

IMMUCELL CORP /DE/
Form 10-Q
May 14, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2012

001-12934

(Commission file number)

ImmuCell Corporation

(Exact name of registrant as specified in its charter)

Delaware 01-0382980
(State of incorporation) (I.R.S. Employer Identification No.)

56 Evergreen Drive, Portland, ME 04103
(Address of principal executive office) (Zip Code)

(207) 878-2770

(Registrant's telephone number)

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 check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

The number of shares of the Registrant's common stock outstanding at May 11, 2012 was 3,019,034.

ImmuCell Corporation

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ImmuCell Corporation**PART 1. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****BALANCE SHEETS**

	(Unaudited) March 31, 2012	December 31, 2011
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,571,064	\$ 781,516
Short-term investments	3,483,000	4,178,000
Trade accounts receivable, net of allowance for doubtful accounts of \$14,000 at March 31, 2012 and \$16,000 at December 31, 2011	594,568	346,447
Income taxes receivable	648	648
Other receivables	26,695	36,701
Inventory	1,583,383	1,666,465
Prepaid expenses	125,472	81,807
Current portion of deferred tax asset	36,796	59,016
 Total current assets	 7,421,626	 7,150,600
NET PROPERTY, PLANT AND EQUIPMENT , at cost	2,514,888	2,515,331
LONG-TERM PORTION OF DEFERRED TAX ASSET	1,215,863	1,306,335
OTHER ASSETS , net	18,587	19,006
 TOTAL ASSETS	 \$ 11,170,964	 \$ 10,991,272
 LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	\$ 239,005	\$ 303,900
Accounts payable	219,612	149,877
Current portion of bank debt	175,086	172,973
Deferred revenue	8,250	8,250
 Total current liabilities	 641,953	 635,000
 LONG-TERM LIABILITIES:		
Long-term portion of bank debt	1,223,343	1,267,939

Interest rate swap	58,566	67,900
Total long-term liabilities	1,281,909	1,335,839
TOTAL LIABILITIES	1,923,862	1,970,839
STOCKHOLDERS' EQUITY:		
Common stock, \$0.10 par value per share, 8,000,000 shares authorized, 3,261,148 shares issued at March 31, 2012 and December 31, 2011	326,115	326,115
Capital in excess of par value	9,945,398	9,911,914
Accumulated deficit	(459,554)	(614,315)
Treasury stock, at cost, 242,114 and 257,114 shares at March 31, 2012 and December 31, 2011, respectively	(529,655)	(562,469)
Accumulated other comprehensive (loss) income: interest rate swap	(35,202)	(40,812)
Total stockholders' equity	9,247,102	9,020,433
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$11,170,964	\$10,991,272

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

ImmuCell Corporation

(Unaudited)

STATEMENTS OF OPERATIONS

	For the Three-Month Periods Ended March 31,	
	2012	2011
Product sales	\$ 1,717,109	\$ 1,555,701
Costs of goods sold	704,541	687,466
Gross margin	1,012,568	868,235
Product development expenses	247,807	472,134
Administrative expenses	242,319	208,887
Sales and marketing expenses	241,209	204,072
Other operating expenses	731,335	885,093
NET OPERATING INCOME (LOSS)	281,233	(16,858)
Other (expenses) revenues, net	(10,509)	(14,638)
INCOME (LOSS) BEFORE INCOME TAXES	270,724	(31,496)
Income tax expense (benefit)	115,963	(8,383)
NET INCOME (LOSS)	\$ 154,761	\$ (23,113)
Weighted average common shares outstanding:		
Basic	3,016,067	2,973,652
Diluted	3,102,848	2,973,652
NET INCOME (LOSS) PER SHARE:		
Basic	\$ 0.05	\$ (0.01)
Diluted	\$ 0.05	\$ (0.01)

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

ImmuCell Corporation

(Unaudited)

STATEMENTS OF COMPREHENSIVE INCOME

	For the Three-Month Periods Ended March 31,	
	2012	2011
Net income (loss)	\$ 154,761	\$ (23,113)
Other comprehensive income:		
Interest rate swap, before taxes	9,334	8,794
Income tax applicable to interest rate swap	(3,724)	(7,350)
Other comprehensive income, net of tax	5,610	1,444
Total comprehensive income (loss)	\$ 160,371	\$ (21,669)

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

Other comprehensive income – interest rate swap, net of taxes	—	—	—	—	—	—	1,444	1,444
Stock-based compensation	—	—	7,911	—	—	—	—	7,911
BALANCE, March 31, 2011	3,261,148	\$326,115	\$9,788,303	\$(227,918)	287,496	\$(628,932)	\$ 11,075	\$9,268,643

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

ImmuCell Corporation

(Unaudited)

STATEMENTS OF CASH FLOWS

	For the Three-Month Periods Ended March 31,	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	\$ 154,761	\$ (23,113)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation	103,213	105,157
Amortization	719	1,686
Deferred income taxes	108,968	(1,137)
Stock-based compensation	8,656	7,911
Changes in:		
Receivables	(238,115)	(20,301)
Inventory	83,081	30,517
Prepaid expenses and other assets	(43,965)	9,036
Accrued expenses	(64,895)	71,791
Accounts payable	79,429	44,943
Deferred revenue	—	8,250
Net cash provided by operating activities	191,852	234,740
CASH FLOWS FROM INVESTING ACTIVITIES :		
Purchase of property, plant and equipment	(112,463)	(130,364)
Maturities of short-term investments	1,195,000	—
Purchases of short-term investments	(500,000)	(1,195,000)
Net cash provided by (used for) investing activities	582,537	(1,325,364)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from debt issuance	—	600,000
Debt principal repayments	(42,483)	(20,935)
Proceeds from exercise of stock options	50,800	—
Tax benefits related to stock options	6,842	—
Net cash provided by financing activities	15,159	579,065
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	789,548	(511,559)
BEGINNING CASH AND CASH EQUIVALENTS	781,516	1,398,985
ENDING CASH AND CASH EQUIVALENTS	\$ 1,571,064	\$ 887,426
INTEREST EXPENSE PAID	\$ 19,586	\$ 16,541

INCOME TAXES PAID	\$ 152	\$ 102
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable	\$ (9,693) \$(41,103)
Net change in fair value of interest rate swap	\$ (5,610) \$(1,444)

