

IMMUCELL CORP /DE/  
Form 10-Q  
August 15, 2011

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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 ACT OF 1934

For the quarterly period ended June 30, 2011

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

001-12934  
(Commission file number)

ImmuCell Corporation  
(Exact name of registrant as specified in its charter)

Delaware  
(State of incorporation)

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

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

04103  
(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 August 12, 2011 was 2,983,652.

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ImmuCell Corporation  
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ImmuCell Corporation  
PART 1. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## BALANCE SHEETS

	(Unaudited) June 30, 2011	December 31, 2010
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$891,247	\$ 1,398,985
Short-term investments	4,184,000	3,227,000
Trade accounts receivable, net of allowance for doubtful accounts of \$15,000 at June 30, 2011 and \$13,000 at December 31, 2010	487,644	465,278
Income taxes receivable	648	948
Other receivables	31,465	31,287
Inventory	1,638,795	1,601,016
Prepaid expenses	168,199	241,191
Current portion of deferred tax asset	13,376	—
Total current assets	7,415,374	6,965,705
NET PROPERTY, PLANT AND EQUIPMENT, at cost	2,617,451	2,710,891
LONG-TERM PORTION OF DEFERRED TAX ASSET	1,238,598	1,040,606
OTHER ASSETS, net	17,227	33,977
<b>TOTAL ASSETS</b>	<b>\$11,288,650</b>	<b>\$ 10,751,179</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accrued expenses	\$652,882	\$ 372,052
Accounts payable	58,484	105,739
Current portion of bank debt	168,868	42,384
Current portion of deferred tax liability	—	4,843
Deferred revenue	8,250	—
Total current liabilities	888,484	525,018
<b>LONG-TERM LIABILITY:</b>		
Long-term portion of bank debt	1,355,529	943,760
<b>TOTAL LIABILITIES</b>	<b>2,244,013</b>	<b>1,468,778</b>
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, Par value - \$0.10 per share, Authorized - 8,000,000 shares, Issued - 3,261,148 shares at June 30, 2011 and December 31, 2010	326,115	326,115

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Capital in excess of par value	9,820,589	9,780,392
Accumulated deficit	(486,136 )	(204,805 )
Treasury stock at cost - 280,496 shares at June 30, 2011 and 287,496 shares at December 31, 2010	(613,619 )	(628,932 )
Accumulated other comprehensive (loss) income - interest rate swap	(2,312 )	9,631
Total stockholders' equity	9,044,637	9,282,401
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$11,288,650</b>	<b>\$ 10,751,179</b>

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

ImmuCell Corporation  
(Unaudited)  
STATEMENTS OF OPERATIONS FOR THE THREE-MONTH AND  
SIX-MONTH PERIODS ENDED JUNE 30, 2011 AND 2010

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2011	2010	2011	2010
Product sales	\$1,247,443	\$1,077,672	\$2,803,144	\$2,389,419
Costs of goods sold	552,917	459,055	1,240,383	1,031,645
Gross margin	694,526	618,617	1,562,761	1,357,774
Product development expenses	672,763	333,320	1,144,896	738,782
Administrative expenses	222,566	224,569	431,453	463,495
Sales and marketing expenses	232,057	108,358	436,130	277,526
Other operating expenses	1,127,386	666,247	2,012,479	1,479,803
NET OPERATING LOSS	432,860	47,630	449,718	122,029
Other (expenses) revenues, net	(23,793 )	10,908	(38,430 )	20,501
LOSS BEFORE INCOME TAXES	456,653	36,722	488,148	101,528
Income tax benefit	198,435	30,283	206,817	41,823
NET LOSS	\$258,218	\$6,439	\$281,331	\$59,705
Weighted average common shares outstanding:				
Basic	2,974,245	2,970,652	2,973,950	2,970,652
Diluted	2,974,245	2,970,652	2,973,950	2,970,652
NET LOSS PER SHARE:				
Basic	\$0.09	\$0.00	\$0.09	\$0.02
Diluted	\$0.09	\$0.00	\$0.09	\$0.02

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

ImmuCell Corporation  
(Unaudited)  
STATEMENTS OF STOCKHOLDERS' EQUITY

FOR THE SIX-MONTH PERIOD ENDED JUNE 30, 2011

	Common Stock \$0.10 Par Value		Capital in Excess of Par Value	Accumulated Deficit	Treasury Shares	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	
	Shares	Amount	Par Value	Deficit	Shares	Amount	Equity	
<b>BALANCE,</b> December 31, 2010	3,261,148	\$ 326,115	\$ 9,780,392	\$(204,805)	287,496	\$(628,932)	\$ 9,631	\$ 9,282,401
Net loss	—	—	—	(281,331)	—	—	—	(281,331 )
Other comprehensive loss – interest rate swap, net of taxes	—	—	—	—	—	—	(11,943)	(11,943 )
Total comprehensive loss	—	—	—	—	—	—	—	(293,274 )
Exercise of stock options	—	—	15,057	—	(7,000 )	15,313	—	30,370
Tax benefits related to stock options	—	—	7,404	—	—	—	—	7,404
Stock-based compensation	—	—	17,736	—	—	—	—	17,736
<b>BALANCE,</b> June 30, 2011	3,261,148	\$ 326,115	\$ 9,820,589	\$(486,136)	280,496	\$(613,619)	\$(2,312 )	\$ 9,044,637

