

IMMUCELL CORP /DE/  
Form 10-Q  
November 14, 2011

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2011

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 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 November 11, 2011 was 3,000,652.



ImmuCell Corporation  
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ImmuCell Corporation  
PART 1. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## BALANCE SHEETS

	(Unaudited) September 30, 2011	December 31, 2010
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 563,544	\$ 1,398,985
Short-term investments	4,181,000	3,227,000
Trade accounts receivable, net of allowance for doubtful accounts of \$16,000 at September 30, 2011 and \$13,000 at December 31, 2010	420,923	465,278
Income taxes receivable	648	948
Other receivables	27,429	31,287
Inventory	1,756,801	1,601,016
Prepaid expenses	101,031	241,191
Current portion of deferred tax asset	45,516	—
<b>Total current assets</b>	<b>7,096,892</b>	<b>6,965,705</b>
<b>NET PROPERTY, PLANT AND EQUIPMENT, at cost</b>	<b>2,541,640</b>	<b>2,710,891</b>
<b>LONG-TERM PORTION OF DEFERRED TAX ASSET</b>	<b>1,320,417</b>	<b>1,040,606</b>
<b>OTHER ASSETS, net</b>	<b>19,725</b>	<b>33,977</b>
<b>TOTAL ASSETS</b>	<b>\$ 10,978,674</b>	<b>\$ 10,751,179</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accrued expenses	\$ 331,398	\$ 372,052
Accounts payable	96,413	105,739
Current portion of bank debt	170,874	42,384
Current portion of deferred tax liability	—	4,843
Deferred revenue	8,250	—
<b>Total current liabilities</b>	<b>606,935</b>	<b>525,018</b>
<b>LONG-TERM LIABILITIES:</b>		
Long-term portion of bank debt	1,312,184	943,760
Interest rate swap	65,157	—

TOTAL LIABILITIES	1,984,276	1,468,778
STOCKHOLDERS' EQUITY:		
Common stock, Par value - \$0.10 per share, Authorized - 8,000,000 shares, Issued - 3,261,148 shares at September 30, 2011 and December 31, 2010	326,115	326,115
Capital in excess of par value	9,895,474	9,780,392
Accumulated deficit	(613,785 )	(204,805 )
Treasury stock at cost – 262,496 shares at September 30, 2011 and 287,496 shares at December 31, 2010	(574,242 )	(628,932 )
Accumulated other comprehensive (loss) income - interest rate swap	(39,164 )	9,631
Total stockholders' equity	8,994,398	9,282,401
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 10,978,674	\$ 10,751,179

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

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

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2011	2010	2011	2010
Product sales	\$1,003,451	\$873,722	\$3,806,595	\$3,263,141
Costs of goods sold	477,417	516,453	1,717,801	1,548,097
Gross margin	526,034	357,269	2,088,794	1,715,044
Product development expenses	304,082	312,158	1,448,977	1,050,940
Administrative expenses	216,487	195,364	647,940	658,859
Sales and marketing expenses	197,855	197,289	633,985	474,816
Other operating expenses	718,424	704,811	2,730,902	2,184,615
NET OPERATING INCOME (LOSS)	(192,390 )	(347,542 )	(642,108 )	(469,571 )
Other (expenses) revenues, net	(18,539 )	(3,040 )	(56,970 )	17,461
INCOME (LOSS) BEFORE INCOME TAXES	(210,929 )	(350,582 )	(699,078 )	(452,110 )
Income tax benefit	83,280	153,466	290,098	195,289
NET INCOME (LOSS)	\$(127,649 )	\$(197,116 )	\$(408,980 )	\$(256,821 )
Weighted average common shares outstanding:				
Basic	2,980,652	2,970,652	2,973,652	2,970,652
Diluted	2,980,652	2,970,652	2,973,652	2,970,652
NET INCOME (LOSS) PER SHARE:				
Basic	\$(0.04 )	\$(0.07 )	\$(0.14 )	\$(0.09 )
Diluted	\$(0.04 )	\$(0.07 )	\$(0.14 )	\$(0.09 )