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

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS

March 31, 2012

1. BASIS OF PRESENTATION

We have prepared the accompanying financial statements without audit reflecting all adjustments, all of which are of a normal recurring nature, that are, in our opinion, necessary in order to make the financial statements not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP issued by the FASB in these footnotes are to the FASB *Accounting Standards Codification*TM (Codification). Certain information and footnote disclosures normally included in the annual financial statements 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 for the year ended December 31, 2011 and the notes thereto, contained in our 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. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits per financial institution are maintained in money market accounts at financial institutions that are insured, in part, by the Securities Investor Protection Corporation. Short-term investments are classified as held to maturity and are comprised principally of certificates of deposit that mature in more than three months from their purchase dates and not more than twelve months from the balance sheet date and are held at different financial institutions that are insured by the FDIC within the FDIC insurance limit of \$250,000 per institution per depositor. We are required by bank debt covenant to maintain at least \$1,000,000 of otherwise unrestricted cash, cash equivalents and short-term investments. Cash, cash equivalents and short-term investments consisted of the following (in thousands):

	As of March 31, 2012	As of December 31, 2011	Increase (Decrease)
Cash and cash equivalents	\$ 1,571	\$ 782	\$ 789
Short-term investments	3,483	4,178	(695)
	\$ 5,054	\$ 4,960	\$ 94

3. INVENTORY

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

	As of March 31, 2012	As of December 31, 2011	Increase (Decrease)
Raw materials	\$ 256	\$ 218	\$ 38
Work-in-process	1,016	1,000	16
Finished goods	311	448	(137)
	\$ 1,583	\$ 1,666	\$ (83)

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ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2012

4. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following, at cost (in thousands):

	As of March 31, 2012	As of December 31, 2011
Laboratory and manufacturing equipment	\$ 3,021	\$ 2,979
Building and improvements	2,705	2,667
Office furniture and equipment	256	253
Construction in progress	21	1
Land	50	50
Property, plant and equipment, gross	6,053	5,950
Accumulated depreciation	(3,538)	(3,435)
Property, plant and equipment, net	\$ 2,515	\$ 2,515

5.**OTHER ASSETS**

Other assets consisted of the following (in thousands):

	As of March 31, 2012	As of December 31, 2011
Security deposits	\$ 1	\$ 1
Debt issue costs	26	26
Other assets, gross	27	27
Accumulated amortization of debt issue costs	(8)	(8)
Other assets, net	\$ 19	\$ 19

6.**BANK DEBT**

During the third quarter of 2010, we agreed to terms of certain credit facilities with TD Bank, N.A. aggregating up to approximately \$2,100,000, which are secured by substantially all of our assets. These credit facilities are comprised of

a \$1,000,000 ten-year mortgage loan, a \$600,000 fifty-four month note and a \$500,000 line of credit. Proceeds from the \$1,000,000 mortgage were received during the third quarter of 2010. Based on a 15-year amortization schedule, a balloon principal payment of approximately \$452,000 will be due in the third quarter of 2020. We hedged our interest rate exposure on this mortgage loan with an interest rate swap agreement that effectively converted a floating interest rate to the fixed rate of 6.04%. All derivatives are recognized on the balance sheet at their fair value. The agreement has been determined to be highly effective in hedging the variability of the identified cash flows and has been designated as a cash flow hedge of the variability in the hedged interest payments. Changes in the fair value of the interest rate swap agreement are recorded in other comprehensive income (loss), net of taxes. The original notional amount of the interest rate swap agreement of \$1,000,000 amortizes in accordance with the amortization of the mortgage. As the result of our decision to hedge this interest rate risk, we recorded accumulated other comprehensive loss in the amount of approximately \$35,000 and \$41,000 as of March 31, 2012 and December 31, 2011, respectively, which reflects the fair value of the interest rate swap liability, net of taxes. The fair value of the interest rate swap has been determined using observable market-based inputs or unobservable inputs that are corroborated by market data. Accordingly, the interest rate swap is classified as level 2 within the fair value hierarchy provided in Codification Topic 820, *Fair Value Measurements and Disclosures*. Proceeds from the \$600,000 note were received during the first quarter of 2011. Interest on the note is variable at the higher rate of 4.25% or the one month London Interbank Offered Rate (LIBOR) plus 3.25%. The \$500,000 line of credit is available as needed and has been extended through May 31, 2012 and is renewable annually thereafter. Interest on any borrowings against the line of credit will be variable at the higher rate of 4.25% or the one month LIBOR plus 3.50%. These credit facilities are subject to certain financial covenants. We are in compliance with all applicable covenants as of March 31, 2012. Principal payments due under debt outstanding as of March 31, 2012 are reflected in the following table by the period that payments are due (in thousands):

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2012

	Nine-Month Period Ending December 31, 2012	Years Ending December 31,						Total
		2013	2014	2015	2016	2017	Thereafter	
\$1,000,000 mortgage	\$ 34	\$48	\$51	\$54	\$ 57	\$ 61	\$ 627	\$932
\$600,000 note	97	134	139	96	—	—	—	466
Total	\$ 131	\$182	\$190	\$150	\$ 57	\$ 61	\$ 627	\$1,398

7. OTHER (EXPENSES) REVENUES, NET

Other (expenses) revenues, net, consisted of the following (in thousands):

	For the Three-Month Periods Ended March 31,	
	2012	2011
Royalty income	\$ 4	\$ 2
Interest income	5	4
Interest expense	(20)	(20)
Other gains (losses)	—	(1)
	\$ (11)	\$ (15)

8. STOCK-BASED COMPENSATION

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model. Accordingly, we recorded compensation expense pertaining to stock-based compensation of \$9,000 and \$8,000 during the three-month periods ended March 31, 2012 and 2011, respectively. Codification Topic 718 requires us to reflect gross tax savings resulting from tax deductions in excess of expense reflected in our financial statements as a financing cash flow.

9.

INCOME TAXES

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which 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 believe it is more likely than not that the deferred tax assets will be realized through future taxable income and 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. Codification Topic 740-10 clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position must meet before being recognized in the financial statements. In the ordinary course of business, there are transactions and calculations where the ultimate tax outcome is uncertain. In addition, we are subject to periodic audits and examinations by the IRS and other taxing authorities. We have evaluated the positions taken on our filed tax returns. We have concluded that no uncertain tax positions exist as of March 31, 2012. Although we believe that our estimates are reasonable, actual results could differ from these estimates.