FOR THE SIX-MONTH PERIOD ENDED JUNE 30, 2010

	Common Stock \$0.10 Par Value		Capital in Excess of Par Value	Accumulated Surplus	Treasury Shares	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	
	Shares	Amount	Par Value	Surplus	Shares	Amount	Equity	
<b>BALANCE,</b> December 31, 2009	3,261,148	\$ 326,115	\$ 9,751,442	\$ 179,879	290,496	\$(635,495)	—	\$ 9,621,941

Net loss	—	—	—	(59,705 )	—	—	—	(59,705 )
Other comprehensive income – interest rate swap	—	—	—	—	—	—	—	—
Total comprehensive loss	—	—	—	—	—	—	—	(59,705 )
Stock-based compensation	—	—	14,391	—	—	—	—	14,391
BALANCE, June 30, 2010	3,261,148	\$ 326,115	\$ 9,765,833	\$ 120,174	290,496	\$ (635,495)	—	\$ 9,576,627

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



ImmuCell Corporation  
(Unaudited)  
STATEMENTS OF CASH FLOWS FOR THE SIX-MONTH PERIODS  
ENDED JUNE 30, 2011 AND 2010

	Six-Month Periods Ended June 30,	
	2011	2010
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(281,331 )	\$(59,705 )
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation	210,920	210,945
Amortization	3,372	—
Deferred income taxes	(216,211 )	(41,897 )
Stock-based compensation	17,736	14,391
Loss on disposal of fixed assets	9,582	—
Changes in:		
Receivables	(22,244 )	(141,874 )
Inventory	(37,779 )	(267,293 )
Prepaid expenses and other assets	74,427	42,140
Accrued expenses	280,830	(18,351 )
Accounts payable	(21,773 )	(12,922 )
Deferred revenue	8,250	—
Net cash provided by (used for) operating activities	25,779	(274,566 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES :</b>		
Purchase of property, plant and equipment	(152,544 )	(94,175 )
Maturities of short-term investments	735,000	2,371,000
Purchases of short-term investments	(1,692,000)	(1,233,000)
Net cash (used for) provided by investing activities	(1,109,544)	1,043,825
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from debt issuance	600,000	—
Debt principal repayments	(61,747 )	—
Proceeds from exercise of stock options	30,370	—
Tax benefits related to stock options	7,404	—
Net cash provided by financing activities	576,027	—
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(507,738 )</b>	<b>769,259</b>
<b>BEGINNING CASH AND CASH EQUIVALENTS</b>	<b>1,398,985</b>	<b>975,490</b>
<b>ENDING CASH AND CASH EQUIVALENTS</b>	<b>\$891,247</b>	<b>\$1,744,749</b>
<b>INTEREST EXPENSE PAID</b>	<b>\$(37,841 )</b>	<b>\$—</b>
<b>INCOME TAXES PAID</b>	<b>\$(153 )</b>	<b>\$(74 )</b>
<b>NON-CASH ACTIVITIES:</b>		

Change in capital expenditures included in accounts payable	\$(25,482 )	\$(3,098 )
Decrease in fair value of interest rate swap, net of taxes	\$11,943	\$—

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

ImmuCell Corporation  
NOTES TO UNAUDITED FINANCIAL STATEMENTS  
June 30, 2011

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, commonly referred to as the 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™ (Codification). The FASB finalized the Codification effective for periods ending on or after September 15, 2009. Certain prior year accounts have been reclassified to conform with the 2011 financial statement presentation. 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, 2010 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 June 30, 2011	As of December 31, 2010	(Decrease) Increase
Cash and cash equivalents	\$ 891	\$ 1,399	\$ (508 )
Short-term investments	4,184	3,227	957
	\$ 5,075	\$ 4,626	\$ 449

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 June 30, 2011	As of December 31, 2010	Increase (Decrease)
Raw materials	\$ 271	\$ 237	\$ 34
Work-in-process	1,038	977	61

Finished goods	330	387	(57 )
	\$ 1,639	\$ 1,601	\$ 38

ImmuCell Corporation  
NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)  
June 30, 2011

4. PROPERTY, PLANT AND EQUIPMENT

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

	As of June 30, 2011	As of December 31, 2010
Laboratory and manufacturing equipment	\$ 2,905	\$ 2,870
Building and improvements	2,651	2,553
Office furniture and equipment	227	225
Construction in progress	19	40
Land	50	50
Property, plant and equipment, gross	5,852	5,738
Less-accumulated depreciation	3,235	3,027
Property, plant and equipment, net	\$ 2,617	\$ 2,711

5. OTHER ASSETS

Other assets consisted of the following (in thousands):