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

## ImmuCell Corporation

(Unaudited)

STATEMENTS OF STOCKHOLDERS' EQUITY  
FOR THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2011

	Common Stock \$0.10 Par Value		Capital in Excess of	Accumulated	Treasury Stock		Accumulated Other Comprehensive Income	Total Stockholders'
	Shares	Amount	Par Value	Deficit	Shares	Amount	(Loss)	Equity
BALANCE, December 31, 2010	3,261,148	\$ 326,115	\$ 9,780,392	\$ (204,805)	287,496	\$ (628,932)	\$ 9,631	\$ 9,282,401
Net income (loss)	—	—	—	(408,980)	—	—	—	(408,980 )
Other comprehensive loss – interest rate swap, net of taxes	—	—	—	—	—	—	(48,795)	(48,795 )
Total comprehensive loss	—	—	—	—	—	—	—	(457,775 )
Exercise of stock options	—	—	73,480	—	(25,000 )	54,690	—	128,170
Tax benefits related to stock options	—	—	13,568	—	—	—	—	13,568
Stock-based compensation	—	—	28,034	—	—	—	—	28,034
BALANCE, September 30, 2011	3,261,148	\$ 326,115	\$ 9,895,474	\$ (613,785)	262,496	\$ (574,242)	\$ (39,164)	\$ 8,994,398

FOR THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2010

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

BALANCE, December 31, 2009								
Net income (loss)	—	—	—	(256,821 )	—	—	—	(256,821 )
Other comprehensive loss – interest rate swap, net of taxes	—	—	—	—	—	—	(39,215 )	(39,215 )
Total comprehensive loss	—	—	—	—	—	—	—	(296,036 )
Stock-based compensation	—	—	26,386	—	—	—	—	26,386
BALANCE, September 30, 2010								
	3,261,148	\$326,115	\$9,777,828	\$(76,942 )	290,496	\$(635,495)	\$(39,215 )	\$9,352,291

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



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

	Nine-Month Periods Ended September 30,	
	2011	2010
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income (loss)	\$(408,980 )	\$(256,821 )
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	306,531	313,564
Amortization	4,521	907
Deferred income taxes	(304,177 )	(195,733 )
Stock-based compensation	28,034	26,386
Loss on disposal of fixed assets	9,582	575
Changes in:		
Receivables	48,513	13,132
Inventory	(155,785 )	(373,239 )
Prepaid expenses and other assets	140,260	55,850
Accrued expenses	(40,654 )	(14,928 )
Accounts payable	31,746	43,066
Deferred revenue	8,250	—
Net cash used for operating activities	(332,159 )	(387,241 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES :</b>		
Purchase of property, plant and equipment	(187,934 )	(110,167 )
Maturities of short-term investments	2,229,000	3,859,000
Purchases of short-term investments	(3,183,000)	(2,478,000)
Net cash (used for) provided by investing activities	(1,141,934)	1,270,833
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from debt issuance	600,000	1,000,000
Debt principal repayments	(103,086 )	(3,464 )
Debt issuance costs	—	(26,489 )
Proceeds from exercise of stock options	128,170	—
Tax benefits related to stock options	13,568	—
Net cash provided by financing activities	638,652	970,047
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(835,441 )</b>	<b>1,853,639</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>\$563,544</b>	<b>\$2,829,129</b>
<b>INTEREST EXPENSE PAID</b>	<b>\$(58,650 )</b>	<b>\$(5,201 )</b>
<b>INCOME TAXES PAID</b>	<b>\$(209 )</b>	<b>\$(100 )</b>

NON-CASH ACTIVITIES:

Change in capital expenditures included in accounts payable	\$(41,072 )	\$(8,263 )
Decrease in fair value of interest rate swap, net of taxes	\$48,795	\$39,215

