

IMMUCELL CORP /DE/  
Form 10-Q  
November 13, 2012

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2012**

**001-12934**

**(Commission file number)**

**ImmuCell Corporation**

**(Exact name of registrant as specified in its charter)**

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

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

**(207) 878-2770**

**(Registrant's telephone number)**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

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

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

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

Yes  No

The number of shares of the Registrant's common stock outstanding at November 13, 2012 was 3,019,034.

**ImmuCell Corporation**

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

	(Unaudited) As of September 30, 2012	As of December 31, 2011
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,585,304	\$ 781,516
Short-term investments	3,235,000	4,178,000
Trade accounts receivable, net of allowance for doubtful accounts of \$14,105 at September 30, 2012 and \$16,359 at December 31, 2011	432,285	346,447
Income taxes receivable	348	648
Other receivables	34,453	36,701
Inventory	1,799,770	1,666,465
Prepaid expenses	148,310	81,807
Current portion of deferred tax asset	33,150	59,016
Total current assets	7,268,620	7,150,600
<b>NET PROPERTY, PLANT AND EQUIPMENT</b> , at cost	2,434,343	2,515,331
LONG-TERM PORTION OF DEFERRED TAX ASSET	1,251,266	1,306,335
<b>OTHER ASSETS</b> , net	16,750	19,006
<b>TOTAL ASSETS</b>	<b>\$ 10,970,979</b>	<b>\$ 10,991,272</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accrued expenses	\$ 205,282	\$ 303,900
Accounts payable	165,254	149,877
Current portion of bank debt	179,360	172,973
Deferred revenue	—	8,250
Total current liabilities	549,896	635,000
<b>LONG-TERM LIABILITIES:</b>		
Long-term portion of bank debt	1,132,942	1,267,939
Interest rate swap	88,732	67,900
Total long-term liabilities	1,221,674	1,335,839

TOTAL LIABILITIES	1,771,570		1,970,839
STOCKHOLDERS' EQUITY:			
Common stock, \$0.10 par value per share, 8,000,000 shares authorized, 3,261,148 shares issued at September 30, 2012 and December 31, 2011	326,115		326,115
Capital in excess of par value	9,964,222		9,911,914
Accumulated deficit	(507,940)	)	(614,315)
Treasury stock, at cost, 242,114 shares at September 30, 2012 and 257,114 shares at December 31, 2011	(529,655)	)	(562,469)
Accumulated other comprehensive loss: interest rate swap	(53,333)	)	(40,812)
Total stockholders' equity	9,199,409		9,020,433
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 10,970,979		\$ 10,991,272

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

**ImmuCell Corporation**

(Unaudited)

## STATEMENTS OF OPERATIONS

	For the Three-Month Periods Ended September 30,		For the Nine-Month Periods Ended September 30,	
	2012	2011	2012	2011
Product sales	\$ 1,076,749	\$ 1,003,451	\$ 3,968,984	\$ 3,806,595
Costs of goods sold	455,791	477,417	1,664,940	1,717,801
Gross margin	620,958	526,034	2,304,044	2,088,794
Product development expenses	223,771	304,082	683,285	1,448,977
Administrative expenses	230,751	216,487	701,484	647,940
Sales and marketing expenses	252,562	197,855	686,772	633,985
Operating expenses	707,084	718,424	2,071,541	2,730,902
NET OPERATING (LOSS) INCOME	(86,126 )	(192,390 )	232,503	(642,108 )
Other expenses, net	8,265	18,539	29,136	56,970
(LOSS) INCOME BEFORE INCOME TAXES	(94,391 )	(210,929 )	203,367	(699,078 )
Income tax (benefit) expense	(30,817 )	(83,280 )	96,992	(290,098 )
NET (LOSS) INCOME	\$ (63,574 )	\$ (127,649 )	\$ 106,375	\$ (408,980 )
Weighted average common shares outstanding:				
Basic	3,019,034	2,980,652	3,018,049	2,973,652
Diluted	3,019,034	2,980,652	3,111,099	2,973,652
<b>NET (LOSS) INCOME PER SHARE:</b>				
Basic	\$ (0.02 )	\$ (0.04 )	\$ 0.04	\$ (0.14 )
Diluted	\$ (0.02 )	\$ (0.04 )	\$ 0.03	\$ (0.14 )

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

**ImmuCell Corporation**

(Unaudited)

## STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

	For the Three-Month Periods		For the Nine-Month Periods	
	Ended September 30,		Ended September 30,	
	2012	2011	2012	2011
Net (loss) income	\$ (63,574 )	\$ (127,649 )	\$ 106,375	\$ (408,980 )
Other comprehensive loss:				
Interest rate swap, before taxes	(7,156 )	(61,310 )	(20,831 )	(74,789 )
Income tax applicable to interest rate swap	2,854	24,459	8,310	25,994
Other comprehensive loss, net of tax	(4,302 )	(36,851 )	(12,521 )	(48,795 )
Total comprehensive (loss) income	\$ (67,876 )	\$ (164,500 )	\$ 93,854	\$ (457,775 )

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





Net income (loss)								
Other comprehensive loss – interest rate swap, net of taxes	—	—	—	—	—	—	(48,795 )	(48,795 )
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
<b>BALANCE,</b> September 30, 2011	3,261,148	\$326,115	\$9,895,474	\$(613,785 )	262,496	\$(574,242)	\$(39,164 )	\$8,994,398

*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,	
	2012	2011
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ 106,375	\$(408,980 )
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:		
Depreciation	304,511	306,531
Amortization	2,156	4,521
Deferred income taxes	89,245	(304,177 )
Stock-based compensation	27,480	28,034
Loss on disposal of fixed assets	288	9,582
Changes in:		
Receivables	(83,290 )	48,513
Inventory	(133,305 )	(155,785 )
Prepaid expenses and other assets	(66,403 )	140,260
Accrued expenses	(98,618 )	(40,654 )
Accounts payable	41,138	31,746
Deferred revenue	(8,250 )	8,250
Net cash provided by (used for) operating activities	181,327	(332,159 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES :</b>		
Purchase of property, plant and equipment	(249,571 )	(187,934 )
Maturities of short-term investments	3,183,000	2,229,000
Purchases of short-term investments	(2,240,000 )	(3,183,000 )
Net cash provided by (used for) investing activities	693,429	(1,141,934 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from debt issuance	—	600,000
Debt principal repayments	(128,610 )	(103,086 )
Proceeds from exercise of stock options	50,800	128,170
Tax benefits related to stock options	6,842	13,568
Net cash (used for) provided by financing activities	(70,968 )	638,652
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>803,788</b>	<b>(835,441 )</b>
<b>BEGINNING CASH AND CASH EQUIVALENTS</b>	<b>781,516</b>	<b>1,398,985</b>
<b>ENDING CASH AND CASH EQUIVALENTS</b>	<b>\$ 1,585,304</b>	<b>\$ 563,544</b>

