IMMUCELL CORP /DE/
Form 10-Q
May 14, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2013

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 x 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 x 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 x

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

Yes ¨ No x

The number of shares of the Registrant’s common stock outstanding at May 8, 2013 was 3,019,034.

ImmuCell Corporation

TABLE OF CONTENTS

March 31, 2013

PART I: FINANCIAL INFORMATION

ImmuCell Corporation

PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BALANCE SHEETS

	(Unaudited) As of March 31, 2013	As of December 31, 2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,320,437	$ 2,673,719
Short-term investments	2,985,000	2,240,000
Trade accounts receivable, net of allowance for doubtful accounts of $14,957 as of March 31, 2013 and $15,111 as of December 31, 2012	689,600	574,146
Other receivables	22,945	36,860
Income taxes receivable	348	348
Inventory	1,442,977	1,649,002
Prepaid expenses	202,496	157,930
Current portion of deferred tax asset	3,063	31,177
Total current assets	7,666,866	7,363,182
NET PROPERTY, PLANT AND EQUIPMENT, at cost	2,277,755	2,357,609
LONG-TERM PORTION OF DEFERRED TAX ASSET	1,103,851	1,245,982
OTHER ASSETS, net	63,015	63,634
TOTAL ASSETS	$ 11,111,487	$ 11,030,407
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$ 232,599	$ 255,568
Accounts payable	168,558	228,711
Current portion of bank debt	183,669	181,491
Total current liabilities	584,826	665,770
LONG-TERM LIABILITIES:		
Long-term portion of bank debt	1,039,757	1,086,568
Interest rate swap	73,720	83,386
Total long-term liabilities	1,113,477	1,169,954

TOTAL LIABILITIES	1,698,303	1,835,724
STOCKHOLDERS' EQUITY:		
Common stock, $0.10 par value per share, 8,000,000 shares authorized, 3,261,148 shares issued as of March 31, 2013 and December 31, 2012	326,115	326,115
Capital in excess of par value	9,981,527	9,973,146
Accumulated deficit	(320,493)	(524,803)
Treasury stock, at cost, 242,114 shares as of March 31, 2013 and December 31, 2012	(529,655)	(529,655)
Accumulated other comprehensive loss	(44,310)	(50,120)
Total stockholders' equity	9,413,184	9,194,683
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 11,111,487	$ 11,030,407

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,	
	2013	2012
Product sales	$1,846,734	$1,717,109
Costs of goods sold	793,167	704,541
Gross margin	1,053,567	1,012,568
Product development expenses	266,479	247,807
Administrative expenses	239,014	242,319
Sales and marketing expenses	221,408	241,209
Operating expenses	726,901	731,335
NET OPERATING INCOME	326,666	281,233
Other revenues (expenses), net	44,032	(10,509)
INCOME BEFORE INCOME TAXES	370,698	270,724
Income tax expense	166,388	115,963
NET INCOME	$204,310	$154,761
Weighted average common shares outstanding:		
Basic	3,019,034	3,016,067
Diluted	3,083,546	3,102,848
NET INCOME PER SHARE:		
Basic	$0.07	$0.05
Diluted	$0.07	$0.05

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,	
	2013	2012
Net income	$ 204,310	$ 154,761
Other comprehensive income:		
Interest rate swap, before taxes	9,666	9,334
Income tax applicable to interest rate swap	(3,856)	(3,724)
Other comprehensive income, net of taxes	5,810	5,610
Total comprehensive income	$ 210,120	$ 160,371

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

ImmuCell Corporation

(Unaudited)

STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock $0.10 Par Value		Capital in Excess of	Accumulated	Treasury Stock		Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Par Value	Deficit	Shares	Amount	Loss	Equity
BALANCE, December 31, 2012	3,261,148	$326,115	$9,973,146	$(524,803)	242,114	$(529,655)	$(50,120)	$9,194,683
Net income	—	—	—	204,310	—	—	—	204,310
Other comprehensive income, net of taxes	—	—	—	—	—	—	5,810	5,810
Stock-based compensation	—	—	8,381	—	—	—	—	8,381
BALANCE, March 31, 2013	3,261,148	$326,115	$9,981,527	$(320,493)	242,114	$(529,655)	$(44,310)	$9,413,184

