IMMUCELL CORP /DE/
Form 10-Q
November 08, 2010
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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 September 30, 2010

¨ **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

As of November 5, 2010, the registrant had 2,970,652 shares of Common Stock, par value $0.10 per share, outstanding.

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September 30, 2010

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BALANCE SHEETS

	December 31, 2009	(Unaudited) September 30, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 975,490	$ 2,829,129
Short-term investments	3,610,000	2,229,000
Trade accounts receivable, net of allowance for doubtful accounts of $10,000 and $12,000 at December 31, 2009 and September 30, 2010, respectively	390,242	374,661
Income taxes receivable	1,248	948
Other receivables	24,022	26,771
Inventories	1,087,391	1,460,630
Prepaid expenses	179,828	124,104
Current portion of deferred tax asset	38,507	31,129
Total current assets	6,306,728	7,076,372
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	2,820,425	2,867,809
Building and improvements	2,537,602	2,548,083
Office furniture and equipment	190,799	225,023
Land	50,000	50,000
	5,598,826	5,690,915
Less accumulated depreciation	2,619,828	2,924,154
Net property, plant and equipment	2,978,998	2,766,761
LONG-TERM PORTION OF DEFERRED TAX ASSET	698,085	901,196
DEBT ISSUE COSTS AND OTHER ASSETS, NET	900	26,358
TOTAL ASSETS	$ 9,984,711	$ 10,770,687
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$ 222,885	$ 207,957
Accounts payable	139,885	174,688
Current portion of bank debt		41,772
Total current liabilities	362,770	424,417
LONG-TERM LIABILITIES:		
Long-term portion of bank debt		954,764
Interest rate swap liability		39,215

Total long-term liabilities		993,979
TOTAL LIABILITIES	362,770	1,418,396
STOCKHOLDERS EQUITY:		
Common stock, Par value-$0.10 per share		
Authorized-8,000,000 shares, Issued-3,261,148 shares at December 31, 2009 and September 30, 2010	326,115	326,115
Capital in excess of par value	9,751,442	9,777,828
Accumulated surplus (deficit)	179,879	(76,942)
Treasury stock at cost 290,496 shares at December 31, 2009 and September 30, 2010	(635,495)	(635,495)
Accumulated other comprehensive income interest rate swap		(39,215)
Total stockholders equity	9,621,941	9,352,291
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 9,984,711	$ 10,770,687

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

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STATEMENTS OF OPERATIONS FOR THE

THREE-MONTH AND NINE-MONTH PERIODS ENDED SEPTEMBER 30, 2009 AND 2010

(Unaudited)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2009	2010	2009	2010
REVENUES:				
Product sales	$ 1,010,707	$ 873,722	$ 3,471,615	$ 3,263,141
Royalty income	915	411	2,842	2,386
Total revenues	1,011,622	874,133	3,474,457	3,265,527
COSTS AND EXPENSES:				
Product costs	412,162	516,453	1,664,685	1,548,097
Product development expenses	328,430	312,158	1,249,869	1,050,940
General and administrative expenses	201,766	195,364	667,015	658,859
Sales and marketing expenses	107,966	197,289	319,841	474,816
Total costs and expenses	1,050,324	1,221,264	3,901,410	3,732,712
Net operating loss	(38,702)	(347,131)	(426,953)	(467,185)
Interest income and other income, net	18,606	4,664	87,948	23,190
Interest expense		(8,115)		(8,115)
Interest and other income, net	18,606	(3,451)	87,948	15,075
LOSS BEFORE INCOME TAXES	(20,096)	(350,582)	(339,005)	(452,110)
INCOME TAX BENEFIT	(1,193)	(153,466)	(137,653)	(195,289)
NET LOSS	$ (18,903)	$ (197,116)	$ (201,352)	$ (256,821)
NET LOSS PER COMMON SHARE:				
Basic	$ (0.01)	$ (0.07)	$ (0.07)	$ (0.09)
Diluted	$ (0.01)	$ (0.07)	$ (0.07)	$ (0.09)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic	2,970,652	2,970,652	2,954,784	2,970,652
Diluted	2,970,652	2,970,652	2,954,784	2,970,652

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

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STATEMENTS OF STOCKHOLDERS EQUITY

(Unaudited)

FOR THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2009

	Common Stock $0.10 Par Value		Capital in Excess of Par Value	Accumulated Surplus	Treasury Stock		Accumulated Other Comprehensive Income	Total Stockholders Equity
	Shares	Amount			Shares	Amount		
BALANCE, December 31, 2008	3,261,148	$ 326,115	$ 9,722,967	$ 396,372	366,496	$ (801,753)		$ 9,643,701
Net loss				(201,352)				(201,352)
Exercise of stock options, net			(66,508)		(76,000)	166,258		99,750
Stock-based compensation			75,946					75,946
Tax benefits related to stock options			921					921
BALANCE, September 30, 2009	3,261,148	$ 326,115	$ 9,733,326	$ 195,020	290,496	$ (635,495)		$ 9,618,966