INTEREST PAID	\$ (57,637 )	\$ (58,650 )
INCOME TAXES PAID	\$ (605 )	\$ (209 )
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable	\$ (25,762 )	\$ (41,072 )
Net change in fair value of interest rate swap	\$ 12,521	\$ 48,795

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

**ImmuCell Corporation****NOTES TO UNAUDITED FINANCIAL STATEMENTS**

September 30, 2012

**1. BASIS OF PRESENTATION**

We have prepared the accompanying financial statements without audit reflecting all adjustments, all of which are of a normal recurring nature, that are, in our opinion, necessary in order to make the financial statements not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP in these footnotes are to the FASB *Accounting Standards Codification*<sup>TM</sup> (Codification). Certain information and footnote disclosures normally included in the annual financial statements have been condensed or omitted. Accordingly, we believe that although the disclosures are adequate to make the information presented not misleading, these financial statements should be read in conjunction with the financial statements for the year ended December 31, 2011 and the notes thereto, contained in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission.

**2. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS**

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits per financial institution are maintained in money market accounts at financial institutions that are insured, in part, by the Securities Investor Protection Corporation. Short-term investments are classified as held to maturity and are comprised principally of certificates of deposit that mature in more than three months from their purchase dates and not more than twelve months from the balance sheet date and are held at different financial institutions that are insured by the FDIC within the FDIC insurance limit of \$250,000 per institution per depositor. We are required by bank debt covenant to maintain at least \$1,000,000 of otherwise unrestricted cash, cash equivalents and short-term investments. Cash, cash equivalents and short-term investments consisted of the following:

	As of September 30, 2012	As of December 31, 2011	Increase (Decrease)
Cash and cash equivalents	\$ 1,585,304	\$ 781,516	\$ 803,788
Short-term investments	3,235,000	4,178,000	(943,000 )
	\$ 4,820,304	\$ 4,959,516	\$(139,212 )

**3. INVENTORY**

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

	As of September 30, 2012	As of December 31, 2011	Increase (Decrease)
Raw materials	\$ 262,746	\$ 218,104	\$ 44,642
Work-in-process	997,220	1,000,037	(2,817 )
Finished goods	539,804	448,324	91,480
	\$ 1,799,770	\$ 1,666,465	\$ 133,305

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**ImmuCell Corporation**

## NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2012

**4. PROPERTY, PLANT AND EQUIPMENT**

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

	As of September 30, 2012	As of December 31, 2011
Laboratory and manufacturing equipment	\$ 3,041,473	\$ 2,978,716
Building and improvements	2,768,643	2,667,220
Office furniture and equipment	312,979	252,737
Construction in progress	—	1,331
Land	50,000	50,000
Property, plant and equipment, gross	6,173,095	5,950,004
Accumulated depreciation	(3,738,752)	(3,434,673)
Property, plant and equipment, net	\$ 2,434,343	\$ 2,515,331

**5. OTHER ASSETS**

Other assets consisted of the following:

	As of September 30, 2012	As of December 31, 2011
Security deposits	\$ 250	\$ 350
Debt issue costs	26,489	26,489
Other assets, gross	26,739	26,839
Accumulated amortization of debt issue costs	(9,989)	(7,833)
Other assets, net	\$ 16,750	\$ 19,006

**6. BANK DEBT**

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

a \$1,000,000 ten-year mortgage loan, a \$600,000 fifty-four month note and a \$500,000 line of credit. Proceeds from the \$1,000,000 mortgage were received during the third quarter of 2010. Based on a 15-year amortization schedule, a balloon principal payment of \$451,885 will be due in the third quarter of 2020. We hedged our interest rate exposure on this mortgage loan with an interest rate swap agreement that effectively converted a floating interest rate to the fixed rate of 6.04%. All derivatives are recognized on the balance sheet at their fair value. The agreement has been determined to be highly effective in hedging the variability of the identified cash flows and has been designated as a cash flow hedge of the variability in the hedged interest payments. Changes in the fair value of the interest rate swap agreement are recorded in other comprehensive income (loss), net of taxes. The original notional amount of the interest rate swap agreement of \$1,000,000 amortizes in accordance with the amortization of the mortgage. As the result of our decision to hedge this interest rate risk, we recorded accumulated other comprehensive loss in the amount of \$53,333 and \$40,812 as of September 30, 2012 and December 31, 2011, respectively, which reflects the fair value of the interest rate swap liability, net of taxes. The fair value of the interest rate swap has been determined using observable market-based inputs or unobservable inputs that are corroborated by market data. Accordingly, the interest rate swap is classified as level 2 within the fair value hierarchy provided in Codification Topic 820, *Fair Value Measurements and Disclosures*. Proceeds from the \$600,000 note were received during the first quarter of 2011. Interest on the note is variable at the higher rate of 4.25% or the one month London Interbank Offered Rate (LIBOR) plus 3.25%. The \$500,000 line of credit is available as needed and has been extended through May 31, 2013 and is renewable annually thereafter. Interest on any borrowings against the line of credit will be variable at the higher rate of 4.25% or the one month LIBOR plus 3.50%. These credit facilities are subject to certain financial covenants. We are in compliance with all applicable covenants as of September 30, 2012. Principal payments due under debt outstanding as of September 30, 2012 are reflected in the following table by the period that payments are due:

**ImmuCell Corporation**

## NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2012

Period	\$1,000,000 mortgage	\$600,000 note	Total
Three months ending December 31, 2012	\$ 11,733	\$ 32,514	\$44,247
Twelve months ending December 31, 2013	47,908	133,614	181,522
Twelve months ending December 31, 2014	50,900	139,490	190,390
Twelve months ending December 31, 2015	54,044	96,178	150,222
Twelve months ending December 31, 2016	57,384	—	57,384
Twelve months ending December 31, 2017	61,056	—	61,056
After December 31, 2017	627,481	—	627,481
Total	\$ 910,506	\$ 401,796	\$1,312,302

