IMMUCELL CORP /DE/
Form 10-Q
November 04, 2009
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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, 2009

¨ 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 4, 2009, the registrant had 2,970,652 shares of Common Stock, par value $0.10 per share, outstanding.

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IMMUCELL CORPORATION

PART 1. FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

BALANCE SHEETS (UNAUDITED)

	December 31, 2008	(Unaudited) September 30, 2009
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,199,929	$ 1,131,292
Short-term investments	3,854,103	3,813,000
Trade accounts receivable, net of allowance for doubtful accounts of $8,000 and $10,000 at December 31, 2008 and September 30, 2009, respectively	480,752	339,533
Income taxes receivable	362,474	1,548
Other receivables	51,378	35,587
Inventories	596,404	859,438
Prepaid expenses	92,622	86,957
Current portion of deferred tax asset	91,537	101,949
Total current assets	6,729,199	6,369,304
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	2,480,400	2,602,859
Building and improvements	2,402,979	2,442,822
Office furniture and equipment	190,799	190,799
Construction in progress	84,827	212,080
Land	50,000	50,000
	5,209,005	5,498,560
Less accumulated depreciation	2,273,663	2,542,029
Net property, plant and equipment	2,935,342	2,956,531
LONG-TERM PORTION OF DEFERRED TAX ASSET	431,707	559,965
PRODUCT RIGHTS AND OTHER ASSETS, net of accumulated amortization of $1,304,000 and $1,327,000 at December 31, 2008 and September 30 2009, respectively	31,945	8,237
TOTAL ASSETS	$ 10,128,193	$ 9,894,037
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$ 382,855	$ 159,278
Accounts payable	101,637	115,793
Total current liabilities	484,492	275,071

STOCKHOLDERS EQUITY:		
Common stock, Par value-$0.10 per share		
Authorized-8,000,000 shares, Issued-3,261,148 shares at December 31, 2008 and September 30, 2009.	326,115	326,115
Capital in excess of par value	9,722,967	9,733,326
Accumulated surplus	396,372	195,020
Treasury stock at cost 366,496 and 290,496 shares at December 31, 2008 and September 30, 2009, respectively	(801,753)	(635,495)
Total stockholders equity	9,643,701	9,618,966
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 10,128,193	$ 9,894,037

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 NINE-MONTH PERIODS ENDED SEPTEMBER 30, 2008 AND 2009

(Unaudited)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2008	2009	2008	2009
REVENUES:				
Product sales	$ 923,969	$ 1,010,707	$ 3,381,113	$ 3,471,615
Royalty income	33	915	4,814	2,842
Total revenues	924,002	1,011,622	3,385,927	3,474,457
COSTS AND EXPENSES:				
Product costs	621,364	412,162	1,881,925	1,664,685
Product development expenses	485,323	328,430	1,240,571	1,249,869
General and administrative expenses	222,263	201,766	715,616	667,015
Product selling expenses	144,800	107,966	423,413	319,841
Total costs and expenses	1,473,750	1,050,324	4,261,525	3,901,410
Net operating loss	(549,748)	(38,702)	(875,598)	(426,953)
Interest income	49,081	18,231	164,158	86,077
Other income (expense), net	700	375	1,490	1,871
Net interest and other income	49,781	18,606	165,648	87,948
LOSS BEFORE INCOME TAXES	(499,967)	(20,096)	(709,950)	(339,005)
INCOME TAX BENEFIT	(231,522)	(1,193)	(281,382)	(137,653)
NET LOSS	$ (268,445)	$ (18,903)	$ (428,568)	$ (201,352)
NET LOSS PER COMMON SHARE:				
Basic	$ (0.09)	$ (0.01)	$ (0.15)	$ (0.07)
Diluted	$ (0.09)	$ (0.01)	$ (0.15)	$ (0.07)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic	2,894,652	2,970,652	2,893,246	2,954,784
Diluted	2,894,652	2,970,652	2,893,246	2,954,784