FOR THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2010

	Common Stock $0.10 Par Value		Capital in Excess of Par Value	Accumulated Surplus (Deficit)	Treasury Stock		Accumulated Other Comprehensive Loss	Total Stockholders Equity
	Shares	Amount			Shares	Amount		
BALANCE, December 31, 2009	3,261,148	$ 326,115	$ 9,751,442	$ 179,879	290,496	$ (635,495)		$ 9,621,941
Net loss				(256,821)				(256,821)
Other comprehensive loss interest rate swap							(39,215)	(39,215)
Total comprehensive loss								(296,036)
Stock-based compensation			26,386					26,386
BALANCE, September 30, 2010	3,261,148	$ 326,115	$ 9,777,828	$ (76,942)	290,496	$ (635,495)	$ (39,215)	$ 9,352,291

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

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STATEMENTS OF CASH FLOWS FOR THE NINE-MONTH PERIODS

ENDED SEPTEMBER 30, 2009 AND 2010

(Unaudited)

	Nine-Month Periods Ended September 30, 2009	2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (201,352)	$ (256,821)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation	282,416	313,564
Amortization	22,608	907
Deferred income taxes	(138,670)	(195,733)
Stock-based compensation	75,946	26,386
Loss on disposal of fixed assets	29,861	575
Changes in:		
Receivables	157,010	12,832
Income taxes receivable/payable	360,926	300
Inventories	(263,034)	(373,239)
Prepaid expenses and other assets	6,764	55,850
Accrued expenses	(223,577)	(14,928)
Accounts payable	(413)	43,066
Net cash provided by (used for) operating activities	108,485	(387,241)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(318,896)	(110,167)
Maturities of short-term investments	3,651,103	3,859,000
Purchases of short-term investments	(3,610,000)	(2,478,000)
Net cash (used for) provided by investing activities	(277,793)	1,270,833
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from debt issuance		1,000,000
Debt repayments		(3,464)
Debt issuance costs		(26,489)
Tax benefits related to stock options	921	
Proceeds from exercise of stock options, net	99,750	
Net cash provided by financing activities	100,671	970,047
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(68,637)	1,853,639
BEGINNING CASH AND CASH EQUIVALENTS	1,199,929	975,490
ENDING CASH AND CASH EQUIVALENTS	$ 1,131,292	$ 2,829,129
INCOME TAXES REFUNDED (PAID), NET	$ 360,799	$ (100)
NON-CASH INVESTING AND FINANCING ACTIVITIES:		

Change in capital expenditures included in accounts payable	$ 14,569	$ (8,263)

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

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NOTES TO FINANCIAL STATEMENTS

September 30, 2010

1. BASIS OF PRESENTATION

We have prepared the accompanying financial statements without audit and have reflected all adjustments, all of which are of a normal recurring nature, that are, in our opinion, necessary in order to make the financial statements not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP issued by the FASB in these footnotes are to the FASB Accounting Standards Codification (Codification). The FASB finalized the Codification effective for periods ending on or after September 15, 2009. Certain 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, 2009 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. Short-term investments are classified as held to maturity and are comprised of certificates of deposit that mature in more than three months from their purchase and not more than twelve months from the balance sheet date and are held at different financial institutions that are insured by the Federal Deposit Insurance Corporation (FDIC). Our short-term investments held at such financial institutions are within the FDIC insurance limit of $250,000 per institution per depositor.

Cash, cash equivalents and short-term investments consist of the following (in thousands):

	December 31, 2009	September 30, 2010	Increase (Decrease)
Cash and cash equivalents	$ 975	$ 2,829	$ 1,854
Short-term investments	3,610	2,229	(1,381)
	$ 4,585	$ 5,058	$ 473

3. INVENTORIES

Inventories consist of the following (in thousands):

	December 31, 2009	September 30, 2010	Increase
Raw materials	$ 176	$ 261	$ 85
Work-in-process	630	830	200
Finished goods	281	370	89
	$ 1,087	$ 1,461	$ 374

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NOTES TO FINANCIAL STATEMENTS (Continued)

September 30, 2010

4. BANK DEBT

During August 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 loan and a $500,000 line of credit, which is renewable annually. Proceeds from the $1,000,000 mortgage were received in August 2010. Based on a 15-year amortization schedule, a balloon principal payment of approximately $452,000 will be due in August 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%. As the result of our decision to hedge this interest rate risk, we incurred a charge to equity in the amount of approximately $39,000 to reflect the fair value of the interest rate swap liability as of September 30, 2010. 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 loan are expected in February 2011, and the $500,000 line of credit is available as needed. Interest on the loan and the line of credit will be variable at the higher rate of 4.25% or the one month London Interbank Offered Rate (LIBOR) plus 3.25% for the $600,000 loan or the one month LIBOR plus 3.50% for the $500,000 line of credit. In connection with the closing of these credit facilities, we incurred debt issue costs of approximately $26,000, which costs are being amortized to general and administrative expenses over the term of the credit facilities.