**7. PRODUCT DEVELOPMENT EXPENSES**

In 1999, we shifted the primary focus of our product development efforts from human applications of our whey protein purification technology to scientifically-proven and practical products that result in a measurable economic impact on animal health and productivity in the dairy and beef industries. We expect to continue this strategic focus. As anticipated, we reduced product development expenses during the periods being reported primarily because we are spending less money on the development of **Mast Out<sup>®</sup>** with the significant clinical studies now largely complete. Product development expenses decreased by approximately 26%, or \$80,311, to \$223,771 during the three-month period ended September 30, 2012 in comparison to \$304,082 during the same period in 2011. Product development expenses decreased by approximately 53%, or \$765,692, to \$683,285 during the nine-month period ended September 30, 2012 in comparison to \$1,448,977 during the same period in 2011.

**8. OTHER EXPENSES, NET**

Other expenses, net, consisted of the following:

	For the Three-Month Periods		For the Nine-Month Periods	
	Ended September 30,		Ended September 30,	
	2012	2011	2012	2011
Royalty income	\$ (6,028 )	\$ (1,123 )	\$ (14,598 )	\$ (4,185 )
Interest income	(4,437 )	(980 )	(13,817 )	(10,389 )
Interest expense	18,670	20,489	57,134	61,187
Other losses	60	153	417	10,357



\$ 8,265      \$ 18,539      \$ 29,136      \$ 56,970

## 9. STOCK-BASED COMPENSATION

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model. Accordingly, we recorded compensation expense pertaining to stock-based compensation of \$9,463 and \$10,298 during the three-month periods ended September 30, 2012 and 2011, respectively, and \$27,480 and \$28,034 during the nine-month periods ended September 30, 2012 and 2011, respectively.

**ImmuCell Corporation**

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2012

**10. INCOME TAXES**

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. We believe it is more likely than not that the deferred tax assets will be realized through future taxable income and future tax effects of temporary differences between book income and taxable income. Accordingly, we have not established a valuation allowance for the deferred tax assets. Codification Topic 740-10 clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position must meet before being recognized in the financial statements. In the ordinary course of business, there are transactions and calculations where the ultimate tax outcome is uncertain. In addition, we are subject to periodic audits and examinations by the IRS and other taxing authorities. We have evaluated the positions taken on our filed tax returns. We have concluded that no uncertain tax positions exist as of September 30, 2012. Although we believe that our estimates are reasonable, actual results could differ from these estimates.

**11. NET INCOME (LOSS) PER COMMON SHARE**

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

**12. COMMON STOCK RIGHTS PLAN**

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

forth in a Rights Agreement between the Company and American Stock Transfer & Trust Co., as Rights Agent.

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

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

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

## ImmuCell Corporation

### NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2012

On June 8, 2005, our Board of Directors voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2008. As of June 30, 2005, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. No other changes were made to the terms of the Rights or the Rights Agreement at that time. On June 6, 2008, our Board of Directors voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2011 and to increase the ownership threshold for determining "Acquiring Person" status from 15% to 18%. As of June 30, 2008, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase. No other changes were made to the terms of the Rights or the Rights Agreement at that time. On August 5, 2011, our Board of Directors voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2014 and to increase the ownership threshold for determining "Acquiring Person" status from 18% to 20%. As of August 9, 2011, we entered into an amendment to the

Rights Agreement with the Rights Agent reflecting such extension and threshold increase. No other changes were made to the terms of the Rights or the Rights Agreement at that time.

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

### 13. SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

Pursuant to Codification Topic 280, *Segment Reporting*, we operate in one reportable business segment, that being the development, acquisition, manufacture and sale of products that improve the health and productivity of cows for the dairy and beef industries. Almost all of our internally funded product development expenses are in support of such products. Our primary customers for the majority of our product sales (83% and 86% for the three-month periods ended September 30, 2012 and 2011, respectively, and 81% and 84% for the nine-month periods ended September 30, 2012 and 2011, respectively) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 17% and 14% of our total product sales for the three-month periods ended September 30, 2012 and 2011, respectively, and 16% of our total product sales for both of the nine-month periods ended September 30, 2012 and 2011. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

	For the Three-Month Periods				For the Nine-Month Periods			
	Ended September 30,		2011		Ended September 30,		2011	
	2012	%	2011	%	2012	%	2011	%
Animal Health International, Inc. <sup>[1]</sup>	35	%	38	%	35	%	40	%
MWI Veterinary Supply Company <sup>[2]</sup>	17	%	15	%	14	%	14	%

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

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

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

	As of		As of	
	September 30, 2012		December 31, 2011	
		%		%
Animal Health International, Inc.	32	%	23	%
MWI Veterinary Supply Company	22	%	21	%
Robert J. Matthews Company	12	%	*	*
Stearns Veterinary Outlet, Inc.		*	18	%

\* Amount is less than 10%.

**ImmuCell Corporation**

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2012

**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<sup>o</sup>**, **Wipe Out<sup>o</sup> Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased \$220,605 and \$213,912 of products from ImmuCell during the nine-month periods ended September 30, 2012 and 2011, respectively, on terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated \$18,469 and \$60,831 as of September 30, 2012 and December 31, 2011, 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 November 13, 2012, 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, 2012**

*Product Sales*

Product sales increased by approximately 7%, or \$73,000, to \$1,077,000 during the three-month period ended September 30, 2012 in comparison to \$1,003,000 during the same period in 2011. Product sales increased by approximately 4%, or \$162,000, to \$3,969,000 during the nine-month period ended September 30, 2012 in comparison to \$3,807,000 during the same period in 2011. Sales during the nine-month period ended September 30, 2012 included approximately \$116,000 in sales of our bulk reagents used in a drinking water diagnostic test sold by others that did not occur during the same period during 2011. During the nine-month period ended September 30, 2012, domestic sales increased by approximately 1%, or \$34,000, and international sales increased by 21%, or \$129,000, in comparison to the same period in 2011. Product sales increased by approximately 7%, or \$344,000, to \$5,274,000 during the twelve-month period ended September 30, 2012, in comparison to \$4,930,000 during the twelve-month period ended September 30, 2011.

