IMMUCELL CORP /DE/
Form 10-Q
November 12, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2014

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 7, 2014 was 3,027,034.

ImmuCell Corporation

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ImmuCell Corporation

PART 1.
FINANCIAL
INFORMATION

ITEM 1.
FINANCIAL
STATEMENTS

BALANCE
SHEETS

	(Unaudited) As of September 30, 2014	As of December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,166,211	$ 2,270,385
Short-term investments	2,985,000	2,985,000
Inventory	1,039,446	1,206,508
Accounts receivable, net	563,564	631,410
Prepaid expenses and other assets	336,622	159,117
Current portion of deferred tax asset	0	15,212
Total current assets	6,090,843	7,267,632
PROPERTY, PLANT AND EQUIPMENT, net	2,793,624	2,524,765
DEFERRED TAX ASSET	1,340,853	1,154,681
LONG-TERM INVESTMENTS	496,000	0
OTHER ASSETS, net	19,649	13,636
TOTAL ASSETS	$ 10,740,969	$ 10,960,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$ 367,233	$ 293,076
Accounts payable	241,019	152,153
Deferred tax liability	24,688	0
Current portion of bank debt	185,004	190,390
Deferred revenue	6,690	0
Total current liabilities	824,634	635,619

LONG-TERM LIABILITIES:		
Long-term portion of bank debt	759,964	896,224
Interest rate swap	32,680	33,002
Total long-term liabilities	792,644	929,226
TOTAL LIABILITIES	1,617,278	1,564,845
STOCKHOLDERS' EQUITY:		
Common stock, $0.10 par value per share, 8,000,000 shares authorized, 3,261,148 shares issued as of September 30, 2014 and December 31, 2013	326,115	326,115
Capital in excess of par value	10,034,566	10,011,339
Accumulated deficit	(705,194)	(407,408)
Treasury stock, at cost, 234,114 and 235,114 shares as of September 30, 2014 and December 31, 2013, respectively	(512,153)	(514,341)
Accumulated other comprehensive loss	(19,643)	(19,836)
Total stockholders' equity	9,123,691	9,395,869
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 10,740,969	$ 10,960,714

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,	
	2014	2013	2014	2013
Product sales	$1,770,129	$1,234,701	$5,391,599	$4,447,928
Costs of goods sold	692,233	618,984	2,285,285	1,994,967
Gross margin	1,077,896	615,717	3,106,314	2,452,961
Product development expenses	361,232	290,853	1,716,114	829,190
Sales and marketing expenses	373,595	258,237	921,588	725,508
Administrative expenses	302,216	226,594	873,866	707,841
Operating expenses	1,037,043	775,684	3,511,568	2,262,539
NET OPERATING INCOME (LOSS)	40,853	(159,967)	(405,254)	190,422
Other (expenses) revenues, net	(11,246)	236,868	(38,633)	267,646
INCOME (LOSS) BEFORE INCOME TAXES	29,607	76,901	(443,887)	458,068
Income tax (expense) benefit	(19,277)	(19,565)	146,101	(189,970)
NET INCOME (LOSS)	$10,330	$57,336	$(297,786)	$268,098
Weighted average common shares outstanding:				
Basic	3,027,034	3,019,034	3,026,990	3,019,034
Diluted	3,105,832	3,085,300	3,026,990	3,081,984
NET INCOME (LOSS) PER SHARE:				
Basic	$0.00	$0.02	$(0.10)	$0.09
Diluted	$0.00	$0.02	$(0.10)	$0.09

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

ImmuCell Corporation

(Unaudited)

STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	For the Three-Month Periods Ended September 30,		For the Nine-Month Periods Ended September 30,	
	2014	2013	2014	2013
Net income (loss)	$10,330	$57,336	$(297,786)	$268,098
Other comprehensive income:				
Interest rate swap, before taxes	8,347	90	322	40,392
Income tax applicable to interest rate swap	(3,330)	(36)	(129)	(16,113)
Other comprehensive income, net of taxes	5,017	54	193	24,279
Total comprehensive income (loss)	$15,347	$57,390	$(297,593)	$292,377

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

ImmuCell Corporation

(Unaudited)

STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock $0.10 Par Value		Capital in Excess of	Accumulated	Treasury Stock		Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Par Value	Deficit	Shares	Amount	Loss	Equity
Balance as of December 31, 2013	3,261,148	$326,115	$10,011,339	$(407,408)	235,114	$(514,341)	$(19,836)	$9,395,869
Net (loss)	0	0	0	(297,786)	0	0	0	(297,786)
Other comprehensive income, net of taxes	0	0	0	0	0	0	193	193
Exercise of stock options	0	0	962	0	(1,000)	2,188	0	3,150
Stock-based compensation	0	0	22,265	0	0	0	0	22,265
Balance as of September 30, 2014	3,261,148	$326,115	$10,034,566	$(705,194)	234,114	$(512,153)	$(19,643)	$9,123,691

	Common Stock $0.10 Par Value		Capital in Excess of	Accumulated	Treasury Stock		Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Par Value	Deficit	Shares	Amount	Loss	Equity
Balance as of December 31, 2012	3,261,148	$326,115	$9,973,146	$(524,803)	242,114	$(529,655)	$(50,120)	$9,194,683
Net income	0	0	0	268,098	0	0	0	268,098
Other comprehensive income, net of	0	0	0	0	0	0	24,279	24,279

taxes								
Stock-based compensation	0	0	24,261	0	0	0	0	24,261
Balance as of September 30, 2013	3,261,148	$326,115	$9,997,407	$(256,705)	242,114	$(529,655)	$(25,841)	$9,511,321

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,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	$(297,786)	$268,098
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation	330,796	293,116
Amortization	2,158	2,175
Deferred income taxes	(146,401)	189,672
Stock-based compensation	22,265	24,261
Loss on disposal of fixed assets	4,519	36
Changes in:		
Receivables	67,846	208,051
Inventory	167,062	158,478
Prepaid expenses and other assets	(185,676)	44,957
Accrued expenses	74,157	(43,486)
Accounts payable	4,835	(130,532)
Deferred revenue	6,690	0
Net cash provided by operating activities	50,465	1,014,826
CASH FLOWS FROM INVESTING ACTIVITIES :		
Purchase of property, plant and equipment	(520,142)	(120,136)
Maturities of short-term investments	2,489,000	2,240,000
Purchases of short-term investments	(2,489,000)	(2,738,000)
Purchases of long-term investments	(496,000)	0
Net cash (used for) investing activities	(1,016,142)	(618,136)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Debt principal repayments	(141,647)	(135,047)
Proceeds from exercise of stock options	3,150	0
Net cash (used for) financing activities	(138,497)	(135,047)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,104,174)	261,643
BEGINNING CASH AND CASH EQUIVALENTS	2,270,385	2,673,719
ENDING CASH AND CASH EQUIVALENTS	$1,166,211	$2,935,362
INCOME TAXES PAID	$1,752	$0

INTEREST EXPENSE PAID	$44,771	$51,118
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable	$84,031	$68,100
Net change in fair value of interest rate swap	$(193)	$(24,279)

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

ImmuCell Corporation
NOTES TO UNAUDITED FINANCIAL STATEMENTS

September 30, 2014

1. BUSINESS OPERATIONS

ImmuCell Corporation (the Company) is a growing animal health company whose purpose is to create scientifically-proven and practical products that improve animal health and productivity in the dairy and beef industries. The Company has developed products that provide significant, immediate immunity to newborn dairy and beef cattle and is in the late stages of developing a new product that addresses mastitis, the most significant cause of economic loss to the dairy industry.

2. 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 ensure that the financial statements are not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP in these footnotes are to the FASB *Accounting Standards Codification*™ (Codification). Certain prior year accounts have been reclassified to conform with the 2014 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 ensure that the information presented is not misleading, these financial statements should be read in conjunction with the financial statements for the year ended December 31, 2013 and the notes thereto, contained in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission.