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

ImmuCell Corporation  
NOTES TO UNAUDITED FINANCIAL STATEMENTS  
September 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 (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 September 30, 2011	As of December 31, 2010	(Decrease) Increase
Cash and cash equivalents	\$ 564	\$ 1,399	\$ (835 )
Short-term investments	4,181	3,227	954
	\$ 4,745	\$ 4,626	\$ 119

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 September 30, 2011	As of December 31, 2010	Increase
Raw materials	\$ 293	\$ 237	\$ 56
Work-in-process	980	977	3

Finished goods	484	387	97
	\$ 1,757	\$ 1,601	\$ 156

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

4. PROPERTY, PLANT AND EQUIPMENT

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

	As of September 30, 2011	As of December 31, 2010
Laboratory and manufacturing equipment	\$ 2,937	\$ 2,870
Building and improvements	2,651	2,553
Office furniture and equipment	234	225
Construction in progress	—	40
Land	50	50
Property, plant and equipment, gross	5,872	5,738
Less-accumulated depreciation	3,330	3,027
Property, plant and equipment, net	\$ 2,542	\$ 2,711

5. OTHER ASSETS

Other assets consisted of the following (in thousands):

	As of September 30, 2011	As of December 31, 2010
Security deposits	\$ 1	\$ 1
Debt issue costs	26	26
Interest rate swap	—	10
Other assets, gross	27	37
Accumulated amortization of debt issue costs	7	3
Other assets, net	\$ 20	\$ 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 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 (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 other comprehensive loss in the amount of approximately \$39,000 as of September 30, 2011 and other comprehensive income 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 March 31, 2012 and is renewable annually thereafter. Interest on any borrowings against the line of credit will be variable at the higher rate of 4.25% or the one month LIBOR plus 3.50%. These credit facilities are subject to certain financial covenants. 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 September 30, 2011. Principal payments due under debt outstanding as of September 30, 2011 are reflected in the following table by the period that payments are due (in thousands):

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

	Three-Month	Years Ending December 31,						Total
	Period Ending December 31, 2011	2012	2013	2014	2015	2016	Thereafter	
\$1,000,000 mortgage	\$ 11	\$45	\$48	\$51	\$54	\$57	\$ 689	\$955
\$600,000 note payable	31	128	134	139	96	-	-	528
Total	\$ 42	\$173	\$182	\$190	\$150	\$57	\$ 689	\$1,483

7. OTHER (EXPENSES) REVENUES, NET

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

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2011	2010	2011	2010
Royalty income	\$ 1	\$ -	\$ 4	\$ 2
Interest income (expense)	(20 )	(3 )	(51 )	13
Other gains (losses)	-	-	(10 )	2
	\$ (19 )	\$ (3 )	\$ (57 )	\$ 17

8. 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 \$12,000 during the three-month periods ended September 30, 2011 and 2010, respectively, and \$28,000 and \$26,000 during the nine-month periods ended September 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.

9. INCOME TAXES

We account for income taxes in accordance with Codification Topic 740, Income Taxes, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and 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 September 30, 2011. Although we believe that our estimates are reasonable, actual results could differ from these estimates.

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

10. NET INCOME (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 221,000 during the three-month and nine-month periods ended September 30, 2011 and approximately 266,000 during the three-month and nine-month periods ended September 30, 2010.

11. COMMON STOCK RIGHTS PLAN

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

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

Upon the Distribution Date, the holder of each Right not owned by the Acquiring Person would be entitled to purchase common stock at a discount to the initial purchase price of \$70.00 per share, effectively equal to one half of the market price of a share of common stock on the date the Acquiring Person becomes an Acquiring Person. If, after the Distribution Date, the Company should consolidate or merge with any other entity and the Company were not the surviving company, or, if the Company were the surviving company, all or part of the Company's common stock were changed or exchanged into the securities of any other entity, or if more than 50% of the Company's assets or earning power were sold, each Right would entitle its holder to purchase, at the Rights' then-current purchase price, a number of shares of the acquiring or surviving company's common stock having a market value at that time equal to twice the Right's exercise price.

