IMMUCELL CORP /DE/
Form 10-Q
November 10, 2004
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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 September 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	**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 November 8, 2004:
Common Stock, par value $0.10 per share	2,757,817

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BALANCE SHEETS

ASSETS

		(Unaudited)
	December 31, 2003	**September 30, 2004**
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,356,742	$ 1,392,657
Short-term investments	888,320	2,848,439
Accounts receivable, net of allowance for doubtful accounts of $13,000 and $12,000 at December 31, 2003 and September 30, 2004, respectively	369,854	416,627
Inventories	674,507	598,739
Current portion of deferred tax asset	45,043	45,043
Prepaid expenses	46,976	78,784
Total current assets	5,381,442	5,380,289
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	1,456,385	1,676,069
Building and improvements	1,309,781	1,497,969
Construction in progress	210,058	
Office furniture and equipment	91,052	94,188
Land	50,000	50,000
	3,117,276	3,318,226
Less - accumulated depreciation	1,322,691	1,428,219
Net property, plant and equipment	1,794,585	1,890,007
DEFERRED TAX ASSET	782,145	708,700
PRODUCT RIGHTS AND OTHER ASSETS, net of amortization of $142,000 and $172,000 at December 31, 2003 and September 30, 2004, respectively	228,460	198,111
TOTAL ASSETS	$ 8,186,632	$ 8,177,107

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

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IMMUCELL CORPORATION

BALANCE SHEETS

LIABILITIES AND SHAREHOLDERS EQUITY

	December 31, 2003	(Unaudited) September 30, 2004
CURRENT LIABILITIES:		
Accrued expenses	$ 354,540	$ 157,529
Accounts payable	61,640	104,098
Total current liabilities	416,180	261,627
LONG-TERM LIABILITIES:		
Long-term portion of deferred revenue	400,000	400,000
Total long-term liabilities	400,000	400,000
SHAREHOLDERS EQUITY:		
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 September 30, 2004, respectively	313,608	315,332
Capital in excess of par value	8,951,493	8,985,735
Accumulated deficit	(1,295,647)	(1,186,585)
Treasury stock, at cost 395,498 shares at December 31, 2003 and September 30, 2004	(599,002)	(599,002)
Total shareholders equity	7,370,452	7,515,480
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 8,186,632	$ 8,177,107

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

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STATEMENTS OF OPERATIONS FOR THE THREE AND NINE

MONTH PERIODS ENDED SEPTEMBER 30, 2003 AND 2004

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	**2004**	**2003**	**2004**
REVENUES:				
Product sales	$ 745,106	$ 808,021	$ 2,350,237	$ 2,667,691
Grant income	29,409	20,000	111,723	30,000
Royalty income	14,058	17,542	50,590	54,890
Sale of technology rights			20,000	
Total revenues	788,573	845,563	2,532,550	2,752,581
COSTS AND EXPENSES:				
Product costs	335,405	343,047	1,044,243	1,102,266
Research and development expenses	269,627	272,133	873,679	735,366
General and administrative expenses	127,980	141,877	440,573	451,583
Product selling expenses	125,455	108,720	388,037	314,101
Total costs and expenses	858,467	865,777	2,746,532	2,603,316
Net operating (loss) income	(69,894)	(20,214)	(213,982)	149,265
INTEREST AND OTHER INCOME:				
Interest income	10,956	15,216	35,514	40,544
Other income, net	549	95	1,098,626	354
Net interest and other income	11,505	15,311	1,134,140	40,898
(LOSS) INCOME BEFORE INCOME TAXES	(58,389)	(4,903)	920,158	190,163
INCOME TAX (BENEFIT) EXPENSE	(20,638)	171	380,917	81,101
NET (LOSS) INCOME	$ (37,751)	$ (5,074)	$ 539,241	$ 109,062
NET (LOSS) INCOME PER COMMON SHARE:				
Basic	$ (0.01)	$ (0.00)	$ 0.20	$ 0.04
Diluted	$ (0.01)	$ (0.00)	$ 0.19	$ 0.04
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic	2,740,584	2,757,817	2,737,404	2,753,047

Diluted	2,740,584	2,757,817	2,812,795	2,956,712

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

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IMMUCELL CORPORATION

STATEMENTS OF CASH FLOWS FOR THE NINE MONTH PERIODS

ENDED SEPTEMBER 30, 2003 AND 2004

(Unaudited)

