241,309	252,860	463,233	567,046
General and administrative expenses	153,015	194,785	309,707	357,383
Product selling expenses	81,319	83,659	205,381	228,404
Total costs and expenses	775,411	880,296	1,737,540	2,063,416
Net operating (loss) income	(109,943)	103,494	169,478	516,602
INTEREST AND OTHER INCOME:				
Interest income	13,903	30,747	25,328	51,549
Other income, net	614	711	259	1,151
Net interest and other income	14,517	31,458	25,587	52,700
(LOSS) INCOME BEFORE INCOME TAXES	(95,426)	134,952	195,065	569,302
INCOME TAX (BENEFIT) EXPENSE	(37,422)	55,710	80,929	230,586
NET (LOSS) INCOME	\$ (58,004)	\$ 79,242	\$ 114,136	\$ 338,716
NET (LOSS) INCOME PER COMMON SHARE:				
Basic	\$ (0.02)	\$ 0.03	\$ 0.04	\$ 0.12
Diluted	\$ (0.02)	\$ 0.03	\$ 0.04	\$ 0.11

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

WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic	2,757,817	2,803,512	2,750,636	2,799,106
Diluted	2,757,817	2,955,994	2,946,913	2,976,292

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

- 4 -

Table of Contents**IMMUCELL CORPORATION**

STATEMENTS OF CASH FLOWS FOR THE SIX MONTH PERIODS

ENDED JUNE 30, 2004 AND 2005

(Unaudited)

	Six Months Ended	
	June 30,	
	2004	2005
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 114,136	\$ 338,716
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	99,524	134,801
Amortization	20,262	178,893
Deferred income taxes	77,821	90,000
Loss on disposal of fixed assets	1,260	
Changes in:		
Accounts receivable	24,824	7,856
Income taxes receivable/payable	(7,900)	(49,277)
Inventories	150,445	50,404
Prepaid expenses and other assets	(49,760)	(132,262)
Accrued expenses	(204,939)	(58,051)
Accounts payable	12,012	53,199
Deferred revenue		(171,575)
Net cash provided by operating activities	237,685	442,704
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(217,307)	(76,604)
Proceeds from disposal of fixed assets	4,000	
Maturities of short-term investments	395,435	2,456,949
Purchases of short-term investments	(2,259,686)	(3,297,391)
Net cash used for investing activities	(2,077,558)	(917,046)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	33,546	108,942
Net cash provided by financing activities	33,546	108,942
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,806,327)	(365,400)
BEGINNING CASH AND CASH EQUIVALENTS	3,356,742	1,700,567
ENDING CASH AND CASH EQUIVALENTS	\$ 1,550,415	\$ 1,335,167
CASH PAID FOR INCOME TAXES	\$ 9,116	\$ 186,501

NON-CASH FINANCING ACTIVITIES:

Tax benefits related to stock options	\$	6,582
Treasury stock acquired upon exercise of stock options	\$	75,496

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

Table of Contents**IMMUCELL CORPORATION**

Notes to Unaudited Financial Statements

June 30, 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	June 30, 2005	(Decrease)
	_____	_____	_____
Cash and cash equivalents	\$ 1,700,567	\$ 1,335,167	\$ (365,400)
Short-term investments	2,749,596	3,590,038	840,442
	_____	_____	_____
	\$ 4,450,163	\$ 4,925,205	\$ 475,042
	_____	_____	_____

3. INVENTORIES

Inventories consist of the following:

	<u>December 31, 2004</u>	<u>June 30, 2005</u>
Raw materials	\$ 167,241	\$ 136,146
Work-in-process	429,481	367,465
Finished goods	70,944	113,651
	<u>\$ 667,666</u>	<u>\$ 617,262</u>

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**®. We expect to amortize this intangible asset over the period from December 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 June 30, 2005, research and development expenses included approximately \$79,000 of such amortization expense, and total revenues included approximately \$123,000 of such revenue. During the six month period ended June 30, 2005, research and development expenses included approximately \$159,000 of such amortization expense, and total revenues included approximately \$247,000 of such revenue. The Pfizer agreement, among other things, also provides for contingent milestone payments as development objectives are achieved 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 such milestones have been achieved. Any future royalty payments will be recognized as earned based on any future product sales.

Table of Contents**IMMUCELL CORPORATION**

Notes to Unaudited Financial Statements (continued)

June 30, 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 receivable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. The income tax (benefit) expense aggregated \$(37,000) and \$56,000 (41% of income before income taxes) for the three month periods ended June 30, 2004 and 2005, respectively. The income tax expense aggregated \$81,000 (41% of income before income taxes) and \$231,000 (41% of income before income taxes) for the six month periods ended June 30, 2004 and 2005, respectively. 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 June 30, 2005.

