IMMUCELL CORP /DE/
Form 10-Q
May 16, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2011

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

001-12934

(Commission file number)

ImmuCell Corporation

(Exact name of registrant as specified in its charter)

Delaware	**01-0382980**
(State of incorporation)	**(I.R.S. Employer Identification No.)**
56 Evergreen Drive, Portland, ME	**04103**
(Address of principal executive office)	**(Zip Code)**

(207) 878-2770

(Registrant s telephone number)

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The number of shares of the Registrant s common stock outstanding at May 13, 2011 was 2,973,652.

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BALANCE SHEETS

	December 31, 2010	(Unaudited) March 31, 2011
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,398,985	$ 887,426
Short-term investments	3,227,000	4,422,000
Trade accounts receivable, net of allowance for doubtful accounts of $13,000 and $14,000 at December 31, 2010 and March 31, 2011, respectively	465,278	489,817
Income taxes receivable	948	948
Other receivables	31,287	27,049
Inventory	1,601,016	1,570,499
Prepaid expenses	241,191	224,805
Total current assets	6,965,705	7,622,544
NET PROPERTY, PLANT AND EQUIPMENT, at cost	2,710,891	2,694,995
LONG-TERM PORTION OF DEFERRED TAX ASSET	1,040,606	1,050,355
OTHER ASSETS, net	33,977	41,085
TOTAL ASSETS	$ 10,751,179	$ 11,408,979
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$ 372,052	$ 443,843
Accounts payable	105,739	109,579
Current portion of bank debt	42,384	166,915
Current portion of deferred tax liability	4,843	13,455
Deferred revenue		8,250
Total current liabilities	525,018	742,042
LONG-TERM LIABILITY:		
Long-term portion of bank debt	943,760	1,398,294
TOTAL LIABILITIES	1,468,778	2,140,336
STOCKHOLDERS EQUITY:		
Common stock, Par value - $0.10 per share, Authorized - 8,000,000 shares, Issued - 3,261,148 shares at December 31, 2010 and March 31, 2011	326,115	326,115
Capital in excess of par value	9,780,392	9,788,303
Accumulated deficit	(204,805)	(227,918)
Treasury stock at cost - 287,496 shares at December 31, 2010 and March 31, 2011	(628,932)	(628,932)

Accumulated other comprehensive income - interest rate swap	9,631	11,075
Total stockholders equity	9,282,401	9,268,643
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 10,751,179	$ 11,408,979

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

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ImmuCell Corporation

STATEMENTS OF OPERATIONS FOR THE

THREE-MONTH PERIODS ENDED MARCH 31, 2010 AND 2011

(Unaudited)

	Three-Month Periods Ended March 31,	
	2010	**2011**
Product sales	$ 1,311,748	$ 1,555,701
Costs of goods sold	572,589	687,466
Gross margin	739,159	868,235
Product development expenses	405,462	472,134
Administrative expenses	238,926	208,887
Sales and marketing expenses	169,169	204,072
Other operating expenses	813,557	885,093
NET OPERATING LOSS	74,398	16,858
Other revenues (expenses), net	9,592	(14,638)
LOSS BEFORE INCOME TAXES	64,806	31,496
Income tax benefit	11,540	8,383
NET LOSS	$ 53,266	$ 23,113
Weighted average common shares outstanding:		
Basic	2,970,652	2,973,652
Diluted	2,970,652	2,973,652
NET LOSS PER SHARE:		
Basic	$ 0.02	$ 0.01
Diluted	$ 0.02	$ 0.01

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

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ImmuCell Corporation

STATEMENTS OF STOCKHOLDERS EQUITY

(Unaudited)

FOR THE THREE-MONTH PERIOD ENDED MARCH 31, 2010

	Common Stock $0.10 Par Value		Capital in Excess of		Treasury Stock		Accumulated Other Comprehensive	Total Stockholders
	Shares	Amount	Par Value	Accumulated Surplus	Shares	Amount	Income	Equity
BALANCE, December 31, 2009	3,261,148	$ 326,115	$ 9,751,442	$ 179,879	290,496	$ (635,495)		$ 9,621,941
Net loss				(53,266)				(53,266)
Other comprehensive income interest rate swap								
Total comprehensive loss								(53,266)
Stock-based compensation			14,593					14,593
BALANCE, March 31, 2010	3,261,148	$ 326,115	$ 9,766,035	$ 126,613	290,496	$ (635,495)		$ 9,583,268

FOR THE THREE-MONTH PERIOD ENDED MARCH 31, 2011

	Common Stock $0.10 Par Value		Capital in Excess of		Treasury Stock		Accumulated Other Comprehensive	Total Stockholders
	Shares	Amount	Par Value	Accumulated Deficit	Shares	Amount	Income	Equity
BALANCE, December 31, 2010	3,261,148	$ 326,115	$ 9,780,392	$ (204,805)	287,496	$ (628,932)	$ 9,631	$ 9,282,401
Net loss				(23,113)				(23,113)
Other comprehensive income interest rate swap, net of taxes							1,444	1,444
Total comprehensive loss								(21,669)
Stock-based compensation			7,911					7,911
BALANCE, March 31, 2011	3,261,148	$ 326,115	$ 9,788,303	$ (227,918)	287,496	$ (628,932)	$ 11,075	$ 9,268,643

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

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STATEMENTS OF CASH FLOWS FOR THE THREE-MONTH PERIODS

ENDED MARCH 31, 2010 AND 2011

(Unaudited)