	Common Stock $0.10 Par Value		Capital in Excess of	Accumulated	Treasury Stock		Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Par Value	Deficit	Shares	Amount	Loss	Equity
BALANCE, December 31, 2011	3,261,148	$326,115	$9,911,914	$(614,315)	257,114	$(562,469)	$(40,812)	$9,020,433
Net income	—	—	—	154,761	—	—	—	154,761
Other comprehensive income, net of taxes	—	—	—	—	—	—	5,610	5,610
	—	—	17,986	—	(15,000)	32,814	—	50,800

Exercise of stock options								
Tax benefits related to stock options	—	—	6,842	—	—	—	—	6,842
Stock-based compensation	—	—	8,656	—	—	—	—	8,656
BALANCE, March 31, 2012	3,261,148	$326,115	$9,945,398	$(459,554)	242,114	$(529,655)	$(35,202)	$9,247,102

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,	
	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$204,310	$154,761
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	97,123	103,213
Amortization	719	719
Deferred income taxes	166,389	108,968
Stock-based compensation	8,381	8,656
Loss on disposal of fixed assets	37	—
Changes in:		
Receivables	(101,539)	(238,115)
Inventory	206,025	83,081
Prepaid expenses and other assets	(44,666)	(43,965)
Accrued expenses	(22,969)	(64,895)
Accounts payable	(68,510)	79,429
Net cash provided by operating activities	445,300	191,852
CASH FLOWS FROM INVESTING ACTIVITES :		
Purchase of property, plant and equipment	(8,949)	(112,463)
Maturities of short-term investments	500,000	1,195,000
Purchases of short-term investments	(1,245,000)	(500,000)
Net cash (used for) provided by investing activities	(753,949)	582,537
CASH FLOWS FROM FINANCING ACTIVITIES:		
Debt principal repayments	(44,633)	(42,483)
Proceeds from exercise of stock options	—	50,800
Tax benefits related to stock options	—	6,842
Net cash (used for) provided by financing activities	(44,633)	15,159
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(353,282)	789,548
BEGINNING CASH AND CASH EQUIVALENTS	2,673,719	781,516
ENDING CASH AND CASH EQUIVALENTS	$2,320,437	$1,571,064
INCOME TAXES PAID	—	$(152)
INTEREST EXPENSE PAID	$(17,327)	$(19,586)

NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable	$8,357	$(9,693)
Net change in fair value of interest rate swap	$(5,810)	$(5,610)

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

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS

March 31, 2013

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 in these footnotes are to the FASB *Accounting Standards Codification*™ (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, 2012 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:

	As of March 31, 2013	As of December 31, 2012	(Decrease) Increase
Cash and cash equivalents	$ 2,320,437	$ 2,673,719	$(353,282)
Short-term investments	2,985,000	2,240,000	745,000
Total	$ 5,305,437	$ 4,913,719	$391,718

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:

	As of March 31, 2013	As of December 31, 2012	Increase (Decrease)
Raw materials	$ 210,997	$ 198,441	$ 12,556
Work-in-process	1,024,600	986,243	38,357
Finished goods	207,380	464,318	(256,938)
Inventory	$ 1,442,977	$ 1,649,002	$ (206,025)

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2013

4. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following, at cost:

	As of March 31, 2013	As of December 31, 2012
Laboratory and manufacturing equipment	$ 3,038,796	$ 3,029,559
Building and improvements	2,788,270	2,785,698
Office furniture and equipment	313,589	312,979
Construction in progress	4,137	—
Land	50,000	50,000
Property, plant and equipment, gross	6,194,792	6,178,236
Less: accumulated depreciation	3,917,037	3,820,627
Property, plant and equipment, net	$ 2,277,755	$ 2,357,609

5. OTHER ASSETS

Other assets consisted of the following:

	As of March 31, 2013	As of December 31, 2012
Security deposits	$ 350	$ 250
Debt issue costs	26,489	26,489
Other	47,604	47,604
Other assets, gross	74,443	74,343
Less: accumulated amortization of debt issue costs	11,428	10,709
Other assets, net	$ 63,015	$ 63,634

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 $451,885 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, 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 ($44,310) and ($50,120) as of March 31, 2013 and December 31, 2012, 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, 2014 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, 2013. Principal payments due under debt outstanding as of March 31, 2013 are reflected in the following table by the period that payments are due:

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2013

Period	$1,000,000 mortgage	$600,000 note	Total
Nine months ending December 31, 2013	$ 36,175	$ 100,717	$136,892
Twelve months ending December 31, 2014	50,900	139,490	190,390
Twelve months ending December 31, 2015	54,044	96,180	150,224
Twelve months ending December 31, 2016	57,384	—	57,384
Twelve months ending December 31, 2017	61,056	—	61,056
Twelve months ending December 31, 2018	64,876	—	64,876
After December 31, 2018	562,604	—	562,604
Total	$ 887,039	$ 336,387	$1,223,426