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

On June 8, 2005, our Board voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2008. As of June 30, 2005, we entered into an amendment to the

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

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

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

## 12. SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

Pursuant to Codification Topic 280, Segment Reporting, we operate in one reportable business segment, that being the development, acquisition, manufacture and sale of products that improve the health and productivity of cows for the dairy and beef industries. Almost all of our internally funded product development expenses are in support of such products. Our primary customers for the majority of our product sales (86% and 83% for the three-month periods ended September 30, 2011 and 2010, respectively, and 84% and 82% for the nine-month periods ended September 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 14% and 17% of our total product sales for the three-month periods ended September 30, 2011 and 2010, respectively, and 16% and 14% of our total product sales for the nine-month periods ended September 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 September 30,				Nine-Month Periods Ended September 30,			
	2011		2010		2011		2010	
Animal Health International, Inc. [ 1 ]	38	%	35	%	40	%	36	%
MWI Veterinary Supply Company [ 2 ]	15	%	14	%	14	%	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.

[ 2 ] Assumes that the March 2011 acquisition of Nelson Laboratories by MWI had occurred as of the beginning of the periods being reported.

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 September		As of December	
	30, 2011		31, 2010	
Animal Health International, Inc. [ 1 ]	24	%	35	%
MWI Veterinary Supply Company [ 2 ]	21	%	12	%
IBA, Inc.	11	%	*	
Robert J. Matthews Company	*		15	%
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.

[ 2 ] Assumes that the March 2011 acquisition of Nelson Laboratories by MWI had occurred as of the dates being reported.

\* Amount is less than 10%.

13.

RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (a member of our Board of Directors) is a controlling owner of Stearns Veterinary Outlet, Inc., a domestic distributor of ImmuCell products (First Defense®, Wipe Out® Dairy Wipes, and CMT) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased approximately \$214,000 and \$220,000 of products from ImmuCell during the nine-month periods ended September 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 \$18,000 and \$45,000 as of September 30, 2011 and December 31, 2010, respectively.

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

14. SUBSEQUENT EVENTS

We have adopted the disclosure provisions of Codification Topic 855-10-50-1, Subsequent Events, which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued. Entities are required to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. Codification Topic 855-10-50-1 requires additional disclosures only, and therefore did not have an impact on our financial condition, results of operations, earnings per share or cash flows. Public entities must evaluate subsequent events through the date that financial statements are issued. Accordingly, we have evaluated subsequent events through the time of filing on November 14, 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 NINE-MONTH PERIODS ENDED SEPTEMBER 30, 2011

Product Sales

Product sales increased by approximately 15%, or \$130,000, to \$1,003,000 during the three-month period ended September 30, 2011 in comparison to \$874,000 during the same period in 2010. During the three-month period ended September 30, 2011, domestic sales increased by 19%, or \$138,000, and international sales decreased by 5%, or \$8,000, in comparison to the same period in 2010. Product sales increased by approximately 17%, or \$543,000, to \$3,807,000 during the nine-month period ended September 30, 2011 in comparison to \$3,263,000 during the same period in 2010. During the nine-month period ended September 30, 2011, domestic sales increased by 19%, or \$506,000, and international sales increased by 6%, or \$38,000, in comparison to the same period in 2010. Product sales increased by approximately 15%, or \$633,000, to \$4,930,000 during the twelve-month period ended September 30, 2011, in comparison to \$4,297,000 during the same period in 2010.