	Nine Months Ended September 30,	
	2003	**2004**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 539,241	$ 109,062
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	190,140	186,640
Deferred income taxes	367,086	75,865
Loss on disposal of fixed assets	33,695	1,897
Changes in:		
Accounts receivable	111,349	(46,773)
Inventories	74,625	75,768
Prepaid expenses and other assets	(42,066)	(31,853)
Accounts payable	21,473	42,458
Accrued expenses	(37,977)	(197,011)
Deferred revenue	79,990	
Net cash provided by operating activities	1,337,556	216,053
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(127,705)	(257,565)
Proceeds from disposal of fixed assets		4,000
Maturities of short-term investments	1,087,975	1,285,061
Purchases of short-term investments	(1,882,976)	(3,245,180)
Net cash used for investing activities	(922,706)	(2,213,684)
CASH FLOWS FROM FINANCING ACTIVITIES:		
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
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	417,208	(1,964,085)
BEGINNING CASH AND CASH EQUIVALENTS	2,355,970	3,356,742
ENDING CASH AND CASH EQUIVALENTS	$ 2,773,178	$ 1,392,657

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

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IMMUCELL CORPORATION

Notes to Unaudited Financial Statements

September 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:

	December 31, 2003	September 30, 2004	(Decrease) Increase
Cash and cash equivalents	$ 3,356,742	$ 1,392,657	$ (1,964,085)
Short-term investments	888,320	2,848,439	1,960,119
	$ 4,245,062	$ 4,241,096	$ (3,966)

3. INVENTORIES

Inventories consist of the following:

	December 31, 2003	September 30, 2004
Raw materials	$ 86,304	$ 152,678
Work-in-process	405,004	358,259
Finished goods	183,199	87,802
	$ 674,507	$ 598,739

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 $367,000 and $76,000 during the nine month periods ended September 30, 2003 and 2004, respectively. The total income tax expense aggregated $381,000 and $81,000 for the nine month periods ended September 30, 2003 and 2004, respectively. For federal and state income tax purposes, we have remaining net operating loss carryforwards of approximately $540,000 as of December 31, 2003, which expire if they are not utilized to offset taxable income earned during or before the following years: 2009 ($347,000), 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, we elected to increase income for federal income tax purposes by capitalizing research and experimentation expenditures

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Notes to Unaudited Financial Statements

September 30, 2004

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 $112,000 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 September 30, 2003 and 2004 as the effect would be antidilutive, thereby decreasing the diluted net loss per share.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2004	2003	2004
Weighted average number of shares outstanding during the period	2,740,584	2,757,817	2,737,404	2,753,047
Dilutive stock options			242,124	560,972
Shares that could have been repurchased with the proceeds from the dilutive stock options			(166,733)	(357,307)
Diluted number of shares outstanding during the period	2,740,584	2,757,817	2,812,795	2,956,712
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	595,872	573,139	358,915	3,333

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

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 Financial Accounting Standards Board is currently deliberating whether to require companies to record employee stock-based compensation as an expense. 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 September 30,		Nine Months Ended September 30,	
	2003	2004	2003	2004
Net (loss) income, as reported	$ (37,751)	$ (5,074)	$ 539,241	$ 109,062
Less: Pro forma stock-based employee compensation expense determined under the fair value based method, net of related tax effects	(10,515)	(12,408)	(40,184)	(34,652)
Pro forma net (loss) income	$ (48,266)	$ (17,482)	$ 499,057	$ 74,410
Net (loss) income per share:				
Basic: as reported	$ (0.01)	$ (0.00)	$ 0.20	$ 0.04
Basic: pro forma	$ (0.02)	$ (0.01)	$ 0.18	$ 0.03
Diluted: as reported	$ (0.01)	$ (0.00)	$ 0.19	$ 0.04
Diluted: pro forma	$ (0.02)	$ (0.01)	$ 0.18	$ 0.03

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Notes to Unaudited Financial Statements

September 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 (90% for both the three month periods ended September 30, 2003 and 2004, respectively, and 94% and 90% for the nine month periods ended September 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 10% of product sales for both the three month periods ended September 30, 2003 and 2004, respectively, and 6% and 10% of product sales for the nine month periods ended September 30, 2003 and 2004, respectively. Sales made to Walco International, Inc. aggregated 13% and 14% of total product sales during the three month periods ended September 30, 2003 and 2004, respectively, and 19% and 18% of total product sales during the nine month periods ended September 30, 2003 and 2004, respectively. This customer accounted for 21% and 17% of the Company s outstanding accounts receivable as of December 31, 2003 and September 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 (an average purchase price of $2.08 per share) under this plan. As of November 8, 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 we adopted the repurchase plan.

