IMMUCELL CORP /DE/
Form 10-Q
August 16, 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 June 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 August 13, 2010, the registrant had 2,970,652 shares of Common Stock, par value $0.10 per share, outstanding.

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June 30, 2010

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BALANCE SHEETS

	December 31, 2009	(Unaudited) June 30, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 975,490	$ 1,744,749
Short-term investments	3,610,000	2,472,000
Trade accounts receivable, net of allowance for doubtful accounts of $10,000 and $11,000 at December 31, 2009 and June 30, 2010, respectively	390,242	512,037
Income taxes receivable	1,248	1,248
Other receivables	24,022	44,101
Inventories	1,087,391	1,354,684
Prepaid expenses	179,828	137,863
Current portion of deferred tax asset	38,507	23,269
Total current assets	6,306,728	6,289,951
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	2,820,425	2,860,515
Building and improvements	2,537,602	2,546,705
Office furniture and equipment	190,799	223,588
Land	50,000	50,000
	5,598,826	5,680,808
Less accumulated depreciation	2,619,828	2,821,678
Net property, plant and equipment	2,978,998	2,859,130
LONG-TERM PORTION OF DEFERRED TAX ASSET	698,085	755,220
OTHER ASSETS	900	725
TOTAL ASSETS	$ 9,984,711	$ 9,905,026
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$ 222,885	$ 204,534
Accounts payable	139,885	123,865
Total current liabilities	362,770	328,399
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 June 30, 2010	326,115	326,115
Capital in excess of par value	9,751,442	9,765,833
Accumulated surplus	179,879	120,174
Treasury stock at cost 290,496 shares at December 31, 2009 and June 30, 2010, respectively	(635,495)	(635,495)
Total stockholders equity	9,621,941	9,576,627
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 9,984,711	$ 9,905,026

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

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ImmuCell Corporation

STATEMENTS OF OPERATIONS FOR THE

THREE-MONTH AND SIX-MONTH PERIODS ENDED JUNE 30, 2009 AND 2010

(Unaudited)

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2009	2010	2009	2010
REVENUES:				
Product sales	$ 1,000,629	$ 1,077,672	$ 2,460,907	2,389,419
Royalty income	718	1,538	1,927	1,974
Total revenues	1,001,347	1,079,210	2,462,834	2,391,393
COSTS AND EXPENSES:				
Product costs	512,803	459,055	1,252,523	1,031,645
Product development expenses	488,954	333,320	921,439	738,782
General and administrative expenses	231,594	224,569	465,249	463,495
Sales and marketing expenses	83,776	108,358	211,875	277,526
Total costs and expenses	1,317,127	1,125,302	2,851,086	2,511,448
Net operating loss	(315,780)	(46,092)	(388,252)	(120,055)
Interest income	32,432	7,722	67,846	16,441
Other income	903	1,648	1,496	2,086
Interest and other income	33,335	9,370	69,342	18,527
LOSS BEFORE INCOME TAXES	(282,445)	(36,722)	(318,910)	(101,528)
INCOME TAX BENEFIT	(134,625)	(30,283)	(136,461)	(41,823)
NET LOSS	$ (147,820)	$ (6,439)	$ (182,449)	$ (59,705)
NET LOSS PER COMMON SHARE:				
Basic	$ (0.05)	$ (0.00)	$ (0.06)	$ (0.02)
Diluted	$ (0.05)	$ (0.00)	$ (0.06)	$ (0.02)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic	2,970,652	2,970,652	2,946,718	2,970,652
Diluted	2,970,652	2,970,652	2,946,718	2,970,652

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

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ImmuCell Corporation

STATEMENTS OF STOCKHOLDERS EQUITY

(Unaudited)

FOR THE SIX-MONTH PERIOD ENDED JUNE 30, 2009

	Common Stock $0.10 Par Value		Capital in Excess of	Accumulated	Treasury Stock		Total Stockholders
	Shares	Amount	Par Value	Surplus	Shares	Amount	Equity
BALANCE,							
December 31, 2008	3,261,148	$ 326,115	$ 9,722,967	$ 396,372	366,496	$ (801,753)	$ 9,643,701
Net loss				(182,449)			(182,449)
Exercise of stock options, net			(66,508)		(76,000)	166,258	99,750
Stock-based compensation			54,664				54,664
Tax benefits related to stock options			921				921
BALANCE,							
June 30, 2009	3,261,148	$ 326,115	$ 9,712,044	$ 213,923	290,496	$ (635,495)	$ 9,616,587