During the three-month period ended September 30, 2011, domestic sales of First Defense® increased by 29%, and this increase was offset, in part, by an 8% decrease in international sales of First Defense®, in comparison to the same period in 2010. Sales of First Defense® increased by 22% during the three-month period ended September 30, 2011 in comparison to the same period in 2010. This follows a 37% increase in sales of First Defense® during the three-month period ended June 30, 2011 in comparison to the same period in 2010 and a 21% increase during the three-month period ended March 31, 2011 in comparison to the same period in 2010 and a 13% increase during the three-month period ended December 31, 2010 in comparison to the same period in 2009. During the nine-month period ended September 30, 2011, domestic sales of First Defense® increased by 24%, and this increase was complemented by a 39% increase in international sales of First Defense®, in comparison to the same period in 2010. Sales of First Defense® increased by 26% during the nine-month period ended September 30, 2011 in comparison to the same period in 2010. Sales of Wipe Out® Dairy Wipes decreased by 24% and 16% during the three-month and nine-month periods ended September 30, 2011, respectively, in comparison to the same periods in 2010. With Wipe Out® Dairy Wipes, we are competing aggressively on selling price to earn new business against less expensive products and alternative teat sanitizing methods. This product tends to be more popular on smaller dairy operations, and many smaller farms are going out of business.

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. During 2010, a sale of these reagents was made during the second quarter. During 2011, a sale in similar amount was made during the fourth quarter, making the results for the nine-month period ended September 30, 2011 not directly comparable to the same period in the prior year. Our animal health sales (excluding sales of the water diagnostic reagents) increased by 22% during the nine-month period ended September 30, 2011 in comparison to the same period in the prior year. This comparison more accurately reflects the growth of our core animal health business.

Competition for resources that dairy producers allocate to their calf enterprises has been increased by the many new products that have been introduced to the calf market. While milk prices have improved recently, much of this gain has been offset by increases in the cost of feed. Even in this challenging market, 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 fourth quarter of 2011, we sold our 11,000,000th dose of First Defense®. August 2011 marked

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. 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 believe that the growth in sales of First Defense® may reflect, at least in part, the success of our strategic decision to invest in additional sales and marketing efforts. We launched a communications campaign at the end of 2010 that is highlighting how the unique features of First Defense® provide a dependable return on investment for producers. As discussed below under the caption, “Product Development”, we are actively exploring further improvements, extensions or additions to our current product line. During the first quarter of 2011, we initiated sales of our First Defense Technology in a bulk powder format (no capsule), which is delivered with a scoop. Effective for 2011 and renewable 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®. Through two collaborations, we are working to expand sales of our First Defense Technology by accessing the U.S. feed market. During the first quarter of 2011, Agrilabs launched commercial sales of their product, Colostrx, a colostrum supplement with First Defense Technology Inside. During the fourth quarter of 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start® 150 Plus, a colostrum replacer with First Defense Technology Inside.

## ImmuCell Corporation

## Gross Margin

The gross margin as a percentage of product sales was 52% and 41% during the three-month periods ended September 30, 2011 and 2010, respectively. The gross margin as a percentage of product sales was 55% and 53% during the nine-month periods ended September 30, 2011 and 2010, respectively. The gross margin as a percentage of product sales was 54% during the twelve-month periods ended September 30, 2011 and 2010. 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 (except for during the third quarter of 2010). 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 September 30,		Increase	
	2011	2010	Amount	%
Gross margin	\$ 526	\$ 357	\$ 169	47 %
Percent of product sales	52 %	41 %	11 %	27 %

	Nine-Month Periods Ended September 30,		Increase	
	2011	2010	Amount	%
Gross margin	\$ 2,089	\$ 1,715	\$ 374	22 %
Percent of product sales	55 %	53 %	2 %	4 %

	Twelve-Month Periods Ended September 30,		Increase	
	2011	2010	Amount	%
Gross margin	\$ 2,676	\$ 2,306	\$ 370	16 %
Percent of product sales	54 %	54 %	-	-

## Product Development

Product development expenses decreased by approximately 3%, or \$8,000, to \$304,000 during the three-month period ended September 30, 2011 in comparison to the same period in 2010. Product development expenses aggregated 30% and 36% of product sales during the three-month periods ended September 30, 2011 and 2010, respectively. Product development expenses increased by approximately 38%, or \$398,000, to \$1,449,000 during the nine-month period ended September 30, 2011 in comparison to the same period in 2010. Product development expenses aggregated 38% and 32% of product sales during the nine-month periods ended September 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®.