7. PRODUCT DEVELOPMENT EXPENSES

The primary strategic focus of our product development effort is on 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 are spending less on the development of **Mast Out**Ò than we did in recent years, having largely completed the significant clinical studies prior to 2012. Product development expenses increased by the immaterial amount of $18,672 to $266,479 during the three-month period ended March 31, 2013 in comparison to $247,807 during the same period in 2012.

8. OTHER REVENUES (EXPENSES), NET

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

	For the Three-Month Periods Ended March 31,	
	2013	2012
Royalty income	$ (3,000)	$ 4,045
Interest income	2,890	5,004
Interest expense	(17,222)	(19,486)
Other	61,364	(72)
Total, net	$ 44,032	$ (10,509)

9. 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 $8,381 and $8,656 during the three-month periods ended March 31, 2013 and 2012, respectively.

10. 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, 2013. 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, 2013

11. NET INCOME PER COMMON SHARE

The net income 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.

12. 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 of Directors 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 of Directors 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 of Directors 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.

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2013

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 of Directors feels that the Rights Plan could enhance stockholder value by providing management with negotiating leverage.

13. 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 (83% and 80% for the three-month periods ended March 31, 2013 and 2012, 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 17% and 20% of our total product sales for the three-month periods ended March 31, 2013 and 2012, 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,			
	2013		2012	
Animal Health International, Inc.	38	%	40	%
MWI Veterinary Supply Company	15	%	14	%

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, 2013		As of December 31, 2012	
Animal Health International, Inc.	32	%	28	%
MWI Veterinary Supply Company	18	%	14	%
Leedstone, Inc.	10	%	*	
TCS BioSciences, Ltd.	*		15	%

* Amount is less than 10%.

14. RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (Chairman of our Board of Directors) is a controlling owner of Leedstone Inc. (formerly Stearns Veterinary Outlet, Inc.), a domestic distributor of ImmuCell products (**First Defense**Ò, **Wipe Out**Ò **Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., a Japanese export company. His affiliated companies purchased $104,528 and $89,105 of products from ImmuCell during the three-month periods ended March 31, 2013 and 2012, 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 $67,090 and $27,348 as of March 31, 2013 and December 31, 2012, respectively.

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2013

15. 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 and 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, 2013, the date we have issued this Quarterly Report on Form 10-Q.

ImmuCell Corporation

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

Financial Condition

In 1999, we shifted the primary focus of our product development efforts from human applications of our milk protein purification technology 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. These product opportunities are generally less expensive to develop than the human health product opportunities that we had worked on during the 1990's. 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 had been funded by a partner 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 ($469,000), ($216,000), ($385,000) and ($410,000) during the years ended December 31, 2008, 2009, 2010 and 2011, 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 year ended December 31, 2012, and we continued to be profitable during the first quarter of 2013. We expect our financial results for the year ending December 31, 2013 to be near breakeven. We believe that two important indicators that investors should watch going forward will be the gross margin on our product sales and our net operating income.

We had approximately $5,305,000 in cash and short-term investments as of March 31, 2013. The table below summarizes the changes in selected, key balance sheet items (in thousands, except for percentages):

	As of March 31, 2013	As of December 31, 2012	Increase	
			$	%
Cash, cash equivalents and short-term investments	$ 5,305	$ 4,914	$392	8%
Total assets	$ 11,111	$ 11,030	$81	1%
Net working capital	$ 7,082	$ 6,697	$385	6%
Stockholders' equity	$ 9,413	$ 9,195	$219	2%

Cash, cash equivalents and short-term investments increased by 8%, or $392,000, to $5,305,000 as of March 31, 2013 from $4,914,000 as of December 31, 2012. Net cash provided by operating activities amounted to $445,000 during the three-month period ended March 31, 2013 in comparison to $192,000 during the same period in 2012. Capital investments of $9,000 during the three-month period ended March 31, 2013 compared to capital investments of

$112,000 during the same period in 2012. Total assets increased by less than 1%, or $81,000, to $11,111,000 as of March 31, 2013 from $11,030,000 as of December 31, 2012. Net working capital increased by 6%, or $385,000, to $7,082,000 as of March 31, 2013 from $6,697,000 as of December 31, 2012. During the first quarter of 2013 we repaid $45,000 in bank debt. Stockholders' equity increased by 2%, or $219,000, to $9,413,000 as of March 31, 2013 from $9,195,000 as of December 31, 2012.