Sales of our lead product, **First Defense<sup>®</sup>**, increased by 2% during the nine-month period ended September 30, 2012 and increased by 3% during the twelve-month period ended September 30, 2012, in comparison to the same periods ended in 2011. During the nine-month period ended September 30, 2012, domestic sales of **First Defense<sup>®</sup>** increased by 1%, and international sales of **First Defense<sup>®</sup>** increased by 6%, in comparison to the same period in 2011. With the exception of the anticipated decrease during the second quarter of 2012, we have realized consistently positive sales growth of **First Defense<sup>®</sup>** for seven of the last eight quarters ending with, and including, the third quarter of 2012, as demonstrated below:

- 9%: Third Quarter 2012 over Third Quarter 2011
- (17%): Second Quarter 2012 under the Second Quarter 2011
- 13%: First Quarter 2012 over First Quarter 2011
- 21%: Fiscal Year 2011 over Fiscal Year 2010
- 7%: Fourth Quarter 2011 over Fourth Quarter 2010
- 22%: Third Quarter 2011 over Third Quarter 2010
- 37%: Second Quarter 2011 over Second Quarter 2010

21%: First Quarter 2011 over First Quarter 2010

13%: Fourth Quarter 2010 over Fourth Quarter 2009

We believe that the long-term growth in sales of **First Defense**<sup>®</sup> (despite the drop in the second quarter of 2012) may reflect, at least in part, the success of our strategic decision to invest in additional sales and marketing efforts. Our sales and marketing team currently consists of one director and two regional sales managers. We launched a new communications campaign at the end of 2010 that is highlighting how the unique ability of **First Defense**<sup>®</sup> to provide Immediate Immunity<sup>™</sup> generates a dependable return on investment for producers. Effective for 2011 and 2012 (and renewable for 2013 and 2014 if certain sales growth objectives are met), we entered into a sales and marketing collaboration with Agri Laboratories Ltd. of St. Joseph, Missouri, (AgriLabs<sup>®</sup>), under which the AgriLabs<sup>®</sup> sales and marketing team is working with us to expand market demand for **First Defense**<sup>®</sup>.

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. The weather during the 2012 spring calving season was extremely mild in North America. Warm and dry weather reduces the producer's perception of the need for **First Defense**<sup>®</sup>. The severe heat and drought conditions during the summer of 2012 in many key agricultural regions in the U.S. has caused a significant increase in the cost of feed that has offset some improvement in milk prices. The combination of mild weather during the 2012 calving season and the increasing cost of feed has created a very challenging environment in which to sell a disease prevention product. The animal health distribution segment has been aggressively consolidating over the last few years. Larger distributors have been acquiring smaller distributors. In an effort to maximize their efficiencies, one of our largest distributors has reduced warehouse locations by approximately 20%. This may have reduced the inventory of **First Defense**<sup>®</sup> held at the distributor level, thereby reducing **First Defense**<sup>®</sup> sales out our door. Although beef herd numbers are down currently because of drought conditions in many parts of the U.S., projections indicate 2012 could be another year of record high cattle and beef prices. This upswing would increase a producer's likelihood to invest in **First Defense**<sup>®</sup> for their calf crop. Even in this challenging market, **First Defense**<sup>®</sup> continues to benefit from wide acceptance as an effective tool to prevent bovine enteritis (scours) in newborn calves. The third quarter of 2011 marked the 20<sup>th</sup> anniversary of the original USDA approval of this product in 1991. During the fourth quarter of 2011, we sold our 11,000,000<sup>th</sup> dose of **First Defense**<sup>®</sup>. 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.



## ImmuCell Corporation

We are developing new product applications of our **First Defense Technology™**, which is a unique whey protein concentrate that is purified utilizing our proprietary whey protein processing methods, for the nutritional and feed supplement markets without the claims of our USDA-licensed product. Through our **First Defense Technology™**, we are selling whey concentrate globulin proteins in different formats. During the second quarter of 2011, we initiated sales of **First Defense Technology™** in a bulk powder format (no capsule), which is delivered with a scoop and mixed with colostrum for feeding. During the first quarter of 2012, we initiated a limited launch of a tube delivery format of our **First Defense Technology™** in a gel solution. 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<sup>®</sup> launched commercial sales of their product, Colostrx<sup>®</sup>, 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<sup>®</sup> 150 Plus, a colostrum replacer with **First Defense Technology™ Inside**.

### *Gross Margin*

The gross margin as a percentage of product sales was 58% and 52% during the three-month periods ended September 30, 2012 and 2011, respectively. The gross margin as a percentage of product sales was 58% and 55% during the nine-month periods ended September 30, 2012 and 2011, respectively. The gross margin as a percentage of product sales was 57% and 54% during the twelve-month periods ended September 30, 2012 and 2011, respectively. Our gross margin percentages were 55%, 52% and 53% for the years ended December 31, 2011, 2010 and 2009, respectively. Our objective is to maintain the full-year gross margin percentage over 50%, and we have achieved this objective during the periods being reported. We expect some fluctuations in gross margin percentages from quarter to quarter. We believe that a number of factors can cause our costs to be variable. Biological yields from the raw material used in the production of **First Defense<sup>®</sup>** 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<sup>®</sup>** and our bulk reagents used in a drinking water diagnostic test and a lower gross margin on **Wipe Out<sup>®</sup> 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<sup>®</sup>** 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:

**ImmuCell Corporation**

	Three-Month Periods				Increase	
	Ended September 30,					
	2012	2011	Amount	%		
Gross margin	\$ 621	\$ 526	\$95	18%		
Percent of product sales	58 %	52 %	6 %	12%		

	Nine-Month Periods				Increase	
	Ended September 30,					
	2012	2011	Amount	%		
Gross margin	\$ 2,304	\$ 2,089	\$215	10%		
Percent of product sales	58 %	55 %	3 %	5 %		

	Twelve-Month Periods				Increase	
	Ended September 30,					
	2012	2011	Amount	%		
Gross margin	\$ 3,029	\$ 2,676	\$353	13%		
Percent of product sales	57 %	54 %	3 %	6 %		

*Product Development*

In 1999, we shifted the primary focus of our product development efforts from human applications of our whey protein purification technology to scientifically-proven and practical products that result in a measurable economic impact on animal health and productivity in the dairy and beef industries. We expect to continue this strategic focus. As anticipated, we reduced product development expenses during the periods being reported primarily because we are spending less money on the development of **Mast Out**<sup>®</sup> with the significant clinical studies now largely complete. Product development expenses decreased by approximately 26%, or \$80,000 to \$224,000 during the three-month period ended September 30, 2012 in comparison to \$304,000 during the same period in 2011. Product development expenses decreased by approximately 53%, or \$766,000, to \$683,000 during the nine-month period ended September 30, 2012 in comparison to \$1,449,000 during the same period in 2011. We spent approximately \$1,720,000, \$1,493,000 and \$1,645,000 on product development activities during the years ended December 31, 2011, 2010 and 2009, respectively.