	As of June 30, 2011	As of December 31, 2010
Security deposits	\$ 1	\$ 1
Debt issue costs	26	26
Interest rate swap (liability) asset	(4 )	10
Other assets, gross	23	37
Accumulated amortization of debt issue costs	6	3
Other assets, net	\$ 17	\$ 34

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 loan 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 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 (loss) 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 loan. As the result of our decision to hedge this interest rate risk, we recorded a debit to equity in the amount of approximately \$2,000 as of June 30, 2011 and a credit to equity in the amount of approximately \$10,000 as of December 31, 2010, which reflect the fair value of the interest rate swap (liability) asset, 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 October 31, 2011 and is renewable annually thereafter. Interest on 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. A technical non-compliance with one of these covenants as of December 31, 2010 was waived by the bank. Because these covenants were calculated anticipating much higher spending on product development expenses than we currently plan, we expect to be in compliance with these covenants going forward. We are in compliance with all applicable covenants as of June 30, 2011. Principal payments due under debt outstanding as of June 30, 2011 are reflected in the following table by the period that payments are due (in thousands):

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ImmuCell Corporation  
NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)  
June 30, 2011

	Six-Month Period Ending		Years Ending December 31,					Thereafter	Total
	December 31, 2011	2012	2013	2014	2015	2016			
\$1,000,000 mortgage	\$ 22	\$45	\$48	\$51	\$54	\$57	\$ 688	\$965	
\$600,000 note payable	62	128	134	139	96	-	-	559	
Total	\$ 84	\$173	\$182	\$190	\$150	\$57	\$ 688	\$1,524	

7. COMMITMENTS AND CONTINGENT LIABILITIES

In connection with a Development and Manufacturing Agreement entered into during the third quarter of 2010 with Lonza Sales Ltd., we have committed approximately an additional \$614,000 (46% paid during the fourth quarter of 2010 and 39% paid early in the third quarter of 2011 and the balance due upon completion, which is expected to occur during the third quarter of 2011) to Lonza to generate the manufacturing data required for a regulatory submission to the FDA pertaining to the development of Mast Out®. Approximately 95% and 25% of this work was complete as of June 30, 2011 and December 31, 2010, respectively. Accordingly, we expensed approximately \$426,000 and \$155,000 to product development expenses during the six-month period ended June 30, 2011 and the year ended December 31, 2010, respectively, on the percentage of completion basis. This commitment is in addition to approximately \$137,000 that we paid to Lonza during the fourth quarter of 2009 for technology transfer related work. Approximately 97% and 71% of this work was complete as of June 30, 2011 and December 31, 2010, respectively. Accordingly, we expensed approximately \$35,000 and \$98,000 to product development expenses during the six-month period ended June 30, 2011 and the year ended December 31, 2010, respectively. This work was completed early in the third quarter of 2011.

8. OTHER (EXPENSES) REVENUES, NET

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

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2011	2010	2011	2010
Royalty income	\$ 1	\$ 1	\$ 3	\$ 2
Interest income (expense)	(16 )	8	(31 )	17
Other gains (losses)	( 9 )	2	(10 )	2
	\$ (24 )	\$ 11	\$ (38 )	\$ 21

ImmuCell Corporation  
NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)  
June 30, 2011

9. EMPLOYEE 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 \$10,000 and \$0 during the three-month periods ended June 30, 2011 and 2010, respectively, and \$18,000 and \$14,000 during the six-month periods ended June 30, 2011 and 2010, 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, but there were no significant tax deductions during the three-month or six-month periods ended June 30, 2011 or 2010.

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 carry forwards 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 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 June 30, 2011. Although we believe that our estimates are reasonable, actual results could differ from these estimates.

11. NET LOSS PER COMMON SHARE

The net loss per common share has been computed in accordance with Codification Topic 260-10, Earnings Per Share, 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. Outstanding stock options not included in the calculation aggregated approximately 244,500 during the three-month and six-month periods ended June 30, 2011 and approximately 273,000 during the three-month and six-month periods ended June 30, 2010.

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 or surviving company's common stock having a market value at that time equal to twice the Right's exercise price.

ImmuCell Corporation  
NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)  
June 30, 2011

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 to 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%. We entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase as of August 9, 2011. No other changes were made to the terms of the Rights or the Rights Agreement at that time.

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 be true and resulted in a potential threat through an unsolicited acquisition effort or otherwise, the Board 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 (84% and 74% for the three-month periods ended June 30, 2011 and 2010, respectively, and 83% and 82% for the six-month periods ended June 30, 2011 and 2010, 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 16% and 13% of our total product sales for the three-month periods ended June 30, 2011 and 2010, respectively, and 17% and 13% of our total product sales for the six-month periods ended June 30, 2011 and 2010, respectively. Sales to significant distributors that amounted to 10% or more of total product sales are detailed in the following table:

Three-Month Periods Ended June 30,				Six-Month Periods Ended June 30,			
2011		2010		2011		2010	
38	%	37	%	40	%	36	%

Animal Health International, Inc. [ 1 ]									
MWI Veterinary Supply Center	12	%	12	%	13	%	12	%	
TCS Biosciences, Ltd.	*		13	%	*		*		

[ 1 ] Assumes that the June 2011 acquisition of Animal Health International by Lextron had occurred as of the beginning of the periods being reported.