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 loan were received during the third quarter of 2010. Proceeds from the $600,000 note were received during the first quarter of 2011. As of March 31, 2013, our outstanding bank debt balance was approximately $1,223,000. The $500,000 line of credit is available as needed. 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 unlikely. We believe that this debt financing (together with available cash and gross margin from ongoing product sales) provides us with sufficient funding to meet our working capital requirements and to finance our ongoing business operations during at least the next twelve months.

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The principal remaining hurdle to approval by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA) and commercialization of **Mast Out**Ò is the commissioning and approval of a full-scale facility for the manufacture of Nisin, the Active Pharmaceutical Ingredient (API). Our initial plan was to have the API produced for us under contract in order to avoid the investment in a manufacturing facility. By the end of 2011, we determined that the large minimum production volumes and high cost imposed by the selected contract manufacturer were not commercially sustainable. We believe that controlling the manufacture of the API ourselves, rather than hiring a contractor, would improve our competitiveness and increase our opportunity for success. Therefore, we developed a plan to build a production facility for the API. With assistance from prospective builders and based on limited data, we preliminarily estimated that it would require approximately $13,000,000 to construct a new manufacturing facility. Because we do not have this amount of cash currently and because of the risk that the actual cost could be higher than we originally estimated, we have evaluated strategic alternatives to new construction. During the fourth quarter of 2012, we projected that we could reduce this upfront investment by leasing an existing facility rather than constructing a new one, and we engaged an engineering firm to estimate these costs. The resulting engineering report estimated these costs to be in the range of $11,000,000 to $13,000,000. In addition to the use of some of our cash, we are considering debt issuance, equity financing and/or an investment from a partner as well as possible state and other financial incentives to support the investment required to manufacture the API. Absent such funding, we have not initiated the construction of our own API manufacturing facility or the leasing of an existing facility as of this date. Because we believe that the appropriate development and marketing partner would maximize the commercial sales potential for **Mast Out**Ò, we are actively seeking a partner to help us complete the development and commercialization effort by providing guaranteed cash and/or minimum levels of funding and ongoing revenue in return for marketing rights. Although there is no assurance that we will obtain FDA approval of our New Animal Drug Application (NADA), the information that we have learned during negotiations with potential partners to date has increased our confidence in the likelihood of achieving FDA approval and in the potential value of the market opportunity for **Mast Out**®. We believe that the evolution of our thinking relating to these strategic alternatives demonstrates the flexibility and creativity required to solve this financing challenge.

As part of our sustained investment in compliance with current Good Manufacturing Practice (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. During the first quarter of 2013, the FDA inspected our facilities and operations. The report from this inspection was very favorable, and we are responding to the few, minor observations that were noted. The size of this investment in capital expenditures for facility modifications and production equipment is subject to review and approval by our Board of Directors. As of April 1, 2013, we had remaining available authorization to spend up to approximately $148,000 on capital expenditures.

Results of Operations

Product Sales

Product sales increased by approximately 8%, or $130,000, to $1,847,000 during the three-month period ended March 31, 2013 in comparison to $1,717,000 during the same period in 2012. During the three-month period ended March 31, 2013, domestic sales increased by approximately 11%, or $153,000, and international sales decreased by 7%, or $24,000, in comparison to the same period in 2012. Product sales increased by approximately 5%, or $247,000, to $5,520,000 during the twelve-month period ended March 31, 2013 in comparison to $5,273,000 during the twelve-month period ended March 31, 2012.

Sales of our lead product, **First Defense**Ò, increased by 6% during the three-month period ended March 31, 2013 and increased by 3% during the twelve-month period ended March 31, 2013, in comparison to the same periods ended in 2012. During the three-month period ended March 31, 2013, domestic sales of **First Defense**Ò increased by 10%, in comparison to the same period in 2012. Due to the timing of orders from our three principle international distributors, international sales of **First Defense**Ò decreased by 7%, in comparison to the same period in 2012. With the exception of the decrease during the second quarter of 2012, we have realized consistently positive sales growth of **First Defense**Ò for nine of the last ten quarters, as demonstrated below:

6%: First Quarter 2013 over First Quarter 2012
5%: Full Year 2012 over Full Year 2011
16%: Fourth Quarter 2012 over Fourth Quarter 2011
9%: Third Quarter 2012 over Third Quarter 2011
(17%): Second Quarter 2012 under the Second Quarter 2011
13%: First Quarter 2012 over First Quarter 2011
21%: Full Year 2011 over Full 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

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We believe that the long-term 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. Our sales and marketing team currently consists of one director and two regional sales managers. Our office manager and facilities manager support our sales efforts by performing the order entry, inside sales and shipping duties. We launched a new communications campaign at the end of 2010 that is highlighting how the unique ability of **First Defense®** to provide **Immediate Immunity™** generates a dependable return on investment for dairy and beef producers.