	Three-Month Periods Ended March 31,	
	2010	**2011**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (53,266)	$ (23,113)
Adjustments to reconcile net loss to net cash (used for) provided by operating activities:		
Depreciation	105,099	105,157
Amortization		1,686
Deferred income taxes	(11,562)	(1,137)
Stock-based compensation	14,593	7,911
Changes in:		
Receivables	(139,016)	(20,301)
Inventory	(134,700)	30,517
Prepaid expenses and other assets	34,953	9,036
Accrued expenses	(35,912)	71,791
Accounts payable	52,812	44,943
Deferred revenue		8,250
Net cash (used for) provided by operating activities	(166,999)	234,740
CASH FLOWS FROM INVESTING ACTIVITES :		
Purchase of property, plant and equipment	(79,410)	(130,364)
Maturities of short-term investments	396,000	
Purchases of short-term investments		(1,195,000)
Net cash provided by (used for) investing activities	316,590	(1,325,364)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from debt issuance		600,000
Debt principal repayments		(20,935)
Net cash provided by financing activities		579,065
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	149,591	(511,559)
BEGINNING CASH AND CASH EQUIVALENTS	975,490	1,398,985
ENDING CASH AND CASH EQUIVALENTS	$ 1,125,081	$ 887,426
INTEREST EXPENSE PAID	$	$ 16,541
INCOME TAXES PAID	$ 22	$ 102
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable	$ (8,263)	$ (41,103)
Increase in fair value of interest rate swap, net of taxes	$	$ (1,444)

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

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ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS

March 31, 2011

1. BASIS OF PRESENTATION

We have prepared the accompanying financial statements without audit reflecting all adjustments, all of which are of a normal recurring nature, that are, in our opinion, necessary in order to make the financial statements not misleading. We follow accounting standards set by the Financial Accounting Standards Board, commonly referred to as the FASB. The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP issued by the FASB in these footnotes are to the FASB *Accounting Standards Codification* (Codification). The FASB finalized the Codification effective for periods ending on or after September 15, 2009. Certain prior year accounts have been reclassified to conform with the 2011 financial statement presentation. Certain information and footnote disclosures normally included in the annual financial statements have been condensed or omitted. Accordingly, we believe that although the disclosures are adequate to make the information presented not misleading, these financial statements should be read in conjunction with the financial statements for the year ended December 31, 2010 and the notes thereto, contained in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission.

2. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

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

	As of December 31, 2010	As of March 31, 2011	(Decrease) Increase
Cash and cash equivalents	$ 1,399	$ 887	$ (512)
Short-term investments	3,227	4,422	1,195
	$ 4,626	$ 5,309	$ 683

3. INVENTORY

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

	As of December 31, 2010	As of March 31, 2011	Increase (Decrease)
Raw materials	$ 237	$ 237	$
Work-in-process	977	1,001	24
Finished goods	387	332	(55)

	$	1,601	$	1,570	$ (31)

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ImmuCell Corporation

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2011

4. PROPERTY, PLANT AND EQUIPMENT

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

	As of December 31, 2010	As of March 31, 2011
Laboratory and manufacturing equipment	$ 2,870	$ 2,903
Building and improvements	2,553	2,650
Office furniture and equipment	225	225
Construction in progress	40	
Land	50	50
Property, plant and equipment, gross	5,738	5,828
Less-accumulated depreciation	3,027	3,133
Property, plant and equipment, net	$ 2,711	$ 2,695

5. OTHER ASSETS

Other assets consisted of the following (in thousands):

	As of December 31, 2010	As of March 31, 2011
Security deposits	$ 1	$ 1
Debt issue costs	26	26
Interest rate swap	10	18
Other assets, gross	37	45
Accumulated amortization of debt issue costs	3	4
Other assets, net	$ 34	$ 41

6. BANK DEBT

During the third quarter of 2010, we agreed to terms of certain credit facilities with TD Bank, N.A. aggregating up to approximately $2,100,000, which are secured by substantially all of our assets. These credit facilities are comprised of a $1,000,000 ten-year mortgage loan, a $600,000 fifty-four month note payable and a $500,000 line of credit. Proceeds from the $1,000,000 mortgage were received during the third quarter of 2010. Based on a 15-year amortization schedule, a balloon principal payment of approximately $452,000 will be due in the third quarter of 2020. We hedged our interest rate exposure on this mortgage with an interest rate swap agreement that effectively converted a floating interest rate to the fixed rate of 6.04%. All derivatives are recognized on the balance sheet at their fair value. The agreement has been determined to be highly effective in hedging the variability of identified cash flows and has been designated as a cash flow hedge of the variability in the hedged interest payments. Changes in the fair value of the interest rate swap agreement are recorded in other comprehensive income, net of taxes. The original

notional amount of the interest rate swap agreement of $1,000,000 amortizes in accordance with the amortization of the mortgage. As the result of our decision to hedge this interest rate risk, we recorded credits to equity in the amount of approximately $10,000 and $11,000, which reflects the fair value of the interest rate swap asset, net of taxes, as of December 31, 2010 and March 31, 2011, respectively. 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 payable were received

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NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2011

during the first quarter of 2011. Interest on the note payable is variable at the higher rate of 4.25% or the one month London Interbank Offered Rate (LIBOR) plus 3.25%. The $500,000 line of credit, which is renewable annually, is available as needed. Interest on the line of credit will be variable at the higher rate of 4.25% or the one month LIBOR plus 3.50%. These credit facilities are subject to certain financial covenants. A technical non-compliance with one of these covenants as of December 31, 2010 was waived by the bank. Because these covenants were calculated anticipating much higher spending on product development expenses than we currently plan, we expect to be in compliance with these covenants going forward. We are in compliance with all applicable covenants as of March 31, 2011. Principal payments due under debt outstanding as of March 31, 2011 are reflected in the following table by the year that payments are due (in thousands):