FOR THE SIX-MONTH PERIOD ENDED JUNE 30, 2010

	Common Stock $0.10 Par Value		Capital in Excess of	Accumulated	Treasury Stock		Total Stockholders
	Shares	Amount	Par Value	Surplus	Shares	Amount	Equity
BALANCE,							
December 31, 2009	3,261,148	$ 326,115	$ 9,751,442	$ 179,879	290,496	$ (635,495)	$ 9,621,941
Net loss				(59,705)			(59,705)
Stock-based compensation			14,391				14,391
BALANCE,							
June 30, 2010	3,261,148	$ 326,115	$ 9,765,833	$ 120,174	290,496	$ (635,495)	$ 9,576,627

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

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ImmuCell Corporation

STATEMENTS OF CASH FLOWS FOR THE SIX-MONTH PERIODS

ENDED JUNE 30, 2009 AND 2010

(Unaudited)

	Six-Month Periods Ended June 30,	
	2009	**2010**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (182,449)	$ (59,705)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	189,911	210,945
Amortization	15,072	
Deferred income taxes	(137,477)	(41,897)
Stock-based compensation	54,664	14,391
Loss on disposal of fixed assets	29,861	
Changes in:		
Receivables	17,842	(141,874)
Inventories	(91,078)	(267,293)
Prepaid expenses and other assets	(27,659)	42,140
Accrued expenses	(189,329)	(18,351)
Accounts payable	87,698	(12,922)
Net cash used for operating activities	(232,944)	(274,566)
CASH FLOWS FROM INVESTING ACTIVITES :		
Purchase of property, plant and equipment	(105,765)	(94,175)
Maturities of short-term investments	2,502,103	2,371,000
Purchases of short-term investments	(2,371,000)	(1,233,000)
Net cash provided by investing activities	25,338	1,043,825
CASH FLOWS FROM FINANCING ACTIVITIES:		
Tax benefits related to stock options	921	
Proceeds from exercise of stock options, net	99,750	
Net cash provided by financing activities	100,671	
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(106,935)	769,259
BEGINNING CASH AND CASH EQUIVALENTS	1,199,929	975,490
ENDING CASH AND CASH EQUIVALENTS	$ 1,092,994	$ 1,744,749
INCOME TAXES PAID	$ (90)	$ (74)
NON-CASH INVESTING AND FINANCING ACTIVITIES:	$ 7,313	$ (3,098)

Change in capital expenditures included in accounts payable

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

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NOTES TO FINANCIAL STATEMENTS

June 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 FDIC insurance limits. The Emergency Economic Stabilization Act of 2008 increased these insurance limits from $100,000 to $250,000 per institution per depositor for the period from October 3, 2008 to December 31, 2009. During the second quarter of 2009, this period of increased insurance limits was extended through December 31, 2013. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act extended this $250,000 limit indefinitely.

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

	December 31, 2009	June 30, 2010	Increase (Decrease)
Cash and cash equivalents	$ 975	$ 1,745	$ 770
Short-term investments	3,610	2,472	(1,138)
	$ 4,585	$ 4,217	$ (368)

3. INVENTORIES

Inventories consist of the following (in thousands):

	December 31, 2009	June 30, 2010	Increase (Decrease)
Raw materials	$ 176	$ 216	$ 40
Work-in-process	630	609	(21)
Finished goods	281	530	249

$ 1,087	$ 1,355	$ 268

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NOTES TO FINANCIAL STATEMENTS (Continued)

June 30, 2010

4. 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.

5. 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 386,000 and 273,000 during the three-month and the six-month periods ended June 30, 2009 and 2010, respectively.

6. 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 $23,000 and $0 during the three-month periods ended June 30, 2009 and 2010, respectively, and $55,000 and $14,000 during the six-month periods ended June 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 273,000 stock options outstanding as of June 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 June 30, 2010, total unrecognized compensation costs related to non-vested stock-based compensation arrangements aggregated approximately $111,000. 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.

7. 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.

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NOTES TO FINANCIAL STATEMENTS (Continued)

June 30, 2010

8. 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 (69% and 74% for the three-month periods ended June 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 13% of product sales for the three-month periods ended June 30, 2009 and 2010, respectively. Our primary customers for the majority (73% and 82% for the six-month periods ended June 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 21% and 13% of product sales for the six-month periods ended June 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 June 30,		Six-Month Periods Ended June 30,	
	2009	2010	2009	2010
Animal Health International, Inc.	20%	26%	25%	22%
Lextron, Inc./Vet Pharm, Inc.	17%	11%	16%	14%
MWI Veterinary Supply Co.	10%	12%	*	12%
TCS Biosciences, Ltd.	13%	13%	*	*

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

	December 31, 2009	June 30, 2010
Animal Health International, Inc.	44%	26%
MWI Veterinary Supply Co.	10%	13%
TCS Biosciences, Ltd.	*	26%

* Amount is less than 10%.