3. NEW ACCOUNTING PRONOUNCEMENTS

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. ASU 2014-09 is effective for the Company on January 1, 2017. Early application is not permitted. ASU 2014-09 permits the use of either the retrospective or cumulative effect transition method. We have evaluated the effect that ASU 2014-09 would have on our consolidated financial statements and related disclosures and determined that ASU 2014-09 will have no significant effect on our ongoing

financial reporting.

4. CASH, CASH EQUIVALENTS, SHORT-TERM AND LONG-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 of $250,000 per financial institution per depositor 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. Long-term investments are similar to short-term investments except that they mature in more than twelve months from the balance sheet date. Amounts in excess of FDIC limits per bank that are not invested in securities backed by the U.S. government aggregated $666,000 and $1,770,000 at September 30, 2014 and December 31, 2013, respectively. Cash, cash equivalents, short-term and long-term investments consisted of the following:

	As of September 30, 2014	As of December 31, 2013	(Decrease) Increase
Cash and cash equivalents	$ 1,166,211	$ 2,270,385	$(1,104,174)
Short-term investments	2,985,000	2,985,000	0
Subtotal	4,151,211	5,255,385	(1,104,174)
Long-term investments	496,000	0	496,000
Total	$ 4,647,211	$ 5,255,385	$(608,174)

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2014

5. 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, 2014	As of December 31, 2013	Increase (Decrease)
Raw materials	$ 292,364	$ 270,355	$ 22,009
Work-in-process	507,319	783,060	(275,741)
Finished goods	239,763	153,093	86,670
Inventory	$ 1,039,446	$ 1,206,508	$ (167,062)

6. ACCOUNTS RECEIVABLE

Accounts receivable consisted of the following:

	As of September 30, 2014	As of December 31, 2013	(Decrease) Increase
Trade accounts receivable, gross	$ 550,401	$ 609,638	$ (59,237)
Less: allowance for bad debt and product returns	15,704	13,952	1,752
Trade accounts receivable, net	534,697	595,686	(60,989)
Other receivables	27,367	35,676	(8,309)
Income taxes receivable	1,500	48	1,452
Accounts receivable, net	$ 563,564	$ 631,410	$ (67,846)

7. PROPERTY, PLANT AND EQUIPMENT

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

	As of September 30, 2014	As of December 31, 2013	Increase
Laboratory and manufacturing equipment	$ 3,439,164	$ 3,182,686	$256,478
Building and improvements	2,963,717	2,940,239	23,478
Office furniture and equipment	467,230	354,243	112,987
Construction in progress	204,253	9,600	194,653
Land	50,000	50,000	0
Property, plant and equipment, gross	7,124,364	6,536,768	587,596
Less: accumulated depreciation	4,330,740	4,012,003	318,737
Property, plant and equipment, net	$ 2,793,624	$ 2,524,765	$268,859

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2014

8. 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, which is renewable annually. 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 based on the London Interbank Offered Rate (LIBOR) of 3.40% as of September 30, 2014 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 loan. The notional amount of the interest rate swap was $813,209 as of September 30, 2014. Payments required by the interest rate swap totaled $5,538 and $5,791 during the three-month periods ended September 30, 2014 and 2013, respectively, and $16,726 and $17,417 during the nine-month periods ended September 30, 2014 and 2013, respectively. As the result of our decision to hedge this interest rate risk, we recorded other comprehensive income, net of taxes, in the amount of $5,017 and $54 for the three-month periods ended September 30, 2014 and 2013, respectively, and $193 and $24,279 for the nine-month periods ended September 30, 2014 and 2013, respectively, which reflects the change in fair value of the interest rate swap 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 per annum of 4.25% or the LIBOR plus 3.25%. As of September 30, 2014, the effective interest rate on this note was 4.25%. The $500,000 line of credit is available as needed and has been extended through May 31, 2015 and is renewable annually thereafter. The line of credit was unused as of September 30, 2014 and December 31, 2013. Interest on any borrowings against the line of credit would be variable at the higher rate per annum of 4.25% or the 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, 2014. Principal payments due under debt outstanding as of September 30, 2014 are reflected in the following table by the period that payments are due:

Period	$1,000,000 mortgage	$600,000 note	Total
Three months ending December 31, 2014	$ 13,245	$35,436	$48,681

Twelve months ending December 31, 2015	54,044	96,323	150,367
Twelve months ending December 31, 2016	57,384	0	57,384
Twelve months ending December 31, 2017	61,056	0	61,056
Twelve months ending December 31, 2018	64,876	0	64,876
Twelve months ending December 31, 2019	68,908	0	68,908
Eight months ending August 31, 2020	493,696	0	493,696
Total outstanding	$813,209	$131,759	$944,968

9. OTHER (EXPENSES) REVENUES, NET

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

	For the Three-Month Periods Ended September 30,		For the Nine-Month Periods Ended September 30,	
	2014	2013	2014	2013
License option fee[1]	$0	$250,000	$0	$250,000
Royalty income	0	0	0	(3,000)
Interest income	3,912	3,271	11,607	9,789
Interest expense	(14,514)	(16,522)	(44,148)	(50,623)
Other	(644)	119	(6,092)	61,480
Other (expenses) revenues, net	$(11,246)	$236,868	$(38,633)	$267,646

[1]During the second quarter of 2013, we received a $250,000 exclusive option payment from a prospective partner for the development and marketing of **Mast Out®**. This payment was recorded as deferred revenue upon receipt. During the third quarter of 2013, this prospective partner decided not to execute a license after its final due diligence. Accordingly, the deferred revenue was recognized during the third quarter of 2013.

10. 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 $4,974 and $7,940 during the three-month periods ended September 30, 2014 and 2013, respectively, and $22,265 and $24,261 during the nine-month periods ended September 30, 2014 and 2013, 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.

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2014

11. 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 Internal Revenue Service 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, 2014. Although we believe that our estimates are reasonable, actual results could differ from these estimates.

12. NET INCOME (LOSS) PER 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.

13. 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.

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2014

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

On June 8, 2005, our Board of Directors voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2008. As of June 30, 2005, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. No other changes were made to the terms of the Rights or the Rights Agreement at that time. On June 6, 2008, our Board of Directors voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2011 and to increase the ownership threshold for determining Acquiring Person status from 15% to 18%. As of June 30, 2008, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase. No other changes were made to the terms of the Rights or the Rights Agreement at that time. On August 5, 2011, our Board of Directors voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2014 and to increase the ownership threshold for determining Acquiring Person status from 18% to 20%. As of August 9, 2011, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase. No other changes were made to the terms of the Rights or the Rights Agreement at that time. On June 10, 2014, our Board of Directors voted to authorize an amendment to the Rights Agreement to extend the final expiration date by an additional three years to September 19, 2017. As of June 16, 2014, we entered into an amendment to the Rights Agreements with the Rights Agent reflecting such extension. No other changes have been made to the terms of the Rights or the Rights Agreement.

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

14. 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 animal health and productivity in the dairy and beef industries. Almost all of our internally funded product development expenses are in support of such products. Our primary customers for the majority of our product sales (84% and 89% for the three-month periods ended September 30, 2014 and 2013, respectively, and 82% and 84% for the nine-month periods ended September 30, 2014 and 2013, 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 11% of our total product sales for both of the three-month periods ended September 30, 2014 and 2013, and 13% and 14% of our total product sales for the nine-month periods ended September 30, 2014 and 2013, respectively. The percentage of our total sales that were made to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

	For the Three-Month Periods Ended September 30,				For the Nine-Month Periods Ended September 30,			
	2014		2013		2014		2013	
Animal Health International, Inc.	34	%	40	%	37	%	38	%
MWI Veterinary Supply Company[(1)]	23	%	21	%	22	%	22	%

[(1)] Assumes the acquisition of IVESCO by MWI Veterinary Supply Company (which closed as of November 1, 2013) had closed as of January 1, 2013.

ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2014

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 September 30, 2014		As of December 31, 2013	
MWI Veterinary Supply Company	33	%	26	%
Animal Health International, Inc.	25	%	39	%
Robert J. Matthews Company	14	%	10	%

15. RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone Inc. (formerly Stearns Veterinary Outlet, Inc.), a domestic distributor of ImmuCell products (**First Defense**Ò, **Wipe Out**Ò **Dairy Wipes**, and **CMT**) and of Jt Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased $283,287 and $288,360 of products from ImmuCell during the nine-month periods ended September 30, 2014 and 2013, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of $6,355 and $5,072 to these affiliated companies during the nine-month periods ended September 30, 2014 and 2013, respectively. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated $2,070 and $31,445 as of September 30, 2014 and December 31, 2013, respectively.

16. SUBSEQUENT EVENTS

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

subsequent events through the time of filing on November 12, 2014, the date we have issued this Quarterly Report on Form 10-Q.

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

Financial Condition

We had approximately $4,647,000 in available cash, cash equivalents, short-term and long-term investments as of September 30, 2014. The table below summarizes the changes in selected, key balance sheet items (in thousands, except for percentages):

	As of September 30, 2014	As of December 31, 2013	(Decrease) Amount	%
Cash, cash equivalents, short-term and long-term investments	$ 4,647	$ 5,255	$(608)	(12%)
Net working capital	5,266	6,632	(1,366)	(21%)
Total assets	10,741	10,961	(220)	(2 %)
Stockholders' equity	$ 9,124	$ 9,396	$(272)	(3 %)

The decrease in net working capital resulted, in part, from a $496,000 increase in long-term investments and a $520,000 investment in fixed assets. Net cash provided by operating activities amounted to $50,000 during the nine-month period ended September 30, 2014 compared to net cash provided by operating activities of $1,015,000 during the nine-month period ended September 30, 2013. Capital investments of $520,000 during the first nine months of 2014 compared to capital investments of $120,000 during the same period in 2013. As of September 30, 2014, our outstanding bank debt balance was approximately $945,000. Our $500,000 line of credit is available as needed, but was unused as of September 30, 2014. We have utilized debt financing because we believe that the option to generate funds through the sale of equity securities at an acceptable level of stockholder dilution is unlikely. Together with gross margin earned from ongoing product sales, 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.

Since 1999, our strategy has been focused on developing, manufacturing and selling 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 were profitable for each of the nine years in the period ended December 31, 2007 and have funded most of our product development expenses principally from product sales. Our strategic decision to continue developing **Mast Out**Ò 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 a former partner from late 2004 to mid-2007. As a result, we incurred net losses of $469,000,

$216,000, $385,000 and $410,000 during the years ended December 31, 2008, 2009, 2010 and 2011, respectively. Having largely completed the significant clinical studies for **Mast Out**Ò, we reduced product development expenses during 2012 and were profitable again during 2012 and 2013, as anticipated. These expenses are increasing again in 2014, as we invest in a project to complete the regulatory approval process for **Mast Out**Ò (see next paragraph). This specifically targeted increase in product development expenses and capital expenditures resulted in a net loss during the first nine months of 2014. Despite a projected return to profitability during the last six months of 2014, we expect a net loss for the year ending December 31, 2014. Our cumulative investment in product development expenses of approximately $20,286,000 during the 15.75 year period that began on January 1, 1999 (the year we first re-focused our business strategy on animal health) and ended on September 30, 2014 was offset, in part, by $4,130,000 in licensing revenue, technology sales and grant income. We may, on occasion, seek additional research grant support as a means of leveraging the funds that we are able to spend developing new products. We continue to look for new product acquisition opportunities that would have a strategic fit with the products that we currently sell.

We are making an investment in our facility in Portland, Maine comprised of two projects with a total cost aggregating approximately $3,000,000. This investment is an integral part of our strategy to: 1) increase production capacity for our current products, 2) maintain compliance with current Good Manufacturing Practice (cGMP) regulations in all of our operations and 3) integrate the production of pharmaceutical-grade Nisin for **Mast Out**Ò and our topical wipe products. The specific objective of the first project is to modify and equip a portion of our facility to produce pharmaceutical-grade Nisin. This project was substantially completed on budget and in accordance with our timeline at the beginning of the third quarter of 2014. The specific objective of the second project is to construct a two-story addition to our facility to provide us with approximately 7,200 additional square feet for cold storage, production and warehouse space. We expect to complete this construction project and begin utilizing the new space during the fourth quarter of 2014. The following chart details the status of spending on these two projects:

	Total Expenses	Total Fixed Assets	Total Expenses and Fixed Assets
Three-month period ended December 31, 2013	$110,000	$0	$110,000
Nine-month period ended September 30, 2014	970,000	447,000	1,416,000
Twelve-month period ended September 30, 2014	1,080,000	447,000	1,526,000
Budgeted and not yet spent	32,000	1,441,000	1,474,000
Total investment budget	$1,112,000	$1,888,000	$3,000,000

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We are making a sustained investment in increasing our current production capacity for **First Defense**Ò and maintaining compliance with cGMP regulations, which is required for the production of **Mast Out**Ò and **Wipe Out**® **Dairy Wipes**, and we have elected to implement these quality standards with respect to all of our products. This effort requires an ongoing investment in personnel, equipment and facility modifications to increase the efficiency and quality of our operations. During the first quarter of 2013, the U.S. Food and Drug Administration conducted a routine inspection of our facilities and operations. The report from this inspection was very favorable, and we responded to the few, minor observations that were noted. As of October 1, 2014, we had remaining available authorization from our Board of Directors to spend up to approximately $633,000 on additional capital expenditures, which amount is separate from the $3,000,000 investment described above.

Results of Operations

Product Sales

Total product sales for the three-month period ended September 30, 2014 increased by 43%, or $535,000, to $1,770,000 from $1,235,000 during the same period in 2013. Total product sales for the nine-month period ended September 30, 2014 increased by 21%, or $944,000, to $5,392,000 from $4,448,000 during the same period in 2013. Total product sales for the twelve-month period ended September 30, 2014 increased by 18%, or $1,082,000, to $6,951,000 from $5,869,000 during the twelve-month period ended September 30, 2013. During the nine-month period ended September 30, 2014, domestic product sales increased by 21%, or $784,000, and international sales increased by 22%, or $160,000, in comparison to the first nine months of 2013.

Our lead product, **First Defense**Ò, continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent scours (bovine enteritis or diarrhea) in newborn calves. We believe that the annual cost of scours is approximately $349,000,000 to the dairy industry and approximately $412,000,000 to the beef industry (totaling approximately $761,000,000 to the calf industry). These figures include estimates of the costs of deaths, treatments, reduced weight gains and reduced milk production. The actual costs of scours may be higher or lower. Sales growth of our product may be attributed, in part, to a shortage of inventory being experienced by the manufacturer of a competitive product. We are expecting to see continued growth in product sales throughout 2014. Based on market research that we acquired, we estimate that during 2012 approximately 22% of all calves that were treated with one of the three leading U.S. Department of Agriculture (USDA) approved scours preventative products were treated with our product. We estimate that our market share increased to approximately 25% during 2013, and we project that our market share will increase to approximately 28% during 2014. The actual market share of our product line could be higher or lower.