	Nine-Month Period Ending December 31, 2011	Years Ending December 31, 2012	2013	2014	2015	2016	Thereafter	Total
$1,000,000 mortgage	$ 32	$ 45	$ 48	$ 51	$ 54	$ 57	$ 689	$ 976
$600,000 note payable	92	128	134	139	96			589
Total	$ 124	$ 173	$ 182	$ 190	$ 150	$ 57	$ 689	$ 1,565

7. COMMITMENTS AND CONTINGENT LIABILITIES

In connection with a Development and Manufacturing Agreement entered into during the third quarter of 2010 with Lonza Sales Ltd., we have committed approximately an additional $567,000 (50% paid during the fourth quarter of 2010 and the balance due upon completion of the work) to Lonza to generate the manufacturing data required for a regulatory submission to the FDA pertaining to the development of **Mast Out®**. Approximately 27% and 57% of this work was complete as of December 31, 2010 and March 31, 2011, respectively. Accordingly, we expensed approximately $155,000 and $173,000 to product development expenses during the year ended December 31, 2010 and the three-month period ended March 31, 2011, respectively, on the percentage of completion basis. This work is expected to be completed during the second quarter of 2011. This commitment is in addition to approximately $137,000 that we paid to Lonza during the fourth quarter of 2009 for technology transfer related work. Approximately 71% and 83% of this work was complete as of December 31, 2010 and March 31, 2011, respectively. Accordingly, we expensed approximately $98,000 and $16,000 to product development expenses during the year ended December 31, 2010 and the three-month period ended March 31, 2011, respectively. This work is expected to be completed during the second quarter of 2011.

8. OTHER REVENUES (EXPENSES), NET

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

	Three-month periods ended March 31, 2010	2011
Royalty income	$ 1	$ 2
Interest income	8	4
Interest expense		(20)
Other gains (losses)	1	(1)

	$ 10	$ (15)

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NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2011

9. EMPLOYEE STOCK-BASED COMPENSATION

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model. Accordingly, we recorded $15,000 and $8,000 of compensation expense pertaining to stock-based compensation, which resulted in an increase in loss before income taxes of less than $0.01 per share, during the three-month periods ended March 31, 2010 and 2011. Codification Topic 718 requires us to reflect gross tax savings resulting from tax deductions in excess of expense reflected in our financial statements as a financing cash flow, but there were no significant tax deductions during the three-month periods ended March 31, 2010 or 2011.

10. INCOME TAXES

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carry forwards to the extent they are realizable. We believe it is more likely than not that the deferred tax assets will be realized through future taxable income and tax effects of temporary differences between book income and taxable income. Accordingly, we have not established a valuation allowance for the deferred tax assets. Codification Topic 740-10 clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position must meet before being recognized in the financial statements. In the ordinary course of business, there are transactions and calculations where the ultimate tax outcome is uncertain. In addition, we are subject to periodic audits and examinations by the IRS and other taxing authorities. We have evaluated the positions taken on our filed tax returns. We have concluded that no uncertain tax positions exist as of March 31, 2011. Although we believe that our estimates are reasonable, actual results could differ from these estimates. Our income tax benefit aggregated $12,000 and $8,000 (18% and 27% of the loss before income taxes) during the three-month periods ended March 31, 2010 and 2011, respectively.

11. NET LOSS PER COMMON SHARE

The net loss per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*, by dividing the net loss by the weighted average number of common shares outstanding during the period, without giving consideration to outstanding stock options because the impact would be anti-dilutive.

12. SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

Pursuant to Codification Topic 280, *Segment Reporting*, we operate in one reportable business segment, that being the development, acquisition, manufacture and sale of products that improve the health and productivity of cows for the dairy and beef industries. Almost all of our internally funded product development expenses are in support of such products. Our primary customers for the majority of our product sales (88% and 82% for the three-month periods ended March 31, 2010 and 2011, respectively) are in the U.S. dairy and beef industry. Product sales to international customers, who are also in the dairy and beef industry, aggregated 12% and 18% of our total product sales for the three-month periods ended March 31, 2010 and 2011, respectively. Sales to significant distributors that amounted to 10% or more of total product sales are detailed in the following table:

	Three-Month Periods Ended March 31,	
	2010	2011

Animal Health International, Inc.	18%	26%
Lextron, Inc./Vet Pharm, Inc.	17%	16%
MWI Veterinary Supply Company	12%	14%

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NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2011

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

	As of December 31, 2010	As of March 31, 2011
Animal Health International, Inc.	27%	26%
Robert J. Matthews Company	15%	*
MWI Veterinary Supply Company	12%	19%
Stearns Veterinary Outlet, Inc.	10%	*

* Amount is less than 10%.

13. RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (a member of our Board of Directors) is a controlling owner of Stearns Veterinary Outlet, Inc., a domestic distributor of ImmuCell products (**First Defense®**, **Wipe Out® Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased approximately $70,000 and $84,000 of products from ImmuCell during the three-month periods ended March 31, 2010 and 2011, respectively, on terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated approximately $45,000 and $44,000 as of December 31, 2010 and March 31, 2011, respectively.

14. SUBSEQUENT EVENTS

We have adopted the disclosure provisions of Codification Topic 855-10-50-1, *Subsequent Events*, which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued. Entities are required to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. Codification Topic 855-10-50-1 requires additional disclosures only, and therefore did not have an impact on our financial condition, results of operations, earnings per share or cash flows. Public entities must evaluate subsequent events through the date that financial statements are issued. Accordingly, we have evaluated subsequent events through the time of filing on May 16, 2011, the date we have issued this Quarterly Report on Form 10-Q.