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2012

10. NET INCOME (LOSS) PER COMMON SHARE

The net income (loss) per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*. The basic net income per share has been computed by dividing the net income by the weighted average number of common shares outstanding during this period. The diluted net income per share has been computed by dividing the net income by the weighted average number of shares outstanding during the period plus all outstanding stock options with an exercise price that is less than the average market price of the common stock during the period less the number of shares that could have been repurchased at this average market price with the proceeds from the hypothetical stock option exercises. The net loss per common share has been computed by dividing the net loss by the weighted average number of common shares outstanding during the period, without giving consideration to outstanding stock options because the impact would be anti-dilutive.

11. COMMON STOCK RIGHTS PLAN

In September 1995, our Board of Directors adopted a Common Stock Rights Plan (the Rights Plan) and declared a dividend of one common share purchase right (a Right) for each of the then outstanding shares of the common stock of the Company. Each Right entitles the registered holder to purchase from the Company one share of common stock at an initial purchase price of \$70.00 per share, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement between the Company and American Stock Transfer & Trust Co., as Rights Agent.

The Rights (as amended) become exercisable and transferable apart from the common stock upon the earlier of i) 10 days following a public announcement that a person or group (Acquiring Person) has, without the prior consent of the Continuing Directors (as such term is defined in the Rights Agreement), acquired beneficial ownership of 20% or more of the outstanding common stock or ii) 10 days following commencement of a tender offer or exchange offer the consummation of which would result in ownership by a person or group of 20% or more of the outstanding common stock (the earlier of such dates being called the Distribution Date).

Upon the Distribution Date, the holder of each Right not owned by the Acquiring Person would be entitled to purchase common stock at a discount to the initial purchase price of \$70.00 per share, effectively equal to one half of the market price of a share of common stock on the date the Acquiring Person becomes an Acquiring Person. If, after the Distribution Date, the Company should consolidate or merge with any other entity and the Company were not the surviving company, or, if the Company were the surviving company, all or part of the Company's common stock were

changed or

exchanged into the securities of any other entity, or if more than 50% of the Company's assets or earning power were sold, each Right would entitle its holder to purchase, at the Rights' then-current purchase price, a number of shares of the acquiring company's common stock having a market value at that time equal to twice the Right's exercise price.

At any time after a person or group becomes an Acquiring Person and prior to the acquisition by such person or group of 50% or more of the outstanding common stock, the Board of Directors of the Company may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of common stock per Right (subject to adjustment). At any time prior to 14 days following the date that any person or group becomes an Acquiring Person (subject to extension by the Board of Directors), the Board of Directors of the Company may redeem the then outstanding Rights in whole, but not in part, at a price of \$0.005 per Right, subject to adjustment.

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 at that time. On June 6, 2008, our Board voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2011 and to increase the ownership threshold for determining "Acquiring Person" status from 15% to 18%. As of June 30, 2008, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase. No other changes were made to the terms of the Rights or the Rights Agreement at that time. On August 5, 2011, our Board voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2014 and to increase the ownership threshold for determining "Acquiring Person" status from 18% to 20%. As of August 9, 2011, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase. No other changes were made to the terms of the Rights or the Rights Agreement at that time.

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ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2012

Our Board of Directors believes that there is some risk that the potential value of the **Mast Out**[®] product development initiative may not be fairly reflected in the market price of our common stock, as it fluctuates from time to time, and that opportunistic buyers could take advantage of that disparity to the detriment of our stockholders. If this were to happen and result in a potential threat through an unsolicited acquisition effort or otherwise, our Board feels that the Rights Plan could enhance stockholder value by providing management with negotiating leverage.

12. SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

Pursuant to Codification Topic 280, *Segment Reporting*, we operate in one reportable business segment, that being the development, acquisition, manufacture and sale of products that improve the health and productivity of cows for the dairy and beef industries. Almost all of our internally funded product development expenses are in support of such products. Our primary customers for the majority of our product sales (80% and 82% for the three-month periods ended March 31, 2012 and 2011, respectively) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 20% and 18% of our total product sales for the three-month periods ended March 31, 2012 and 2011, respectively. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

	For the Three-Month Periods Ended March 31,			
	2012	%	2011	%
Animal Health International, Inc. ^[1]	40	%	42	%
MWI Veterinary Supply Company ^[2]	14	%	15	%

^[1] Assumes that the June 2011 acquisition of Animal Health International by Lextron had occurred as of the beginning of

the periods being reported.

^[2] Assumes that the March 2011 acquisition of Nelson Laboratories and the October 2011 acquisition of Micro Beef Technologies by MWI had occurred as of the beginning of the periods being reported.

Accounts receivable due from significant customers that amounted to 10% or more of total trade accounts receivable are detailed in the following table:

	As of March 31, 2012	%	As of December 31, 2011	%
Animal Health International, Inc.	24	%	23	%
MWI Veterinary Supply Company	18	%	21	%
Robert J. Matthews Company	12	%	*	
Stearns Veterinary Outlet, Inc.	*		18	%

*Amount is less than 10%.

13. RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (a member of our Board of Directors) is a controlling owner of Stearns Veterinary Outlet, Inc., a domestic distributor of ImmuCell products (**First Defense[®]**, **Wipe Out[®] Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased approximately \$89,000 and \$84,000 of products from ImmuCell during the three-month periods ended March 31, 2012 and 2011, respectively, on terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated approximately \$58,000 and \$61,000 as of March 31, 2012 and December 31, 2011, respectively.

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2012

14. SUBSEQUENT EVENTS

We have adopted the disclosure provisions of Codification Topic 855-10-50-1, *Subsequent Events*, which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued. Entities are required to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. Codification Topic 855-10-50-1 requires additional disclosures only, and therefore did not have an impact on our financial condition, results of operations, earnings per share or cash flows. Public entities must evaluate subsequent events through the date that financial statements are issued. Accordingly, we have evaluated subsequent events through the time of filing on May 14, 2012, the date we have issued this Quarterly Report on Form 10-Q.

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ImmuCell Corporation

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

RESULTS OF OPERATIONS FOR THE THREE-MONTH PERIOD ENDED MARCH 31, 2012

Product Sales

Product sales increased by approximately 10%, or \$161,000, to \$1,717,000 during the three-month period ended March 31, 2012 in comparison to \$1,556,000 during the same period in 2011. During the three-month period ended March 31, 2012, domestic sales increased by 8%, or \$105,000, and international sales increased by 19%, or \$56,000, in comparison to the same period in 2011. Product sales increased by approximately 14%, or \$642,000, to \$5,273,000 during the twelve-month period ended March 31, 2012, in comparison to \$4,630,000 during the twelve-month period ended March 31, 2011.