Estimated to cost the U.S. dairy industry approximately \$2 billion per year, mastitis (inflammation of the mammary gland) is the most costly and common disease affecting dairy cows. The disease diminishes the saleable quantity and overall value of milk, in addition to causing other herd health and productivity losses. **Mast Out**<sup>®</sup>, our lead product development initiative, is a Nisin-based intramammary treatment of subclinical mastitis (those cases where cows have infected udders, but still produce saleable milk) in lactating dairy cows. While the benefit of treating clinical mastitis

(which results in abnormal milk that cannot be sold) is widely known, there is a growing awareness of the cascade of adverse events and conditions associated with subclinical mastitis, including reduced or foregone milk quality premiums, lower milk production, shorter shelf life for fluid milk, lower yields and less flavor for cheese, higher rates of clinical mastitis, increased abortions and increased cull rates. In the pivotal effectiveness study, **Mast Out<sup>0</sup>** treatment was associated with a statistically significant reduction in milk somatic cell count (SCC), which is an important measure of milk quality. Some industry experts have estimated that subclinical mastitis costs the U.S. dairy industry approximately \$1 billion per year. 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. Current intervention strategies for subclinical disease are considered inadequate and generally not cost-effective due to milk discard requirements. **Mast Out<sup>0</sup>** presents the option to treat such cases without a milk discard, which could revolutionize the way mastitis is managed in the industry. There is no other FDA-approved intramammary mastitis treatment product that has such a “zero discard” claim. Common milk discard periods cover the duration of treatment and extend from 36 to 96 hours after last treatment, depending on the antibiotic. On average, a cow produces approximately 80 pounds of milk per day. While milk prices vary significantly, at an average value of \$15 per 100 pounds, a cow produces approximately \$12 worth of milk per day. Milk discard costs, ranging from approximately \$40 to \$100 per treated animal, are a significant barrier to the routine treatment of subclinical mastitis. We believe **Mast Out<sup>0</sup>** could expand the subclinical mastitis treatment market niche largely because it would not be subject to this milk discard requirement.

## ImmuCell Corporation

In 2000, we acquired an exclusive license from Nutrition 21, Inc. (formerly Applied Microbiology Inc. or AMBI) to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Mast Out**<sup>®</sup>. 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**<sup>®</sup> **Dairy Wipes**, is an antibacterial peptide. Nisin is known to have activity against most gram positive and some gram negative bacteria. Nisin is a well characterized substance, having been used in food preservation applications for over 50 years. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes methods to achieve pharmaceutical-grade purity.

In 2004, we entered into a product development and marketing agreement with Pfizer Animal Health, a division of Pfizer, Inc., covering **Mast Out**<sup>®</sup>. 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**<sup>®</sup>. 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**<sup>®</sup> might require specific treatment restrictions at the herd level to avoid a potential problem using the milk from treated cows in the manufacture of certain dairy products.

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

Many fear that the possible overuse of antibiotics in livestock may undermine the effectiveness of drugs to combat human illnesses and may be a contributing factor to the rising problem of bacterial drug resistance. The FDA is committed to addressing this public health concern. For example, citing concerns about untreatable, life-threatening infections in humans, new FDA and European regulations are aimed at restricting the use of cephalosporins in food animals and at improving milk quality. New USDA regulations have been implemented to reduce the allowable level of somatic cell counts in milk to 400,000 at the farm level in order to qualify for an EU export certification. In late

2011, The Dutch Veterinary Society proposed strict guidelines for veterinary use of antibiotics in the EU. Additionally, regulators have recently increased their monitoring of antibiotic residues in milk and meat. This current environment could be favorable to the introduction of a new product such as **Mast Out<sup>®</sup>** as an alternative to traditional antibiotics. We continue to believe that this product opportunity justifies ongoing product development efforts necessary to commercialize the product.

Commercial introduction of **Mast Out<sup>®</sup>** in the United States is subject to approval of our New Animal Drug Application (NADA) by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA), which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets outside of the United States and would involve some similar and some different requirements. In 2007, we began the production of pivotal batches of drug product to fulfill the regulatory requirements of effectiveness, stability, target animal safety and human food safety. The NADA is comprised of five principal Technical Sections subject to the FDA's phased review of a NADA. By statute, each Technical Section submission is generally subject to a six-month review cycle by the FDA. The current status of our work on these Technical Sections is as follows:

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

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

## ImmuCell Corporation

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

4) Human Food Safety (HFS): The HFS Technical Section submission was made during the fourth quarter of 2010. This Technical Section determines if a milk discard period or meat withhold period will be required. This Technical Section includes several subsections such as: a) toxicology, b) total metabolism, c) effects of drug residues in food on human intestinal microbiology, d) effects on bacteria of human health concern (antimicrobial resistance) and e) pivotal residue chemistry. During the second quarter of 2011, we announced that the FDA had accepted the subsections described above and granted **Mast Out**<sup>®</sup> 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 submitted the validated analytical method to the FDA during the fourth quarter of 2012 and anticipate receiving a Technical Section Complete Letter from the FDA by the first quarter of 2013.