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. Our sales are normally seasonal, with higher sales expected during the first quarter. Warm and dry weather reduces the producer's perception of the need for **First Defense®** . The severe heat and drought conditions during the summer of 2012 in many key agricultural regions in North America has caused a significant increase in the cost of feed that has offset some improvement in milk prices. The combination of mild weather during the spring 2012 beef calving season and the increasing cost of feed has created a very challenging environment in which to sell a disease prevention product. The harsher winter weather in 2013 may have benefited our sales. The animal health distribution segment has been aggressively consolidating over the last few years. Larger distributors have been acquiring smaller distributors. Although beef herd numbers are down currently because of the 2012 drought conditions in many parts of North America, the value of newborn calves could increase as producers re-build their herd levels. Such an upswing would increase a producer's likelihood to invest in **First Defense®** for their calf crop. 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 2012 marked the 21st anniversary of the original U.S. Department of Agriculture (USDA) approval of this product in 1991. During the third quarter of 2012, we sold our 12,000,000th dose of **First Defense®** . We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product. 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 milk protein processing methods, for the nutritional and feed supplement markets without the claims of our USDA-licensed product. Through our **First Defense Technology™**, we are selling whey concentrate globulin proteins in different formats. During the first quarter of 2011, 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. During the first quarter of 2012, we initiated a limited launch of a tube delivery format of our **First Defense Technology™** in a gel solution. 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**.

Gross Margin

The gross margin as a percentage of product sales was 57% and 59% during the three-month periods ended March 31, 2013 and 2012, respectively. The gross margin as a percentage of product sales was 56% during the twelve-month periods ended March 31, 2013 and 2012. Our gross margin percentages were 57%, 55% and 52% for the years ended December 31, 2012, 2011 and 2010, respectively. Our objective is to maintain the full-year gross margin percentage over 50%, and we have achieved this objective during the periods being reported. 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**Ò do fluctuate over time. Like most manufacturers in the United States, 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**Ò and a lower gross margin on **Wipe Out**Ò **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 from 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**Ò 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:

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	Three-Month Periods Ended March 31,		Increase (Decrease)	
	2013	2012	Amount	%
Gross margin	$ 1,054	$ 1,013	$41	4 %
Percent of product sales	57 %	59 %	(2)%	(3)%

	Twelve-Month Periods Ended March 31,		Increase	
	2013	2012	Amount	%
Gross margin	$ 3,095	$ 2,958	$137	5 %
Percent of product sales	56 %	56 %	—	—

Product Development

Our lead product development initiative is **Mast Out®**, a Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows. As anticipated, we reduced product development expenses in 2012 primarily because we are spending less on the development of **Mast Out™** with the significant clinical studies now largely complete. Product development expenses increased by an immaterial amount (approximately $19,000) to $266,000 during the three-month period ended March 31, 2013 in comparison to $248,000 during the same period in 2012. We spent approximately $918,000, $1,720,000 and $1,493,000 on product development activities during the years ended December 31, 2012, 2011 and 2010, respectively.

During 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™**. 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. In the pivotal effectiveness study, statistically significant **Mast Out™** cure rates were associated with a statistically significant reduction in milk somatic cell count (SCC), which is an important measure of milk quality.

In 2004, we entered into a product development and marketing agreement with Zoetis Inc. (formerly 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. Zoetis elected to terminate the agreement in 2007. Soon thereafter, Zoetis 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 the decision of Zoetis to terminate the agreement was not based on any unanticipated efficacy or regulatory issues. Rather, we believe the decision was primarily market driven, largely relating to their fear that the milk from treated cows could interfere with the manufacture of certain cultured dairy products.

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 commingling 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.

Commercial introduction of **Mast Out™** in the United States is subject to approval of our New Animal Drug Application (NADA) by the 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. 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 generally subject to a six-month review cycle by the FDA. The current status of our work on these Technical Sections is as follows:

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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.