6. NET (LOSS) INCOME 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. Outstanding stock options have not been included in the calculation of the diluted net loss per common share for the three month period ended June 30, 2004 as the effect would be antidilutive, thereby decreasing the diluted net loss per common share. The diluted net income per common share for the three month period ended June 30, 2005 and the six month periods ended June 30, 2004 and 2005 reflects the potential dilution from outstanding stock options as shown in the table below.

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2004	2005	2004	2005
Weighted average number of shares outstanding during the period	2,757,817	2,803,512	2,750,636	2,799,106
Dilutive stock options		405,639	554,889	426,639
Shares that could have been repurchased with the proceeds from the dilutive stock options		(253,157)	(358,612)	(249,453)

Diluted number of shares outstanding during the period	2,757,817	2,955,994	2,946,913	2,976,292
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	568,139	21,000	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 (loss) income and basic and diluted net (loss) income per share would have been reduced to the pro forma amounts indicated in the table below:

Table of Contents**IMMUCELL CORPORATION**

Notes to Unaudited Financial Statements (continued)

June 30, 2005

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2004	2005	2004	2005
Net (loss) income, as reported	\$ (58,004)	\$ 79,242	\$ 114,136	\$ 338,716
Less: Pro forma stock-based employee compensation expense determined under the fair value based method, net of related tax effects	12,221	6,053	22,244	9,226
Pro forma net (loss) income	\$ (70,225)	\$ 73,189	\$ 91,892	\$ 329,490
Net (loss) income per share:				
Basic: as reported	\$ (0.02)	\$ 0.03	\$ 0.04	\$ 0.12
Basic: pro forma	\$ (0.03)	\$ 0.03	\$ 0.03	\$ 0.12
Diluted: as reported	\$ (0.02)	\$ 0.03	\$ 0.04	\$ 0.11
Diluted: pro forma	\$ (0.03)	\$ 0.02	\$ 0.03	\$ 0.11

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 (96% and 82% for the three month periods ended June 30, 2004 and 2005, respectively, and 90% and 84% for the six month periods ended June 30, 2004 and 2005, respectively) of our product sales are in the United States dairy and beef industries. Sales to customers outside of the United States, who are in the dairy and beef industries, aggregated 4% and 9% of product sales for the three month periods ended June 30, 2004 and 2005, respectively, and 10% and 12% for the six month periods ended June 30, 2004 and 2005, respectively. Sales made to Walco International, Inc. aggregated 23% and 19% of total product sales during the three month periods ended June 30, 2004 and 2005, respectively, and 19% and 18% of total product sales during the six month periods ended June 30, 2004 and 2005, respectively. This customer accounted for 16% and 12% of our outstanding accounts receivable as of December 31, 2004 and June 30, 2005, respectively.

9. COMMON STOCK

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 July 28, 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.

During June 2005, two directors and officers and two outside directors exercised stock options covering the aggregate of 71,000 shares of common stock. The exercise of these options was paid for with \$108,942 in cash and a stock-for-stock surrender of 18,504 shares of previously owned common stock with a fair market value of \$75,496 at the time of exercise. The 18,504 reacquired shares have been recorded as treasury stock.

Table of Contents**IMMUCELL CORPORATION**

In September 1995, our Board of Directors adopted a Common Stock Rights Plan, the terms of which were set forth in a Rights Agreement with American Stock Transfer & Trust Co., as a Rights Agent. Pursuant to the Rights Agreement, we issued certain Rights to all holders of our Common Stock. Under the Rights Agreement, the Rights expire on the earlier to occur of the Redemption Date (as defined) or the Final Expiration Date (originally defined to be September 19, 2005). On June 8, 2005, our Board voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years, to September 19, 2008. As of June 30, 2005, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. No other changes were made to the terms of the Rights or the Rights Agreement.

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, 2005**

Product sales increased by 32%, or \$206,000, to \$848,000 during the three month period ended June 30, 2005 in comparison to \$642,000 during the three month period ended June 30, 2004. Product sales increased by 22%, or \$417,000, to \$2,276,000 during the six month period ended June 30, 2005 in comparison to \$1,860,000 during the six month period ended June 30, 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 six month period ended June 30, 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 35% during the six month period ended June 30, 2005 in comparison to the same period in 2004. 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. A decrease in the domestic sales of this product was more than offset by new foreign sales in 2005.