The **First Defense**Ò product line aggregated 90% and 91% of our total product sales during the three-month periods ended September 30, 2014 and 2013, respectively. The **First Defense**Ò product line aggregated 90% and 91% of our total product sales during the nine-month periods ended September 30, 2014 and 2013, respectively. Sales of the **First Defense**Ò product line increased by 41% during the three-month period ended September 30, 2014, in comparison to the same period in 2013. Sales of the **First Defense**Ò product line increased by 20% during the nine-month period ended September 30, 2014, in comparison to the same period in 2013. We have realized consistently positive sales growth of the **First Defense**Ò product line for the last nine consecutive quarters and for fifteen of the last sixteen quarters (with the single exception being the second quarter of 2012) in comparison to the same quarters of the prior year, as demonstrated in the following chart:

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We believe that this long-term growth in sales of **First Defense®** may reflect, at least in part, the success of our strategic decision initiated in 2010 to invest in additional sales and marketing efforts. With the addition of a new regional sales and marketing manager in both Wisconsin and California during the third quarter of 2014, our sales and marketing team currently consists of one director and five regional sales and marketing managers. Our office manager and facilities manager support our sales efforts by performing order entry, sales support and shipping duties. We launched a new communications campaign at the end of 2010 that continues to emphasize the unique ability of **First Defense®** to deliver **Immediate Immunity™** to newborn calves against *E. coli* and coronavirus infections, reducing morbidity and mortality caused by scours. Preventing newborn calves from becoming sick helps them to reach their genetic potential. Scours-afflicted calves can be compromised for the remainder of their lives, rarely achieving their optimal weight potential and milk production. Progressive dairy and beef producers understand the value of shifting to a disease prevention strategy to avoid the higher costs of disease treatment. **First Defense®** provides maximal protection when used during the first 12 hours after birth in conjunction with good colostrum and nutrition feeding programs. During early 2014, we conducted a targeted marketing campaign focusing on the beef industry, which has received a positive response. As we continue to introduce **First Defense®** to new customers, our product sales are benefiting from the relatively strong price of milk and beef, which increases the value of calves and cows.

Competition for resources that dairy and beef producers allocate to their calf enterprises has been increased by the many new products that have been introduced to the calf market. The animal health distribution segment has been aggressively consolidating over the last few years with larger distributors acquiring smaller distributors. Our sales are normally seasonal, with higher sales expected during the first quarter. It appears that warm and dry weather reduces the producer's perception of the need for **First Defense®**. Heat stress on calves caused by extremely hot summer weather can increase the incidence of scours. The severe heat and drought conditions during the summer of 2012 in many key agricultural regions in North America caused a significant increase in the cost of feed that offset some improvement in milk prices. The harsh winter weather in late 2013 and early 2014 and an improving milk price may have benefited our sales. Although beef herd numbers are down currently because of the continuing effects of the 2012 drought conditions in many parts of North America, the value of newborn calves has increased as producers re-build their herd levels. We believe that such an upswing increases a producer's likelihood to invest in **First Defense®** for their calf crop.

In addition to the **First Defense®** capsule in a 5-dose and 30-dose box, we are selling product applications of our **First Defense Technology™**, which is a unique whey protein concentrate derived from colostrum that is processed utilizing our proprietary milk protein purification methods, for the nutritional and feed supplement markets without the claims of our product that is licensed by the USDA. Through our **First Defense Technology™**, we are selling concentrated whey proteins in different formats. During the first quarter of 2011, we initiated sales of **First Defense Technology™** in a bulk powder format (no capsule), which is delivered with a scoop and mixed with colostrum for feeding to calves. 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**. 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.

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We sell topical wipes that are pre-moistened with a Nisin-based formulation in two product formats. Since 1999, we have been selling **Wipe Out® Dairy Wipes** (our second leading source of product sales) for use in preparing the teat area of a cow for milking. Sales of **Wipe Out® Dairy Wipes** decreased by 3% during the nine-month period ended September 30, 2014 in comparison to the same period during 2013. We are competing aggressively on selling price against less expensive products and alternative teat sanitizing methods. We believe that sales growth potential for **Wipe Out® Dairy Wipes** is limited because most of our sales of this product tend to be to smaller dairies that are under continued financial pressures. Such pressures are forcing many small dairy producers out of business. While our product is a high quality tool, there are less expensive ways to sanitize a cow's udder prior to milking, and many producers opt for a less expensive alternative. During the first quarter of 2013, we initiated sales of Nisin-based wipes for pets in a 120-count canister (Preva™ wipes) to Bayer HealthCare Animal Health of St. Joseph, Missouri for commercial sales to pet owners. A 73% increase in sales of this product during the first nine months of 2014 in comparison to the first nine months of 2013, turned the drop in sales of **Wipe Out® Dairy Wipes** into a 14% increase in sales of the topical wipe product line as a whole.

Sales of our **California Mastitis Test (CMT)** (our third leading source of animal health product sales) were essentially unchanged during the nine-month period ended September 30, 2014 in comparison to the same period during 2013. We also make and sell bulk reagents for Isolate™ (formerly known as Crypto-Scan®), which is a drinking water test that is sold by our distributor in Europe. Sales of Isolate™ amounted to approximately 3% and 2% of the total product sales during the nine-month periods ended September 30, 2014 and 2013, respectively.

Gross Margin

We implemented a price increase for the **First Defense®** product line effective August 1, 2014. Previously, the most recent price increase (a modest one) was during the first quarter of 2008. Prior to that, we had generally held our product selling prices without increase during the seven-year period ended December 31, 2007. We have limited our price increases, believing that we could benefit more from higher unit sales than through a higher average selling price per unit. This strategy recognizes that while selling a premium-priced product, we must be very efficient with our manufacturing costs to maintain a healthy gross margin. Changes in the gross margin on product sales are summarized in the following table for the respective periods (in thousands, except for percentages):

	For the Three-Month Periods Ended September 30,		Increase	
	2014	2013	Amount	%
Gross margin	$1,078	$616	$462	75%

Percent of product sales	61 %	50 %	11 %	22%

	For the Nine-Month Periods Ended September 30,		Increase	
	2014	2013	Amount	%
Gross margin	$3,106	$2,453	$653	27%
Percent of product sales	58 %	55 %	2 %	4 %

	For the Twelve-Month Periods Ended September 30,		Increase (Decrease)	
	2014	2013	Amount	%
Gross margin	$3,714	$3,203	$511	16%
Percent of product sales	53 %	55 %	(1 %)	(2 %)

The gross margin as a percentage of product sales was 51% and 57% during the years ended December 31, 2013 and 2012, respectively. The Company expects margins to be maintained above 50% throughout 2014. However, the gross margin dropped to 44% during the six-month period ended December 31, 2013 principally because we reduced production output during that period in order to upgrade certain pieces of critical manufacturing equipment. These investments were completed during the fourth quarter of 2013. Our inventory balance was reduced by 23%, or $366,000, to $1,207,000 at December 31, 2013 from $1,573,000 as of June 30, 2013. This level of investment as of June 30, 2013 helped us prevent a backlog of orders, while we slowed inventory production to make the equipment upgrades during the second half of 2013. As of September 30, 2014, our inventory balance was $1,039,000. We are working to rebuild inventory back to historical levels, during a time of growing sales, with production back at full and increased capacity. A number of other factors contribute to the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter. The gross margin on **First Defense**Ò is affected by biological yields from our raw material, which do vary over time. Like most U.S. manufacturers, we have been experiencing increases in the cost of raw materials that we purchase. The costs for production of **First Defense**Ò and **Wipe Out**Ò **Dairy Wipes** have increased due to increased labor costs and other expenses associated with our efforts to sustain compliance with cGMP regulations in our production processes. We have been able to minimize the impact of these cost increases by implementing process improvements that have resulted in better yields. Product mix also affects gross margin in that we earn a higher gross margin on **First Defense**Ò and a lower gross margin on **Wipe Out**Ò **Dairy Wipes**. It is our production and customer service objective to ship orders within one day of receipt. We have been operating generally in accordance with this objective since the third quarter of 2009. However, from February to early May of 2014, we experienced a few, short delays in shipping customer orders of **First Defense**Ò, while we were rebuilding our inventory on-hand to the desired levels. Given current production and sales projections, we do not expect further shipment delays.