9. 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 $127,000 and $142,000 of products from ImmuCell during the six-month periods ended June 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 less than $1,000 as of December 31, 2009 and June 30, 2010, respectively. Additionally, we spent less than $5,000 on marketing support for affiliated companies controlled by Dr. Tomsche during both of the six-month periods ended June 30, 2009 and 2010.

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. During the six-month periods ended June 30, 2009 and

2010, we made payments of less than $10,000 to Argenta for consulting services.

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NOTES TO FINANCIAL STATEMENTS (Continued)

June 30, 2010

10. 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 or are available to be 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 August 13, 2010, the date we have issued this Quarterly Report on Form 10-Q.

During July 2010, we entered into a development and long-term supply agreement with Lonza Sales, Ltd of Basel, Switzerland covering the exclusive manufacture of pharmaceutical-grade Nisin by Lonza for us. In connection therewith, we committed almost $550,000 to Lonza to generate the data required for a first submission of the CMC Technical Section. This work is expected to be completed during the second half of 2010. 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.

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 ten-year mortgage loan of $1,000,000, a $600,000 five-year 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.

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

RESULTS OF OPERATIONS FOR THE THREE-MONTH AND SIX-MONTH PERIODS ENDED JUNE 30, 2010

Product Sales

Product sales increased by approximately 8%, or $77,000, to $1,078,000 during the three-month period ended June 30, 2010 in comparison to $1,001,000 during the same period in 2009. Product sales decreased by approximately 3%, or $71,000, to $2,389,000 during the six-month period ended June 30, 2010 in comparison to $2,461,000 during the same period in 2009. During the first six months of 2010, domestic sales increased by 8%, or $150,000, but foreign sales decreased by 33%, or $221,000, in comparison to the same period in 2009. We had no backlog of orders as of June 30, 2010. As of June 30, 2009, we had a backlog of orders aggregating approximately $287,000. If this backlog of orders had shipped prior to July 1, 2009, our product sales during the second quarter of 2010 would have been down by approximately 16%, or $210,000, and our product sales during the first six months of 2010 would have been down by 13%, or $358,000.

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. We have sold over 9,000,000 doses of **First Defense®** since receiving USDA approval of this product in 1991. Sales are normally seasonal, with higher sales expected during the first and fourth quarters and lower sales expected during the second and third quarters. 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. Sales of **First Defense®** decreased by 2% during the six-month period ended June 30, 2010 in comparison to the same period in 2009. Domestic sales of **First Defense®** increased by 9%, but this increase was more than offset by a decline in foreign sales of **First Defense®**. Sales of **Wipe Out® Dairy Wipes** increased by 9% during the six-month period ended June 30, 2010 in comparison to the same period in 2009. Despite this increase, domestic sales of this premium product continue to be under competitive pressure from less expensive products, alternative teat sanitizing methods and the continuing economic difficulties faced by the U.S. dairy industry.

Gross Margin

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

	Three-Month Periods Ended June 30,		Increase	
	2009	2010	Amount	%
Gross margin	$ 488	$ 619	$ 131	27%
Percent of product sales	49%	57%	8%	16%

	Six-Month Periods Ended June 30,		Increase	
	2009	2010	Amount	%
Gross margin	$ 1,208	$ 1,358	$ 150	12%
Percent of product sales	49%	57%	8%	16%

	Twelve-Month Periods Ended June 30,		Increase	
	2009	2010	Amount	%
Gross margin	$ 2,081	$ 2,547	$ 466	22%
Percent of product sales	45%	57%	12%	27%

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ImmuCell Corporation

The gross margin as a percentage of product sales was 57% and 49% during the three-month periods ended June 30, 2010 and 2009, respectively. The gross margin as a percentage of product sales was 57% and 49% during the six-month periods ended June 30, 2010 and 2009, respectively. The gross margin as a percentage of product sales was 57% and 45% during the twelve-month periods ended June 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 2008, we have experienced improvement since then. Our current annual objective for gross margin percentage is 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 did implement a modest increase to the selling price of **First Defense®** and have held that selling price without increase since then.

Product Development

Product development expenses decreased by approximately 32%, or $156,000, to $333,000 during the three-month period ended June 30, 2010 in comparison to the same period in 2009. Product development expenses aggregated 31% and 49% of product sales during the three-month periods ended June 30, 2010 and 2009, respectively. Product development expenses decreased by approximately 20%, or $183,000, to $739,000 during the six-month period ended June 30, 2010 in comparison to the same period in 2009. Product development expenses aggregated 31% and 37% of product sales during the six-month periods ended June 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.