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

RESULTS OF OPERATIONS FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2004

Product sales increased by 8%, or $63,000, to $808,000 during the three month period ended September 30, 2004 in comparison to $745,000 during the three month period ended September 30, 2003. Product sales increased by 14%, or $317,000, to $2,668,000 during the nine month period ended September 30, 2004 in comparison to $2,350,000 during the nine month period ended September 30, 2003. 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 22% during the nine month period ended September 30, 2004 in comparison to the same period in 2003. Sales have been positively affected by the recent increase in the price that dairy producers are paid for the milk that they produce and sell. Sales of **Wipe Out® Dairy Wipes** decreased by 12% during the nine month period ended September 30, 2004 in comparison to the same period in 2003. Sales of this premium product have been challenged by less expensive competitive products.

Total revenues increased by 7%, or $57,000, to $846,000 during the three month period ended September 30, 2004 in comparison to the same period in 2003. Total revenues increased by 9%, or $220,000, to $2,753,000 during the nine month period ended September 30, 2004 in comparison to the same period in 2003. Grant income of $30,000 and $112,000 was earned during the nine month period ended September 30, 2004 and 2003, respectively. The 2004 grant income supported the development of a bovine milk immunoglobulin supplement to prevent diarrhea in humans. The 2003 grant income supported the development of **Mast Out®** and topical skin sanitizing applications of Nisin. Royalty income increased by $4,000 to $55,000 during the nine month period ended September 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.

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Gross margin as a percentage of product sales was 58% and 55% during the three month periods ended September 30, 2004 and 2003, respectively. The total gross margin increased by 13%, or $55,000, to $465,000 during the three month period ended September 30, 2004, as compared to the same period in 2003. Gross margin as a percentage of product sales was 59% and 56% during the nine month periods ended September 30, 2004 and 2003, respectively. The total gross margin increased by 20%, or $259,000, to $1,565,000 during the nine month period ended September 30, 2004, as compared to the same period in 2003. 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 September 30, 2004, research and development expenses increased by 1%, or $3,000, to $272,000, as compared to the same period in 2003. Research and development expenses aggregated 32% and 34% of total revenues during the three month periods ended September 30, 2004 and 2003, respectively. During the nine month period ended September 30, 2004, research and development expenses decreased by 16%, or $138,000, to $735,000, as compared to the same period in 2003. Research and development expenses aggregated 27% and 34% of total revenues during the nine month periods ended September 30, 2004 and 2003, respectively. Research and development expenses exceeded grant income by $705,000 (which net amount equals 26% of product sales) during the nine month period ended September 30, 2004. Research and development expenses exceeded grant income by $762,000 (which net amount equals 32% of product sales) during the nine month period ended September 30, 2003.

During 2000, we initiated the development of **Mast Out®**, an intramammary infusion product utilizing Nisin (the same natural, antibacterial peptide that is the active ingredient in **Wipe Out Dairy Wipes**) as an alternative to traditional antibiotics in the treatment of mastitis in lactating dairy cows. It is the standard of treatment with traditional antibiotics to discard some of the milk from treated cows. The safety profile of Nisin and its accepted use as a food preservative form the basis for our petition to permit the use of the product without the discard requirement. 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. 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. After certain manufacturing and regulatory development objectives are accomplished, we intend to initiate a pivotal efficacy trial of this product during the first half of 2005. Assuming that it should take about one year to complete the trial, our objective is to file for final FDA approval during the first half of 2006. If FDA review and approval is successfully completed in approximately one year, commercial sales of the product could begin in 2007. In September 2004, the U.S. Patent and Trademark Office issued to us patent #6,794,181 entitled Method of Purifying Lantibiotics , covering a key step in the manufacturing process for pharmaceutical-grade Nisin. This patent (together with several issued patents licensed from Nutrition 21, Inc. in 2000) and certain proprietary know-how comprise the principal intellectual property protection covering **Mast Out**.