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ImmuCell Corporation

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

RESULTS OF OPERATIONS FOR THE THREE-MONTH PERIOD ENDED MARCH 31, 2011

Product Sales

Product sales increased by approximately 19%, or $244,000, to $1,556,000 during the three-month period ended March 31, 2011 in comparison to $1,312,000 during the same period in 2010. The volatility of the global economy, and its impact on the dairy industry, continues to affect our product sales both domestically and internationally. During the first three months of 2011, domestic sales increased by 10%, or $118,000, and international sales increased by 78%, or $126,000, in comparison to the same period in 2010. Product sales increased by approximately 14% during the six-month period ended March 31, 2011 and by approximately 6% during the twelve-month period ended March 31, 2011, in comparison to the same periods ended March 31, 2010. We believe that this growth may reflect, at least in part, the success of our strategic decision to invest in additional sales and marketing efforts. It is our production and customer service objective to ship orders within one day of receipt. We have been operating in accordance with this objective since the third quarter of 2009. Competition for resources that dairy producers allocate to their calf enterprises has been increased by the severe economic challenges that producers have been facing since the start of the current down cycle in 2008 and by the many new products that have been introduced to the calf market. This competitive pressure increases the importance for us to be successful with new development initiatives such as product line extensions and the addition of a new rotavirus claim for **First Defense®**. In an effort to counter these market dynamics, we launched a communications campaign at the end of 2010 that is highlighting how the unique features of **First Defense®** provide a dependable return on investment for producers.

We appreciate the growing volume of business that we have maintained during these difficult economic times when many of our customers are taking cost-cutting measures. Even in this challenging market with moderately higher milk prices but persistently high feed costs, our lead product, **First Defense®**, continues to benefit from wide acceptance as an effective tool to prevent bovine enteritis (scours) in newborn calves. During the third quarter of 2010, we sold our 10,000,000th dose of **First Defense®** . The fourth quarter of 2011 will mark the 20th anniversary of the original USDA approval of this product in 1991. We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product. Sales are normally seasonal, with higher sales expected during the first quarter. Sales of **First Defense®** increased by 21% during the three-month period ended March 31, 2011 in comparison to the same period in 2010. This follows a 13% increase in sales of **First Defense®** during the three-month period ended December 31, 2010 in comparison to the same period in 2009. Sales of **First Defense®** increased by 18% during the six-month period ended March 31, 2011 in comparison to the six-month period ended March 31, 2010. During the three-month period ended March 31, 2011, domestic sales of **First Defense®** increased by 13%, and this increase was widened by a 74% increase in international sales of **First Defense®**, in comparison to the same period in 2010. Sales of **Wipe Out® Dairy Wipes** decreased by 14% during the three-month period ended March 31, 2011 in comparison to the same period in 2010. We are competing aggressively on selling price to earn new business against less expensive products and alternative teat sanitizing methods.

Gross Margin

The gross margin as a percentage of product sales was 56% during the three-month periods ended March 31, 2011 and 2010. Our annual objective for gross margin percentage is approximately 50%, and our gross margin as a percentage of product sales has been maintained moderately above that target during the periods being reported. The gross margin as a percentage of product sales was 53% and 55% during the twelve-month periods ended March 31, 2011 and 2010, respectively. Our gross margin percentages were 52%, 53% and 45% for the years ended December 31, 2010, 2009 and 2008, respectively. We expect some fluctuations in gross margin percentages from quarter to quarter. We believe that a number of factors can cause our costs to be variable. Biological yields from the raw material used in the production of **First Defense®** do fluctuate over time. Like most manufacturers in the U.S., we have been experiencing increases in the cost of raw materials that we purchase. Product mix also affects gross margin in that we earn a higher gross margin on **First Defense®** and a lower gross margin on **Wipe Out® Dairy Wipes**. We had held our selling prices without significant increase for approximately the seven-year period ended December 31, 2007, believing that we could benefit more from higher unit sales volume than through a higher average selling price per unit. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense®** and have held that selling price without increase since then. Changes in the gross margin on product sales are summarized in the following table for the respective periods (in thousands, except for percentages):

	Three-Month Periods Ended March 31,		Increase	
	2010	2011	Amount	%
Gross margin	$ 739	$ 868	$ 129	17%
Percent of product sales	56%	56%	0%	0%

	Twelve-Month Periods Ended March 31,		Increase (Decrease)	
	2010	2011	Amount	%
Gross margin	$ 2,417	$ 2,432	$ 15	1%
Percent of product sales	55%	53%	(2%)	(4%)

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Product Development

Product development expenses increased by approximately 16%, or $67,000, to $472,000 during the three-month period ended March 31, 2011 in comparison to the same period in 2010. Product development expenses aggregated 30% and 31% of product sales during the three-month periods ended March 31, 2011 and 2010, respectively. The product development expenses principally reflect the costs of funding the development of **Mast Out®** and to a lesser extent product line extensions to **First Defense®**. We expect product development expenses to be above historical levels during the first six months of 2011 as we increasingly fund costs related to the development of the commercial manufacturing process for **Mast Out®** and to the field studies investigating a rotavirus claim for **First Defense®**.