Total revenues increased by 48%, or \$318,000, to \$984,000 during the three month period ended June 30, 2005 in comparison to the same period in 2004. Total revenues increased by 35%, or \$673,000, to \$2,580,000 during the six month period ended June 30, 2005 in comparison to the same period in 2004. We recognized \$123,000 and \$247,000 in deferred revenue as a sale of technology rights during the three and six month periods ended June 30, 2005, respectively, related to the \$1,500,000 up front payment received from Pfizer in December 2004. No revenue from the sale of technology rights was earned during the same periods in 2004. We earned no grant income during the three months ended June 30, 2005 as compared to \$10,000 of grant income during the same period in 2004. We earned \$38,000 of grant income during the six months ended June 30, 2005 as compared to \$10,000 during the same period in 2004. This grant income supported the development of a bovine milk immunoglobulin supplement to prevent diarrhea in humans. We earned royalties of \$12,000 and \$13,000 during the three month periods ended June 30, 2005 and 2004, respectively, and \$19,000 and \$37,000 during the six month periods ended June 30, 2005 and 2004, respectively. 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 59% and 53% during the three month periods ended June 30, 2005 and 2004, respectively. The total gross margin increased by 46%, or \$156,000, to \$499,000 during the three month period ended June 30, 2005, as compared to the same period in 2004. Gross margin as a percentage of product sales was 60% and 59% during the six month periods ended June 30, 2005 and 2004, respectively. The total gross margin increased by 24%, or \$265,000, to \$1,366,000 during the six month period ended June 30, 2005, as compared to the same period in 2004. 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**.

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

During the three month period ended June 30, 2005, research and development expenses increased by 5%, or \$12,000, to \$253,000, as compared to the same period in 2004. During the six month period ended June 30, 2005, research and development expenses increased by 22%, or \$104,000, to \$567,000, as compared to the same period in 2004. During the three and six month periods ended June 30, 2005, this expense included \$79,000 and \$159,000, respectively, 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. Research and development expenses aggregated 26% and 36% of total revenues during the three month periods ended June 30, 2005 and 2004, respectively. Research and development expenses exceeded grant income and revenue from the sale of technology rights by \$130,000 (which net amount equaled 15% of product sales) during the three month period ended June 30, 2005 and by \$231,000 (which net amount equaled 36% of product sales) during the three month period ended June 30, 2004. Research and development expenses aggregated 22% and 24% of total

Table of Contents**IMMUCELL CORPORATION**

revenues during the six month periods ended June 30, 2005 and 2004, respectively. Research and development expenses exceeded grant income and revenue from the sale of technology rights by \$283,000 (which net amount equaled 12% of product sales) during the six month period ended June 30, 2005 and by \$453,000 (which net amount equaled 24% of product sales) during the six month period ended June 30, 2004. No revenue from the sale of technology rights was earned during the three or six month periods ended June 30, 2004.

During 2000, we initiated the development of **Mast Out®**, a Nisin-based treatment for mastitis in lactating dairy cows. Nisin, a natural antibacterial peptide, is also the active ingredient in our product, **Wipe Out® Dairy Wipes**. **Mast Out®** has become the primary focus of our research and development investment. 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. During the first half of 2005, we completed our contractual obligation to supply certain clinical trial material to Pfizer. We are also continuing to fulfill our contractual obligation to perform stability testing of the clinical trial material. These activities comprised most of our research and development expenses during the first half of 2005.

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 also evaluating new formulations for the preparation and sanitization of udders before and after milking. 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.

Capitalizing on certain scientific knowledge gained while working on a milk antibody product to prevent *Cryptosporidium parvum* infections in humans during the early 1990 s, we developed the water diagnostic test, **Crypto-Scan®**. This non-animal health product utilizes our immunomagnetic separation technology. Despite gaining U.K. regulatory approval in November 2000, 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 purchased an initial order of product from us. TCS has obtained the necessary regulatory approval of the modified test and has initiated commercial sales of this product under their name, Isolate *Cryptosporidium*. We would benefit from the exclusive supply agreement if TCS achieves market acceptance of the product.