5. COMMITMENTS

In connection with a Development and Manufacturing Agreement entered into in July 2010 with Lonza Sales Ltd., we committed approximately $570,000 to Lonza to generate the manufacturing data required for a regulatory submission to the FDA pertaining to the development of **Mast Out®**. Approximately 5% of this work was complete as of September 30, 2010, and, accordingly, we accrued approximately $29,000 to product development expenses during the third quarter of 2010 on the percentage of completion basis. Most of this work is expected to be completed during the fourth quarter of 2010, and the balance should be completed in the first quarter of 2011. Subject to obtaining acceptable results from this work, we may choose to make additional and larger financial commitments to Lonza on a stage-by-stage basis to complete the manufacturing process development.

6. INCOME TAXES

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*. This Topic 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 tax effects of temporary differences between book income and taxable income. Accordingly, we have not established a valuation allowance for the deferred tax assets. Effective January 1, 2007, we implemented the provisions of Codification Topic 740-10, which clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax provision must meet before being recognized in the financial statements. Adoption of this Topic did not have an impact on our financial condition, results of operations, earnings per share or cash flows. 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. Although we believe that our estimates are reasonable, actual results could differ from these estimates.

7. NET LOSS PER COMMON SHARE

In accordance with Codification Topic 260-10, *Earnings Per Share*, 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. Outstanding stock options not included in the calculation aggregated approximately 400,000 during the three-month and the nine-month periods ended September 30, 2009 and 266,000 during the three-month and the nine-month periods ended

September 30, 2010.

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NOTES TO FINANCIAL STATEMENTS (Continued)

September 30, 2010

8. EMPLOYEE STOCK-BASED COMPENSATION

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. Accordingly, we recorded compensation expense pertaining to stock-based compensation of approximately $21,000 and $12,000 during the three-month periods ended September 30, 2009 and 2010, respectively, and $76,000 and $26,000 during the nine-month periods ended September 30, 2009 and 2010, respectively. Half of this expense is allocated to general and administrative expenses and half to product development expenses.

The exercise price of the 266,000 stock options outstanding as of September 30, 2010 ranged from $1.70 to $7.00 per share. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, as detailed in Note 5(b) to the financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2009. As of September 30, 2010, total unrecognized compensation costs related to non-vested stock-based compensation arrangements aggregated approximately $89,000. That cost is expected to be recognized through the first quarter of 2013, which represents the remaining vesting period of the outstanding, non-vested stock options.

9. COMMON STOCK

In September 1995, our Board of Directors adopted a Common Stock Rights Plan, the terms of which were set forth in a Rights Agreement with American Stock Transfer & Trust Co., as Rights Agent. Pursuant to the Rights Agreement, we issued certain rights to all holders of our common stock. Under the Rights Agreement, the rights expire on the earlier to occur of the Redemption Date (as defined in the Rights Agreement) or the Final Expiration Date (originally defined to be September 19, 2005). On June 8, 2005, our Board voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years, to September 19, 2008. On June 6, 2008 our Board voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years, to September 19, 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.

10. 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 sales of products that improve the health and productivity of cows for the dairy and beef industries. Almost all of the Company s internally funded product development expenses are in support of such products. Our primary customers for the majority (94% and 83% for the three-month periods ended September 30, 2009 and 2010, respectively) of our product sales are in the United States dairy and beef industries. Sales to non-U.S. customers who are in the dairy and beef industries aggregated 6% and 17% of product sales for the three-month periods ended September 30, 2009 and 2010, respectively. Our primary customers for the majority (79% and 82% for the nine-month periods ended September 30, 2009 and 2010, respectively) of our product sales are in the United States dairy and beef industries. Sales to non-U.S. customers who are in the dairy and beef industries aggregated 17% and 14% of product sales for the nine-month periods ended September 30, 2009 and 2010, respectively.

Sales to significant customers, as a percentage of total product sales, are detailed in the following table:

	Three-Month Periods Ended September 30,	Nine-Month Periods Ended September 30,

	2009	2010	2009	2010
Animal Health International, Inc.	26%	21%	25%	22%
Lextron, Inc./Vet Pharm, Inc.	13%	14%	15%	14%
MWI Veterinary Supply Co.	12%	14%	10%	12%

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NOTES TO FINANCIAL STATEMENTS (Continued)

September 30, 2010

Accounts receivable due from significant customers, as a percentage of total trade accounts receivable, are detailed in the following table:

	December 31, 2009	September 30, 2010
Animal Health International, Inc.	44%	24%
MWI Veterinary Supply Co.	10%	12%
Stearns Veterinary Outlet, Inc.	*	16%
Lextron, Inc./Vet Pharm, Inc.	*	14%

* Amount is less than 10%.

11. 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 $195,000 and $220,000 of products from ImmuCell during the nine-month periods ended September 30, 2009 and 2010, respectively, on terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated approximately $22,000 and $61,000 as of December 31, 2009 and September 30, 2010, respectively.