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

In 2000, we acquired an exclusive license from Nutrition 21, Inc. to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Mast Out®**, our intramammary infusion product. In 2004, we paid Nutrition 21 approximately $965,000 to buy out this royalty and milestone-based license to Nisin, thereby acquiring control of the animal health applications of Nisin. Nisin, the same active ingredient contained in **Wipe Out® Dairy Wipes**, is an antibacterial peptide. Nisin is known to have activity against most gram positive and some gram negative bacteria. Nisin is a well characterized substance, having been used in food preservation applications for over 50 years. Nisin has been granted GRAS (Generally Regarded as Safe) status by the FDA for food preservative applications, which may be of some help in obtaining approval for the use of **Mast Out®** on organic farms. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes methods to achieve pharmaceutical-grade purity.

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

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In 2004, we entered into a product development and marketing agreement with Pfizer Animal Health, a division of Pfizer, Inc., covering **Mast Out®**. Under that agreement (as amended and supplemented and later terminated), we received $2,375,000 in payments from Pfizer. Pfizer elected to terminate the agreement in 2007. Soon thereafter, Pfizer returned to us all rights, data, information, files, regulatory filings, materials and stocks of Nisin and Nisin producing cultures relating to the development of **Mast Out ®**. We believe that Pfizer s decision to terminate the agreement was not based on any unanticipated efficacy or regulatory issues. Rather, we believe Pfizer s decision was primarily market driven, largely relating to concerns that the use of **Mast Out®** may require specific treatment restrictions at the herd level.

A significant risk to the market success of **Mast Out®** is that its use may require specific treatment restrictions at the herd level when used to treat subclinical mastitis with no milk discard. Due to its antibacterial nature, Nisin in bulk tank milk could interfere with the manufacture of certain (but not all) cultured milk products, such as some kinds of cheese and yogurt, if a high enough percentage of animals from a herd is treated at any one time. We are evaluating potential strategies to quantify and manage this risk. Milk that is sold exclusively for fluid milk products would not be subject to this restriction. We believe that the benefits of using **Mast Out®** would outweigh the management costs associated with implementing a potential treatment restriction. Another risk is that **Mast Out®** likely will be priced at a premium to the traditional antibiotic products currently on the market, that are all sold subject to a milk discard requirement. However, we believe that we can demonstrate a return on the investment to the producer that will justify this premium.

Mastitis is estimated to cost U.S. dairy producers approximately $2 billion per year. These losses include the cost of treatment products, reduced milk production, discarded milk and lost cows. We estimate that the U.S. market for the use of antibiotics to treat clinical mastitis in lactating cows is approximately $40,000,000 per year and that similar market opportunities also exist outside of the United States and for the treatment of dry (non-lactating) cows. Because milk from cows treated with traditional antibiotics must be discarded for a period of time during and after treatment due to concerns about antibiotic residue in the milk, currently it is not common practice to treat subclinical mastitis (those cases where cows have infected udders, but still produce saleable milk). The ability to treat such cases without a milk discard could revolutionize the way mastitis is managed in a herd. If **Mast Out®** is approved by the FDA as the first treatment for mastitis without a milk discard requirement, we believe it could open the market to treatment of subclinical mastitis and could compete effectively against the traditional antibiotic products currently on the market, which are all sold subject to a milk discard. It is difficult to evaluate the potential size of the as-yet undeveloped subclinical mastitis treatment market.

In 2007, we began the production of registration batches of drug product at 10% of commercial scale to fulfill the pivotal regulatory requirements of effectiveness, target animal safety and stability. During the second quarter of 2008, we initiated the pivotal effectiveness study. Positive results from the study were announced during the third quarter of 2009. With enrollment of approximately 300 qualified cows with subclinical mastitis, the **Mast Out®** treatment group showed a statistically highly significant ($p<0.0001$) overall cure rate in comparison to the placebo group. We believe that the breakdown of the data by species suggests both the necessary numerical superiority and clinical relevancy to support robust product performance in the field. For example, one of the most important mastitis pathogens, coagulase-negative staphylococci, predominated in our study, and **Mast Out®** achieved almost 10-fold higher cure rates than the placebo-treated animals against this pathogen. Further, **Mast Out®** treatment was associated with a statistically significant ($p<0.005$) reduction in milk somatic cell count (SCC), which is an important measure of milk quality.

Commercial introduction of **Mast Out®** in the United States is subject to approval of our New Animal Drug Application (NADA) by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA) which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets outside of the United States and would involve some similar and some different requirements. The NADA is comprised of five principal Technical Sections subject to the FDA s phased review of a NADA. By statute, each Technical Section submission is subject to a six-month review cycle by the FDA. The current status of our work on these Technical Sections is as follows:

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

2) Effectiveness: During the third quarter of 2010, we made our first submission of the Effectiveness Technical Section. This 65 volume submission contains the results from our pivotal trial conducted from 2008 to 2009 as well as all supporting data related to the effectiveness of Nisin, demonstrating the effectiveness of **Mast Out®** in the field at a level

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similar to currently marketed intramammary antibiotics and confirming prior results from two major field studies conducted since 2003. During the first quarter of 2011, we received an Effectiveness Technical Section Incomplete Letter from the FDA. The FDA requested additional information and clarification in the areas of raw data, subject eligibility and statistical analyses and has requested that certain treatment outcomes be changed or justified. Additional clinical studies were not required. Our response to the FDA does not materially change our initial conclusions about the product s effectiveness. We expect to make a second submission of this Technical Section that will be responsive to the questions raised by the FDA during the second quarter of 2011. We expect to receive the FDA s response to this second submission during the fourth quarter of 2011 after one, six-month review cycle.