Sales of our lead product, **First Defense**[®], increased by 18% during the twelve-month period ended March 31, 2012 in comparison to the same period in 2011. During the three-month period ended March 31, 2012, domestic sales of **First Defense**[®] increased by 10%, and international sales of **First Defense**[®] increased by 25%, in comparison to the same period in 2011. We have been experiencing consistently positive sales growth of **First Defense**[®] since the fourth quarter of 2010, as demonstrated below:

13%: First Quarter 2012 over First Quarter 2011

21%: Fiscal Year 2011 over Fiscal Year 2010

7%: Fourth Quarter 2011 over Fourth Quarter 2010

22%: Third Quarter 2011 over Third Quarter 2010

37%: Second Quarter 2011 over Second Quarter 2010

21%: First Quarter 2011 over First Quarter 2010

13%: Fourth Quarter 2010 over Fourth Quarter 2009

We believe that the growth in sales of **First Defense**[®] may reflect, at least in part, the success of our strategic decision to invest in additional sales and marketing efforts. We launched a communications campaign at the end of 2010 that is highlighting how the unique features of **First Defense**[®] provide a dependable return on investment for producers. Our sales and marketing team currently consists of one director and two regional sales managers. Effective for 2011 and 2012, and renewable for 2013 and 2014 if certain sales growth objectives are met, we entered into a sales and marketing collaboration with Agri Laboratories Ltd. of St. Joseph, Missouri, (AgriLabs[®]), under which the AgriLabs sales and marketing teams are working with us to expand market demand for **First Defense**[®]. The AgriLabs national marketing network consists of 20 independent distributors operating approximately 125 branch locations with more than 700 sales representatives. AgriLabs has developed and markets more than 750 products through its own branded product lines. The AgriLabs sales team is comprised of approximately 22 well-trained, experienced professionals that cover the United States.

Competition for resources that dairy producers allocate to their calf enterprises has been increased by the many new products that have been introduced to the calf market. While milk prices have improved, much of this gain has been offset by increases in the cost of feed. Even in this challenging market, **First Defense**[®] continues to benefit from wide acceptance as an effective tool to prevent bovine enteritis (scours) in newborn calves. The third quarter of 2011 marked the 20th anniversary of the original USDA approval of this product in 1991. During the fourth quarter of 2011, we sold our 11,000,000th dose of **First Defense**[®]. We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product. Sales are normally seasonal, with higher sales expected during the first quarter. The weather during the 2012 spring calving season was extremely mild in North America. Warm and dry weather reduces the producer's perception of the need for **First Defense**[®]. However, sales to our distributors remained strong during the first quarter of 2012. The possibility of high inventory levels in our distributor warehouses could have a negative impact on our sales during the second quarter. It is our production and customer service objective to ship orders within one day of receipt. We have been operating in accordance with this objective since the third quarter of 2009.

We are developing new product applications of our **First Defense Technology**[™], which is a unique whey protein concentrate that is purified utilizing our proprietary whey protein processing methods, for the nutritional and feed supplement markets. It does not carry the claims of our USDA-licensed product. Through our **First Defense Technology**[™], we are selling whey concentrate globulin proteins in different formats. We initiated sales of **First Defense Technology**[™] in a bulk powder format (no capsule), which is delivered with a scoop and mixed with colostrum for feeding. We also initiated a limited launch of a tube delivery format of our **First Defense Technology**[™] in a gel solution. Through two collaborations, we are working to expand sales of our **First Defense Technology**[™] by accessing the U.S. feed market. During the first quarter of 2011, AgriLabs launched commercial sales of their product, Colostrx[®], a colostrum supplement with **First Defense**

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Technology™ Inside. During the fourth quarter of 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start[®] 150 Plus, a colostrum replacer with **First Defense Technology™ Inside**.

Sales of **Wipe Out[®] Dairy Wipes** decreased by 10% during the three-month period ended March 31, 2012 and decreased by 17% during the twelve-month period ended March 31, 2012, in comparison to the same periods in 2011. With **Wipe Out[®] Dairy Wipes**, we are competing aggressively on selling price to earn new business against less expensive products and alternative teat sanitizing methods. This product tends to be more popular with smaller dairy operations, a market segment that continues to shrink.

Gross Margin

The gross margin as a percentage of product sales was 59% and 56% during the three-month periods ended March 31, 2012 and 2011, respectively. The gross margin as a percentage of product sales was 56% and 53% during the twelve-month periods ended March 31, 2012 and 2011, respectively. Our annual objective for gross margin percentage is approximately 50%, and our gross margin as a percentage of product sales has been maintained moderately above that target during the periods being reported. Our gross margin percentages were 55%, 52% and 53% for the years ended December 31, 2011, 2010 and 2009, respectively. We expect some fluctuations in gross margin percentages from quarter to quarter. We believe that a number of factors can cause our costs to be variable. Biological yields from the raw material used in the production of **First Defense[®]** do fluctuate over time. Like most manufacturers in the U.S., we have been experiencing increases in the cost of raw materials that we purchase. Product mix also affects gross margin in that we earn a higher gross margin on **First Defense[®]** and a lower gross margin on **Wipe Out[®] Dairy Wipes**. We had held our selling prices without significant increase for approximately the seven-year period ended December 31, 2007, believing that we could benefit more from higher unit sales volume than through a higher average selling price per unit. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense[®]** and have held that selling price without increase since then. Changes in the gross margin on product sales are summarized in the following table for the respective periods (in thousands, except for percentages):

	Three-Month Periods Ended March 31,		Increase	
	2012	2011	Amount	%
Gross margin	\$1,013	\$868	\$144	17%
Percent of product sales	59 %	56 %	3 %	6 %

	Twelve-Month Periods Ended March 31,		Increase	
	2012	2011	Amount	%
Gross margin	\$2,958	\$2,432	\$527	22%
Percent of product sales	56 %	53 %	4 %	7 %

Product Development

In 1999, we shifted the primary focus of our product development efforts from applications of our whey protein purification technology for humans to scientifically-proven and practical products that result in a measurable economic impact on animal health and productivity in the dairy and beef industries. We expect to continue this strategic focus. As anticipated, we reduced product development expenses primarily because we are spending less money on the development of **Mast Out[®]** at this stage. Product development expenses decreased by approximately 48%, or \$224,000, to \$248,000 during the three-month period ended March 31, 2012 in comparison to \$472,000 during the same period in 2011. We spent approximately \$1,720,000, \$1,493,000 and \$1,645,000 on product development activities during the years ended December 31, 2011, 2010 and 2009, respectively. If a partner agrees to fund the completion of the **Mast Out[®]** product development effort, these expenses could increase, but only if they are off set, at least in part, by the funds that we would receive from the potential strategic collaboration.