3) Effectiveness: During the third quarter of 2012, we received the Effectiveness Technical Section Complete Letter from the FDA.

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 the subsections described above and granted **Mast Out**Ò 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 a FDA laboratory. We submitted the validated analytical method to the FDA during the fourth quarter of 2012. We now expect to receive the HFS Technical Section Complete Letter from the FDA during the second half of 2013.

5) Chemistry, Manufacturing and Controls (CMC): We are party to agreements with three manufacturers to produce inventory for us utilizing our proprietary technologies 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**Ò. These syringes were used for all pivotal studies of **Mast Out**Ò. Second, we could have the Active Pharmaceutical Ingredient (API) produced for us under a Development and Manufacturing Agreement with Lonza Sales, Ltd. of Basel, Switzerland, which provides for the exclusive manufacture of the API. The Lonza site in Europe is FDA-approved, compliant with cGMP regulations and subject to future FDA approval and inspection. 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**Ò. The selection of and financing for the API production facility is a critical decision. We have been considering four options: 1) having this work done by a qualified contract manufacturer, 2) building a new facility, 3) leasing and modifying an existing facility and 4) transferring our technology to a partner's facility. Leasing an existing facility or transferring the technology to a partner's facility would provide us with more control and flexibility with regards to production volumes and costs than would be possible if we relied on a contract manufacturer to produce the API for us and could be less expensive and quicker to market than building a new facility. We estimate that it would

take approximately eighteen months to two years to complete the necessary facility modifications and equipment installations. During the fourth quarter of 2012, we withdrew our first submission to the FDA of the CMC Technical Section because of changes we have made to our regulatory filing and manufacturing strategies. As soon as we have prepared all of the relevant information, we expect to make a revised first submission for a six-month review cycle by the FDA. We anticipate that our second submission would include the three, required validation batches produced at the FDA-inspected commercial production facility. After completing this work, we would be eligible to receive the CMC Technical Section Complete Letter from the FDA following 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 NADA approval and commercial sales. 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 administrative submission is subject to a statutory sixty-day review period.

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In addition to our work on **Mast Out**Ò, we are actively exploring further improvements, extensions or additions to our current product line. For example, we currently are developing treatments that could prevent bovine enteritis (calf scours) caused by enteric pathogens other than *E. coli* K99 and bovine coronavirus (the current disease claims for **First Defense**®). 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 formulation during the third quarter of 2011 without seeing the anticipated level of effectiveness needed for regulatory approval and market acceptance. After optimizing the challenge model, we directed our efforts to 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 the second half of 2013. During the third quarter of 2012, we entered into an exclusive option to a license with North Carolina State University covering certain recombinant *Cryptosporidium parvum* technology that may have utility in the development of a dry (non-lactating) cow vaccine. We are developing nutritional and feed supplement product applications (that are not delivered in the capsule format) of our **First Defense Technology**™, which is a unique whey protein concentrate that is purified utilizing our proprietary milk protein processing methods that does not carry the claims of our USDA-licensed product. As additional opportunities arise to commercialize our own technology, or licensable technology, we may 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.

Administrative Expenses

During the three-month period ended March 31, 2013, administrative expenses decreased by 1%, or $3,000

to $239,000 as compared to $242,000 during the same period in 2012. 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 legally required or deemed appropriate by management. Additional information about us is available in our annual Proxy Statement. All of these reports are filed with the Securities and Exchange Commission and are available on-line and 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**Ò. 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 reporting to the Securities and Exchange Commission 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, 2013, sales and marketing expenses decreased by 8%, or $20,000, to $221,000 in comparison to $241,000 during the same period in 2012, aggregating 12% and 14% of product sales during the three-month periods ended March 31, 2013 and 2012, respectively. Our current budgetary objective is to invest up to 20% of product sales in sales and marketing expenses for the full year 2013. This level of investment was expected and planned given our strategic decision beginning in 2010 to invest in additional sales and marketing efforts. This investment may have driven, at least in part, our recent increase in product sales.

Income Before Income Taxes and Net Income

Our income before income taxes was $371,000 during the three-month period ended March 31, 2013 in comparison to income before income taxes of $271,000 during the three-month period ended March 31, 2012. Our income tax expense was 45% and 43% of our income before income taxes during the three-month periods ended March 31, 2013 and 2012, respectively. Our net income for the three-month period ended March 31, 2013 was $204,000, or $0.07 per share, in comparison to a net income of $155,000, or $0.05 per share, during the three-month period ended March 31, 2012. The improved financial performance is largely due to increased gross margin from sales of **First Defense®**.