5) Chemistry, Manufacturing and Controls (CMC): During the fourth quarter of 2012, we withdrew our first submission to the FDA of the CMC Technical Section because of changes we have made to our regulatory filing and manufacturing strategies. We intend to make a revised first submission for a six-month review cycle by the FDA as soon as all of the relevant information is prepared. We are party to agreements with two manufacturers to produce inventory for us utilizing our proprietary technology and processes. First, a long-term, exclusive supply agreement with Plas-Pak Inc. of Norwich, Connecticut covers the proprietary syringe that was developed specifically for **Mast Out**<sup>®</sup>. These syringes were used for all pivotal studies of **Mast Out**<sup>®</sup>. Second, an exclusive Contract Manufacture Agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved drug product manufacturer, covers the formulation of the Active Pharmaceutical Ingredient (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**<sup>®</sup>. During the fourth quarter of 2012, we expect to enter into a lease with respect to a facility in which we intend to install the equipment and infrastructure necessary to produce the API. This strategy allows us to move forward with the regulatory approval process without needing outside funding to construct a new facility and allows us to avoid the cost and time delay of constructing a new facility during the winter season. It also provides us with more control and flexibility with regards to production volumes and costs than would be possible if we relied on a contract manufacturer to produce the API for us. It is our objective to complete the necessary facility modifications and equipment installations over the next twelve to eighteen months. At that time, the site would be ready for the production of validation batches of API required for approval of the CMC Technical Section and for inspection by the FDA. This would complete the CMC Technical Section and make us eligible for a Technical Section Complete Letter from the FDA, after a six-month review cycle.

Obtaining FDA approval of the CMC Technical Section defines the critical path to the submission of the administrative NADA to the FDA and ultimately to commercial sales. After obtaining the final Technical Section Complete Letter and after preparing materials responsive to other administrative requirements, the administrative

NADA submission can be assembled for review by the FDA. This final submission would be subject to a statutory sixty-day review period.

In addition to our work on **Mast Out<sup>0</sup>**, we are actively exploring further improvements, extensions or additions to our current product line. For example, we currently are developing treatments that could prevent calf scours (diarrhea) caused by enteric pathogens other than *E. coli* K99 and bovine coronavirus (the current disease claims for **First Defense<sup>®</sup>**). In connection with that effort, during the second quarter of 2009 we entered into an exclusive license with Baylor College of Medicine covering certain rotavirus vaccine technology. This perpetual license (if not terminated for cause) is subject to milestone and royalty payments. Results from pilot studies completed during the first quarter of 2009 justified continued product development. We completed a pivotal effectiveness study of this experimental formulation during the third quarter of 2011 without seeing the anticipated level of effectiveness needed for regulatory approval and market acceptance. We are currently conducting additional pilot studies of different formulations of this antibody preparation. If positive results from these pilot studies are achieved, a second pivotal effectiveness study could be initiated during the first half of 2013. During the third quarter of 2012, we entered into an exclusive option to a license with North Carolina State University covering certain recombinant *Cryptosporidium parvum* technology that may have utility in the development of a dry cow vaccine. 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.

## ImmuCell Corporation

### *Administrative Expenses*

During the three-month period ended September 30, 2012, administrative expenses increased by 7%, or \$14,000 to \$231,000 as compared to the same period in 2011. During the nine-month period ended September 30, 2012, administrative expenses increased by 8%, or \$54,000, to \$701,000 as compared to the same period in 2011. While we implement efficiencies where possible, we continue to incur costs associated with complying with the Sarbanes-Oxley Act of 2002 and other costs associated with being a publicly-held company. At this stage in our development, we have limited our investment in investor relations spending. We provide a full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as Current Reports on Form 8-K when desired or deemed appropriate by management. Additional information about us is available in our annual Proxy Statement. All of these reports are filed with the SEC and are available on-line and upon request to the Company. At this time, our financial and time resources are committed principally to managing our commercial business and developing **Mast Out**<sup>®</sup>. Our Board of Directors is very involved with and supportive of this resource allocation. While this strategy of providing cost-effective investor relations through our SEC reporting is subject to change, we believe that this focus currently is in the best long-term interest of all stockholders.

### *Sales and Marketing Expenses*

During the three-month period ended September 30, 2012, sales and marketing expenses increased by 28%, or \$55,000, to \$253,000 in comparison to the same period in 2011, aggregating 23% and 20% of product sales during the three-month periods ended September 30, 2012 and 2011, respectively. During the nine-month period ended September 30, 2012, sales and marketing expenses increased by 8%, or \$53,000, to \$687,000 in comparison to the same period in 2011, aggregating 17% of product sales during both the nine-month periods ended September 30, 2012 and 2011. This level of investment in 2012 and 2011 was expected and planned given our strategic decision to invest in additional sales and marketing efforts. This investment may have driven, at least in part, our recent increase in product sales. Our current budgetary objective is to maintain the ratio of product selling expenses to product sales below 20% for the full year 2012.

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

Our loss before income taxes was (\$94,000) during the three-month period ended September 30, 2012 in comparison to a loss before income taxes of (\$211,000) during the three-month period ended September 30, 2011. Our income tax benefit was (33%) and (39%) of our loss before income taxes during the three-month periods ended September 30, 2012 and 2011, respectively. Our net loss for the three-month period ended September 30, 2012 was (\$64,000), or



(\$0.02) per share, in comparison to a net loss of (\$128,000), or (\$0.04) per share, during the three-month period ended September 30, 2011. Our income before income taxes was \$203,000 during the nine-month period ended September 30, 2012 in contrast to a loss before income taxes of (\$699,000) during the nine-month period ended September 30, 2011. Our income tax expense (benefit) was 48% and (41%) of our income (loss) before income taxes during the nine-month periods ended September 30, 2012 and 2011, respectively. Our net income for the nine-month period ended September 30, 2012 was \$106,000, or \$0.03 per share, in contrast to a net loss of (\$409,000), or (\$0.14) per share, during the nine-month period ended September 30, 2011. The improved financial performance is principally due to planned reductions in product development expenses associated with our **Mast Out**<sup>®</sup> initiative, as well as increased gross margin for sales of **First Defense**<sup>®</sup> during both the three-month and nine-month periods ended September 30, 2012.

## LIQUIDITY AND CAPITAL RESOURCES

Since 1999, our strategy has been focused on selling and developing products that improve animal health and productivity in the dairy and beef industries. These product opportunities are generally less expensive to develop than the human health product opportunities that we had worked on during the 1990's. We funded most of our product development expenses principally from product sales and were profitable for each of the nine years in the period ended December 31, 2007. During the nine years of profitability from 1999 through 2007, our cumulative investment in product development expenses of \$9,894,000 was supported, in small part, by \$975,000 in grant awards. The investment of an additional \$6,604,000 in product development expenses during 2011, 2010, 2009 and 2008, together with an additional \$683,000 during the first nine months of 2012, brings our cumulative investment to \$17,182,000 during the 13.75-year period ended September 30, 2012.