In 2000, we acquired an exclusive license from Nutrition 21, Inc. (formerly Applied Microbiology Inc. or AMBI) to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Mast Out[®]**, our intramammary infusion product. In 2004, we paid Nutrition 21 approximately \$965,000 to buy out this royalty and milestone-based license to Nisin, thereby acquiring control of the animal health applications of Nisin. Nisin, the same active ingredient contained in **Wipe Out[®] Dairy Wipes**, is an antibacterial peptide. Nisin is known to have activity against most gram positive and some gram negative bacteria. Nisin is a well characterized substance, having been used in food preservation applications for over 50 years. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes methods to achieve pharmaceutical-grade purity.

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In 2004, we entered into a product development and marketing agreement with Pfizer Animal Health, a division of Pfizer, Inc., covering Mast Out[®]. Under that agreement (as amended and supplemented and later terminated), we received \$2,375,000 in payments from Pfizer. Pfizer elected to terminate the agreement in 2007. Soon thereafter, Pfizer returned to us all rights, data, information, files, regulatory filings, materials and stocks of Nisin and Nisin producing cultures relating to the development of Mast Out[®]. We believe that Pfizer's decision to terminate the agreement was not based on any unanticipated efficacy or regulatory issues. Rather, we believe Pfizer's decision was primarily market driven, largely relating to their concern that the use of Mast Out[®] might require specific treatment restrictions at the herd level to avoid a potential problem using the milk from treated cows in the manufacture of cheese.

Due to the zero milk discard feature, there is a risk that Nisin from milk of cows treated with **Mast Out[®]** could interfere with the manufacture of certain (but not all) commercial cultured dairy products, such as some kinds of cheese and yogurt, if a process tank contains milk from a high enough percentage of treated cows. We have conducted a formal risk assessment to quantify the impact that milk from treated cows may have on cultured dairy products. This study concluded that the dilution of milk from treated cows through comingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when **Mast Out[®]** is used in accordance with the product label. Milk from treated cows that is sold exclusively for fluid milk products presents no such risk. Another risk is that **Mast Out[®]** likely will be priced at a premium to the traditional antibiotic products currently on the market, which are all sold subject to a milk discard requirement. However, we believe that the product's value proposition demonstrates a return on investment to the producer that will justify this premium.

Many fear that the possible overuse of antibiotics in livestock could undermine the effectiveness of drugs to combat human illnesses and may be a contributing factor to the rising problem of bacterial drug resistance. The FDA is committed to addressing its concern with respect to this important public health issue. Citing concerns about untreatable, life-threatening infections in humans, new FDA regulations proposed to go into effect in April 2012 would further restrict the use of cephalosporins in food animals. Effective January 2012, new USDA regulations are expected to reduce the allowable level of somatic cell counts in milk to 400,000 at the farm level in order to qualify for an EU export certification. In late 2011, The Dutch Veterinary Society proposed strict guidelines for veterinary use of antibiotics in the EU. This current environment could be favorable to the introduction of a new product such as **Mast Out[®]** as an alternative to traditional antibiotics. We continue to believe that this product opportunity justifies ongoing product development efforts.

Commercial introduction of **Mast Out[®]** in the United States is subject to approval of our New Animal Drug Application (NADA) by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA), which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets outside of the United States and would involve some similar and some different requirements. In 2007, we began the production of pivotal batches of drug product to fulfill the regulatory requirements of effectiveness, stability, target animal safety

and human food safety. The NADA is comprised of five principal Technical Sections subject to the FDA's phased review of a NADA. By statute, each Technical Section submission is subject to a six-month review cycle by the FDA. The current status of our work on these Technical Sections is as follows:

- 1) Environmental Impact: During the third quarter of 2008, we received the Environmental Impact Technical Section Complete Letter from the FDA.

- 2) Target Animal Safety: During the second quarter of 2012, we received the Target Animal Safety Technical Section Complete Letter from the FDA.

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3) Effectiveness: During the second quarter of 2008, we initiated the pivotal effectiveness study. Positive results from the study were announced during the third quarter of 2009. With enrollment of approximately 300 qualified cows with subclinical mastitis, the **Mast Out[®]** treatment group showed a statistically highly significant overall cure rate in comparison to the placebo group. We believe that the breakdown of the data by species suggests both the necessary numerical superiority and clinical relevancy to support robust product performance in the field. For example, one of the most important mastitis pathogens, coagulase-negative staphylococci, predominated in our study, and **Mast Out[®]** achieved almost 10-fold higher cure rates than the placebo-treated animals against this pathogen. Further, **Mast Out[®]** treatment was associated with a statistically significant reduction in milk somatic cell count (SCC), which is an important measure of milk quality. During the third quarter of 2010, we made our first submission of the Effectiveness Technical Section. This 65 volume submission contained the results from our pivotal trial conducted from 2008 to 2009 as well as all supporting data related to the effectiveness of Nisin, demonstrating the effectiveness of **Mast Out[®]** in the field at a level similar to currently marketed intramammary antibiotics and confirming prior results from two major field studies conducted since 2003. During the first quarter of 2011, we received an Effectiveness Technical Section Incomplete Letter from the FDA. The FDA requested additional information and clarification in the areas of raw data, subject eligibility and statistical analyses and has requested that certain treatment outcomes be changed or justified. Additional clinical studies were not required. Our response to the FDA, which was submitted during the fourth quarter of 2011, does not materially change our initial conclusions about the product's effectiveness. We expect to receive the FDA's response to this second submission during the second quarter of 2012 after a six-month review cycle.