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Product Development Expenses

Product development expenses increased by 24%, or $70,000, to $361,000 during the three-month period ended September 30, 2014, as compared to $291,000 during the same period in 2013. Product development expenses aggregated 20% and 24% of product sales during the third quarters of 2014 and 2013, respectively. Product development expenses increased by 107%, or $887,000, to $1,716,000 during the nine-month period ended September 30, 2014, as compared to $829,000 during the same period in 2013. Product development expenses aggregated 32% and 19% of product sales during the first nine months of 2014 and 2013, respectively. The majority of our product development budget from 2000 through the present has been focused on the development of **Mast Out**Ò. The balance of our efforts has been primarily focused on other improvements, extensions or additions to our **First Defense**Ò product line, including initiatives to prevent scours in calves caused by pathogens other than those within the current **First Defense**Ò disease claims (*E. coli* K99 and coronavirus) such as rotavirus. During the third quarter of 2014, approximately 16%, or $57,000, of the $361,000 that we invested in product development expenses was related to the modifications we are making to our manufacturing facility to fulfill Nisin manufacturing requirements for **Mast Out**Ò. During the first nine months of 2014, approximately 57%, or $970,000, of the $1,716,000 we invested in product development expenses was related to this initiative. We also remain interested in acquiring other new products and technologies that fit with our sales focus on the dairy and beef industries.

Our lead product development initiative is **Mast Out®**, a Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows. During 2000, we acquired an exclusive license from Nutrition 21, Inc. (formerly Applied Microbiology Inc. or AMBI) to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Mast Out**Ò. 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**Ò **Dairy Wipes**, is an antibacterial peptide known to be effective against most gram positive and some gram negative bacteria. In our pivotal effectiveness study, statistically significant **Mast Out**Ò cure rates were associated with a statistically significant reduction in milk somatic cell count, which is an important measure of milk quality. 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.

It is difficult to estimate the potential size of a market that is largely unserved at this point (that market being the treatment of subclinical mastitis). We have estimated that first year sales of our product could be approximately $5,400,000 and that sales could grow to approximately $31,700,000 by the tenth year after market launch. Actual sales results could be higher or lower. Key assumptions underlying these estimates include there being 7,868,000 cows in lactation in the United States and the treatment of 1.15 quarters per cow on average with three doses per treatment at approximately $8.99 per dose. We believe that approximately 20-30% of the U.S. dairy herd is affected by subclinical mastitis caused by gram positive organisms falling within the **Mast Out**Ò claim spectrum. We assumed that 0.40% of all cows would be treated at market launch and 3.37% after 10 years.

During the 14.75 year period that began on January 1, 2000 (the year we began the development of **Mast Out^{Ò}**) and ended on September 30, 2014, we invested the aggregate of approximately $10,839,000 in the development of **Mast Out^{Ò}**. This estimated allocation to **Mast Out^{Ò}** reflects only direct expenditures and includes no allocation of product development or administrative overhead expenses. Approximately $2,891,000 of this investment was offset by product licensing revenues and grant income related to **Mast Out^{Ò}**.

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In 2004, we entered into a product development and marketing agreement with Zoetis (formerly Pfizer Animal Health) covering **Mast Out**Ò. Under that agreement (as amended and supplemented and later terminated), we received $2,375,000 in payments. Zoetis elected to terminate the agreement in 2007. Soon thereafter, Zoetis returned to us all rights, data, information, files, regulatory filings, materials and stocks of Nisin and Nisin producing cultures relating to the development of **Mast Out**Ò. We believe that the decision of Zoetis to terminate the agreement was not based on any unanticipated efficacy or regulatory issues. Rather, we believe the decision was primarily driven by a marketing concern relating to their fear that the milk from treated cows could interfere with the manufacture of certain cultured dairy products.

Milk from cows treated with any of the intramammary mastitis treatment products on the market today must be discarded for a specified period of time during and after treatment. We believe that all milk from cows treated with **Mast Out**Ò will be saleable in the United States. This is a significant competitive advantage for our product. Due to this zero milk discard feature, there is a risk that Nisin from milk of cows treated with **Mast Out**Ò 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. The impact of this potential interference ranges from a delay in the manufacturing process, which does happen at times for other reasons, to the less likely stopping of a cheese starter culture. Milk from cows that have been treated with **Mast Out**Ò that is sold exclusively for fluid milk products presents no such risk. We worked with scientists and mastitis experts to conduct 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**Ò is used in accordance with the product label. Monitoring of several important variables relevant to the manufacture of cheese would be advisable if **Mast Out**Ò were to be used as part of a whole herd (“blitz”) treatment protocol. We do not see this as a significant problem as modern “precision dairying” practices support reducing the indiscriminate use of drug treatments.

The commercial introduction of **Mast Out**Ò in the United States is subject to approval of our New Animal Drug Application (NADA) by the U.S. Food and Drug Administration’s Center for Veterinary Medicine (FDA), which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets outside of the United States, which would involve some similar and some different requirements. The NADA is comprised of five principal Technical Sections that are subject to the FDA’s phased review. By statute, each Technical Section submission is generally subject to a six-month review cycle by the FDA. Each Technical Section can be reviewed and approved separately. Upon review and assessment by the FDA that all requirements for a Technical Section have been met, the FDA may issue a Technical Section Complete Letter. 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.

3) Effectiveness: During the third quarter of 2012, we received the Effectiveness Technical Section Complete Letter from the FDA. The draft product label carries claims for the treatment of subclinical mastitis in lactating cows associated with *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, and coagulase-negative staphylococci in lactating dairy cattle.

L) Human Food Safety (HFS): The HFS Technical Section submission was made during the fourth quarter of 2010. This Technical Section includes several subsections such as: a) toxicology, b) total metabolism, c) effects of drug residues in food on human intestinal microbiology, d) effects on bacteria of human health concern (antimicrobial resistance) and e) pivotal residue chemistry. During the second quarter of 2011, we announced that the FDA had accepted the subsections described above and granted **Mast Out**Ò a zero milk discard period and a zero meat withhold period during and after treatment. Before we can obtain this Technical Section Complete Letter, we must adapt our analytical method that measures Nisin residues in milk around the assigned tolerance limit and transfer that method to a FDA laboratory. We first submitted the validated analytical method to the FDA during the fourth quarter of 2012. We have submitted additional data, which we believe to be responsive to the FDA's review comments, during the third quarter of 2013 and the first quarter of 2014. We are working to complete the method transfer to the FDA laboratory. Due to additional regulatory requirements, completion of the HFS Technical Section is currently anticipated by the end of 2015.

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5) Chemistry, Manufacturing and Controls (CMC): Obtaining FDA approval of the CMC Technical Section defines the critical path to approval of our NADA by the FDA and to initial commercial sales. We are party to agreements with three manufacturers to produce inventory for us utilizing our proprietary technologies and processes. First, a long-term, exclusive supply agreement with Plas-Pak Inc. of Norwich, Connecticut covers the proprietary syringe that was developed specifically for treating cows with **Mast Out**Ò. These syringes were used for all pivotal studies of **Mast Out**Ò. Second, we could have the pharmaceutical-grade Nisin produced for us under a Development and Manufacturing Agreement with Lonza Sales, Ltd. of Basel, Switzerland. If we elect to proceed under this agreement, Lonza would produce the pharmaceutical-grade Nisin exclusively for us. The Lonza site in Europe is FDA-approved, compliant with cGMP regulations and subject to future FDA approval and inspection. Third, an exclusive Contract Manufacture Agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved drug product manufacturer, covers the formulation of the pharmaceutical-grade Nisin into drug product, the sterile-fill of syringes and the final packaging. Norbrook has provided these services for clinical material used in all pivotal studies of **Mast Out**Ò. 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. Our goal is to make the first submission of the CMC Technical Section to the FDA during early 2015. It is very common for the CMC Technical Section to require two, six-month review periods by the FDA.