\* Amount is less than 10%.

ImmuCell Corporation  
NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)  
June 30, 2011

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

	As of June 30, 2011		As of December 31, 2010	
Animal Health International, Inc. [ 1 ]	41	%	35	%
Robert J. Matthews Company	15	%	15	%
MWI Veterinary Supply Company	*		12	%
Stearns Veterinary Outlet, Inc.	*		10	%

[ 1 ] Assumes that the June 2011 acquisition of Animal Health International by Lextron had occurred as of the dates being reported.

\* Amount is less than 10%.

14. 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 \$139,000 and \$142,000 of products from ImmuCell during the six-month periods ended June 30, 2011 and 2010, 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 \$31,000 and \$45,000 as of June 30, 2011 and December 31, 2010, respectively.

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 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 August 15, 2011, 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

RESULTS OF OPERATIONS FOR THE THREE-MONTH AND SIX-MONTH PERIODS ENDED JUNE 30, 2011

Product Sales

Product sales increased by approximately 16%, or \$170,000, to \$1,247,000 during the three-month period ended June 30, 2011 in comparison to \$1,078,000 during the same period in 2010. Product sales increased by approximately 17%, or \$414,000, to \$2,803,000 during the six-month period ended June 30, 2011 in comparison to \$2,389,000 during the same period in 2010. Product sales increased by approximately 8% during the twelve-month period ended June 30, 2011, in comparison to the same period ended June 30, 2010. The volatility of the global economy, and its impact on the dairy industry, continues to affect our product sales both domestically and internationally. During the three-month period ended June 30, 2011, domestic sales increased by 31%, or \$250,000, and international sales decreased by 29%, or \$80,000, in comparison to the same period in 2010. During the first six months of 2011, domestic sales increased by 19%, or \$368,000, and international sales increased by 10%, or \$46,000, in comparison to the same period in 2010.

The timing of our sales of bulk reagents for use in a drinking water diagnostic test sold by others can influence the reported changes in our total product sales. A sale of these reagents made during the second quarter of 2010 did not repeat during the second quarter of 2011 but is expected to be made during the fourth quarter of 2011. Our animal health sales (excluding sales of the water diagnostic reagents) increased by 32%, 24% and 12% during the three-month, six-month and twelve-month periods ended June 30, 2011, respectively, in comparison to the same periods in the prior year. These figures more accurately reflect the health of our core animal health business.

We believe that this growth 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. Effective for 2011 and renewable annually by mutual agreement, we entered into a sales and marketing collaboration with Agri Laboratories Ltd. of St. Joseph Missouri, under which the AgriLabs sales and marketing teams are working with us to expand market demand for First Defense®. 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. Competition for resources that dairy producers allocate to their calf enterprises has been increased by the severe economic challenges that producers have been facing since the start of the current down cycle in 2008 and by the many new products that have been introduced to the calf market. This competitive pressure increases the importance for us to be successful with new development initiatives such as product line extensions and the addition of a new rotavirus claim for First Defense®.

We appreciate the growing volume of business that we have achieved during these difficult economic times when many of our customers are taking cost-cutting measures. Even in this challenging market with moderately higher milk prices but persistently high feed costs, our lead product, First Defense®, continues to benefit from wide acceptance as an effective tool to prevent bovine enteritis (scours) in newborn calves. During the third quarter of 2010, we sold our 10,000,000th dose of First Defense®. The fourth quarter of 2011 will mark the 20th anniversary of the original USDA approval of this product in 1991. 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. During the three-month period ended June 30, 2011, domestic sales of First Defense® increased by 36%, and this increase was complemented by a 46% increase in international sales of First Defense®, in comparison

to the same period in 2010. During the six-month period ended June 30, 2011, domestic sales of First Defense® increased by 22%, and this increase was complemented by a 61% increase in international sales of First Defense®, in comparison to the same period in 2010. Sales of First Defense® increased by 37% during the three-month period ended June 30, 2011 in comparison to the same period in 2010. This follows a 21% increase in sales of First Defense® during the three-month period ended March 31, 2011 in comparison to the same period in 2010 and a 13% increase in sales of First Defense® during the three-month period ended December 31, 2010 in comparison to the same period in 2009. Sales of First Defense® increased by 28% during the six-month period ended June 30, 2011 in comparison to the six-month period ended June 30, 2010. Sales of Wipe Out® Dairy Wipes decreased by 12% during the six-month period ended June 30, 2011 in comparison to the same period in 2010. We are competing aggressively on selling price to earn new business against less expensive products and alternative teat sanitizing methods.