AlcheraBio LLC is a wholly-owned subsidiary of Argenta of New Zealand. Dr. Linda Rhodes (a member of our Board of Directors) is co-founder of AlcheraBio and currently serves as its Vice President, Clinical Affairs. We made payments of approximately $37,000 and $8,000 to Argenta for consulting services during the nine-month periods ended September 30, 2009 and 2010, respectively.

12. SUBSEQUENT EVENTS

We have adopted the disclosure provisions of Codification Topic, 855-10-50-1, 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. 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. Accordingly, we have evaluated subsequent events through the time of filing on November 8, 2010, 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 AND NINE-MONTH PERIODS ENDED SEPTEMBER 30, 2010

Product Sales

Product sales decreased by approximately 14%, or $137,000, to $874,000 during the three-month period ended September 30, 2010 in comparison to $1,011,000 during the same period in 2009. It is our production and customer service objective to ship orders within one day of receipt. We are operating in accordance with this objective currently, but some production problems did create a backlog of orders in 2009. We had no backlog of orders as of September 30, 2010, June 30, 2010 or September 30, 2009, but we did have a backlog of orders aggregating approximately $287,000 as of June 30, 2009 that shipped to customers during the third quarter of 2009. If this backlog of orders had shipped prior to July 1, 2009, our product sales during the third quarter of 2010 would have shown an increase of approximately 21%, or $150,000, in comparison to product sales ordered and recorded during the third quarter of 2009. Product sales decreased by approximately 6%, or $208,000, to $3,263,000 during the nine-month period ended September 30, 2010 in comparison to $3,472,000 during the same period in 2009. 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 nine months of 2010, domestic sales decreased by 3%, or $70,000, and foreign sales decreased by 19%, or $139,000, in comparison to the same period in 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 are launching a communications campaign by year-end that will highlight how the unique features of **First Defense®** provide a dependable return on investment for producers. Because we believe that market opportunities for growth of **First Defense®** sales exist in foreign territories, we are working with in-country consultants in key markets to help us through the process of seeking foreign regulatory approvals. Regulatory authorities in some foreign territories may require that our manufacturing operations be compliant with cGMP regulations. Because of import restrictions, in-country production may be required to gain regulatory approval to sell **First Defense®** in Australia and New Zealand. In March 2008, we entered into a license agreement with Immuron, Ltd. of Australia (formerly known as Anadis). Under this agreement, we gained access to relevant production technology and capabilities of Immuron in Australia. We are obligated to pay Immuron a royalty on any sales of **First Defense®** manufactured in Australia in collaboration with Immuron. This regulatory effort is currently on hold pending our success achieving a rotavirus claim for **First Defense®** because we believe that such a claim would be essential to market success in that territory.

We appreciate the 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 low milk prices and 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®** since receiving USDA approval of this product in 1991. We believe this milestone demonstrates 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®** decreased by 7% during the nine-month period ended September 30, 2010 in comparison to the same period in 2009. Domestic sales of **First Defense®** decreased by 4%, and this decrease was widened by a 21% decline in foreign sales of **First Defense®**. Sales of **Wipe Out® Dairy Wipes** increased by 11% during the nine-month period ended September 30, 2010 in comparison to the same period in 2009. 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 41% and 59% during the three-month periods ended September 30, 2010 and 2009, respectively. The gross margin as a percentage of product sales was 53% and 52% during the nine-month periods ended September 30, 2010 and 2009, respectively. The gross margin as a percentage of product sales was 54% and 50% during the twelve-month periods ended September 30, 2010 and 2009, respectively. This compares to gross margin percentages of 53%, 45% and 52% for the years ended December 31, 2009, 2008 and 2007, respectively. While our gross margin as a percentage of product sales dropped during the third quarter of 2010, due principally to some difficulties with certain manufacturing equipment that have recently been rectified, it has been maintained at or moderately above target during the other periods being reported. Our current annual objective for gross margin percentage is

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approximately 50%. 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 increases for approximately the seven-year period ended December 31, 2007, believing that we could benefit more from higher unit sales volume than through a higher average selling price per unit. During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense**® and have held that selling price without increase since then.

Changes in the gross margin on product sales are summarized in the following table for the respective periods (in thousands, except for percentages):

	Three-Month Periods Ended September 30,		Decrease	
	2009	2010	Amount	%
Gross margin	$ 599	$ 357	$ 242	40%
Percent of product sales	59%	41%	18%	31%

	Nine-Month Periods Ended September 30,		(Decrease) Increase	
	2009	2010	Amount	%
Gross margin	$ 1,807	$ 1,715	$ (92)	(5)%
Percent of product sales	52%	53%	1%	2%

	Twelve-Month Periods Ended September 30,		(Decrease) Increase	
	2009	2010	Amount	%
Gross margin	$ 2,377	$ 2,306	$ (71)	(3)%
Percent of product sales	50%	54%	4%	8%