3) Human Food Safety (HFS): The HFS Technical Section submission was made during the fourth quarter of 2010. This Technical Section determines if a milk discard period or meat withhold period will be required. This Technical Section includes several subsections such as: a) toxicology, b) total metabolism, c) effects of drug residues in food on human intestinal microbiology, d) effects on bacteria of human health concern (antimicrobial resistance) and e) pivotal residue chemistry. A zero meat withhold requirement, during the course of and following treatment, has been granted. The Acceptable Daily Intake (ADI) level for humans consuming milk from treated cows has been accepted by the FDA, and this ADI supports a zero milk discard claim. We expect to receive the FDA s response to this submission during the second quarter of 2011 after one, six-month review cycle.

4) Target Animal Safety: Under a protocol approved in advance by the FDA, the pivotal Target Animal Safety trial was completed during the first quarter of 2010. We expect to submit the Target Animal Safety Technical Section to the FDA for review during the second quarter of 2011. We expect to receive the FDA s response to this submission during the fourth quarter of 2011 after one, six-month review cycle.

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

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

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In addition to our work on **Mast Out®**, we are actively exploring further improvements, extensions or additions to our current product line. For example, we currently are investigating therapies that could prevent scours in calves caused by enteric pathogens other than *E. coli* K99 and bovine coronavirus (the current **First Defense®** claims). In connection with that effort, during the second quarter of 2009 we entered into an exclusive license with Baylor College of Medicine covering certain rotavirus vaccine technology. This perpetual license (if not terminated for cause) is subject to milestone and royalty payments. Results from pilot studies completed during the first quarter of 2009 justify continued product development. We initiated a pivotal effectiveness study during the second quarter of 2011. Successful results could position us for USDA approval in 2011 of an additional disease claim for **First Defense®** to prevent scours caused by rotavirus. 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 focus on the dairy and beef industries.

General and Administrative Expenses

During the three-month period ended March 31, 2011, general and administrative expenses decreased by 13%, or $30,000, to $209,000 as compared to the same period in 2010. While we implement efficiencies where possible, we continue to incur costs associated with complying with the Sarbanes-Oxley Act of 2002 and other costs associated with being a publicly-held company. At this stage in our development, we have limited our investment in investor relations spending. We provide a full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year. Additional information about us is available in our annual Proxy Statement. All of these reports are filed with the SEC and are available on-line or upon request to the Company. At this time, our financial and time resources are committed principally to managing our commercial business and developing **Mast Out®**. Our board of directors is very involved with and supportive of this resource allocation. While this strategy of providing cost-effective investor relations through our SEC reporting is subject to change, we believe that this focus currently is in the best long-term interest of all stockholders.

Sales and Marketing Expenses

During the three-month period ended March 31, 2011, sales and marketing expenses increased by 21%, or $35,000, to $204,000, as compared to the same period in 2010, aggregating 13% of product sales during the three-month periods ended March 31, 2011 and 2010. This increase was expected and planned given our strategic decision to invest in additional sales and marketing personnel and efforts. These initiatives may have created, at least in part, our recent increase in product sales. Our objective is to maintain the ratio of product selling expenses to product sales below 20% for the full year 2011.

Loss Before Income Taxes and Net Loss

Our loss before income taxes of $31,000 during the three-month period ended March 31, 2011 compares to our loss before income taxes of $65,000 during the three-month period ended March 31, 2010. Our income tax benefit was 27% and 18% of our loss before income taxes during the three-month periods ended March 31, 2011 and 2010, respectively. Our net loss for the three-month period ended March 31, 2011 was $23,000, or $0.01 per share, in comparison to a net loss of $53,000, or $0.02 per share, during the three-month period ended March 31, 2010.

LIQUIDITY AND CAPITAL RESOURCES

Our decision to continue developing **Mast Out®** after the product rights were returned to us in 2007 has caused us to increase our spending on product development expenses that were previously funded by Pfizer. After the nine consecutive years of profitability that we recorded during the years ended December 31, 1999 to December 31, 2007, we incurred net losses of $469,000, $216,000, and $385,000 during 2008, 2009, and 2010, respectively, and $23,000 during the three-month period ended March 31, 2011. We are projecting a net loss during the six-month period ending June 30, 2011. We have committed approximately $570,000 (50% paid during the fourth quarter of 2010 and the balance due upon completion) to Lonza (our API manufacturer) for the scale-up and testing of the Nisin Active Pharmaceutical Ingredient (API) manufacturing process required for a first submission of the CMC Technical Section. This work is expected to be completed during the second quarter of 2011. We are seeking a partner to fund the additional and larger financial commitments to Lonza to complete the manufacturing process development and to fund production facility modifications and full-scale manufacturing batches that would be required to make a second submission of the CMC Technical Section. Subject to obtaining this partner funding, we expect to have product to sell in a test market, subject to timely FDA approval, during 2012. We believe that the commercial prospects for **Mast Out®** warrant this level of investment. We expect to return to positive net operating income (before other revenues (expenses), net and income taxes) during the six-month period ending December 31, 2011.

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During the third quarter of 2010, we agreed to terms of certain credit facilities with TD Bank, N.A. aggregating up to approximately $2,100,000, which are secured by substantially all of our assets. These credit facilities are comprised of a of a $1,000,000 ten-year mortgage loan, a $600,000 fifty-four month note payable and a $500,000 line of credit. Proceeds from the $1,000,000 mortgage were received during the third quarter of 2010. Proceeds from the $600,000 note payable were received during the first quarter of 2011, and the $500,000 line of credit is available as needed. We believe that this debt financing (together with available cash and gross margin from ongoing product sales) provides us with sufficient funding to finance our working capital requirements while completing the first submissions to the FDA of all Technical Sections pertaining to **Mast Out®**. We chose debt financing because we believe that in this market environment, the option to generate funds through the sale of equity securities at an acceptable level of stockholder dilution is very unlikely.