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ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

None

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, 2013. 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 and an increase in other revenues.

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, 2013 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; 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 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; timing and future costs of a facility to produce API for **Mast Out®**; the timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future expense ratios; future compliance with bank debt covenants; future realization of deferred tax assets; costs associated with sustaining compliance with cGMP regulations in our current operations and attaining such compliance for the facility to produce API for **Mast Out®**; factors that may affect the dairy and beef industries and future demand for our products; the accuracy of our understanding of our distributors’ ordering patterns; anticipated changes in our manufacturing capabilities and efficiencies; 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”, “will”, “plans”, “believes”, “estimates”, “targets”, “pro 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 financial support, 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.

Projection of net income: After nine consecutive years of reporting net income, we reported net losses for the years ended December 31, 2008, 2009, 2010 and 2011, due in large part to our product development strategy. By reducing our investment in the development of **Mast Out**Ò and increasing sales of **First Defense®**, we were able to record net operating income of $245,000 and net income of $90,000 during the year ended December 31, 2012. We continued this positive trend by recording net operating income of $327,000 and net income of $204,000 during the three-month period ended March 31, 2013. Due principally to an anticipated increase in product development expenses during 2013 (over 2012 levels, but still less than 2011 levels), we expect 2013 results to be near breakeven. 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 increase our net income. Conversely, weaker than expected sales of **First Defense®** could lead to less profits.

*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 either the nine consecutive years in the period ended December 31, 2007, or during the year ended December 31, 2012, or during the quarter ended March 31, 2013, without the gross margin that we earned from the sale of **First Defense®**.

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Economics of the dairy industry: The U.S. dairy industry has been facing very difficult economic pressures. Sales of our products may be influenced by the prices of milk, calves and milking cows. 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 declined to 9,119,000 in 2010 before increasing to 9,194,000 in 2011 and further increasing to 9,232,000 in 2012. During 2012, the total cattle inventory in the United States fell to the lowest level in 60 years, largely due to the drought which scorched pastures, causing many ranchers to shrink herds. As of January 1, 2013, dairy and beef farmers held approximately 90.8 million head of cattle, which was down 2.1% from a year earlier and represented the lowest level since 1952. While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk, demand for milk has been influenced by very volatile international demand for milk products. 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. For 2011, this price level averaged $18.37, which represented a 27% increase from 2010. This average price level for 2011 was higher than the annual average reached in any of the past 30 years, but then it began to decline in 2012. For 2012, this price level averaged $17.44, which represented a 5% decrease from 2011. This average price level remained unchanged for the first quarter of 2013. The actual level of milk prices may be less important than its level relative to costs. The recent improvement in milk prices has been offset, in part, by higher feed costs. One measure of this relationship is known as the milk-to-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 2011, this ratio averaged approximately 1.88, which represented a 17% decrease from 2010. For 2012, this ratio averaged approximately 1.52, which represented a 19% decrease from 2011. This ratio remained unchanged for the first quarter of 2013. The ratio of 1.52 is the lowest recorded since this ratio was first reported in 1985. This means that a dairy producer can buy only 1.52 pounds of feed for every pound of milk sold. An increase in feed costs also has a negative impact on the beef industry. Widespread severe drought conditions in key U.S. agricultural regions during 2012 drove feed costs higher. Another indication of the economic condition of the dairy industry is the average price for animals sold for dairy herd replacement. This price (reported as of January, April, July and October) averaged approximately $1,420 in 2011, which represented a 7% increase from 2010. This price averaged approximately $1,428 in 2012, which represented a 1% increase from 2011. The industry data referred to above is compiled from USDA databases. Another factor in the demand for our product is the decline in the value of bull calves. We are trying to maintain and grow our sales for use with heifer calves to offset what we assume is a relatively low use of our product for bull calves. Given our focus on the dairy and beef industries, the financial insecurity of our primary end users is a risk to our ability to maintain and grow sales at a profitable level. It also heightens the challenge of selling premium-priced animal health products (such as **Mast Out**Ò) into such a market. 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.

*Regulatory requirements for **Mast Out***Ò: The commercial introduction of **Mast Out**Ò 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**Ò, 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**Ò in that territory. However, the assigned milk discard period may be shorter for **Mast Out**Ò than it is for other products on the market.