## ImmuCell Corporation

## Gross Margin

The gross margin as a percentage of product sales was 56% and 57% during the three-month periods ended June 30, 2011 and 2010, respectively. The gross margin as a percentage of product sales was 56% and 57% during the six-month periods ended June 30, 2011 and 2010, respectively. The gross margin as a percentage of product sales was 52% and 57% during the twelve-month periods ended June 30, 2011 and 2010, 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 52%, 53% and 45% for the years ended December 31, 2010, 2009 and 2008, 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 June 30,		Increase (Decrease)	
	2011	2010	Amount	%
Gross margin	\$ 695	\$ 619	\$ 76	12 %
Percent of product sales	56 %	57 %	(1 )%	(2 )%

	Six-Month Periods Ended June 30,		Increase (Decrease)	
	2011	2010	Amount	%
Gross margin	\$ 1,563	\$ 1,358	\$ 205	15 %
Percent of product sales	56 %	57 %	(1 )%	(2 )%

	Twelve-Month Periods Ended June 30,		(Decrease)	
	2011	2010	Amount	%
Gross margin	\$ 2,507	\$ 2,547	\$ (40 )	(2 )%
Percent of product sales	52 %	57 %	(5 )%	(9 )%

## Product Development

Product development expenses increased by approximately 102%, or \$339,000, to \$673,000 during the three-month period ended June 30, 2011 in comparison to the same period in 2010. Product development expenses aggregated 54% and 31% of product sales during the three-month periods ended June 30, 2011 and 2010, respectively. Product development expenses increased by approximately 55%, or \$406,000, to \$1,145,000 during the six-month period

ended June 30, 2011 in comparison to the same period in 2010. Product development expenses aggregated 41% and 31% of product sales during the six-month periods ended June 30, 2011 and 2010, respectively. The product development expenses principally reflect the costs related to the development of the commercial manufacturing process for Mast Out® and to the studies investigating a rotavirus claim for First Defense®.

We spent approximately \$1,493,000, \$1,645,000 and \$1,746,000 on product development activities during the years ended December 31, 2010, 2009 and 2008, respectively. We expect higher product development expenses during the year ending December 31, 2011. We are currently seeking a partner to complete the development of Mast Out® and to support the manufacturing, marketing and sales efforts. Additional investments, related principally to manufacturing scale-up and preparations of full-scale batches of Mast Out®, could amount to approximately \$6,000,000 prior to receiving FDA approval. If a partner agrees to fund the completion of the Mast Out® product development effort, our product development expenses would be expected to increase even higher, but only if they are offset, at least in part, by the funds contributed by such a partner in a potential strategic collaboration.



ImmuCell Corporation

In 2000, we acquired an exclusive license from Nutrition 21, Inc. 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. Nisin has been granted GRAS (Generally Regarded as Safe) status by the FDA for food preservative applications, which may be of some help in obtaining approval for the use of Mast Out® on organic farms. 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.

Traditional antibiotic products currently on the market for use in the treatment of mastitis are sold subject to a regulatory requirement to discard milk from treated cows during the course of and for a period following antibiotic treatment (the milk discard requirement). Currently, mastitis treatment is generally limited to only clinical cases - those cases where cows are producing abnormal milk - since that milk already is unsuitable for commercial sale. Because milk from cows infected with subclinical mastitis (those with infected udders, but still producing normal milk) can be sold, dairy producers generally do not treat subclinical mastitis. Doing so would give rise to the milk discard requirement and a resulting loss in revenue to the dairy producer. Without a milk discard requirement, we believe Mast Out® could expand the subclinical mastitis treatment market niche. We are not aware of any other intramammary mastitis treatment product that has such a “zero discard” claim. While the benefit of treating clinical mastitis is widely known, there is a growing awareness of the cascade of events associated with subclinical mastitis, including reduced or foregone milk quality premiums, increased abortions, lower milk production and increased cull rates. Some industry experts have estimated that subclinical mastitis costs the U.S. dairy industry approximately \$1 billion per year. Regulations in the European Union will likely require that Mast Out® be sold subject to a milk discard requirement in that territory, although the duration of the milk discard requirement may be shorter than the discard requirement applicable to competitive products on the market.

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 concerns that the use of Mast Out® may require specific treatment restrictions at the herd level.

Due to its antibacterial nature, Nisin in bulk tank milk could interfere with the manufacture of certain (but not all) cultured milk products, such as some kinds of cheese and yogurt, if a high enough percentage of animals from a herd is treated at any one time. We have developed potential strategies to quantify and manage this risk. Milk that is sold exclusively for fluid milk products would not be subject to this restriction. We believe that the benefits of using Mast Out® would outweigh the management costs associated with implementing a potential treatment restriction. Another risk is that Mast Out® likely will be priced at a premium to the traditional antibiotic products currently on the market, that are all sold subject to a milk discard requirement. However, we believe that we can demonstrate a return on the investment to the producer that will justify this premium.