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

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IMMUCELL CORPORATION

STATEMENTS OF STOCKHOLDERS EQUITY

(Unaudited)

FOR THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2008

	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, 2007	3,261,148	$ 326,115	$ 9,668,872	$ 864,929	368,672	$ (802,945)	$ 10,056,971
Net loss				(428,568)			(428,568)
Exercise of stock options, net			(1,190)		(2,176)	1,192	2
Stock-based compensation			83,099				83,099
BALANCE,							
September 30, 2008	3,261,148	$ 326,115	$ 9,750,781	$ 436,361	366,496	$ (801,753)	$ 9,711,504

FOR THE NINE-MONTH PERIOD ENDED SEPTEMBER 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				(201,352)			(201,352)
Exercise of Stock Options			(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

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

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IMMUCELL CORPORATION

STATEMENTS OF CASH FLOWS FOR THE NINE-MONTH PERIODS

ENDED SEPTEMBER 30, 2008 AND 2009

(Unaudited)

	Nine-Month Periods Ended September 30,	
	2008	**2009**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (428,568)	$ (201,352)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation	269,745	282,416
Amortization	27,798	22,608
Deferred income taxes	12,000	(138,670)
Stock-based compensation	83,099	75,946
Loss on disposal of fixed assets	50,010	29,861
Changes in:		
Receivables	279,841	157,010
Income taxes receivable/payable	(208,623)	360,926
Inventories	(115,385)	(263,034)
Prepaid expenses and other assets	(69,949)	6,764
Accrued expenses	(42,616)	(223,577)
Accounts payable	165,608	(413)
Net cash provided by operating activities	22,960	108,485
CASH FLOWS FROM INVESTING ACTIVITIES :		
Purchase of property, plant and equipment	(358,677)	(318,896)
Maturities of short-term investments	4,230,903	3,651,103
Purchases of short-term investments	(4,147,103)	(3,610,000)
Net cash used for investing activities	(274,877)	(277,793)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Tax benefits related to stock options		921
Proceeds from exercise of stock options, net	2	99,750
Net cash provided by financing activities	2	100,671
NET DECREASE IN CASH AND CASH EQUIVALENTS	(251,915)	(68,637)
BEGINNING CASH AND CASH EQUIVALENTS	1,192,637	1,199,929
ENDING CASH AND CASH EQUIVALENTS	$ 940,722	$ 1,131,292
INCOME TAXES (PAID) REFUNDED, NET	$ (892)	$ 360,799

NON-CASH INVESTING AND FINANCING ACTIVITIES:

Change in capital expenditures included in accounts payable	$	$ 14,569

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

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IMMUCELL CORPORATION

NOTES TO UNAUDITED FINANCIAL STATEMENTS

September 30, 2009

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, commonly referred to as the FASB . The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP issued by the FASB in these footnotes are to the *FASB Accounting Standards Codification* , sometimes referred to as the Codification or ASC . 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, 2008 and the notes thereto, contained in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission. Certain prior year accounts have been reclassified to conform with the 2009 financial statement presentation.

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 principally 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.

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

	December 31, 2008	September 30, 2009	Decrease
Cash and cash equivalents	$ 1,200	$ 1,131	$ 69
Short-term investments	3,854	3,813	41
	$ 5,054	$ 4,944	$ 110

3. INVENTORIES

Inventories consist of the following (in thousands):

	December 31, 2008	September 30, 2009	Increase
Raw materials	$ 180	$ 193	$ 13
Work-in-process	292	471	179
Finished goods	124	195	71

	$ 596	$ 859	$ 263

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IMMUCELL CORPORATION

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2009

4. INCOME TAXES

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, (formerly known as Statement of Financial Accounting Standards (SFAS) No. 109, *Accounting for Income Taxes*). This topic requires that we recognize a current tax liability or asset for current taxes payable or receivable 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 a material impact on our financial condition, results of operations, earnings per share or cash flows.