4) Human Food Safety (HFS): The HFS Technical Section submission was made during the fourth quarter of 2010. This Technical Section determines if a milk discard period or meat withhold period will be required. This Technical Section includes several subsections such as: a) toxicology, b) total metabolism, c) effects of drug residues in food on human intestinal microbiology, d) effects on bacteria of human health concern (antimicrobial resistance) and e) pivotal residue chemistry. During the second quarter of 2011, we announced that the FDA had accepted our pivotal Nisin residue in milk data and granted **Mast Out[®]** a zero milk discard time and a zero meat withhold period. Before we can obtain the Technical Section Complete Letter, we must adapt our analytical method that measures Nisin residues in milk around the newly assigned tolerance limit and transfer that method to the FDA laboratory. We anticipate being able to complete this work during the third quarter of 2012, at which point we would be eligible to receive the Technical Section Complete Letter from the FDA.

5) Chemistry, Manufacturing and Controls (CMC): We have entered into agreements with three manufacturers to produce inventory for us utilizing our proprietary technology and processes. First, a long-term, exclusive supply agreement with Plas-Pak Inc. of Norwich, Connecticut covers the proprietary syringe that was developed specifically for **Mast Out[®]**. These syringes were used for all pivotal studies of **Mast Out[®]**. Second, a Development and Manufacturing Agreement with Lonza Sales, Ltd. of Basel, Switzerland provides for the exclusive manufacture of the Active Pharmaceutical Ingredient (API). The Lonza site in Europe is FDA-approved, compliant with current Good Manufacturing Practices (cGMP) regulations and subject to future FDA inspection and approval. Through discussions with partner prospects, we have recently determined that current Lonza contract provisions could result in unfavorable product volumes and costs. Therefore, we are currently seeking contractual amendments with Lonza while

simultaneously investigating a self-sourcing strategy. While a self-sourcing strategy would provide us with more control and flexibility with regards to production volumes and costs, the amount of the required investment would be similar for both options. However, construction of a new production facility could add time to the anticipated market launch date. Third, an exclusive Contract Manufacture Agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved drug product manufacturer, covers the formulation of the API into drug product, the sterile-fill of syringes and the final packaging. Norbrook provided these services for clinical material used in all pivotal studies of **Mast Out**[®]. We expect to make a submission of this Technical Section during the second quarter of 2012, which would enable us to receive review comments from the FDA by year-end after a six-month review cycle. Obtaining FDA approval of the CMC Technical Section defines the critical path to the submission of the administrative NADA to the FDA and ultimately to commercial sales.

6) Several Administrative Requirements: After obtaining the final Technical Section Complete Letter and after preparing materials responsive to other administrative requirements, the administrative NADA submission can be assembled for review by the FDA. This final submission would be subject to a statutory sixty-day review period.

In addition to our work on **Mast Out**[®], we are actively exploring further improvements, extensions or additions to our current product line. For example, we currently are developing therapies that could prevent scours in calves caused by enteric pathogens other than *E. coli* K99 and bovine coronavirus (the current **First Defense**[®] claims). In connection with that effort, during the second quarter of 2009 we entered into an exclusive license with Baylor College of Medicine covering certain rotavirus vaccine technology. This perpetual license (if not terminated for cause) is subject to milestone and royalty payments. Results from pilot studies completed during the first quarter of 2009 justified continued product development. We completed a pivotal effectiveness study of this experimental, three-claim formulation during the third quarter of 2011 without seeing the anticipated level of effectiveness needed for regulatory approval and market acceptance. We are currently conducting additional pilot studies of different formulations of this antibody preparation. If positive results from these pilot studies are achieved, a second pivotal effectiveness study could be initiated during 2012. As additional opportunities arise to commercialize our own technology, or licensable technology, we begin new development projects. While we continue to pursue internally funded product development programs, we also remain interested in acquiring new products and technologies that fit with our sales and marketing focus on the dairy and beef industries.

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Administrative Expenses

During the three-month period ended March 31, 2012, administrative expenses increased by 16%, or \$33,000, to \$242,000 as compared to the same period in 2011. While we implement efficiencies where possible, we continue to incur costs associated with complying with the Sarbanes-Oxley Act of 2002 and other costs associated with being a publicly-held company. At this stage in our development, we have limited our investment in investor relations spending. We provide a full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as Current Reports on Form 8-K when desired or deemed appropriate by management. Additional information about us is available in our annual Proxy Statement. All of these reports are filed with the SEC and are available on-line or upon request to the Company. At this time, our financial and time resources are committed principally to managing our commercial business and developing **Mast Out[®]**. Our board of directors is very involved with and supportive of this resource allocation. While this strategy of providing cost-effective investor relations through our SEC reporting is subject to change, we believe that this focus currently is in the best long-term interest of all stockholders.

Sales and Marketing Expenses

During the three-month period ended March 31, 2012, sales and marketing expenses increased by 18%, or \$37,000, to \$241,000 in comparison to the same period in 2011, aggregating 14% and 13% of product sales during the three-month periods ended March 31, 2012 and 2011, respectively. This increase was expected and planned given our strategic decision to invest in additional sales and marketing efforts. This investment may have created, at least in part, our recent increase in product sales. Our current budgetary objective is to maintain the ratio of product selling expenses to product sales below 20% for the full year 2012.

Income (Loss) Before Income Taxes and Net Income (Loss)

Our income before income taxes was \$271,000 during the three-month period ended March 31, 2012 in contrast to a loss before income taxes of (\$31,000) during the three-month period ended March 31, 2011. Our income tax expense (benefit) was 43% and 27% of our income (loss) before income taxes during the three-month periods ended March 31, 2012 and 2011, respectively. Our net income for the three-month period ended March 31, 2012 was \$155,000, or \$0.05 per share, in contrast to a net loss of (\$23,000), or (\$0.01) per share, during the three-month period ended March 31, 2011. This improvement in our financial performance, which we anticipated, is primarily attributable to increased gross margin from sales of **First Defense[®]** and lower product development expenses.

LIQUIDITY AND CAPITAL RESOURCES

Since 1999, our strategy has been focused on selling and developing products that improve animal health and productivity in the dairy and beef industries. These product opportunities are generally less expensive to develop than the human health product opportunities that we had worked on during the 1990's. We funded most of our product development expenses principally from product sales and were profitable for each of the nine years in the period ended December 31, 2007. During the nine years of profitability from 1999 through 2007, our cumulative investment in product development expenses of \$9,894,000 was supported, in small part, by \$975,000 in grant awards. The investment of an additional \$6,604,000 in product development expenses during 2011, 2010, 2009 and 2008 brings our cumulative investment to \$16,498,000 during the thirteen-year period ended December 31, 2011. We may, on occasion, seek additional research grant support as a means of leveraging the funds that we are able to spend developing new products.