Product development risks: The development of new products is subject to financial, scientific, regulatory and market risks. Our current business growth strategy relies heavily on the development of **Mast Out**Ò which requires (and will continue to require) a substantial investment. Our efforts will be subject to inspection and approval by the FDA. There is no assurance whether or when we will obtain all of the data necessary to support regulatory approval for this product.

*Risks associated with **Mast Out**Ò funding strategy:* Completing the development of **Mast Out**Ò through to the submission of the administrative NADA to the FDA involves a great deal of risk. We may not be able to obtain financing to fund the completion of this product development effort on terms acceptable to us. We are evaluating alternative financial strategies in order to gain NADA approval and to support the product launch, which may result in our becoming dependent upon the skills and level of effort of a collaborative partner.

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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.

Concentration of sales: During 2012, 80% of our product sales was made to customers in the U.S. dairy and beef industries in comparison to 81% during of 2011. During the three-month period ended March 31, 2013, 83% of our product sales was made to customers in the U.S. dairy and beef industries. A large portion of our product sales (49%, 52% and 50% for the years ended December 31, 2012, 2011, and 2010, respectively) was made to two large distributors. During the three-month period ended March 31, 2013, 53% of our sales was made to these two distributors, compared to 54% during the same period in 2012. A large portion of our trade accounts receivable (42% as of December 31, 2012 and 45% as of December 31, 2011) was due from these two distributors. As of March 31, 2013, 49% of our trade accounts receivable was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us.

*Regulatory requirements for **First Defense™***: **First Defense®**, and modifications and extensions thereto, is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991. Similar regulatory oversight risks exist in territories outside of the United States where we sell our products. 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 the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product.

Product risks generally: The sale of our products is subject to financial, efficacy, regulatory, competitive and other market risks. We cannot be sure that we will be able to maintain the regulatory compliance required to continue selling our products. There is no assurance that we will continue to achieve market acceptance at a profitable price level or that we can continue to manufacture our products at a sufficient gross margin.

Product Liability: The manufacture and sale of certain of our products entails a risk of product liability. Our exposure to product liability is mitigated to some extent by the fact that our products are principally directed towards the animal health market. We have maintained product liability insurance in an amount which we believe is reasonable in relation to our potential exposure in this area.

Regulatory requirements for ***Wipe Out*** *Dairy Wipes*: While the FDA regulates the manufacture and sale of **Wipe Out Dairy Wipes**, this type of product is permitted to be sold without a NADA approval, in accordance with the FDA's Compliance Policy Guide 7125.30 ("Teat Dips and Udder Washes for Dairy Cows and Goats"). This policy guide could be withdrawn at the FDA's discretion, in which case we would likely discontinue sales of the product. The manufacture of **Wipe Out Dairy Wipes** is subject to Part 211 of the cGMP regulations. As such, our operations are subject to inspection by the FDA. We continue to invest in personnel, facility improvements and new equipment to sustain compliance with cGMP regulations across our entire product line. In June 2007, we received a Warning Letter from the FDA citing deficiencies in specific areas of the cGMP regulations. We filed a response to the FDA in June 2007, and we responded to a request for additional information in April 2008. During the first quarter of 2013, the FDA again inspected our facilities and operations. The report from this inspection was very favorable, and we are responding to the few, minor observations that were noted. We remain subject to the risk of adverse action by the FDA in this respect.

Competition from others: Many of our competitors are significantly larger and more diversified in the relevant markets, and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Zoetis, Merck and Boehringer Ingelheim. There is no assurance that **Mast Out** will compete successfully in this market. We may not be aware of other companies that compete with us or intend to compete with us in the future.

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No expectation to pay any dividends for the foreseeable future: We do not anticipate paying any dividends to our stockholders for the foreseeable future. Instead, we expect to use cash to fund product development costs. Any debt or equity financing we obtain to assist in funding our product development programs may include terms prohibiting or restricting our paying dividends or repurchasing stock for a lengthy period. Stockholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, contractual restrictions, restrictions imposed by applicable laws and other factors our Board of Directors deems relevant.

Market for common stock: Our common stock trades on the NASDAQ Stock Market (NASDAQ: ICCC). Our average daily trading volume is lower than the volume for most other companies and the bid/ask stock price spread can be larger, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire.

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.

101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

ImmuCell Corporation

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) 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, 2013 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer
and Principal Financial Officer

ImmuCell Corporation

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