The selection of and (if applicable) the financing for the pharmaceutical-grade Nisin commercial production facility is a critical decision. We have considered four options: 1) having this work done by a qualified contract manufacturer, such as Lonza, 2) building a new facility, 3) leasing and modifying an existing facility or 4) transferring our technology to a partner's facility. Our initial plan was to have the pharmaceutical-grade Nisin produced for us under contract in order to avoid the investment in a manufacturing facility. By the end of 2011, we determined that the large minimum production volumes and high cost imposed by the selected contract manufacturer might make the product commercially unsustainable. For this reason, we engaged an engineering firm to estimate the cost of controlling the production of the pharmaceutical-grade Nisin ourselves in a plant that we either built or leased. We do not have the estimated amount of approximately $13,000,000 to pay for this investment (without some combination of new debt, equity or partner funding), and there is a risk that the actual cost could be higher than we estimated. Alternatively, a somewhat smaller plant than the one designed to meet commercial sales projections four or five years after commercial launch could cost a few million dollars less and still be able to meet market demand at launch and for a few years thereafter. We presented this product opportunity to a variety of large and small animal health companies. During the second quarter of 2013, we received a non-refundable $250,000 exclusive option payment from a prospective partner who decided during the third quarter of 2013 not to execute a license for the development and marketing of **Mast Out**®. We were informed by the prospective partner that it had determined that, in its opinion, it could not cost effectively commercialize the product. We are encouraged by the feedback from prospective partners, following their due diligence, that our novel mastitis treatment can achieve FDA approval and have a significant, positive impact on the dairy industry. We continue to believe in the potential value of making this novel treatment option available to dairy producers in order to reduce their reliance on penicillin and cephalosporin-based products. During the third quarter of 2013, we suspended our active pursuit of a partner for **Mast Out**® for the present time while continuing our pursuit of FDA approval by completing the HFS Technical Section and the CMC Technical Section on our own. While recognizing the commercial and near-term financial advantages which could have been realized via a partnering agreement with a larger company, we believe that, among the currently available options, the greatest long-term value for our stockholders could be achieved by retaining full product ownership through an

independent strategy at this stage, subject to the likely need for third party funding described above. We believe that the evolution of our thinking relating to these strategic alternatives demonstrates the flexibility and creativity required to solve this challenge. We will continue to evaluate the four potential options, described above, as we actively pursue the alternative strategy discussed below.

At the beginning of the third quarter of 2014, we substantially completed an investment in facility modifications and processing equipment necessary to produce pharmaceutical-grade Nisin. The four primary goals of this investment are to: 1) establish the equivalence of the pharmaceutical-grade Nisin produced in this plant to the pharmaceutical-grade Nisin that was used in all completed clinical studies, 2) produce the validation batches required to complete the CMC Technical Section, 3) confirm process yields and the related cost of production and 4) produce inventory for test marketing and limited initial sales in the United States after FDA approval. In short, we aim to secure regulatory approval of the product and demonstrate its commercial viability. During the last six months of 2014, we are validating this new equipment and production space while optimizing the production process. We believe that success with these efforts will enhance our position in any further financing or partnering discussions, should we elect to pursue either of these paths to fund expanded manufacturing capacity for the commercialization of **Mast Out**Ò. This investment and the resulting short-term loss is the vehicle by which we expect to optimize the long-term value of this asset for our stockholders. We intend to take all appropriate steps to pursue a successful commercialization of **Mast Out**®. This strategy allows us to advance the regulatory approval process while controlling our decision of whether and when to invest in larger scale production on our own, or with a partner.

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After obtaining the final Technical Section Complete Letter and after preparing materials responsive to other administrative requirements, the administrative NADA submission will be assembled for review by the FDA. This final administrative submission is subject to a statutory sixty-day review period. Given this, we believe we could be in a position to achieve the NADA approval and test market the product during 2016. At some point, a further investment to increase our production capacity of pharmaceutical-grade Nisin would be required to meet anticipated market demand. Our options include doing the work on our own (with externally generated financing) or through an alliance with others, the out-licensing of the product or the sale of the product rights.

In addition to our work on **Mast Out**Ò, we are actively exploring further improvements, extensions or additions to our current **First Defense®** product line. For example, we currently are developing treatments that could prevent calf scours caused by enteric pathogens in addition to *E. coli* K99 and bovine coronavirus (the current disease claims for **First Defense®**). In connection with that effort, during the second quarter of 2009 we entered into an exclusive license with the Baylor College of Medicine covering the underlying rotavirus vaccine technology used to generate the specific antibodies. This perpetual license (if not terminated for cause) is subject to milestone and royalty payments. Results from pilot studies completed during the first quarter of 2009 justified continued product development. We completed a pivotal effectiveness study of this experimental formulation during the third quarter of 2011 without seeing the anticipated level of effectiveness needed for regulatory approval and market acceptance. After optimizing the challenge model, we directed our efforts to conducting additional pilot studies of different formulations of this antibody preparation. Having achieved positive results from these pilot studies, we initiated a second pivotal effectiveness study at Cornell University at the end of the second quarter of 2014. The enrollment of calves is expected to be complete around the end of 2014, making USDA approval possible in 2015, if positive results are obtained. Because the size of the dose required to achieve the anticipated effectiveness is too large to fit in our capsule, we aim to deliver this product in a small bag as a colostrum replacer. Our commercial objective is to manufacture and market a unique colostrum replacer product with USDA-approved claims against *E. coli*, coronavirus and rotavirus in addition to Failure of Passive Transfer. As additional opportunities arise to commercialize our own technology, or licensable technology, we may begin new development projects. While we continue to pursue internally funded product development programs, we also remain interested in acquiring new products and technologies that fit with our sales and marketing focus on the dairy and beef industries.

Sales and Marketing Expenses

Sales and marketing expenses increased by approximately 45%, or $115,000, to $374,000 during the third quarter of 2014 in comparison to $258,000 during the third quarter of 2013, remaining at 21% of product sales during both periods. Sales and marketing expenses increased by approximately 27%, or $196,000, to $922,000 during the first nine months of 2014 in comparison to $726,000 during the first nine months of 2013, increasing to 17% of product sales during the 2014 period from 16% during the same period in 2013. We continue to leverage the efforts of our small, but growing, sales force by using veterinary distributors. These expenses have been increasing since our 2010

strategic decision to invest more to support **First Defense**Ò sales. This investment may have created, at least in part, our recent increase in product sales. Historically, we have invested approximately up to 20% of product sales in sales and marketing expenses on an annual basis. This percentage tends to be lower during the first quarter when our seasonal sales are the highest. We are increasing our investment in sales and marketing expenses further during the second half of 2014. By adding new regional sales and marketing managers in Wisconsin and California during the third quarter of 2014, our sales team now consists of one director, five regional sales and marketing managers and one inside sales representative. Initially, this could increase this expense ratio to approximately 20%. The financial objective of this strategy is to create an increase in product sales so that this expense ratio is reduced back below 20% in 2015.