Mastitis is estimated to cost U.S. dairy producers approximately \$2 billion per year. These losses include the cost of treatment products, reduced milk production, discarded milk and lost cows. We estimate that the U.S. market for the

use of antibiotics to treat clinical mastitis in lactating cows is approximately \$40,000,000 per year and that similar market opportunities also exist outside of the United States and for the treatment of dry (non-lactating) cows. Because milk from cows treated with traditional antibiotics must be discarded for a period of time during and after treatment due to concerns about antibiotic residue in the milk, currently it is not common practice to treat subclinical mastitis (those cases where cows have infected udders, but still produce saleable milk). The ability to treat such cases without a milk discard could revolutionize the way mastitis is managed in a herd. If Mast Out® is approved by the FDA as the first treatment for mastitis without a milk discard requirement, we believe it could open the market to treatment of subclinical mastitis and could compete effectively against the traditional antibiotic products currently on the market, which are all sold subject to a milk discard. It is difficult to evaluate the potential size of the as-yet undeveloped subclinical mastitis treatment market.

ImmuCell Corporation

In 2007, we began the production of registration batches of drug product at 10% of commercial scale to fulfill the pivotal regulatory requirements of effectiveness, target animal safety and stability. 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 ( $p < 0.0001$ ) 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 ( $p < 0.005$ ) reduction in milk somatic cell count (SCC), which is an important measure of milk quality.

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. 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) Effectiveness: During the third quarter of 2010, we made our first submission of the Effectiveness Technical Section. This 65 volume submission contains 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 does not materially change our initial conclusions about the product's effectiveness. We expect to make a second submission of this Technical Section responsive to the questions raised by the FDA during the third quarter of 2011. We expect to receive the FDA's response to this second submission during the first quarter of 2012 after one, six-month review cycle.

3) 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.

4) Target Animal Safety: Under a protocol approved in advance by the FDA, the pivotal Target Animal Safety trial was completed during the first quarter of 2010. We submitted the Target Animal Safety Technical Section to the FDA for review during the third quarter of 2011. We expect to receive the FDA's response to this submission during the

first quarter of 2012 after one, six-month review cycle.

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## ImmuCell Corporation

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. We have entered into a long-term, exclusive supply agreement with Plas-Pak Inc. of Norwich, Connecticut covering the proprietary syringe that was developed specifically for Mast Out®. These syringes were used for all pivotal studies of Mast Out®. During the third quarter of 2010, we entered into a Development and Manufacturing Agreement with Lonza Sales, Ltd. of Basel, Switzerland covering the exclusive manufacture of the Active Pharmaceutical Ingredient (API) by Lonza for Mast Out®. The identified manufacturing site in Europe is FDA-approved, compliant with current Good Manufacturing Practices (cGMP) regulations and subject to future FDA approval and inspection. During the third quarter of 2010, we entered into an exclusive Contract Manufacture Agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved drug product manufacturer, to formulate the API into drug product, conduct sterile-fill of syringes and perform final packaging. Norbrook provided these services for clinical material used in all pivotal studies of Mast Out®. Our successful operation under these collaborative agreements with these highly qualified partners is crucial to the success of the Mast Out® development initiative. We expect to make our first submission of the CMC Technical Section to the FDA for review during the third quarter of 2011. We expect to receive the FDA's response to this submission during the first quarter of 2012 after its first, six-month review cycle. We expect that a second CMC Technical Section submission will be required because production facility modifications and full-scale manufacturing batches (which will not be completed for the first submission) will be required for approval of this Technical Section. The completion of this work and compilation of the relevant data is subject to our establishing a third party strategic funding collaboration providing financial support for Mast Out® development, manufacturing, sales and marketing, as discussed above. The timing of the second submission of the CMC Technical Section and the following six-month FDA review cycle defines the critical path to the submission of the administrative NADA to the FDA.

6) Several Administrative Requirements: After obtaining the last Technical Section Complete Letter, preparing materials responsive to other administrative requirements and assembling the administrative NADA submission for final review by the FDA - a statutory sixty-day review period of the administrative NADA would be expected. The timing of the administrative NADA submission and the timing of a potential market launch (if the FDA grants approval) will be determined by the FDA's responses to our outstanding Technical Section submissions and by the successful resolution of any identified issues. Product produced for the validation batches under the CMC Technical Section could be sold in test markets upon FDA approval. Assuming our entry into a satisfactory development support arrangement with a marketing partner this year and timely receipt of the remaining required Technical Section approvals from the FDA, we could commence sale of Mast Out® by the end of 2012. The FDA may grant a period of five years of market exclusivity for Mast Out® (meaning the FDA might not grant approval to a second and similar NADA for a period of five years after the first NADA approval is granted) under Section 512(c)(2)F of the Federal Food, Drug, and Cosmetic Act.

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 investigating 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 justify continued product development. We initiated a pivotal effectiveness study during the second quarter of 2011. Successful results could position us for USDA approval of an additional disease claim for First Defense® to prevent scours caused by rotavirus by the first quarter of 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.

#### Administrative Expenses

During the three-month period ended June 30, 2011, administrative expenses decreased by 1%, or \$2,000, to \$223,000 as compared to the same period in 2010. During the six-month period ended June 30, 2011 administrative expenses decreased by 7%, or \$32,000, to \$431,000 as compared to the same period in 2010. 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. 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.