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 is a well characterized substance, having been used in food preservation applications for over 50 years. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes methods to achieve pharmaceutical-grade purity. 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. **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. 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. We have not evaluated the milk discard regulations for new products in other foreign territories.

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. In July 2007, we received notice from Pfizer that it had elected to terminate the product development and marketing agreement. 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

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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. We believe that such a product has significant sales potential in the U.S. dairy market

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, 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 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. 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: 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.

3) 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 intend to submit the Target Animal Safety Technical Section to the FDA for review during the third quarter of 2010.

4) 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 third 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. All of these subsections must be completed before the Human Food Safety Technical Section Complete Letter establishing a zero milk discard (or a milk discard period) can be issued by the FDA.

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5) Chemistry, Manufacturing and Controls (CMC): We are developing collaborations with 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 long-term supply agreement with Lonza Sales, Ltd of Basel, Switzerland covering the exclusive manufacture of pharmaceutical-grade Nisin 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. We are negotiating a manufacturing relationship with an FDA-approved drug product manufacturer to formulate the Active Pharmaceutical Ingredient (API) into drug product, conduct sterile-fill of syringes and perform final packaging. 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 fourth quarter of 2010. We expect that a second submission will be required by the FDA before a Technical Section Complete Letter could be issued.

6) Several Administrative Requirements: After we obtain all the Technical Section Complete Letters and we prepare materials responsive to the other administrative requirements, we would assemble the administrative NADA submission for final review by the FDA. 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. Assuming no unanticipated delays in this process, we believe we could make the administrative NADA submission to the FDA by the end of 2011. A sixty-day review period of the administrative NADA would be expected. Test market sales of product produced for the validation batches under the CMC Technical Section could be initiated upon FDA approval.

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 expect to initiate a pivotal effectiveness study during the fourth quarter of 2010. Successful results could position us for USDA approval of an additional disease claim for **First Defense®** to prevent scours caused by rotavirus in 2011. 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.

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.

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 of our products and may open access to foreign markets where such standards are imposed.

General and Administrative Expenses

During the three-month period ended June 30, 2010, general and administrative expenses decreased by 3%, or $7,000, to $225,000 as compared to the same period in 2009. During the six-month period ended June 30, 2010, general and administrative expenses decreased by less than 1%, or $2,000, to $463,000 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 on 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

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are available on-line or upon request to the Company. At this time, our financial and time resources are heavily committed to principally developing **Mast Out®** and operating our commercial business. Our board of directors is very involved with this resource allocation. While this strategy 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 June 30, 2010, sales and marketing expenses increased by 29%, or $25,000, to $108,000, as compared to the same period in 2009, aggregating 10% and 8% of product sales during the three-month periods ended June 30, 2010 and 2009, respectively. During the six-month period ended June 30, 2010, sales and marketing expenses increased by 31%, or $66,000, to $278,000, as compared to the same period in 2009, aggregating 12% and 9% of product sales during the six-month periods ended June 30, 2010 and 2009, respectively. The increases were expected 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 below 15% on an annual basis.

Loss Before Income Taxes and Net Loss

Our loss before income taxes of $(37,000) during the three-month period ended June 30, 2010 compares to our loss before income taxes of $(282,000) during the three-month period ended June 30, 2009. Our income tax benefit was 82% and 48% of our loss before income taxes during the three-month periods ended June 30, 2010 and 2009, respectively. Our net loss for the three-month period ended June 30, 2010 was $(6,000), or less than $(0.01) per share, in comparison to a net loss of $(148,000), or $(0.05) per share, during the three-month period ended June 30, 2009. Our loss before income taxes of $(102,000) during the six-month period ended June 30, 2010 compares to our loss before income taxes of $(319,000) during the six-month period ended June 30, 2009. Our income tax benefit was 41% and 43% of our loss before income taxes during the six-month periods ended June 30, 2010 and 2009, respectively. Our net loss for the six-month period ended June 30, 2010 was $(60,000), or $(0.02) per share, in comparison to a net loss of $(182,000), or $(0.06) per share, during the six-month period ended June 30, 2009.

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 $(216,000) and $(469,000) during 2009 and 2008, respectively, and $(60,000) during the six-month period ended June 30, 2010. We are projecting further net losses during the second half of 2010 and for 2011. We believe that the commercial prospects for **Mast Out®** warrant this level of investment.