As part of our sustained investment in compliance with cGMP regulations across our product lines and as we make other process improvements, we are investing in personnel, equipment and facility modifications to increase the efficiency and quality of our operations. In 2008, our Board of Directors authorized an investment of approximately $1,314,000 for capital expenditures (facility modifications and production equipment). We have not increased this authorized limit to date. As of April 1, 2011, we had remaining authorization to spend up to $197,000 on capital expenditures, net of expenditures made from January 1, 2008 through March 31, 2011.

Cash, cash equivalents and short-term investments increased by 15%, or $683,000, to $5,309,000 at March 31, 2011 from $4,626,000 at December 31, 2010. Net cash provided by operating activities amounted to $235,000 during the three-month period ended March 31, 2011 in contrast to net cash used for operating activities of $167,000 during the three-month period ended March 31, 2010. Net working capital increased by 7%, or $440,000, to $6,881,000 at March 31, 2011 from $6,441,000 at December 31, 2010. Proceeds from bank debt received during the first quarter of 2011 aggregated $579,000, net of debt repayments made prior to April 1, 2011. Total assets increased by 6%, or $658,000, to $11,409,000 at March 31, 2011 from $10,751,000 at December 31, 2010. Stockholders equity decreased by less than 1% or $14,000, to $9,269,000 at March 31, 2011 from $9,282,000 at December 31, 2010. We believe that we have sufficient capital resources to meet our working capital requirements and to finance our ongoing business operations during at least the next twelve months. However, as noted above, in order to compete the planned development and commercialization of **Mast Out®** we will need to receive approximately $6,000,000 in financial support from a marketing partner to complement the internally generated and borrowed funds that we are willing to commit to this initiative. The production of commercial batches of inventory for a market launch of **Mast Out®** (if the product is approved by the FDA) would require a significant amount of additional capital. It is not necessary for this funding to occur within the next twelve months.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of the individual who serves as our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2011. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms and (ii) is accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

The individual who serves as our principal executive and principal financial officer periodically evaluates any change in internal control over financial reporting which has occurred during the prior fiscal quarter. Management has concluded that there was no change in our internal control over financial reporting that occurred during the quarter ended March 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable

ITEM 1A. RISK FACTORS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: projections of future financial performance; future compliance with bank debt covenants; the scope and timing of future product development work and commercialization of our products; future costs of product development efforts; future sources of financial support for our product development and marketing efforts; the timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future realization of deferred tax assets; factors that may affect the dairy industry and future demand for our products; the accuracy of our understanding of our distributors ordering patterns; anticipated changes in our manufacturing capabilities and efficiencies; the amount and timing of future investments in facility modifications and production equipment or the availability and cost of alternative manufacturing and/or distribution resources; the future adequacy of our working capital and the availability of third party financing; future expense ratios; costs and timing associated with sustaining compliance with cGMP regulations; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as expects , may , anticipates , intends , would , could , should , will , plans , believes , estimates , targets and similar words and e there can be no assurance that future developments affecting us will be those that we anticipate, especially considering the effects the distress in credit and capital markets will have on our current and prospective customers and the global economy and the uncertainties surrounding the potential for a prolonged global recession. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, the uncertainties associated with product development, manufacturing reliance upon third parties for products and services, changes in laws and regulations, decision making by regulatory authorities, currency fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized below as well as other risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2010 and uncertainties otherwise referred to in this Quarterly Report.

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*Risks associated with **Mast Out**® funding strategy:* There are risks associated with our decision not to internally fund the development of **Mast Out**® through to the submission of the administrative NADA to the FDA. A development and marketing partner may not be willing to step in and fund the completion of this product development effort on terms acceptable to us. If a partner does help us complete the submission, the FDA may not grant approval of this product. If a partner is not willing to come to acceptable terms on this collaboration with us, we will need to re-evaluate alternative strategies in order to get full NADA approval and to support the product launch. After we have made first submissions of all required Technical Sections to the FDA, this product development effort would essentially be put on hold pending a funding agreement with a partner or implementation of an alternative strategy, while we would turn our focus to our commercial business.

Projections of loss before income taxes and net loss: After nine consecutive years of reporting net income, we reported a loss before income taxes and a net loss for the years ended December 31, 2008, 2009 and 2010. Further, we incurred a loss before income taxes of $31,000 and a net loss of $23,000 for the three-month period ended March 31, 2011 due in large part to our current product development strategy. Continued development of **Mast Out**® will likely result in a net loss for the six-month period ending June 30, 2011. Our decision not to fund, with internally generated or borrowed funds, the majority of the remaining expenses to complete the development of **Mast Out**® may allow us to return to positive net operating income (before other revenues (expenses), net and income taxes) during the last six months of 2011. Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Stronger than expected sales of **First Defense**®, for example, could diminish the overall loss. Conversely, weaker than expected sales of **First Defense**® could lead to larger losses. Prior to 2008, we had not publicly disclosed our projections of future profitability. We did so in 2008, 2009 and 2010 and have done so again for 2011 to make it clear to our stockholders that the decision to pursue internal development of **Mast Out**® entails an important change in our financial model and strategy that, we believe, is in the long-term interests of the Company and our stockholders.