5. NET LOSS PER COMMON SHARE

The net loss per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*, (formerly known as SFAS No. 128, *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 418,000 and 400,000 during the three-month periods ended September 30, 2008 and 2009, respectively, and approximately 418,000 and 400,000 during the nine-month periods ended September 30, 2008 and 2009, respectively.

6. EMPLOYEE STOCK-BASED COMPENSATION

We account for stock-based compensation in accordance with Codification Topic 718*, Compensation-Stock Compensation*, (formerly known as Revised SFAS No. 123, *Share-Based Payments*), 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 $29,000 and $21,000 during the three-month periods ended September 30, 2008 and 2009, respectively, and $83,000 and $76,000 during the nine-month periods ended September 30, 2008 and 2009, respectively. Half of this expense is allocated to general and administrative expenses and half to product development expenses.

The exercise price of the 400,000 stock options outstanding as of September 30, 2009 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, 2008. As of September 30, 2009, total unrecognized compensation costs related to non-vested stock-based compensation arrangements aggregated approximately $154,000. That cost is expected to be recognized through the third quarter of 2012, which represents the remaining vesting period of the outstanding, non-vested stock options.

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IMMUCELL CORPORATION

NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2009

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.

8. SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

Pursuant to Codification Topic 280, *Segment Reporting*, (formerly SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*), 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. The significant accounting policies of this segment are described in Note 7 to the financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2008.

Our primary customers for the majority (94% for the three-month periods ended September 30, 2008 and 2009) 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 4% and 6% of product sales for the three-month periods ended September 30, 2008 and 2009, respectively.

Our primary customers for the majority (88% and 79% for the nine-month periods ended September 30, 2008 and 2009, 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 11% and 17% of product sales for the nine-month periods ended September 30, 2008 and 2009, 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,	
	2008	2009	2008	2009
Animal Health International, Inc.	19%	26%	21%	25%
Lextron, Inc.	18%	13%	17%	15%
MWI Veterinary Supply Co.	13%	12%	11%	10%

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

	December 31, 2008	September 30, 2009
Animal Health International, Inc.	37%	25%
Lextron, Inc.	*	11%

MWI Veterinary Supply Co.	14%	*

* Amount is less than 10%.

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NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2009

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 **California Mastitis Test (CMT)** and of J-t Enterprises of Melrose, Inc., an exporter of **First Defense®**. His affiliated companies purchased approximately $164,000 and $195,000 of products from us during the nine-month periods ended September 30, 2008 and 2009, respectively.

AlcheraBio LLC is a wholly-owned subsidiary of Argenta of New Zealand. Dr. Linda Rhodes (a member of our Board of Directors) is a co-founder of AlcheraBio and currently serves as its Vice President, Clinical Affairs. During the nine-month period ended September 30, 2009, we incurred approximately $37,000 in fees to AlcheraBio for clinical trial consulting services.

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 November 3, 2009, the date we have issued this Quarterly Report on Form 10-Q.

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, 2009

Product Sales

Product sales increased by approximately 9%, or $87,000, to $1,011,000 during the three-month period ended September 30, 2009 in comparison to $924,000 during the same period in 2008. Sales during the third quarter of 2009 included the shipment of a backlog of orders as of June 30, 2009 aggregating approximately $287,000. There was no backlog of orders as of June 30, 2008. Product sales increased by 3%, or $91,000, to $3,472,000 during the nine-month period ended September 30, 2009 in comparison to $3,381,000 during the same period in 2008.