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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 funding from a partner to complete the development of Mast Out® and to support the manufacturing, sales and marketing efforts. Additional investments, related principally to manufacturing scale-up and preparations of full-scale validation batches of Mast Out®, could amount to approximately \$6,000,000 to \$9,000,000 prior to receiving FDA approval.

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.

Mastitis is estimated to cost U.S. dairy producers approximately \$2 billion per year, making it the leading cause of economic harm to the dairy industry. These losses include the cost of treatment products, reduced milk production, discarded milk and increased cull 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. The ability to treat mastitis 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. Subclinical mastitis is associated with its own significant economic losses and is recognized as a significant contributor to clinical mastitis cases. Current intervention strategies are considered inadequate and generally not cost-effective due to milk discard requirements. It is difficult to evaluate the potential size of the as-yet undeveloped subclinical mastitis treatment market.

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 are hesitant to 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, lower milk production, increased abortions 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 their concern that the use of Mast Out® might require specific treatment restrictions at the herd level to avoid a problem in the manufacture of cheese.

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Due to its antibacterial nature, 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 is comprised of milk from a high enough percentage of treated cows. We have conducted a formal risk assessment to quantify the impact that milk from treated cows may have on cultured dairy products. This study concluded

that the dilution of milk from treated cows through comingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when Mast Out® is used in accordance with the product label. Milk from treated cows that is sold exclusively for fluid milk products presents no such risk. Another risk is that Mast Out® likely will be priced at a premium to the traditional antibiotic products currently on the market, 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.

In 2007, we began the production of pivotal batches of drug product to fulfill the regulatory requirements of effectiveness, stability, target animal safety and human food safety. 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 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. During the third quarter of 2010, we made our first submission of the Effectiveness Technical Section. This 65 volume submission contained the results from our pivotal trial conducted from 2008 to 2009 as well as all supporting data related to the effectiveness of Nisin, demonstrating the effectiveness of Mast Out® in the field at a level similar to currently marketed intramammary antibiotics and confirming prior results from two major field studies conducted since 2003. During the first quarter of 2011, we received an Effectiveness Technical Section Incomplete Letter from the FDA. The FDA requested additional information and clarification in the areas of raw data, subject eligibility and statistical analyses and has requested that certain treatment outcomes be changed or justified. Additional clinical studies were not required. Our response to the FDA 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 fourth quarter of 2011. We expect to receive the FDA's response to this second submission during the second 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. We anticipate being able to complete this work by the second quarter of 2012, at which point we would be eligible to receive the Technical Section Complete Letter from the FDA.

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 second quarter of 2011. We expect to receive the FDA's response to this submission during the fourth quarter of 2011 after one, six-month review cycle.

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. A long-term, exclusive supply agreement with Plas-Pak Inc. of Norwich, Connecticut covers the proprietary syringe that was developed specifically for Mast Out®. These syringes were used for all pivotal studies of Mast Out®. A Development and Manufacturing Agreement with Lonza Sales, Ltd. of Basel, Switzerland provides for the exclusive manufacture of the Active Pharmaceutical Ingredient (API) by Lonza for Mast Out®. The Lonza site in Europe is FDA-approved, compliant with current Good Manufacturing Practices (cGMP) regulations and subject to future FDA approval and inspection. 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®. The CMC Technical Section submission requires the identification of all facilities that will be used in the manufacture of the product. We are delaying this submission until partnering discussions are complete in order to: 1) maintain maximum flexibility in site selection for the production of Mast Out® and 2) have the opportunity to consider strategic input from a potential partner, in the event that a partnership to jointly complete the regulatory approval process and to launch commercial sales of Mast Out® is consummated. When or if a partnership to fund the completion of the development of Mast Out® is initiated is not known currently. We will make a public announcement of such a deal if and when it occurs. No approval would be granted until three full-scale manufacturing batches are produced in an approved facility. Obtaining FDA approval of the CMC Technical Section defines the critical path to the submission of the administrative NADA to the FDA.