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Sales and Marketing Expenses

During the three-month period ended June 30, 2011, sales and marketing expenses increased by 114%, or \$124,000, to \$232,000, as compared to the same period in 2010, aggregating 19% and 10% of product sales during the three-month periods ended June 30, 2011 and 2010, respectively. During the six-month period ended June 30, 2011, sales and marketing expenses increased by 57%, or \$159,000, to \$436,000 as compared to the same period in 2010, aggregating 16% and 12% of product sales during the six-month period ended June 30, 2011 and 2010, respectively. This increase was expected and planned given our strategic decision to invest in additional sales and marketing personnel and efforts. This investment may have created, at least in part, our recent increase in product sales. Our objective is to maintain the ratio of product selling expenses to product sales below 20% for the full year 2011.

Loss Before Income Taxes and Net Loss

Our loss before income taxes of \$457,000 during the three-month period ended June 30, 2011 compares to a loss before income taxes of \$37,000 during the three-month period ended June 30, 2010. Our income tax benefit was 43% and 82% of our loss before income taxes during the three-month periods ended June 30, 2011 and 2010, respectively. Our net loss for the three-month period ended June 30, 2011 was \$258,000, or \$0.09 per share, in comparison to a net loss of \$6,000, or \$0.00 per share, during the three-month period ended June 30, 2010.

Our loss before income taxes of \$488,000 during the six-month period ended June 30, 2011 compares to a loss before income taxes of \$102,000 during the six-month period ended June 30, 2010. Our income tax benefit was 42% and 41% of our loss before income taxes during the six-month periods ended June 30, 2011 and 2010, respectively. Our net loss for the six-month period ended June 30, 2011 was \$281,000, or \$0.09 per share, in comparison to a net loss of \$60,000, or \$0.02 per share, during the six-month period ended June 30, 2010.

LIQUIDITY AND CAPITAL RESOURCES

Our strategic decision to continue developing Mast Out® after the product rights were returned to us in 2007 has caused us to increase our spending on product development expenses that were previously funded by Pfizer. 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 \$385,000, \$216,000, and \$469,000 during the years ended December 31, 2010, 2009, and 2008, respectively, and \$281,000 during the six-month period ended June 30, 2011. We have committed approximately \$614,000 (46% paid during the fourth quarter of 2010 and 39% paid during the third quarter of 2011 and the balance due upon completion, which is expected to occur during the third quarter of 2011) to Lonza (our API manufacturer) for the scale-up and testing of the Nisin Active Pharmaceutical Ingredient (API) manufacturing process required for a first submission of the CMC Technical Section. We are working to make the first submission of the CMC Technical Section during the third quarter of 2011. This submission will be subject to a six-month review by the FDA.

Third party funding is required to pay for the additional and larger financial commitments to Lonza required for production facility modifications and full-scale manufacturing batches that would be required to make a second submission of the CMC Technical Section, which commitments are beyond the scope of what we are willing to invest internally. While we have always been very open about our view of the commercial prospects of Mast Out® in our SEC disclosures and with prospective partners, we did not initiate serious partnering discussions until the second quarter of 2011 in order to give us time to advance the product development initiative to the point when we believe we have the best opportunity for success. All anticipated initial discussions are now complete, and some prospective partners are conducting their due diligence. It is difficult to predict when or if this partnering effort will be successful.

This second submission of the CMC Technical Section would also be subject to a six-month review by the FDA. Anticipating Technical Section complete letters on all other FDA submissions and allowing for a 60-day review of our administrative NADA submission at the end, the timing of the second CMC submission defines the critical path to potential FDA approval and market launch. We believe that the commercial prospects for Mast Out® warrant this level of investment.

As we reduce product development spending on Mast Out®, we expect to return to profitable operations. We have not invested the time and resources to carefully make an exact projection about the timing of our anticipated return to profitability. The direction is clear, and the actual results will be reported quarterly. We believe that the three key indicators that investors should watch going forward will be our gross margin, our net operating income (loss) and our net income (loss).



ImmuCell Corporation

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. 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. In 2008, our Board of Directors authorized an investment of approximately \$1,314,000 for capital expenditures (facility modifications and production equipment). We have not increased this authorized limit to date. As of July 1, 2011, we had remaining authorization to spend up to \$159,000 on capital expenditures, net of expenditures made from January 1, 2008 through June 30, 2011.

Cash, cash equivalents and short-term investments increased by 10%, or \$449,000, to \$5,075,000 at June 30, 2011 from \$4,626,000 at December 31, 2010. Net cash provided by operating activities amounted to \$26,000 during the six-month period ended June 30, 2011 in contrast to net cash used for operating activities of \$275,000 during the six-month period ended June 30, 2010. Net working capital increased by 1%, or \$86,000, to \$6,527,000 at June 30, 2011 from \$6,441,000 at December 31, 2010. Proceeds from bank debt received during the first six months of 2011 aggregated \$538,000, net of debt repayments made prior to July 1, 2011. Total assets increased by 5%, or \$537,000, to \$11,289,000 at June 30, 2011 from \$10,751,000 at December 31, 2010. Stockholders' equity decreased by 3%, or \$238,000, to \$9,045,000 at June 30, 2011 from \$9,282,000 at December 31, 2010. 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. However, as noted above, in order to complete the planned development and commercialization of Mast Out® we will need to receive approximately \$6,000,000 in financial support from a marketing partner to complement the internally generated and borrowed funds that we are willing to commit to this initiative. The production of commercial batches of inventory and other market launch expenses (if Mast Out® is approved by the FDA) would require a significant amount of additional capital. It is not necessary for all of this funding to occur within the next twelve months.