We appreciate the volume of business that we have maintained during these difficult economic times when our customers are being forced to cut costs wherever possible to stay in business. Even in this market with low milk prices, 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 1% during the nine-month period ended September 30, 2009 in comparison to the same period in 2008. Sales of **Wipe Out® Dairy Wipes** decreased by 10% during the nine-month period ended September 30, 2009 in comparison to the same period in 2008. Domestic sales of this premium product are challenged by less expensive competitive products and by the continuing economic pressure in the U.S. dairy industry that is forcing many producers out of business. The decline in sales of **First Defense®** and **Wipe Out® Dairy Wipes** during the nine-month period ended September 30, 2009 was more than offset by increases in the sales of **Isolate**, our water diagnostic test reagents, and **CMT**, our California Mastitis Test.

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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 September 30,		Increase	
	2008	2009	Amount	%
Gross margin	$ 303	$ 599	$ 296	98%
Percent of product sales	33%	59%	26%	79%

	Nine-Month Periods Ended September 30,		Increase	
	2008	2009	Amount	%
Gross margin	$ 1,499	$ 1,807	$ 308	21%
Percent of product sales	44%	52%	8%	18%

	Twelve-Month Periods Ended September 30,		Increase	
	2008	2009	Amount	%
Gross margin	$ 2,338	$ 2,377	$ 39	2%
Percent of product sales	48%	50%	2%	4%

The gross margin as a percentage of product sales was 59% and 33% during the three-month periods ended September 30, 2009 and 2008, respectively. The gross margin as a percentage of product sales was 52% and 44% during the nine-month periods ended September 30, 2009 and 2008, respectively. The gross margin as a percentage of product sales was 50% and 48% during the twelve-month periods ended September 30, 2009 and 2008, respectively. This compares to gross margin percentages of 45%, 52% and 56% for the years ended December 31, 2008, 2007 and 2006, respectively. While our gross margin as a percentage of product sales dropped during 2008, we did experience some improvement during the three-month, nine-month and twelve-month periods ended September 30, 2009. Our current annual target for gross margin percentage is approximately 50%. We expect some fluctuations in gross margin percentages from quarter to quarter. We feel that a number of factors account for the relative increase in costs and for their variability. Biological yields from the raw material used in the production of **First Defense®** do fluctuate over time. The unusually lower yields experienced in the third quarter of 2008 have largely been corrected in 2009. 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**. Because **First Defense®** customers are price sensitive, we held its selling price without significant increase for approximately seven years, believing that we could benefit more from higher unit sales volume than through a higher average selling price per unit. However, 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 $157,000, to $328,000 during the three-month period ended September 30, 2009 in comparison to the same period in 2008. Product development expenses aggregated 32% and 53% of total revenues during the three-month periods ended September 30, 2009 and 2008, respectively. Product development expenses increased by less than 1%, or $9,000, to $1,250,000 during the nine-month period ended September 30, 2009 in comparison to the same period in 2008. Product development expenses aggregated 36% and 37% of total revenues during the nine-month periods ended September 30, 2009 and 2008, respectively. The product development expenses principally reflect the costs of funding the development of **Mast Out®**and to a lesser extent line extensions to **First Defense®**.

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

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antibacterial peptide that is commonly used as a preservative in dairy food products. 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. The use of antibiotics in food-producing animals may be a contributing factor to the rising human public health problem of bacterial drug resistance. **Mast Out®** could potentially reduce the use of traditional antibiotics in the treatment of mastitis.

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) and to withhold treated cows from slaughter during the course of and for a period following antibiotic treatment (the meat withhold requirement). As a result, mastitis treatment is generally limited to only clinical cases - those cases where cows are producing abnormal milk - since that milk 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. The safety profile of Nisin and its long history as a food preservative may allow for the use of **Mast Out®** in the U.S. without a milk discard requirement or a meat withhold requirement, which would be a significant competitive advantage. No other intramammary mastitis treatment product has such a zero discard or zero withhold claim. Without the milk discard or meat withhold requirements, 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 and meat withhold requirement in that territory.

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 as compared to the placebo group. The currently proposed treatment regimen is one dose at each of three consecutive milkings.