Our strategic decision to continue developing **Mast Out[®]** after the product rights were returned to us in 2007 caused us to increase our spending on product development expenses that were previously funded by Pfizer from late 2004 to mid-2007. After the nine consecutive years of profitability that we recorded during the years ended December 31, 1999 to December 31, 2007, we incurred net losses of \$410,000, \$385,000, \$216,000, and \$469,000 during the years ended December 31, 2011, 2010, 2009, and 2008, respectively. Resulting principally from increased gross margin from sales of **First Defense[®]** and reduced product development spending on **Mast Out[®]**, we returned to profitability during the first quarter of 2012. We believe that the three key indicators that investors should watch going forward will be the gross margin on our product sales, our net operating income (loss) and our net income (loss).

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We estimate that it will require approximately \$13,000,000 to complete the development of **Mast Out**[®] and bring the product to market, sales of which are subject to FDA approval. This investment budget is comprised of costs primarily related to the manufacture of full-scale validation batches and commercial inventory. In addition to the use of some of our cash, we are seeking partner funding, debt issuance and state and other financial incentives to support this manufacturing investment. By the second quarter of 2011, we had advanced the product development effort internally to the point where we could begin earnest negotiations with prospective partners. All anticipated initial discussions are now complete, and some prospective partners are conducting their due diligence. When or if a partnership to help fund the completion of the development of **Mast Out**[®] will be initiated is not known currently. We will make a public announcement of such a deal if and when it occurs. Although these partnering discussions are taking longer than we would like or had initially anticipated, we believe that the commercial prospects for **Mast Out**[®] warrant our continued efforts and patience with the process.

We had approximately \$5,054,000 in available cash and short-term investments as of March 31, 2012. The table below summarizes the changes in selected, key balance sheet items (in thousands, except for percentages):

	As of March 31, 2012	As of December 31, 2011	Increase	
			\$	%
Cash, cash equivalents and short-term investments	\$ 5,054	\$ 4,960	\$95	2%
Total Assets	11,171	10,991	180	2
Net working capital	6,780	6,516	264	4
Stockholders' equity	\$ 9,247	\$ 9,020	\$227	3%

Net cash provided by operating activities amounted to \$192,000 during the three-month period ended March 31, 2012 as compared to net cash provided by operating activities of \$235,000 during the three-month period ended March 31, 2011. Capital investments of \$112,000 during the first quarter of 2012 compared to capital investments of \$130,000 during the first quarter of 2011. 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.

During the third quarter of 2010, we agreed to terms of certain credit facilities with TD Bank, N.A. aggregating up to approximately \$2,100,000, which are secured by substantially all of our assets. These credit facilities are comprised of a \$1,000,000 ten-year mortgage loan, a \$600,000 fifty-four month note and a \$500,000 line of credit. Proceeds from the \$1,000,000 mortgage were received during the third quarter of 2010. Proceeds from the \$600,000 note were received during the first quarter of 2011. The \$500,000 line of credit is available as needed. We believe that this debt financing (together with available cash and gross margin from ongoing product sales) provides us with sufficient funding to finance our working capital requirements while completing the first submissions to the FDA of all Technical Sections pertaining to **Mast Out**[®]. We chose debt financing because we believe that in this market environment, the option to generate funds through the sale of equity securities at an acceptable level of stockholder

dilution is very unlikely.

As part of our sustained investment in compliance with cGMP regulations across our product lines and as we make other process improvements, we are investing in personnel, equipment and facility modifications to increase the efficiency and quality of our operations. Our Board of Directors authorizes the size of this investment in capital expenditures (facility modifications and production equipment). As of April 1, 2012, we had remaining available authorization to spend up to \$204,000 on capital expenditures, net of \$1,360,000 in investments made from January 1, 2008 through March 31, 2012, which authorized amount includes a \$100,000 increase that was approved by our Board of Directors during the first quarter of 2012.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

None

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ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of the individual who serves as our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2012. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. 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 (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

The individual who serves as our principal executive and principal financial officer periodically evaluates any change in internal control over financial reporting which has occurred during the prior fiscal quarter. Management has concluded that there was no change in our internal control over financial reporting that occurred during the quarter ended March 31, 2012 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 1A. RISK FACTORS

This Quarterly Report on Form 10-Q 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: projections of future financial performance; future compliance with bank debt covenants; the scope and timing of future product development work and commercialization of our products; future costs of product development efforts; future sources of financial support for our product development, manufacturing and marketing efforts; the timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future realization of deferred tax assets; factors that may affect the dairy industry and future demand for our products; the accuracy of our understanding of our distributors’ ordering patterns; anticipated changes in our manufacturing capabilities and efficiencies; the amount and timing of future investments in facility modifications and production equipment or the availability and cost of alternative manufacturing and/or distribution resources; the future adequacy of our working capital and the availability of third party financing; future expense ratios; costs and timing associated with sustaining compliance with cGMP regulations; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as “expects”, “may”, “anticipates”, “intends”, “would”, “could”, “should”, “plans”, “believes”, “estimates”, “targets” and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate, especially considering the effects the distress in credit and capital markets will have on our current and prospective customers and the global economy and the uncertainties surrounding the potential for a prolonged global recession. 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, manufacturing reliance upon third parties for products and services, changes in laws and regulations, decision making by regulatory authorities, currency fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized below and uncertainties otherwise referred to in this Quarterly Report.