Administrative Expenses

Administrative expenses increased by approximately 33%, or $76,000, to $302,000 during three-month period ended September 30, 2014 as compared to $227,000 during the three-month period ended September 30, 2013. Administrative expenses increased by approximately 23%, or $166,000, to $874,000 during the nine-month period ended September 30, 2014, as compared to $708,000 during the nine-month period ended September 30, 2013, due largely to increased consulting expenses. We strive to be efficient with these expenses while funding costs associated with complying with the Sarbanes-Oxley Act of 2002 and other costs associated with being a publicly-held company. 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 in Current Reports on Form 8-K when legally required or deemed appropriate by management. Additional information about us is available in our annual Proxy Statement. All of these reports are filed with the Securities and Exchange Commission (SEC) and are available on-line or upon request to the Company. Historically, we had limited our investment in investor relations spending. Effective April 1, 2014, our Board of Directors authorized an investment in a more actively managed investor relations program to broadly introduce the Company to the national investment community. The original slide presentation used in meetings with these investors was filed with the SEC on Form 8-K on May 19, 2014. As minor changes and updates are made, the current versions of the presentation have been and will be posted on our web-site. When we added market estimates for both **First Defense**Ò and **Mast Out**Òto this slide presentation, the key elements of and assumptions underlying these market estimates were filed with the SEC on a Form 8-K under Regulation Fair Disclosure on July 16, 2014.

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Other (Expenses) Revenues, net

Interest income was $4,000 and $3,000 during the third quarters of 2014 and 2013, respectively. Interest expense decreased by approximately 12%, or $2,000, to $15,000 during the third quarter of 2014, in comparison to $17,000 during the third quarter of 2013. Interest income was $12,000 during the first nine months of 2014, in comparison to $10,000 during the first nine months of 2013. Interest expense decreased by approximately 13%, or $6,000, to $44,000 during the first nine months of 2014 in comparison to $51,000 during the first nine months of 2013.

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

Our income before income taxes was $30,000 during the three-month period ended September 30, 2014 in comparison to income before income taxes of $77,000 during the three-month period ended September 30, 2013. The income before income taxes includes $104,000 and $98,000 of non-cash depreciation and amortization expenses during the three-month periods ended September 30, 2014 and 2013, respectively. The 2014 results include $57,000 in non-recurring, infrequent and unusual product development expenses related to our investment in processing equipment and modifications to our facility to produce pharmaceutical-grade Nisin. We recorded an income tax expense equal to 65% of our income before income taxes during the three-month period ended September 30, 2014 in comparison to income tax expense equal to 25% of our income before income taxes during the same period in 2013. The income tax rate during these periods is not reflective of our long-term tax rate principally because the amount of our income before income taxes is so low in terms of absolute dollars. Our net income was $10,000, or $0.00 per diluted share, during the three-month period ended September 30, 2014, in comparison to net income of $57,000, or $0.02 per diluted share, during the three-month period ended September 30, 2013.

Our (loss) before income taxes was ($444,000) during the nine-month period ended September 30, 2014 in contrast to income before income taxes of $458,000 during the nine-month period ended September 30, 2013. The (loss) income before income taxes includes $333,000 and $295,000 of non-cash depreciation and amortization expenses during the nine-month periods ended September 30, 2014 and 2013, respectively. The 2014 results include $970,000 in non-recurring, infrequent and unusual product development expenses related to our investment in processing equipment and modifications to our facility to produce pharmaceutical-grade Nisin. We recorded an income tax benefit equal to 33% of our loss before income taxes during the nine-month period ended September 30, 2014, in contrast to the income tax expense equal to 41% of our income before income taxes during the same period in 2013. Our net (loss) was ($298,000), or ($0.10) per share, during the nine-month period ended September 30, 2014, in contrast to net income of $268,000, or $0.09 per diluted share, during the nine-month period ended September 30, 2013.

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, 2014. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures and an increase in other revenues.

Changes in Internal Controls over Financial Reporting. The individual who serves as our principal executive and principal financial officer periodically evaluates any change in internal control over financial reporting which has occurred during the prior fiscal quarter. Management has concluded that there was no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1 - LEGAL PROCEEDINGS

None

ITEM 1A - RISK FACTORS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: projections of future financial performance; the scope and timing of future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence of subclinical mastitis; future market share of and revenue generated by products still in development; future sources of financial support for our product development, manufacturing and marketing efforts; the amount and timing of future investments in facility modifications and production equipment; the future adequacy of our working capital and the availability of third party financing; timing and future costs of a facility to produce pharmaceutical-grade Nisin for **Mast Out®**; the timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; future realization of deferred tax assets; costs associated with sustaining compliance with cGMP regulations in our current operations and attaining such compliance for the facility to produce pharmaceutical-grade Nisin for **Mast Out®**; factors that may affect the dairy and beef industries and future demand for our products; the cost-effectiveness of additional sales and marketing expenditures and resources; the accuracy of our understanding of our distributors’ ordering patterns; anticipated changes in our manufacturing capabilities and efficiencies; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as “expects”, “may”, “anticipates”, “aims”, “intends”, “would”, “could”, “should”, “will”, “plans”, “believes”, “estimates”, “targets”, “projects”, “forecasts” and similar words and ex addition, there can be no assurance that future developments affecting us will be those that we anticipate. 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, pharmaceutical-grade Nisin manufacturing, our potential reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making by regulatory authorities, currency fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized below and uncertainties otherwise referred to in this Quarterly Report.

Projection of net income: After nine consecutive years of reporting net income, we reported net losses for the years ended December 31, 2008, 2009, 2010 and 2011, due in large part to our product development strategy. By reducing our investment in the development of **Mast Out**Ò and increasing sales of **First Defense®**, we were able to record net operating income of $245,000 and net income of $90,000 during the year ended December 31, 2012. We continued this positive trend by recording a net operating (loss) of just ($20,000) and net income of $117,000 during the year ended December 31, 2013. Given our strategic decision to invest approximately $970,000 during the nine-month period ended September 30, 2014 in the manufacture of pharmaceutical-grade Nisin, we recorded a net loss during the first nine months of 2014 as expected. Despite a projected return to profitability during the last six months of 2014, we expect to record a loss for the year ending December 31, 2014. In line with this projection, we did record net income of $10,000 during the third quarter of 2014. Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Stronger than expected sales of **First Defense®**, for example, could increase our net income. Conversely, weaker than expected sales of **First Defense®** could lead to less profits or an operating loss. Large investments in product development can result in a net loss.

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*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, or during the years ended December 31, 2012 and 2013, or during the third quarter of 2014, without the gross margin that we earned on sales of **First Defense®**.

Concentration of sales: During the year ended December 31, 2013, 83% of our product sales were made to customers in the U.S. dairy and beef industries in comparison to 80% during 2012. A large portion of our product sales (60%, 55% and 58% for the years ended December 31, 2013, 2012, and 2011, respectively) was made to two large distributors (adjusting for certain acquisitions made by those distributors). A large portion of our trade accounts receivable (65% and 47% as of December 31, 2013 and 2012, respectively) was due from these two distributors (also adjusting for certain acquisitions made by those distributors). During the third quarter of 2014, 84% of our product sales were made to customers in the U.S. dairy and beef industries, in comparison to 89% during the third quarter of 2013. During the third quarter of 2014, 57% of our product sales were made to two large distributors, in comparison to 61% (adjusting for an acquisition made by one of these distributors) during the third quarter of 2013. During the first nine months of 2014, 82% of our product sales were made to customers in the U.S. dairy and beef industries, in comparison to 84% during the first nine months of 2013. During the first nine months of 2014, 60% of our product sales were made to two large distributors, in comparison to 60% (adjusting for an acquisition made by one of these distributors) during the first nine months of 2013. A large portion of our trade accounts receivable (58% and 64% as of September 30, 2014 and December 31, 2013, respectively) was due from these two distributors. Approximately 72% and 75% of our trade accounts receivable were due from three distributors as of September 30, 2014 and December 31, 2013, respectively. 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, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us.