We also conduct early stage product development research. Among these smaller projects are: continuing efforts to expand the **First Defense** claims against additional pathogens, evaluations of an oral colostrum supplement for calves, the evaluation of new formulations for the preparation and sanitization of udders before and after milking, and additional animal health applications of our Nisin technology.

General and administrative expenses were $142,000 during the three month period ended September 30, 2004 compared to $128,000 during the same period in 2003. General and administrative expenses were $452,000 during the nine month period ended September 30, 2004 compared to $441,000 during the same period in 2003.

During the three month period ended September 30, 2004, product selling expenses decreased by 13%, or $17,000, to $109,000, as compared to the same period in 2003, aggregating 13% and 17% of product sales during the three month periods ended September 30, 2004 and 2003, respectively. During the nine month period ended September 30, 2004, product selling expenses decreased by 19%, or $74,000 to $314,000, as compared to the same period in 2003, aggregating 12% and 17% of product sales during the nine month periods ended September 30, 2004 and 2003, respectively. These decreases result principally from the elimination of a marketing position at the end of 2003. Our objective is to maintain the ratio of product selling expenses to product sales at or below 15% on an annual basis.

The net loss for the three months ended September 30, 2004 of $5,000 compares to a net loss of $38,000 ($0.01 per share) for the three months ended September 30, 2003. Income before income taxes for the nine months ended September 30, 2004 was $190,000. Income before income taxes for the nine months ended September 30, 2003 of $920,000 included $1,100,000 in other

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income earned from the sale of our 50% interest in a non-core joint venture. The net income for the nine months ended September 30, 2004 of $109,000 ($0.04 per diluted share) compares to net income of $539,000 ($0.19 per diluted share) for the nine months ended September 30, 2003. The effective income tax rate was 43% and 41% for the nine month periods ended September 30, 2004 and 2003, respectively.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and short-term investments decreased by an immaterial amount to $4,241,000 at September 30, 2004 from $4,245,000 at December 31, 2003. Net cash provided by operating activities amounted to $216,000 during the nine months ended September 30, 2004 as compared to $1,338,000 during the nine months ended September 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 $197,000 during the first nine months of 2004 as expenses accrued at the end of 2003 in connection with the completion of the experimental field trial of **Mast Out®** were paid. Total assets decreased by $10,000 to $8,177,000 at September 30, 2004 from $8,187,000 at December 31, 2003. The Company has no outstanding bank debt. Net working capital increased by $153,000 to $5,119,000 at September 30, 2004 from $4,965,000 at December 31, 2003. Shareholders equity increased by $145,000 to $7,515,000 at September 30, 2004 from $7,370,000 at December 31, 2003 as the result of the $109,000 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. By completing this project in July 2004 for a total cost of approximately $425,000, we eliminated our prior reliance on a subcontractor to perform this function. We are currently using this plant principally to produce Nisin for clinical trial material for **Mast Out**. After the effort to produce clinical material is complete, the plant will be used principally for commercial production of Nisin for sale in **Wipe Out® 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 non-cGMP Nisin.

In March 2001, we received a two year Development Award aggregating $400,000 from the Maine Technology Institute supporting the development of manufacturing processes related to **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 has been 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 supporting the pivotal efficacy trial of **Mast Out**. This funding is subject to similar accounting and repayment terms. None of this funding has yet been received. The repayment of these grants could be subject to a 100% penalty in certain circumstances under which the sale or licensing of the funded technology to a third party leads to the relocation of the Company outside of Maine. We do not anticipate such a relocation.

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 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.

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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.

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®** and **Wipe Out® Dairy Wipes**. Any disruption in the services at this facility could negatively effect the production of inventory.

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

First Defense is sold in the United States subject to a product license approval from the USDA first obtained in 1991. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the Reference Standard). Due to the unique nature of the **First Defense** label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if, at any time, the USDA does not approve the requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product.

The potential for epidemics of bovine diseases such as Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) present a risk to us and our customers. A documented case of BSE in the U.S. in 2003 has led to an overall tightening of regulations pertaining to ingredients of animal (especially bovine) origin. For example, the FDA 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 us and our customers.

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 September 30, 2004. Based on this evaluation, we have concluded that, as of September 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 September 30, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

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

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. No repurchases were made during the three or nine month periods ended September 30, 2004.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

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

None

ITEM 5. OTHER INFORMATION

None

ITEM 6. 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.

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: November 8, 2004

By: /s/ Michael F. Brigham

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