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), we received $2,375,000 in payments from Pfizer. During 2005, Pfizer completed a study further supporting the effectiveness of **Mast Out®** in cows with subclinical mastitis. During 2006, Pfizer made significant progress developing data required for product registration in the areas of effectiveness, manufacturing and pharmacokinetics. In July 2007, Pfizer elected to terminate the product development and marketing agreement. In accordance with the termination provisions in the agreement, Pfizer returned to us all rights, data, information, files, regulatory filings, materials and stocks of Nisin and Nisin producing cultures relating to the development of **Mast Out®**.

We do not believe that Pfizer s decision to terminate the product development and marketing agreement was based on any unanticipated efficacy or regulatory issues. Rather, we believe Pfizer s decision was primarily market driven, largely relating to concerns that the use of **Mast Out®** may require specific treatment restrictions at the herd level, 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 believe that this risk can be eliminated by following a herd-level treatment guideline, currently estimated at approximately 2% of the herd on **Mast Out®** treatment in any given week. This guideline would require the subclinically mastitic cows in a herd to be treated over a period of weeks rather than at the same time, in order to ensure that Nisin levels in bulk tank milk remain below levels that could affect the susceptible starter cultures. 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 guideline. Over time and with market acceptance of **Mast Out®**, Nisin-resistant starter cultures could be developed. Starter culture development and improvement programs are common in the cheese industry for development of desirable culture characteristics such as phage-resistance and flavor development. These activities could result in relaxation or elimination of the herd-level treatment guidance. Our decision to continue product development efforts reflects our belief that **Mast Out®** is approvable by the FDA without a milk discard requirement. We believe that such a product has significant sales potential in the U.S. dairy market. Foreign regulatory approvals would be required for sales in key markets outside of the United States.

Commercial introduction of **Mast Out®** in the United States is subject to approval of our New Animal Drug Application (NADA) by the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine, which approval cannot be assured. The NADA is comprised of several Technical Sections under the FDA s phased review of a NADA. 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) Pivotal Effectiveness

In July 2007, we began preparations for the pivotal effectiveness study. Such preparations included the production of registration batches of drug product to fulfill the pivotal regulatory requirements of effectiveness, target animal safety, and stability at no less than 10% of the scale anticipated for commercial manufacture. In June 2008, we initiated the treatment phase of the pivotal effectiveness study at sixteen sites across the U.S. In June 2009, we completed the treatment phase of this study. On September 30, 2009, we announced that we had met the pivotal effectiveness study end point. 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. The preliminary breakdown of the data by species suggests both the necessary numerical superiority and clinical relevancy to support robust product performance in the field. 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.

3) Target Animal Safety

The protocol for the pivotal trial, that is planned for the fourth quarter of 2009, has been approved by the FDA.

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 (which is in progress), 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 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.

5) Chemistry, Manufacturing and Controls (CMC)

We have determined that constructing, commissioning and obtaining FDA approval of a new facility to produce the Active Pharmaceutical Ingredient (API) for **Mast Out®** at commercial scale would be too lengthy and expensive to be a feasible alternative. Therefore, we have been and are currently in negotiations with an FDA-approved manufacturer that may produce the API for us under contract. This manufacturing site must be compliant with current Good Manufacturing Practice (cGMP) regulations and will be subject to FDA approval and inspection. Ultimately, the investments required for full commercial manufacture of API for **Mast Out®** could potentially deplete most of our available cash. We have a manufacturing relationship with an FDA-approved drug product manufacturer to formulate the API into drug product, conduct sterile-fill of syringes and perform final packaging. This manufacturer helped us prepare clinical trial material for the pivotal effectiveness study of **Mast Out®**. We are negotiating a commercial contract with this manufacturer.