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

Not Applicable

### 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 June 30, 2011. 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 (i) is recorded, processed, summarized and reported within the

time periods specified in the Securities and Exchange Commission's rules and forms and (ii) is 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 June 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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ImmuCell Corporation  
PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable

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 as well as other risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2010 and uncertainties otherwise referred to in this Quarterly Report.

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 get full NADA approval and to support the product launch. If a partner does help us complete the submission, the FDA may not grant approval of this product. After we have made first submissions of all required Technical Sections to the FDA, this product development effort would essentially be put on hold pending a funding agreement with a partner or implementation of an alternative strategy, while we would turn our focus to our existing commercial business.

Projections of loss before income taxes and 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, 2010, 2009 and 2008. Further, we

incurred a loss before income taxes of \$488,000 and a net loss of \$281,000 for the six-month period ended June 30, 2011 due in large part to our current 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® may allow us to return to positive net operating income (before other (expenses) revenues, net and before income taxes) during the last six months of 2011. We would expect to share, in some fashion, in a portion of the revenues or earnings generated by Mast Out® with the partner who had provided such funding, thereby affecting our future result of operations. 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. Conversely, weaker than expected sales of First Defense® could lead to larger losses. Prior to 2008, we had not publicly disclosed our projections of future profitability. We did so in 2010, 2009 and 2008 and have done so again for 2011 to make it clear to our stockholders that the decision to pursue internal development of Mast Out® entails an important change in our financial model and strategy that, we believe, is in the long-term interests of the Company and our stockholders.

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Economics of the dairy industry: The U.S. dairy industry has been facing very difficult economic pressures, which are forcing many dairy producers out of business. 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 9,117,000 in 2010. For the first six months of 2011, the monthly average was 9,182,000 cows, with herd size of 9,210,000 being reported for June. 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 represents a 27% increase from 2009 but is well below the 2007 and 2008 levels. As of June 2011, this price level averaged \$17.06. 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 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 the first six months of 2011, this ratio averaged approximately 1.93. This means that a dairy producer can buy only 1.93 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. To date in 2011, this price averaged approximately \$1,400. 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.

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 years ended December 31, 2010, 2009 and 2008 as well as during the six-month period ended June 30, 2011 without the gross margin that we earned from the sale of First Defense®.

Concentration of sales: A large portion of our product sales (53% and 48% for the six-month period ended June 30, 2011 and 2010, respectively) was made to two large distributors. A large portion of our trade accounts receivable (50% as of June 30, 2011 and 47% as of December 31, 2010) was due from these two distributors. Both of these calculations assume that the June 2011 acquisition of Animal Health International by Lextron had occurred as of the beginning of the period being reported. 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. During the first six months of

2011, 83% of our product sales were made to customers in the U.S. dairy and beef industries.

Product development risks: Our current business growth strategy relies heavily on the development of new products, the most important of which is 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/Schering-Plough/Intervet and Boehringer Ingelheim. There is no assurance that Mast Out® will compete successfully in this market.

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**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®. 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.

**Risks associated with USDA regulatory oversight:** First Defense®, and modifications and extensions thereto, is subject to the jurisdiction of the Center for Veterinary Biologics, USDA. Recent budgetary constraints at the USDA have caused significant delays in rulings and responses to submissions, according to the Association of Veterinary Biologics Companies, of which we are a member. Similar regulatory oversight risks exist in territories outside of the United States where we sell our products.

**Regulatory requirements for First Defense®:** First Defense® is sold in the United States subject to a product license approval from the USDA, first obtained in 1991. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the “Reference Standard”). Due to the unique nature of the First Defense® label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if 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. During 2006, certain regional organic certifying agencies determined that the ingredients in First Defense® are in compliance with the National Organic Program (NOP) and may be considered for use on organic farms. First Defense® should be considered a preventative vaccine as described in USDA-NOP regulations for organic producer consideration when establishing management plans.

**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.

**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 do we, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. We may not be aware of other companies that compete with us or intend to compete with us in the future. Our competitive position will be highly influenced by our ability to attract and retain key scientific and managerial personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products and to continue to profitably sell our current products. We currently compete on the basis of product performance, price and distribution capability. We continue to monitor our network of independent distributors to maintain our competitive position.

**Small size:** We are a small company with 27 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.

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

Not applicable

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4. RESERVED

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ITEM 5. OTHER INFORMATION

Not applicable

ITEM 6. EXHIBITS

Exhibit 4.1 Third Amendment to Rights Agreement dated as of August 9, 2011.

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: August 15, 2011

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