Economics of the dairy industry: The U.S. dairy industry has been facing very difficult economic pressures. The size (annual average) of the U.S. dairy herd ranged from approximately 9,011,000 to 9,199,000 cows from 1998 to 2007. This annual average jumped to 9,315,000 cows in 2008. The annual average then declined to 9,203,000 in 2009 and further to 9,119,000 in 2010 before increasing to 9,194,000 in 2011. The average herd size further increased to 9,254,000 during the first quarter of 2012. The size of the milking herd affects the price of milk. Over time, the impact on the milk supply from a decrease in cows has been offset, in part, by an increase in milk production per cow. While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk to the market, demand for milk has been largely influenced by very volatile international demand for milk products. Sales of our products may be influenced by the prices of milk, milking cows and calves. The Class III milk price is an industry benchmark that reflects the value of product used to make cheese. The Class III milk price (which is largely out of the direct control of individual dairy producers) is an important indicator because it defines our customers' revenue level. The average Class III milk price for 2009 was \$11.36, which represented a 35% decrease from 2008. The average price for 2009 was 36% lower than the average experienced during the two-year period ended December 31, 2008. For 2010, this price level averaged \$14.41, which represented a 27% increase from 2009 but was well below the 2007 and 2008 levels. This price level averaged \$18.37 for 2011, which represents a 27% increase from 2010. This average price level is higher than the annual average reached in any of the past 30 years. For the first quarter of 2012, this price level averaged \$16.28. The actual level of milk prices may be less important than their level relative to costs because recent improvement in milk prices has been offset, in part, by higher feed costs. One measure of this relationship is known as the milk-feed price ratio, which represents the amount of feed that one pound of milk can buy. Whenever this ratio meets or exceeds 3.0, it is considered profitable to buy feed and produce milk. For 2009, this ratio averaged 1.78, representing a 12% decrease compared to 2008. For 2010, this ratio averaged 2.26, representing a 27% increase compared to 2009. For 2011, this ratio averaged approximately 1.88 representing a 17% decrease compared to 2010. For the first quarter of 2012, this ratio averaged approximately 1.58. This means that a dairy producer can buy only 1.58 pounds of feed for every pound of milk sold. An increase in feed costs also has a negative impact on the beef industry. Another indication of the economic condition of the dairy industry is the average price for animals sold for dairy herd replacement. In 2009, this average price (reported as of January, April, July and October) was estimated to be approximately \$1,385, which was a 29% decrease in comparison to the same period in 2008. This price averaged approximately \$1,330 in 2010, which represented a 4% decrease in comparison to the same period in 2009. This price averaged approximately \$1,420 in 2011, which represents a 7% increase in comparison to the same period in 2010. This price averaged approximately \$1,450 from the January and April 2012 reports. The dairy industry data referred to above is compiled from USDA databases. Another factor in the demand for our product is the value of bull calves. A decline in the price of bull calves reduces the return on investment from a dose of **First Defense**[®] for bull calves. We are trying to maintain and grow our sales for use with heifer calves to offset what we assume is a significant decrease in the use of our product for bull calves. Given our focus on the dairy and beef industries, the financial insecurity of our primary customer base is a risk to our ability to maintain and grow sales at a profitable level. Further, the loss of farms from which we buy raw material for **First Defense**[®] could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms on suitable terms.

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Risks associated with Mast Out[®] funding strategy: There are risks associated with our decision not to internally fully fund the completion of the development of Mast Out[®] through to the submission of the administrative NADA to the FDA. A partner may not be willing to step in and fund the completion of this product development effort on terms acceptable to us. If a partner is not willing to agree to acceptable terms on this collaboration with us, we will need to re-evaluate alternative strategies in order to gain NADA approval and to support the product launch. If we do complete the submission, the FDA may not grant approval of this product.

Income (loss) before income taxes and income net (loss): After nine consecutive years of reporting net income, we reported a loss before income taxes and a net loss for the years ended December 31, 2011, 2010, 2009 and 2008, due in large part to our product development strategy. Our decision not to fund, with internally generated or borrowed funds, the majority of the remaining expenses to complete the development of Mast Out[®] allowed us to record net operating income of \$281,000 during the first quarter of 2012. Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Stronger than expected sales of First Defense[®], for example, could diminish the overall loss or increase our net income. Conversely, weaker than expected sales of First Defense[®] could lead to less profits or larger losses.

Product development risks: Our current business growth strategy relies heavily on the development of Mast Out[®]. The development of new products is subject to financial, scientific, regulatory and market risks. In particular, the development of Mast Out[®] requires (and will continue to require) substantial investments by us and by a potential partner, and there is no assurance whether or when we will obtain all of the clinical and other data necessary to support regulatory approval for this product or secure a partner on acceptable terms. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Pfizer, Merck and Boehringer Ingelheim. There is no assurance that Mast Out[®] will compete successfully in this market.

Regulatory requirements for Mast Out[®]: The commercial introduction of Mast Out[®] in the United States will require us to obtain appropriate FDA approval for this product. It presently is uncertain whether or when this approval will be achieved. We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce Mast Out[®], who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. International regulatory approvals would be required for sales outside of the United States. European regulatory authorities are not expected to approve a product with a zero milk discard claim, which would remove a significant competitive advantage of Mast Out[®] in that territory. However, the milk discard period may be shorter for Mast Out[®] than it is for other products on the market.

Reliance on sales of First Defense[®]: We are heavily reliant on the market acceptance of First Defense[®] to generate product sales and fund our operations. Our business would not have been profitable during the nine consecutive years

in the period ended December 31, 2007, and our net losses would have been larger during the four years in the period ended December 31, 2011, without the gross margin that we earned from the sale of **First Defense**[®]. We could not have been profitable during the first quarter of 2012 without **First Defense**[®] sales.

Uncertainty of market estimates: Even assuming that **Mast Out**[®] achieves regulatory approval in the United States with a zero milk discard requirement, estimating the size of the market for this product is subject to numerous uncertainties. Some of the uncertainties surrounding our product include the development of the subclinical mastitis treatment market, coverage of relevant pathogens, selling price and its effect on market penetration, cost of manufacture, integration of milk from treated cows into cheese starter cultures and market acceptance.

ImmuCell Corporation

Small size; dependence on key employees: We are a small company with 26 full-time and 3 part-time employees. As such, we rely on certain key employees to support different operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained.

Access to raw materials: Our policy is to maintain more than one source of supply for the components used to manufacture and test our products. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. We are dependent on our manufacturing operations and facility at 56 Evergreen Drive in Portland, Maine for the production of **First Defense**[®] and **Wipe Out**[®] **Dairy Wipes**. The specific antibodies that we purify for **First Defense**[®] and the Nisin we produce by fermentation for **Wipe Out**[®] **Dairy Wipes** are not readily available from other sources. We expect to be dependent on Plas-Pak and Norbrook for the manufacture of **Mast Out**[®] if that product proceeds to commercialization. Any significant damage to or other disruption in the services at these facilities could adversely affect the production of inventory and result in significant added expenses and loss of sales.

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

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURES

None

ITEM 5. OTHER INFORMATION

None

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 thereunto duly authorized.

ImmuCell Corporation
Registrant

Date: May 14, 2012 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive
Officer
and Principal Financial
Officer

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