6) Several Administrative Requirements

Currently, our objective is to submit all the Technical Sections required for product approval to the FDA by approximately the end of 2010. If we achieve that objective, then the timing of the FDA s decision regarding our NADA and the timing of a market launch (if the FDA grants approval) will be determined by our resolution of the issues described under the CMC Technical Section paragraph, above. As we move forward internally funding product development expenses for **Mast Out®**, we will remain open to any potential opportunities to enter into an alliance with a partner that could help underwrite the costs of commercial manufacture and market launch, with the objective of reaching an agreement on suitable terms that would enable us to preserve available cash for other uses. However, we do not believe that such an alliance is essential in order for us to manufacture and sell **Mast Out®**.

In addition to our work on **Mast Out®**, we are actively developing 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

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certain rotavirus 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, which could position us for USDA approval in 2011 of a product effective against 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 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. 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. (formerly Anadis, Ltd.) of Australia. Under this agreement, we gained access to relevant production technology and capabilities of Immuron. 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 current Good Manufacturing Practice (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 September 30, 2009, general and administrative expenses decreased by 9%, or $20,000, to $202,000 as compared to the same period in 2008. During the nine-month period ended September 30, 2009, general and administrative expenses decreased by 7%, or $49,000, to $667,000 as compared to the same period in 2008. 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.

Product Selling Expenses

During the three-month period ended September 30, 2009, product selling expenses decreased by 25%, or $37,000, to $108,000, as compared to the same period in 2008, aggregating 11% and 16% of product sales during the three-month periods ended September 30, 2009 and 2008, respectively. During the nine-month period ended September 30, 2009, product selling expenses decreased by 24%, or $104,000, to $320,000, as compared to the same period in 2008, aggregating 9% and 13% of product sales during the nine-month periods ended September 30, 2009 and 2008, respectively. The decrease resulted, in large part, from a reduction in advertising expenses. 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 $(20,000) during the three-month period ended September 30, 2009 is significantly lower than our loss before income taxes of $(500,000) during the three-month period ended September 30, 2008. Our income tax benefit was 6% and 46% of our loss before income taxes during the three-month periods ended September 30, 2009 and 2008, respectively. Our net loss for the three-month period ended September 30, 2009 was $(19,000), or $(0.01) per share, in comparison to a net loss of $(268,000), or $(0.09) per share, during the three-month period ended September 30, 2008. The improved bottom line results during the three-month period ended September 30, 2009 largely reflect an improved gross margin and less product development spending.

Our loss before income taxes of $(339,000) during the nine-month period ended September 30, 2009 compares to a loss before income taxes of $(710,000) during the nine-month period ended September 30, 2008. Our income tax benefit was 41% and 40% of our loss before income taxes during the nine-month periods ended September 30, 2009 and 2008, respectively. Our net loss for the nine-month period ended September 30, 2009 of $(201,000), or $(0.07) per share, is significantly lower than the net loss of $(429,000), or $(0.15) per share, during the nine-month period ended September 30, 2008. The improved bottom line results during the nine-month period ended September 30, 2009 largely reflect an improved gross margin.

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LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and short-term investments decreased by 2%, or $110,000, to $4,944,000 at September 30, 2009 from $5,054,000 at December 31, 2008. Net cash provided by operating activities amounted to $108,000 during the nine-month period ended September 30, 2009 in comparison to net cash provided by operating activities of $23,000 during the nine-month period ended September 30, 2008. Total assets decreased by 2%, or $234,000, to $9,894,000 at September 30, 2009 from $10,128,000 at December 31, 2008. We have no outstanding bank debt or open line of credit. Net working capital decreased by 2%, or $150,000, to $6,094,000 at September 30, 2009 from $6,245,000 at December 31, 2008. Stockholders equity decreased by less than 1%, or $25,000, to $9,619,000 at September 30, 2009 from $9,644,000 at December 31, 2008.

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 have not increased this authorized limit during 2009. We have been monitoring the status of the economy and our business as we make decisions pertaining to these investments. As of October 1, 2009, we have remaining authorization to spend up to $542,000 on these capital expenditures, net of payments made since January 1, 2008. Currently, we do not believe that we will need to invest this full amount to meet our objectives.