Economics of the dairy and beef industries: All cattle and calves in the United States as of July 1, 2014 totaled 95,000,000 head, 3% below the 97,800,000 on July 1, 2012. This is the lowest inventory count as of July 1st in decades. 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, which is the highest number recorded during the sixteen-year period from 1998 to 2013, and has not been that high again since then. The average for 2013 was 9,215,000 which represents a slight reduction from the average of 9,232,000 reported for 2012. This average increased slightly to 9,245,000 during the first nine months of 2014. While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk, demand for milk is also 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 annual average price level for 2011 was higher than the annual average reached in any of the previous 30 years. This average price for the month of September 2014 of $24.60 was the highest level since these records were first reported in 1980. The monthly average of $22.72 for the first nine months of 2014 is higher than the annual average reported since those records became available in 1980. The fluctuations in this price level are demonstrated in the following table:

Average Class III Milk Price for the year ended December 31,		Increase (Decrease)
2010	2011	
$14.41	$18.37	27%
2011	2012	
$18.37	$17.44	(5%)
2012	2013	
$17.44	$17.99	3%

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The actual level of milk prices may be less important than its level relative to feed 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. This benchmark level means that a dairy producer could buy 3.0 pounds of feed for every pound of milk sold. The 2012 ratio was the lowest recorded since this ratio was first reported in 1985. The ratio of 2.90 for the month of September 2014 was the highest value since November of 2007, and the average value of 2.48 for the first nine months of 2014 was the highest it has been since the annual average of 2.81 in 2007. The following table demonstrates the annual volatility and the low values of this ratio recently:

Milk-To-Feed Price Ratio for the year ended December 31,		**(Decrease) Increase**
2010	**2011**	
2.26	1.88	(17%)
2011	**2012**	
1.88	1.52	(19%)
2012	**2013**	
1.52	1.74	14%

An increase in feed costs also has a negative impact on the beef industry. Widespread severe drought conditions in key U.S. agricultural regions during 2012 drove feed costs higher and the inventory of all cattle and calves lower. The recent positive trend in these market indices has resulted in an increase in the value of milk cows. The price for a milk cow of $1,970 as of July 2014 is the highest value reported since $1,990 for July 2008. The average of this price reported as of January, April and July 2014 was $1,740, which is the highest value reported since $1,953 for 2008. The industry data referred to above is compiled from USDA databases. Recently, the value of newborn bull calves has risen to the unusually high level of approximately $300 to $500. At this price, producers are more likely to invest in **First Defense®** for their bull calves. Given our focus on the dairy and beef industries, the financial insecurity of our primary end users is a risk to our ability to maintain and grow sales at a profitable level. It also heightens the challenge of selling premium-priced animal health products (such as **Mast OutÒ**) into such a market. Further, the loss of farms from which we buy raw material for **First Defense®** could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms on suitable terms.

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 OutÒ**, which requires (and will

continue to require) a substantial investment. Our efforts will be subject to inspection and approval by the FDA. There is no assurance whether or when we will obtain all of the data necessary to support regulatory approval for this product.

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

*Risks associated with **Mast Out**Ò funding strategy:* Completing the development of **Mast Out**Ò through to the submission of the administrative NADA to the FDA involves a great deal of risk. Our current strategy is to build our own small-scale pharmaceutical-grade Nisin production plant in order to gain NADA approval, obtain better production cost data and test market the product. Uncertainty concerning the availability and terms of financing to develop a larger-scale commercial production plant or alternatively the availability and terms of potential partnering arrangements is a risk that, if materialized, could preclude meaningful commercialization of **Mast Out**Ò.

Uncertainty of market size and product sales estimates: Even assuming that **Mast Out**Ò 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, the effect of a premium selling price on market penetration, cost of manufacture, integration of milk from treated cows with susceptible cheese starter cultures and market acceptance.

Competition from others: Many of our competitors are significantly larger and more diversified in the relevant markets than we are and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. Zoetis and Novartis (pending acquisition by Elanco, the animal health division of Eli Lilly and Co.), among other companies, sell products that compete directly with **First Defense**Ò in preventing scours in newborn calves. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Zoetis, Merck and Boehringer Ingelheim. There is no assurance that **Mast Out**Ò will compete successfully in this market. We may not be aware of other companies that compete with us or intend to compete with us in the future.

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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 facility and operations at 56 Evergreen Drive in Portland, Maine for the production of **First Defense**Ò and **Wipe Out**Ò **Dairy Wipes**. The specific antibodies that we purify for **First Defense**Ò and the Nisin we produce by fermentation for **Wipe Out**Ò **Dairy Wipes** are not readily available from other sources. We will also be reliant on this facility for the production of pharmaceutical-grade Nisin required to obtain regulatory approval. We expect to be dependent on Plas-Pak and Norbrook for a significant portion of the manufacture of **Mast Out**Ò 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.

Small size; dependence on key personnel: We are a small company with 32 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. Our competitive position will be highly influenced by our ability to attract and retain key scientific, managerial and sales and marketing 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.

Failure to protect intellectual property: In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. Instead, we have sought (and may seek in the future) to maintain the confidentiality of any relevant proprietary technology through operational safeguards and contractual agreements. Reliance upon trade secret, rather than patent, protection may cause us to be vulnerable to competitors who successfully replicate our manufacturing techniques and processes. Additionally, there can be no assurance that others may not independently develop similar trade secrets or technology or obtain access to our unpatented trade secrets or proprietary technology. Other companies may have filed patent applications and may have been issued patents involving products or technologies potentially useful to us or necessary for us to commercialize our products or achieve our business goals. There can be no assurance that we will be able to obtain licenses to such patents on terms that are acceptable. There is also a risk that competitors could challenge the claims in patents that have been issued to us.

No expectation to pay any dividends or repurchase stock for the foreseeable future: We do not anticipate paying any dividends to, or repurchasing stock from, our stockholders for the foreseeable future. Instead, we expect to use cash to fund product development costs and investments in our facility and production equipment. Any debt or equity financing we obtain to assist in funding our product development programs may include terms prohibiting or restricting our paying dividends or repurchasing stock for a lengthy period. Stockholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any

determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, contractual restrictions, restrictions imposed by applicable laws and other factors our Board of Directors deems relevant.

Market for common stock: Our common stock trades on the NASDAQ Stock Market (NasdaqCM: ICCC). Our average daily trading volume is lower than the volume for most other companies and the bid/ask stock price spread can be larger, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire. There has been a significant increase in the stock market activity of animal health companies since early 2013 in comparison to years past. Listed in chronological order by date of financing, companies such as Zoetis (ZTS), Aratana (PETX), Kindred (KIN), Phibro (PAHC) and Parnell (PARN) have completed initial public offerings in the relatively recent past. Other deals are rumored to be forthcoming. The stock price of some of these companies has been volatile.

Stock market valuation: There are companies in the animal health sector with market capitalization values that greatly exceed our market capitalization of under $15,000,000. Some of these companies have no product sales. We currently have product sales in excess of $6,000,000. Before gross margin from the sale of new products is achieved, our market capitalization may be heavily dependent on the perceived potential for growth from our products under development.

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Certain provisions might discourage, delay or prevent a change in control of our Company or changes in our management: Provisions of our certificate of incorporation, our bylaws, our Common Stock Rights Plan or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

- limitations on the removal of directors; advance notice requirements for stockholder proposals and nominations;
- the ability of our Board of Directors to alter or repeal our bylaws;
- the ability of our Board of Directors to refuse to redeem rights issued under our Common Stock Rights Plan or otherwise to limit or suspend its operation that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors; and
- Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could depress the trading price of our common stock or limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood of obtaining a premium for our common stock in an acquisition.

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

None

ITEM 3 - DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4 - MINE SAFETY DISCLOSURES

None

ITEM 5 - OTHER INFORMATION

None

ITEM 6 - EXHIBITS

Exhibit 31	Certifications required by Rule 13a-14(a).
Exhibit 32	Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

ImmuCell Corporation

SIGNATURE

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

ImmuCell Corporation
Registrant

Date: November 12, 2014 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer
and Principal Financial Officer

ImmuCell Corporation

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