Product Development

Product development expenses decreased by approximately 5%, or $16,000, to $312,000 during the three-month period ended September 30, 2010 in comparison to the same period in 2009. Product development expenses aggregated 36% and 32% of product sales during the three-month periods ended September 30, 2010 and 2009, respectively. Product development expenses decreased by approximately 16%, or $199,000, to $1,051,000 during the nine-month period ended September 30, 2010 in comparison to the same period in 2009. Product development expenses aggregated 32% and 36% of product sales during the nine-month periods ended September 30, 2010 and 2009, 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**®. During 2009, we were funding the pivotal effectiveness study of **Mast Out**®, which was completed in September 2009. We expect a significant increase in product development expenses above historical levels as we increasingly fund costs related to the development of the commercial manufacturing process for **Mast Out**®. We have committed approximately $570,000 to Lonza (our API manufacturer) to generate data required for a first submission of the CMC Technical Section to the FDA. Most of this work is expected to be completed (and expensed) during the fourth quarter of 2010 with the balance being completed during the first quarter of 2011. Subject to obtaining acceptable results from this work, we may choose to make additional and larger financial commitments to Lonza during 2011 on a stage-by-stage basis to complete the manufacturing process development and scale-up and to fund the production of validation batches of inventory.

In April 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**®. In November 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 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

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technology includes methods to achieve pharmaceutical-grade purity. Nisin is known to have activity against most gram positive and some gram negative bacteria. **Mast Out®**, an intramammary infusion product containing Nisin, is being developed as an alternative to traditional antibiotics used in the treatment of mastitis in lactating dairy cows.

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 with subclinical mastitis (those with infected udders, but still producing normal milk) can be sold, dairy producers generally do not treat subclinical mastitis - as 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 and lower milk production. Some industry experts have estimated that subclinical mastitis costs the U.S. dairy industry $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 for competitive products on the market.

In January 2004, we achieved positive results from an experimental field trial of **Mast Out®** in 139 cows with subclinical mastitis. The placebo-controlled, blinded, multi-farm study was conducted in collaboration with researchers at Cornell University. **Mast Out®** demonstrated a statistically significant overall cure rate in two separate dosage groups in comparison to the placebo group. In December 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 product development and marketing agreement in July 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®**. Our decision to continue product development efforts reflects our belief that **Mast Out®** is approvable by the FDA without a milk discard requirement for sale in the U.S.

A significant risk to the market success of **Mast Out®** is that the use of **Mast Out®** may require specific treatment restrictions at the herd level. Due to its antibacterial nature, Nisin in bulk tank milk could interfere with the manufacture of certain (but not all) cultured milk products, such as some kinds of cheese and yogurt, if a high enough percentage of animals from a herd is treated at any one time. We are evaluating potential strategies to minimize 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 this treatment restriction. Another risk is that **Mast Out®** likely will be priced at a premium to the traditional antibiotic products currently on the market.

In July 2007, we began preparations for the pivotal effectiveness study required for FDA approval of **Mast Out®.** Such preparations included the production of registration batches of drug product at 10% of the scale anticipated for commercial manufacture to fulfill the pivotal regulatory requirements of effectiveness, target animal safety and stability. In June 2008, we initiated the pivotal effectiveness study. Positive results from the study were announced on September 30, 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 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 several 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.

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2) Effectiveness: On September 30, 2009, we announced that we had met the pivotal effectiveness study end point. We accomplished our primary objective, which was to demonstrate effectiveness in the field at a level similar to currently marketed intramammary antibiotics. Additionally, we confirmed prior results from two major field studies conducted since 2003. We submitted the Effectiveness Technical Section to the FDA for review in August 2010. 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 as an intramammary treatment for subclinical mastitis in lactating cows. Allowing for one six-month review cycle, the Effectiveness Technical Section Complete Letter could be issued by the FDA in February 2011.

3) Human Food Safety: The Human Food Safety data determines if a milk discard period or meat withhold period will be required. This Technical Section includes several subsections such as residue chemistry (the necessary laboratory work was completed during the second quarter of 2010, and we expect to make the pivotal residue chemistry submission during the fourth quarter of 2010), total metabolism (which is complete), effects of drug residues in food on human intestinal microbiology (which is complete), effects on bacteria of human health concern or antimicrobial resistance (which is complete) and toxicology (which is complete). A zero meat withhold requirement, during the course of and for any period following treatment, has been granted. The Acceptable Daily Intake (ADI) level for humans proposed by us has been accepted by the FDA, and this ADI continues to support a zero milk discard claim. With all of these subsections now complete, the Human Food Safety Technical Section Complete Letter establishing a zero milk discard (or a milk discard period) could be issued by the FDA 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 fourth quarter of 2010. Allowing for one six-month review cycle, the Target Animal Safety Technical Section Complete Letter could be issued by the FDA during the second quarter of 2011.