During the three month period ended June 30, 2005, general and administrative expenses increased by 27%, or \$42,000, to \$195,000 as compared to \$153,000 during the same period in 2004. During the six month period ended June 30, 2005, general and administrative expenses increased by 15%, or \$48,000, to \$357,000 as compared to \$310,000 during the same period in 2004. During the three month period ended June 30, 2005, product selling expenses increased by 3%, or \$2,000, to \$84,000, as compared to the same period in 2004, aggregating 10% and 13% of product sales during the three month periods ended June 30, 2005 and 2004, respectively. During the six month period ended June 30, 2005, product selling expenses increased by 11%, or \$23,000, to \$228,000, as compared to the same period in 2004, aggregating 10% and 11% of product sales during the six month periods ended June 30, 2005 and 2004, respectively. Our objective is to maintain the ratio of product selling expenses to product sales below 15% on an annual basis.

The income (loss) before income taxes for the three month periods ended June 30, 2005 and 2004 was \$135,000 and \$(95,000), respectively. The net income for the three months ended June 30, 2005 of \$79,000 (\$0.03 per diluted share) compares to a net loss of \$(58,000) (\$0.02 per diluted share) for the three months ended June 30, 2004. The effective income tax rate was 41% for the three month period ended June 30, 2005. Income before income taxes for the six month periods ended June 30, 2005 and 2004 was \$569,000 and \$195,000, respectively. The net income

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

for the six months ended June 30, 2005 of \$339,000 (\$0.11 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, 2005 and 2004.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and short-term investments increased by 11%, or \$475,000, to \$4,925,000 at June 30, 2005 from \$4,450,000 at December 31, 2004. Net cash provided by operating activities amounted to \$443,000 during the six months ended June 30, 2005 as compared to \$238,000 during the six months ended June 30, 2004. Total assets increased by 3%, or \$255,000, to \$9,785,000 at June 30, 2005 from \$9,530,000 at December 31, 2004. The Company has no outstanding

- 10 -

Table of Contents

IMMUCELL CORPORATION

bank debt. Net working capital increased by 11%, or \$535,000, to \$5,533,000 at June 30, 2005 from \$4,998,000 at December 31, 2004. Shareholders' equity increased by 6%, or \$454,000, to \$8,183,000 at June 30, 2005 from \$7,729,000 at December 31, 2004.

The December 2004 product development and marketing agreement with Pfizer for **Mast Out**® provides for contingent milestone payments as development objectives are achieved and royalties based on any future sales, subject to certain minimums. For instance, we received \$1,500,000 upon signing of the agreement. Subject to the satisfaction of designated conditions, 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. During the first half of 2005, we satisfied our contractual obligation to supply clinical trial material to Pfizer, and Pfizer initiated certain clinical trials with this material. We recently entered into a supplemental agreement with Pfizer, under which we are eligible to earn approximately \$181,000 for supplying additional clinical trial material to Pfizer in the second half of 2005 and approximately \$44,000 to perform stability testing of this material over the next two years.

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 milestone payments and other 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.

RISK FACTORS

The sale and development of our products are 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 25 employees. As such, we rely on certain key employees to support different operational functions, with little redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained.

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

Table of Contents

IMMUCELL CORPORATION

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.

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

The potential for epidemics of bovine diseases such as Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) presents a risk to us and our customers. Documented cases of BSE in the U.S. have led to an overall tightening of regulations pertaining to ingredients of animal (especially bovine) origin. **First Defense®** is considered a veterinary medicine rather than a feed ingredient, and it is manufactured from bovine milk and colostrum, which is not considered a BSE risk material. Future regulatory action to increase protection of the human food supply could affect **First Defense®**, although presently we do not anticipate that this will be the case.

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 June 30, 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.

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

In June 2005, we repurchased 18,504 share of Common Stock as part of stock-for-stock exercises of outstanding stock options held by a director and officer and by a director, as follows:

<u>Date</u>	<u>Total Number of Shares Purchased</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</u>
June 16, 2005	14,483	\$ 4.08	0	n/a
June 17, 2005	4,021	\$ 4.08	0	n/a

- 12 -

Table of Contents

IMMUCELL CORPORATION

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

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

At the Annual Meeting of Shareholders held on June 8, 2005, the shareholders voted on one matter, the election of the Board of Directors for the ensuing year. Each of the six nominees recommended to the shareholders by the Board was elected as a director, as follows:

Michael F. Brigham (for: 2,503,619; withhold: 16,042), Anthony B. Cashen (for: 2,430,784; withhold: 88,877), Joseph H. Crabb (for: 2,503,556; withhold: 16,105), William H. Maxwell (for: 2,430,747; withhold: 88,914), Jonathan E. Rothschild (for: 2,503,556; withhold: 16,105) and Mitchel Sayare (for: 2,431,470; withhold: 88,191).

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

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

Date: July 28, 2005

By: /s/ Michael F. Brigham

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

- 13 -