Economics of the dairy industry: The U.S. dairy industry has been facing very difficult economic pressures, which are forcing many dairy producers out of business. The size (annual average) of the U.S. dairy herd ranged from approximately 9,011,000 to 9,199,000 cows from 1998 to 2007. This annual average jumped to 9,315,000 cows in 2008. The annual average was 9,203,000 in 2009 and 9,117,000 in 2010. The size of the milking herd affects the price of milk. The impact on the milk supply from a decrease in cows is offset, in part, by an increase in milk production per cow. While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk to the market, demand for milk has been largely influenced by very volatile international demand for milk products. Sales of our products may be influenced by the prices of milk, milking cows and calves. The Class III milk price is an industry benchmark that reflects the value of product used to make cheese. The Class III milk price (which is largely out of the direct control of individual dairy producers) is an important indicator because it defines our customers revenue level. The average Class III milk price for 2008 was $17.44 per 100 pounds, which represented a 3% decrease from the 2007 average of $18.04. For 2009, this price level averaged $11.36, which represents a 35% decrease from 2008. The average price for 2009 was 36% lower than the average experienced during the two-year period ended December 31, 2008. For 2010, this price level averaged $14.41, which represents a 27% increase from 2009 but is well below the 2007 and 2008 levels. As of March 2011, this price level averaged $16.63. The actual level of milk prices may be less important than their level relative to costs. Recent improvement in milk prices has been offset by higher feed costs. One measure of this relationship is known as the milk-feed price ratio, which represents the amount of feed that one pound of milk can buy. Whenever this ratio meets or exceeds 3.0, it is considered profitable to buy feed and produce milk. For 2008, this ratio averaged 2.01. For 2009, this ratio averaged 1.78, representing a 12% decrease compared to 2008. For 2010, this ratio averaged 2.27, representing a 27% increase compared to 2009. As of March 2011, this ratio averaged approximately 2.05. This means that a dairy producer can buy only 2.05 pounds of feed for every pound of milk sold. An increase in feed costs also has a negative impact on the beef industry. Another indication of the economic condition of the dairy industry is the average price for animals sold for dairy herd replacement. In 2008, this average price (reported as of January, April, July and October) is estimated to have increased to approximately $1,953, which was a 6% increase over 2007. This price average dropped to approximately $1,385 in 2009, which represented a 29% decrease in comparison to the same period in 2008. This price averaged approximately $1,330 in 2010, which represented a 4% decrease in comparison to the same period in 2009. The price averaged approximately $1,360 as of April 2011. The dairy industry data referred to above is compiled from USDA databases. Another factor in the demand for our product is the value of bull calves. A decline in the price of bull calves reduces the return on investment from a dose of **First Defense**® for bull calves. We are trying to maintain and grow our sales for use with heifer calves to offset what we

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assume is a significant decrease in the use of our product for bull calves. Given our focus on the dairy and beef industries, the financial insecurity of our primary customer base is a risk to our ability to maintain and grow sales at a profitable level. Further, the loss of farms from which we buy raw material for **First Defense®** could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms on suitable terms.

*Reliance on sales of **First Defense®**:* We are heavily reliant on the market acceptance of **First Defense®** to generate product sales and fund our operations. Our business would not have been profitable during the nine consecutive years in the period ended December 31, 2007, and our net losses would have been larger during the years ended December 31, 2008, 2009 and 2010 as well as during the three-month period ended March 31, 2011 without the gross margin that we earned from the sale of **First Defense®**.

Concentration of sales: A large portion of our product sales (47% and 56% for the three-month period ended March 31, 2010 and 2011, respectively) was made to three large distributors. A large portion of our trade accounts receivable (47% as of December 31, 2010 and 53% as of March 31, 2011) was due from these three distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us.

Product development risks: Our current business growth strategy relies heavily on the development of new products, the most important of which is **Mast Out®**. The development of new products is subject to financial, scientific, regulatory and market risks. In particular, the development of **Mast Out®** requires (and will continue to require) substantial investments by us and by a potential partner, and there is no assurance whether or when we will obtain all of the clinical and other data necessary to support regulatory approval for this product or secure a partner on acceptable terms. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Pfizer, Merck/Schering-Plough/Intervet and Boehringer Ingelheim. There is no assurance that **Mast Out®** will compete successfully in this market.

*Regulatory requirements for **Mast Out®**:* The commercial introduction of **Mast Out®** in the United States will require us to obtain appropriate FDA approval for this product. Approval of a zero milk discard claim is a critical competitive feature of this product. It presently is uncertain whether or when this approval will be achieved. We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Mast Out®**. International regulatory approvals would be required for sales outside of the United States. European regulatory authorities are not expected to approve a product with a zero milk discard claim, which would remove a significant competitive advantage of **Mast Out®** in that territory.

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

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

Uncertainty of market estimates: Even assuming that **Mast Out®** achieves regulatory approval in the United States with a zero milk discard requirement, estimating the size of the market for this product is subject to numerous uncertainties. Some of the uncertainties surrounding our product include the development of the subclinical mastitis treatment market, coverage of relevant pathogens, selling price and its effect on market penetration, cost of manufacture, integration of milk from treated cows into cheese starter cultures and market acceptance.

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ImmuCell Corporation

Competition from others: Many of our competitors are significantly larger and more diversified in the relevant markets, and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than do we, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. We may not be aware of other companies that compete with us or intend to compete with us in the future. Our competitive position will be highly influenced by our ability to attract and retain key scientific and managerial personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products and to continue to profitably sell our current products. We currently compete on the basis of product performance, price and distribution capability. We continue to monitor our network of independent distributors to maintain our competitive position.

Small size: We are a small company with 27 full-time and 3 part-time employees. As such, we rely on certain key employees to support different operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained.

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

Not applicable

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4. RESERVED

ITEM 5. OTHER INFORMATION

Not applicable

ITEM 6. EXHIBITS

Exhibit 31	Certifications required by Rule 13a-14(a).
Exhibit 32	Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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ImmuCell Corporation

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ImmuCell Corporation
Registrant

Date: May 16, 2011

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