6) Several Administrative Requirements: After obtaining the final Technical Section Complete Letter and after preparing materials responsive to other administrative requirements, the administrative NADA submission can be assembled for review by the FDA. This final submission would be subject to a statutory sixty-day review period. Product produced for the validation batches under the CMC Technical Section could be sold upon FDA approval. 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 developing therapies that could prevent scours in calves caused by enteric pathogens other than E. coli K99 and bovine coronavirus (the current First Defense® claims). In connection with that effort, during the second quarter of 2009 we entered into an exclusive license with Baylor College of Medicine covering certain rotavirus vaccine technology. This perpetual license (if not terminated for cause) is subject to milestone and royalty payments. Results from pilot studies completed during the first quarter of 2009 justified continued product development. We completed a pivotal effectiveness study of this experimental, three-claim formulation during the third quarter of 2011 without seeing the anticipated level of effectiveness needed for regulatory approval and market acceptance. We are currently analyzing these results and conducting additional pilot studies of different formulations of this antibody preparation during the fourth quarter of 2011. Positive results from these pilot studies could support a second pivotal effectiveness study during 2012. Additionally, we are investigating a tube delivery format of our First Defense Technology in a gel solution. 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 September 30, 2011, administrative expenses increased by 11%, or \$21,000, to \$216,000 as compared to the same period in 2010. During the nine-month period ended September 30, 2011 administrative expenses decreased by 2%, or \$11,000, to \$648,000 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.

## ImmuCell Corporation

## Sales and Marketing Expenses

During the three-month period ended September 30, 2011, sales and marketing expenses of \$198,000 were nearly unchanged in comparison to the same period in 2010, aggregating 20% and 23% of product sales during the three-month periods ended September 30, 2011 and 2010, respectively. During the nine-month period ended September 30, 2011, sales and marketing expenses increased by 34%, or \$159,000, to \$634,000 as compared to the same period in 2010, aggregating 17% and 15% of product sales during the nine-month periods ended September 30, 2011 and 2010, respectively. This year-to-date increase was expected and planned given our strategic decision to invest in additional sales and marketing efforts. This investment may have created, at least in part, our recent increase in product sales. Our current budgetary objective is to maintain the ratio of product selling expenses to product sales below 20% for the full year 2011.

## Loss Before Income Taxes and Net Loss

Our loss before income taxes of \$211,000 during the three-month period ended September 30, 2011 compares to a loss before income taxes of \$351,000 during the three-month period ended September 30, 2010. Our income tax benefit was 39% and 44% of our loss before income taxes during the three-month periods ended September 30, 2011 and 2010, respectively. Our net loss for the three-month period ended September 30, 2011 was \$128,000, or \$0.04 per share, in comparison to a net loss of \$197,000, or \$0.07 per share, during the three-month period ended September 30, 2010.

Our loss before income taxes of \$699,000 during the nine-month period ended September 30, 2011 compares to a loss before income taxes of \$452,000 during the nine-month period ended September 30, 2010. Our income tax benefit was 42% and 43% of our loss before income taxes during the nine-month periods ended September 30, 2011 and 2010, respectively. Our net loss for the nine-month period ended September 30, 2011 was \$409,000, or \$0.14 per share, in comparison to a net loss of \$257,000, or \$0.09 per share, during the nine-month period ended September 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 \$409,000 during the nine-month period ended September 30, 2011. 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 or extent of our anticipated return to profitability. We believe that the three key indicators that investors should watch going forward will be the gross margin on our product sales, our net operating income (loss) and our net income (loss).