## ImmuCell Corporation

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

Prior to the fourth quarter of 2012, we had been estimating that it would require approximately \$13,000,000 to complete the development of **Mast Out<sup>®</sup>** and bring the product to market, sales of which are subject to FDA approval. This investment budget was comprised of costs primarily related to the manufacture of full-scale validation batches and commercial inventory. In addition to the use of some of our cash, we had been seeking partner funding, debt issuance, equity financing and state and other financial incentives to support the investment required to manufacture the Active Pharmaceutical Ingredient (API). Absent such funding, we have not initiated the construction of our own API manufacturing facility as of this date. In light of the lack of satisfactory progress in our discussions with prospective commercialization partners, despite many months of effort, we changed our API manufacturing strategy during the fourth quarter of 2012. We have decided to seek a lease to an existing facility and have initiated the planning and engineering process to install the necessary equipment and infrastructure to produce the API in a facility to be leased by us. We estimate that this investment will aggregate approximately \$6,000,000. Given the revised API production strategy, we currently have most of the capital required to execute the initial market launch of **Mast Out<sup>®</sup>** internally, and we expect that we can fill any financing deficit with a modest amount of debt if other more favorable sources of funds do not become available to us. We believe this more frugal commercialization strategy (leasing an existing facility rather than building a new one or relying on a contract manufacturer) improves our competitiveness and increases our opportunity for success. The large minimum production volumes and high cost imposed by a contract manufacturer and the size of the investment required to build a new facility dedicated to the production of the API for this one product have been impediments to closing a partner deal to date. However, we continue to believe that the appropriate marketing partner would maximize the commercial sales potential for the product, and we will continue to seek a partnership that would provide funding in return for marketing rights. The information that we have learned during negotiations with potential partners to date has increased our confidence in the likelihood of achieving FDA approval and in the potential value of the market opportunity for **Mast Out<sup>®</sup>**.

We had approximately \$4,820,000 in available cash and short-term investments as of September 30, 2012. The table below summarizes the changes in selected, key balance sheet items (in thousands, except for percentages):

As of	As of	(Decrease)	
September 30, 2012	December 31, 2011	Increase	%
		\$	

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Cash, cash equivalents and short-term investments	\$ 4,820	\$ 4,960	\$ (140)	(3)%
Total assets	10,971	10,991	(20 )	(0.2 )
Net working capital	6,719	6,516	203	3
Stockholders' equity	\$ 9,199	\$ 9,020	\$179	2 %

Net cash provided by operating activities amounted to \$181,000 during the nine-month period ended September 30, 2012 as compared to net cash used for operating activities of (\$332,000) during the nine-month period ended September 30, 2011. Capital investments of \$250,000 during the first nine months of 2012 compared to capital investments of \$188,000 during the first nine months of 2011. During the third quarter of 2010, we agreed to terms of certain credit facilities with TD Bank, N.A. aggregating up to approximately \$2,100,000, which are secured by substantially all of our assets. These credit facilities are comprised of a \$1,000,000 ten-year mortgage loan, a \$600,000 fifty-four month note and a \$500,000 line of credit. Proceeds from the \$1,000,000 mortgage were received during the third quarter of 2010. Proceeds from the \$600,000 note were received during the first quarter of 2011. The \$500,000 line of credit is available as needed.

We believe that we have sufficient capital resources to meet our working capital obligations and to finance our ongoing business operations during at least the next twelve months. We intend to continue pursuing the availability of debt issuance or equity financing on terms that are acceptable to us to supplement our product development initiatives.

## **ImmuCell Corporation**

As part of our sustained investment in compliance with cGMP regulations across our product lines and as we make other process improvements, we are investing in personnel, equipment and facility modifications to increase the efficiency and quality of our operations. Our Board of Directors authorizes the size of this investment in capital expenditures for facility modifications and production equipment. As of October 1, 2012, we had remaining available authorization to spend up to \$83,000 on capital expenditures, which authorized amount is net of a \$100,000 increase that was approved by our Board of Directors during the first quarter of 2012.

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

None

### **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, 2012. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

#### *Changes in Internal Controls over Financial Reporting*

The individual who serves as our principal executive and principal financial officer periodically evaluates any change in internal control over financial reporting which has occurred during the prior fiscal quarter. Management has concluded that there was no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control

over financial reporting.

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**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

None

**ITEM 1A. RISK FACTORS**

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: projections of future financial performance; future compliance with bank debt covenants; the scope and timing of future product development work and commercialization of our products; future costs of product development efforts; future sources of financial support for our product development, manufacturing and marketing efforts; the timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future realization of deferred tax assets; factors that may affect the dairy industry and future demand for our products; the accuracy of our understanding of our distributors’ ordering patterns; anticipated changes in our manufacturing capabilities and efficiencies; the amount and timing of future investments in facility modifications and production equipment or the availability and cost of alternative manufacturing and/or distribution resources; the future adequacy of our working capital and the availability of third party financing; timing and future costs of our self-sourcing facility to produce API for **Mast Out**<sup>®</sup>; future expense ratios; costs and timing associated with sustaining compliance with cGMP regulations in our current operations and attaining such compliance for our planned self-sourcing facility to produce API for **Mast Out**<sup>®</sup>; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as “expects”, “may”, “anticipates”, “intends”, “would”, “could”, “should”, “will”, “believes”, “estimates”, “targets” and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate, especially considering the effects the distress in credit and capital markets will have on our current and prospective customers and the global economy and the uncertainties surrounding the potential for a prolonged global recession. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, the uncertainties associated with product development, manufacturing reliance upon third parties for products and services, changes in laws and regulations, decision making by regulatory authorities, currency fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized below and uncertainties otherwise referred to in this Quarterly Report.

*Projection of net income:* After nine consecutive years of reporting net income, we reported a net loss for the years ended December 31, 2011, 2010, 2009 and 2008, due in large part to our product development strategy. By reducing our investment in the development of **Mast Out**<sup>®</sup>, we were able to record net operating income of \$233,000 and net income of \$106,000 during the first nine months of 2012. We expect to record net income of approximately \$175,000 for the year ending December 31, 2012. Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Stronger than expected sales of **First Defense**<sup>®</sup>, for example, could increase our net income. Conversely, weaker than expected sales of **First Defense**<sup>®</sup> could lead to less profits. As we invest a significant amount of our capital in the **Mast Out**<sup>®</sup> development initiative, we anticipate replenishing our working capital over time from future profitability.