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 July 2010, we entered into a development and supply agreement with Lonza Sales, Ltd. of Basel, Switzerland covering the exclusive manufacture of the Active Pharmaceutical Ingredient (API) by Lonza for us. 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 September 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**®. The timing of the CMC Technical Section submission and review defines the critical path to FDA approval of the product. We presently expect to make a first submission of the CMC Technical Section to the FDA for review during the first quarter of 2011. We expect that a second submission will be required after a first six-month review cycle by the FDA. We presently expect to make the second submission during the third or fourth quarter of 2011. Allowing for a second six-month review cycle, the CMC Technical Section Complete Letter could be issued by the FDA during the first half of 2012.

6) Several Administrative Requirements: The timing of the administrative NADA submission and the timing of a market launch (if the FDA grants approval) will be determined by the FDA s responses to our Technical Section submissions and successful resolution of any identified issues. After we obtain the final Technical Section Complete Letter and we prepare materials responsive to the other administrative requirements, we estimate that it would take an additional 30 days to assemble the administrative NADA submission for final review by the FDA. A statutory sixty-day review period of the administrative NADA would be expected. Without unanticipated delays, this would allow for approval of the administrative NADA by the FDA around the middle of 2012. Test market sales of product produced for the validation batches under the CMC Technical Section could be initiated upon FDA approval.

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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. It is our objective to initiate a pivotal effectiveness study by the first 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.

We are making a sustained investment to comply with cGMP regulations across our product lines. We believe that compliance with cGMP standards increases our product quality and compliance with current regulations applicable to certain products and may open access to foreign markets where such standards are imposed.

General and Administrative Expenses

During the three-month period ended September 30, 2010, general and administrative expenses decreased by 3%, or $6,000, to $195,000 as compared to the same period in 2009. During the nine-month period ended September 30, 2010, general and administrative expenses decreased by 1%, or $8,000, to $659,000 as compared to the same period in 2009. 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 September 30, 2010, sales and marketing expenses increased by 83%, or $89,000, to $197,000, as compared to the same period in 2009, aggregating 23% and 11% of product sales during the three-month periods ended September 30, 2010 and 2009, respectively. During the nine-month period ended September 30, 2010, sales and marketing expenses increased by 48%, or $155,000, to $475,000, as compared to the same period in 2009, aggregating 15% and 9% of product sales during the nine-month periods ended September 30, 2010 and 2009, respectively. The increases were expected and planned given our strategic decision to invest in additional sales and marketing personnel and efforts. Our objective is to maintain the ratio of product selling expenses to product sales at approximately 15% for the full year 2010.

Loss Before Income Taxes and Net Loss

Our loss before income taxes of $(351,000) during the three-month period ended September 30, 2010 compares to our loss before income taxes of $(20,000) during the three-month period ended September 30, 2009. Our income tax benefit was 44% and 6% of our loss before income taxes during the three-month periods ended September 30, 2010 and 2009, respectively. Our net loss for the three-month period ended September 30, 2010 was $(197,000), or $(0.07) per share, in comparison to a net loss of $(19,000), or $(0.01) per share, during the three-month period ended September 30, 2009. Our loss before income taxes of $(452,000) during the nine-month period ended September 30, 2010 compares to our loss before income taxes of $(339,000) during the nine-month period ended September 30, 2009. Our income tax benefit was 43% and 41% of our loss before income taxes during the nine-month periods ended September 30, 2010 and 2009, respectively. Our net loss for the nine-month period ended September 30, 2010 was $(257,000), or $(0.09) per share, in comparison to a net loss of $(201,000), or $(0.07) per share, during the nine-month period ended September 30, 2009.

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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) and $(216,000) during 2008 and 2009, respectively, and $(257,000) during the nine-month period ended September 30, 2010. We are projecting a net loss during the fourth quarter of 2010 and for 2011. We believe that the commercial prospects for **Mast Out**® warrant this level of investment.

In August 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 ten-year mortgage loan of $1,000,000, a $600,000 fifty-four month loan and a $500,000 line of credit, which is renewable annually. Proceeds from the $1,000,000 mortgage were received in August 2010. Proceeds from the $600,000 loan are expected in February 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 development of **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. At this point, the most expensive and time-consuming initiative remaining to be completed in the development of **Mast Out**® is the scale-up and testing of the Nisin API manufacturing process. We have committed approximately $570,000 to Lonza (our API manufacturer). Most of this work is expected to be completed during the fourth quarter of 2010, with the balance being completed during the first quarter of 2011. Subject to obtaining acceptable results from this work, we may choose to make additional and larger financial commitments to Lonza during 2011 on a stage-by-stage basis to complete the manufacturing process development and to fund the production of validation batches for inventory that would be required to complete the CMC Technical Section. We expect to have product produced for the validation batches under the CMC Technical Section to sell in a test market subject to FDA approval, which is anticipated during the middle of 2012. Additional financing (most likely through a partner) needs to be arranged to pay for commercial batches of product for full market launch in 2012. Upon completion of this product development effort, we expect to return to profitable operations with or without new sales of **Mast Out**®.