The investment required for full commercial manufacture of Nisin API is expected to exceed our cash, cash equivalents and short-term investments balance as of June 30, 2010. 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. 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 five-year 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®**. At this point, the most expensive and time-consuming initiative remaining to be completed is the scale-up and testing of the Nisin API manufacturing process. We have committed almost $550,000 to Lonza (our API manufacturer) to generate the data required for a first submission of the CMC Technical Section. This work is expected to be conducted during the second half of 2010. 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 and to fund the production of validation batches for inventory that would be required for the second submission of the CMC Technical Section. We expect to have product produced for the validation batches under the CMC Technical Section to sell (subject to FDA approval) in a test market by the end of 2011. 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®**.

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As we implement 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 July 1, 2010, we had remaining authorization to spend up to $350,000 on capital expenditures, net of payments made from January 1, 2008 through June 30, 2010.

Cash, cash equivalents and short-term investments decreased by 8%, or $369,000, to $4,217,000 at June 30, 2010 from $4,585,000 at December 31, 2009. Net cash used for operating activities amounted to $(275,000) during the six-month period ended June 30, 2010 in comparison to net cash used for operating activities of $(233,000) during the six-month period ended June 30, 2009. Total assets decreased by less than 1%, or $80,000, to $9,905,000 at June 30, 2010 from $9,985,000 at December 31, 2009. We had no outstanding bank debt or open line of credit as of June 30, 2010. Net working capital increased by less than 1%, or $18,000, to $5,962,000 at June 30, 2010 from $5,944,000 at December 31, 2009. Stockholders equity decreased by less than 1%, or $45,000, to $9,577,000 at June 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.

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 June 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 June 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable

ITEM 1A. RISK FACTORS

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 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 expressions. Such sta 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, changes in laws and regulations, decision making by regulatory authorities 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 customers and the global economy and the uncertainties surrounding the potential for a prolonged global recession.

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 $(102,000) and a net loss of $(60,000) during the six-month period ended June 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 second half of 2010 and during 2011 as well. 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, is 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®**. Historically, we have 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 is either in a recession, or just coming out of a recession, caused principally by the housing, credit and financial crises. The credit markets are very turbulent and uncertain. Sales and financial performance are down at most businesses. This extraordinary period of instability facing the U.S. economy and the financial

markets has been troubling for nearly all

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Americans. To survive, companies are eliminating jobs, cutting or freezing pay, trimming hours, suspending matching contributions to 401(k) plans, reducing or doing away with 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 June 2010, the herd size is estimated to be approximately 9,101,000 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. A common index used in the industry to measure the price of milk is known as the Class III milk price, which indicates the value of 100 pounds of milk sold into the cheese market. 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 six months of 2010, this price level averaged $13.58 in comparison to $10.19 during the first six 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 six months of 2010, this ratio averaged 2.25 in comparison to 1.53 during the first six months of 2009. This means that a dairy producer can buy only 2.25 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 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 and July 2010 was $1,330 as compared to $1,433 as of January, April and July 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. The decline in the price of bull calves has reduced 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 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 six-month period ended June 30, 2010, without the gross margin that we earned from the sale of **First Defense®**.

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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 six months of 2010 and 45% of our trade accounts receivable as of June 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: Two of our products, and modifications and extensions thereto, are 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.

*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 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 better established in the relevant markets, and have substantially greater financial, marketing, manufacturing and human resources and more extensive product

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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. 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 28.5 full-time equivalent 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 that are continuing to increase as provisions of the Sarbanes-Oxley Act of 2002 are implemented.

Access to raw materials: Our policy is to maintain more than one source of supply for the components used to manufacture and test our products. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. We are dependent on our manufacturing operations and facility at 56 Evergreen Drive in Portland, Maine for the production of **First Defense®** and **Wipe Out® Dairy Wipes** and will be dependent on Lonza for the manufacture of **Mast Out®** if that product proceeds to commercialization. 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. 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 shareholders 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. Shareholders 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 many other companies, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire.

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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)]	Development and Manufacturing Agreement between the Company and Lonza Sales, Ltd. dated July 15, 2010.
Exhibit 10.2	Commercial Promissory Note for $1,000,000 between the Company and TD Bank, N.A. dated August 13, 2010.
Exhibit 10.3	Commercial Promissory Note for $600,000 between the Company and TD Bank, N.A. dated August 13, 2010.
Exhibit 10.4	Line of Credit Agreement and Promissory Note for up to $500,000 between the Company and TD Bank, N.A. dated August 13, 2010
Exhibit 10.5[(1)]	Loan Agreement between the Company and TD Bank, N.A. dated August 13, 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: August 16, 2010

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

and Principal Financial Officer