Cash, cash equivalents and short-term investments increased by 3%, or \$119,000, to \$4,745,000 at September 30, 2011 from \$4,626,000 at December 31, 2010. Net cash used for operating activities amounted to \$332,000 during the nine-month period ended September 30, 2011 in comparison to net cash used for operating activities of \$387,000 during the nine-month period ended September 30, 2010. Net working capital increased by 1%, or \$49,000, to \$6,490,000 at September 30, 2011 from \$6,441,000 at December 31, 2010. Proceeds from bank debt received during the first nine months of 2011 aggregated \$497,000, net of debt repayments made prior to October 1, 2011. Total assets increased by 2%, or \$227,000, to \$10,979,000 at September 30, 2011 from \$10,751,000 at December 31,



2010. Stockholders' equity decreased by 3%, or \$288,000, to \$8,994,000 at September 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.

As noted above, in order to complete the planned development and commercialization of Mast Out® we will need to receive approximately \$6,000,000 to \$9,000,000 in financial support to complement the internally generated and borrowed funds that we have already committed and are still willing to commit to this initiative. Outside funding is required to pay for the larger financial commitments required for manufacturing scale-up and preparations of full-scale validation batches of Mast Out®. By the second quarter of 2011, we had advanced the product development effort internally to the point where we could begin earnest negotiations with prospective partners. All anticipated initial discussions are now complete, and some prospective partners are conducting their due diligence. It is difficult to predict when or if this partnering effort will be successful. Although these partnering discussions are taking longer than we would like or had initially anticipated, we believe that the commercial prospects for Mast Out® warrant our continued patience with the process.

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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). As of October 1, 2011, we had available authorization to spend up to \$290,000 on capital expenditures (net of expenditures made from January 1, 2008 through September 30, 2011), which amount includes a \$150,000 increase to this authorized limit that was approved by our Board of Directors during the fourth quarter of 2011.

### 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 September 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 is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

#### Changes in Internal Controls over Financial Reporting

The individual who serves as our principal executive and principal financial officer periodically evaluates any change in internal control over financial reporting which has occurred during the prior fiscal quarter. Management has concluded that there was no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2011 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

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 gain full NADA approval and to support the product launch. If we do complete the submission, the FDA may not grant approval of this product. 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 \$699,000 and a net loss of \$409,000 during the nine-month period ended September 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). 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 nine months of 2011, the monthly average was 9,190,000 cows, with herd size of 9,209,000 being reported for September. 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 September 2011, this price level averaged \$18.28. This average price level is higher than the annual average reached in any of the past 30 years. The actual level of milk prices may be less important than their level relative to costs because recent improvement in milk prices has been offset, in part, by higher feed costs. One measure of this relationship is known as the milk-feed price ratio, which represents the amount of feed that one pound of milk can buy. Whenever this ratio meets or exceeds 3.0, it is considered profitable to buy feed and produce milk. For 2009, this ratio averaged 1.78, representing a 12% decrease compared to 2008. For 2010, this ratio averaged 2.26, representing a 27% increase compared to 2009. For the first nine months of 2011, this ratio averaged approximately 1.89. This means that a dairy producer can buy only 1.89 pounds of feed for every pound of milk sold. An increase in feed costs also has a negative impact on the beef industry. Another indication of the economic condition of the dairy industry is the average price for animals sold for dairy herd replacement. In 2009, this average price (reported as of January, April, July and October) was estimated to be approximately \$1,385, which was a 29% decrease in comparison to the same period in 2008. This price averaged approximately \$1,330 in 2010, which represented a 4% decrease in comparison to the same period in 2009. This price averaged approximately \$1,420 in 2011, which represents a 7% increase in comparison to the same period in 2010. 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 nine-month period ended September 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 (54% and 49% for the nine-month periods ended September 30, 2011 and 2010, respectively) was made to two large distributors. A large portion of our trade accounts receivable (45% as of September 30, 2011 and 47% as of December 31, 2010) was due from these two distributors. These calculations give effect to acquisitions made during the period retroactively to the beginning of the

period. 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 nine months of 2011, 84% of our product sales were made to customers in the U.S. dairy and beef industries. This compares to 82% during the first nine months of 2010.

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

**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 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: November 14, 2011

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