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 did not increase this authorized limit during 2009 or to date in 2010. As of October 1, 2010, we had remaining authorization to spend up to $334,000 on capital expenditures, net of payments made from January 1, 2008 through September 30, 2010.

Cash, cash equivalents and short-term investments increased by 10%, or $473,000, to $5,058,000 at September 30, 2010 from $4,585,000 at December 31, 2009. Net cash used for operating activities amounted to $(387,000) during the nine-month period ended September 30, 2010 in contrast to net cash provided by operating activities of $108,000 during the nine-month period ended September 30, 2009. Net working capital increased by 12%, or $708,000, to $6,652,000 at September 30, 2010 from $5,944,000 at December 31, 2009. Proceeds from bank debt received during the third quarter of 2010 aggregated $970,000, net of debt issuance costs and repayments made prior to October 1, 2010. Total assets increased by 8%, or $786,000, to $10,771,000 at September 30, 2010 from $9,985,000 at December 31, 2009. Stockholders equity decreased by 3%, or $270,000, to $9,352,000 at September 30, 2010 from $9,622,000 at December 31, 2009. 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. Our current resources, together with the proceeds from the debt commitment we entered into during the third quarter of 2010, are expected to be sufficient to fund the completion of the **Mast Out**® product development effort. The production of commercial batches of inventory for a market launch of **Mast Out**® (if the product is approved by the FDA) would require additional funding. 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 September 30, 2010. 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 September 30, 2010 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
Risk Factors; Forward-Looking Statements

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 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 statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, the uncertainties associated with product development, manufacturing reliance upon third parties for products and services, changes in laws and

regulations, decision making by regulatory authorities, currency fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized below and uncertainties otherwise referred to in this Quarterly Report. In addition, there can be no assurance that future developments affecting us will be those that we anticipate, especially considering the effects the distress in credit and capital markets will have on our current and prospective customers and the global economy and the uncertainties surrounding the potential for a prolonged global recession.

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Projections of loss before income taxes and net loss: After nine consecutive years of reporting net income, we reported a loss before income taxes of $(961,000) and a net loss of $(469,000) for the year ended December 31, 2008, a loss before income taxes of $(429,000) and a net loss of $(216,000) for the year ended December 31, 2009 and a loss before income taxes of $(452,000) and a net loss of $(257,000) during the nine-month period ended September 30, 2010, due in large part to our current product development strategy. Continued development of **Mast Out**® will likely result in a net loss during the remainder of 2010 and an increased net loss during 2011. We believe that our current balance of cash and short-term investments is more than sufficient to fund our projected loss in 2010. We believe that our remaining cash and short-term investments, together with gross margin generated from ongoing product sales and the debt financing arranged in August 2010, will be sufficient to fund our projected loss in 2011. The market launch of **Mast Out**® will require additional capital. There is no assurance that we will have sufficient capital to fund our growth plans, but we do expect to return to profitable operations with or without new sales of **Mast Out**® in 2012. Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Stronger than expected sales of **First Defense**®, for example, could diminish the overall loss. Conversely, weaker than expected sales of **First Defense**® could lead to larger losses. Another example of a factor that could increase our loss is if we experience unanticipated costs associated with developing and seeking regulatory approval of **Mast Out**®. Prior to 2008, we had not publicly disclosed our projections of future profitability. We did so in 2008 and 2009 and have done so again for 2010 and 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 its stockholders.

Exposure to risks associated with the current financial downturn and global economic crisis: The U.S. economy appears to be just coming out of a recession, caused principally by the housing, credit and financial crises. The credit markets continue to be very turbulent and uncertain. Sales and financial performance are still down at many businesses. This extraordinary period of instability facing the U.S. economy and the financial markets has been troubling for nearly all Americans. To survive, companies have eliminated jobs, cut or frozen pay, trimmed hours, suspended matching contributions to 401(k) plans, reduced or eliminated health insurance, bonuses, or perks that were offered during better economic times, among other cost-saving measures. A continued and prolonged economic downturn could have a corresponding negative effect on our business and operations.

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. A significant decrease in the herd size was expected in 2009, but the average only declined to 9,200,000. The herd size peaked at 9,334,000 in December 2008 and did decline to 9,082,000 in December 2009. As of September 2010, the herd size is estimated to be approximately 9,116,000 cows. The size of the milking herd affects the price of milk. The impact on the milk supply from this decrease in cows is offset, in part, by an increase in milk production per cow. 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 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. During the first nine months of 2010, this price level averaged $14.07 in comparison to $10.49 during the first nine months of 2009. 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. 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 foreign demand for milk products. However, the actual level of milk prices may be less important than their level relative to costs. Costs to produce milk are significant and to some extent can be managed by dairy producers. 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. During the first nine months of 2010, this ratio averaged 2.27 in comparison to 1.62 during the first nine months of 2009. This means that a dairy producer can buy only 2.27 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

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2007. This price averaged approximately $1,385 in 2009, which represented a 29% decrease in comparison to the same period in 2008. The average of this price as of January, April, July and October 2010 was $1,330 as compared to $1,385 as of January, April, July and October 2009. The dairy industry data referred to above is compiled from USDA databases. Another factor in the demand for our product is the value of bull calves. A decline in the price of bull calves reduces the return on investment from a dose of First **Defense**® for bull calves. We are trying to maintain and grow our sales for use with heifer calves to offset what we assume is a significant loss in our sales 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.