*Reliance on sales of First Defense*<sup>®</sup>: We are heavily reliant on the market acceptance of **First Defense**<sup>®</sup> to generate product sales and fund our operations. Our business would not have been profitable during either the nine consecutive years in the period ended December 31, 2007 or the nine-month period ended September 30, 2012, and our net losses would have been larger during the four years in the period ended December 31, 2011, without the gross margin that we earned from the sale of **First Defense**<sup>®</sup>.

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*Economics of the dairy industry:* The U.S. dairy industry has been facing very difficult economic pressures. Sales of our products may be influenced by the prices of milk, milking cows and calves. The size (annual average) of the U.S. dairy herd ranged from approximately 9,011,000 to 9,199,000 cows from 1998 to 2007. This annual average jumped to 9,315,000 cows in 2008. The annual average then declined to 9,203,000 in 2009 and further to 9,119,000 in 2010 before increasing to 9,194,000 in 2011. The average herd size for the first nine months of 2012 increased to 9,242,000, but the average herd size for the third quarter of 2012 of 9,195,000 was more in line with the annual average for 2011. 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 influenced by very volatile international demand for milk products. The Class III milk price is an industry benchmark that reflects the value of product used to make cheese. The Class III milk price (which is largely out of the direct control of individual dairy producers) is an important indicator because it defines our customers' revenue level. The average Class III milk price for 2009 was \$11.36, which represented a 35% decrease from 2008. The average price for 2009 was 36% lower than the average experienced during the two-year period ended December 31, 2008. For 2010, this price level averaged \$14.41, which represented a 27% increase from 2009 but was well below the 2007 and 2008 levels. This price level averaged \$18.37 for 2011, which represents a 27% increase from 2010. This average price level for 2011 was higher than the annual average reached in any of the past 30 years, but then it began to decline in 2012. For the third quarter of 2012, this price level averaged \$17.80 compared to \$20.71 for the third quarter of 2011. For the first nine months of 2012, this price level averaged \$16.54 compared to \$18.28 for the first nine months of 2011. The actual level of milk prices may be less important than their level relative to costs. The recent improvement in milk prices has been offset, in part, by higher feed costs. One measure of this relationship is known as the milk-to-feed price ratio, which represents the amount of feed that one pound of milk can buy. Whenever this ratio meets or exceeds 3.0, it is considered profitable to buy feed and produce milk. For 2009, this ratio averaged 1.78, representing a 12% decrease compared to 2008. For 2010, this ratio averaged 2.26, representing a 27% increase compared to 2009. For 2011, this ratio averaged approximately 1.88 representing a 17% decrease compared to 2010. For the third quarter of 2012, this ratio averaged approximately 1.39, and for the first nine months of 2012, this ratio averaged approximately 1.45, which represents record lows since the ratio was first recorded in 1985. This means that a dairy producer can buy only 1.45 pounds of feed for every pound of milk sold. An increase in feed costs also has a negative impact on the beef industry. Ongoing widespread severe drought conditions in key U.S. agricultural regions have driven feed costs higher. Another indication of the economic condition of the dairy industry is the average price for animals sold for dairy herd replacement. In 2009, this average price (reported as of January, April, July and October) was estimated to be approximately \$1,385, which was a 29% decrease in comparison to the same period in 2008. This price averaged approximately \$1,330 in 2010, which represented a 4% decrease in comparison to the same period in 2009. This price averaged approximately \$1,420 in 2011, which represents a 7% increase in comparison to the same period in 2010. This price averaged approximately \$1,428 in 2012, which represents a 1% increase in comparison to the same period in 2011. The dairy industry data referred to above is compiled from USDA databases. Another factor in the demand for our product is the decline in the value of bull calves. We are trying to maintain and grow our sales for use with heifer calves to offset what we assume is a 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**<sup>®</sup> could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms on suitable terms.



*Product development risks:* The development of new products is subject to financial, scientific, regulatory and market risks. Our current business growth strategy relies heavily on the development of **Mast Out<sup>0</sup>** which requires (and will continue to require) a substantial investment. Our new self-sourcing strategy for the production of API for **Mast Out<sup>0</sup>** in a facility to be leased by us carries a substantial amount of risk. Absent outside funding, we will invest a substantial amount of our capital into this initiative. Our efforts will be subject to inspection and approval by the FDA. There is no assurance whether or when we will obtain all of the data necessary to support regulatory approval for this product.

*Risks associated with **Mast Out<sup>0</sup>** funding strategy:* Completing the development of **Mast Out<sup>0</sup>** through to the submission of the administrative NADA to the FDA involves a great deal of risk. We may not be able to obtain financing to fund the completion of this product development effort on terms acceptable to us. We estimate that our new strategy to produce the API for **Mast Out<sup>0</sup>** in a leased facility will significantly reduce the amount of this investment. We are evaluating alternative financial strategies in order to gain NADA approval and to support the product launch.

*Regulatory requirements for **Mast Out<sup>0</sup>**:* The commercial introduction of **Mast Out<sup>0</sup>** 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<sup>0</sup>**, who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. International regulatory approvals would be required for sales outside of the United States. European regulatory authorities are not expected to approve a product with a zero milk discard claim, which would remove a significant competitive advantage of **Mast Out<sup>0</sup>** in that territory. However, the milk discard period may be shorter for **Mast Out<sup>0</sup>** than it is for other products on the market.

## **ImmuCell Corporation**

*Uncertainty of market estimates:* Even assuming that **Mast Out**<sup>®</sup> 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.

*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. 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**<sup>®</sup> will compete successfully in this market.

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

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

None

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4. MINE SAFETY DISCLOSURES**

None

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

Exhibit 31 Certifications required by Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit 32 Certification required by Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS XBRL Instance Document.

101.SCH XBRL Taxonomy Extension Schema Document.

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB XBRL Taxonomy Extension Label Linkbase Document.

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

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**ImmuCell Corporation**

**SIGNATURE**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ImmuCell Corporation  
Registrant

Date: November 13, 2012 By: /s/ Michael F. Brigham  
Michael F. Brigham  
President, Chief Executive  
Officer  
and Principal Financial  
Officer