The return of the **Mast Out®** product rights 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 expected a net loss in 2008, and we are projecting another net loss for 2009. We believe that the commercial prospects for **Mast Out®** warrant this level of investment. As of September 30, 2009, we had approximately $4,944,000 in cash and short-term investments. 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable

ITEM 4T. CONTROLS AND PROCEDURES

Disclosure Controls

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, 2009. 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 our last fiscal quarter 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; future expense ratios; costs and timing associated with sustaining compliance with cGMP regulations; 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 , estimat similar words and expressions. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, the uncertainties associated with product development, 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, due in large part to our current product development strategy. Continued development of **Mast Out®** will likely result in a net loss in 2009 as well. We believe that our current balance of cash and short-term investments is more than sufficient to fund our projected loss. Generally speaking, our financial performance can differ significantly from the 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 have done so again in 2009 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, but one that we believe we have sufficient cash reserves to fund and that 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 in 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 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.

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Economics of the dairy industry: The dairy industry in the United States 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 has been expected in 2009. As of September 2009, the herd size is estimated to be approximately 9,126,000 cows. 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. During the first nine months of 2009, this average price level plummeted to $10.49, which represents a 42% decrease from the first nine months of 2008. This price level is similar to the $10.42 average for 2002, and approximates the price levels experienced during the 1970 s. In addition to the decline in the price of milk, the costs to produce milk have increased. 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. The monthly average during the first nine months of 2009 dropped to 1.61, representing a 20% decrease compared to the first nine months of 2008. This means that a dairy producer can buy only 1.61 pounds of feed for every pound of milk sold. Before the milk-feed ratio dropped to these very low levels beginning in early 2008, the ratio had not been this low since the 1970 s. The 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 price received by producers for milking cows. In 2008, this average price is estimated to have increased to approximately $1,953, which is a 6% increase over 2007. This price (reported as of January, April and July 2009) averaged approximately $1,433, which represents a 27% decrease in comparison to the same period in 2008. 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 recent decline in the price of bull calves has reduced the return on investment from a dose of **First Defense®** for bull calves. 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.

*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 loss would have been larger during the year ended December 31, 2008 and during the first nine months of 2009, without the gross margin that we earned from the sale of **First Defense®**.

Concentration of sales: A large portion of our product sales (50% and 49% for the nine-month periods ended September 30, 2009 and 2008, respectively) was made to three large distributors. A large portion of our trade accounts receivable (41% as of September 30, 2009) was due from these three distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us.

Product development risks: Our current 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 substantial investments by us, and there is no assurance that we will obtain the clinical and other data necessary to support regulatory approval for this product. There is also no assurance that our capital resources will prove to be sufficient to cover the costs associated with regulatory approvals, commercial manufacture or market launch of **Mast Out®** or any other new products. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Pfizer, 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 and when this approval will be achieved. Such approval will also require a successful inspection under cGMP standards by the FDA of the facilities used to manufacture the product. We have identified at least one potential commercial manufacturer for Nisin and have a preliminary evaluation of the

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potential costs, but we have not made a final determination of the cost or location of the commercial manufacturing facilities at this time. Foreign regulatory approvals would be required for sales outside of the U.S. European regulatory authorities are not likely 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 declined 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. 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, 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, 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, technical and marketing resources 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.

Small size: We are a small company with approximately 32 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.

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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. As a smaller reporting company, the requirement to implement the provisions of Section 404(b) of the Sarbanes-Oxley Act has been deferred until fiscal year 2010. These reporting obligations will increase our operating costs.

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**. 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 this facility could adversely affect the production of inventory and result in significant added expenses and loss of revenues.

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. 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 and realizing lower proceeds.

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

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable

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ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

Exhibit 31 Certifications required by Rule 13a-14(a).

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

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 3, 2009

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