Product risks generally: The sale of our products is subject to financial, efficacy, regulatory and competitive and other market risks. We cannot be sure that we will be able to maintain the regulatory compliance required to continue selling our products. There is no assurance that we will continue to achieve market acceptance at a profitable price level or that we can continue to manufacture our products at a sufficient gross margin.

Product Liability: The manufacture and sale of certain of our products entails a risk of product liability. Our exposure to product liability is mitigated to some extent by the fact that our products are principally directed towards the animal health market. We have maintained product liability insurance in an amount which we believe is reasonable in relation to our potential exposure in this area.

*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 and 2009 and the nine-month period ended September 30, 2010, 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 49% for the years ended December 31, 2008 and 2009, respectively) was made to three large distributors. A large portion of our trade accounts receivable (62% as of December 31, 2009) was due from these three distributors. These three distributors accounted for 48% of our product sales during the first nine months of 2010 and 50% of our trade accounts receivable as of September 30, 2010. 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 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 there is no assurance that we will obtain all of the clinical and other data necessary to support regulatory approval for this product. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Pfizer, Merck/Intervet/Schering Plough 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 an important competitive feature of this product. It presently is uncertain whether or when this approval will be achieved. Such approval will also require a successful inspection under cGMP standards by the FDA of the facility we have selected to manufacture the product. We are exposed to additional regulatory compliance risk through the subcontractors that we choose to work with to produce **Mast Out**®. Foreign 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.

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*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.

*Regulatory requirements for **Wipe Out® Dairy Wipes***: While the FDA regulates the manufacture and sale of **Wipe Out®**, this type of product is permitted to be sold without a NADA approval, in accordance with the FDA s Compliance Policy Guide 7125.30 (Teat Dips and Udder Washes for Dairy Cows and Goats). This policy guide could be withdrawn at the FDA s discretion, in which case we would likely discontinue sales of the product. The manufacture of **Wipe Out®** is subject to Part 211 of the cGMP regulations. As such, our operations are subject to inspection by the FDA. We continue to invest in personnel, facility improvements and new equipment to sustain compliance with cGMP regulations across our entire product line. In June 2007, we received a Warning Letter from the FDA citing deficiencies in specific areas of the cGMP regulations. We filed a response to the FDA in June 2007, and we responded to a request for additional information in April 2008. We believe we have substantially corrected the deficiencies cited, but have received no further communications from the FDA on this subject. We remain subject to the risk of adverse action by the FDA in this respect.

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

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

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 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 a risk that competitors could challenge the claims in patents that have been issued to us.

Small size: We are a small company with 29 full-time and three 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 reporting obligations as a public company are costly: Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws and the provisions of the Sarbanes-Oxley Act of 2002.

Access to raw materials: Our policy is to maintain more than one source of supply for the components used to manufacture and test our products. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. We are dependent on our manufacturing operations and facility at 56 Evergreen Drive in Portland, Maine for the

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production of **First Defense**® and **Wipe Out**® **Dairy Wipes**. The specific antibodies that we purify for **First Defense**® and the Nisin we produce by fermentation for **Wipe Out**® **Dairy Wipes** are not readily available from other sources. We will be dependent on Lonza for the manufacture of **Mast Out**® 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.

Bovine diseases: The potential for epidemics of bovine diseases such as Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) presents a risk to us and our customers. Documented cases of BSE in the U.S. have led to an overall tightening of regulations pertaining to ingredients of animal origin, especially bovine. **First Defense**® is considered a veterinary medicine rather than a feed ingredient, and it is manufactured from bovine milk and colostrum, which is not considered a BSE risk material. Future regulatory action to increase protection of the human food supply could affect **First Defense**®, although presently we do not anticipate that this will be the case.

Biological terrorism: The threat of biological terrorism is a risk to both the economic health of our customers and to our ability to economically acquire and collect good quality raw material from our contract farms. Any act of widespread bioterrorism against the dairy industry could adversely affect our operations.

No expectation to pay any dividends for the foreseeable future: We do not anticipate paying any dividends to our stockholders for the foreseeable future, instead using cash to fund product development costs. Also, 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 results of operations, financial condition, 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 (NASDAQ: ICCC). Our average daily trading volume is lower than the volume for most other companies, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire.

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 10.1[(1)]	Contract Manufacture Agreement between The Company and Norbrook Laboratories Limited dated as of September 27, 2010.
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.

(1) Confidential Treatment as to certain portions has been requested, which portions have been omitted and filed separately with the Securities and Exchange Commission.

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SIGNATURE

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

ImmuCell Corporation
Registrant

Date: November 8, 2010

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