IMMUCELL CORP /DE/
Form 10-Q
May 05, 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 March 31, 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 May 4, 2009, the registrant had 2,970,652 shares of Common Stock, par value $0.10 per share, outstanding.

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BALANCE SHEETS

	December 31, 2008	(Unaudited) March 31, 2009
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,199,929	$ 1,275,162
Short-term investments	3,854,103	3,865,103
Trade accounts receivable, net of allowance for doubtful accounts of $8,000 at December 31, 2008 and March 31, 2009	480,752	552,958
Income taxes receivable	362,474	386,278
Other receivables	51,378	71,682
Inventories	596,404	548,346
Prepaid expenses	92,622	110,215
Current portion of deferred tax asset	91,537	79,845
Total current assets	6,729,199	6,889,589
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	2,480,400	2,521,587
Building and improvements	2,402,979	2,406,866
Office furniture and equipment	190,799	190,799
Construction in progress	84,827	85,950
Land	50,000	50,000
	5,209,005	5,255,202
Less - accumulated depreciation	2,273,663	2,358,639
Net property, plant and equipment	2,935,342	2,896,563
LONG-TERM PORTION OF DEFERRED TAX ASSET	431,707	422,411
PRODUCT RIGHTS AND OTHER ASSETS, net of accumulated amortization of $1,304,000 and $1,312,000 at December 31, 2008 and March 31, 2009, respectively	31,945	24,659
TOTAL ASSETS	$ 10,128,193	$ 10,233,222
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accrued expenses	$ 382,855	$ 296,882
Accounts payable	101,637	194,574
Total current liabilities	484,492	491,456
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 March 31, 2009.	326,115	326,115
Capital in excess of par value	9,722,967	9,689,403
Accumulated surplus	396,372	361,743

Treasury stock at cost	366,496 and 290,496 shares at December 31, 2008 and March 31, 2009, respectively	(801,753)	(635,495)
Total stockholders equity		9,643,701	9,741,766
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY		$ 10,128,193	$ 10,233,222

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

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STATEMENTS OF OPERATIONS FOR THE

THREE-MONTH PERIODS ENDED MARCH 31, 2008 AND 2009

(Unaudited)

	Three-Month Periods Ended March 31,	
	2008	**2009**
REVENUES:		
Product sales	$ 1,631,024	$ 1,460,279
Royalty income	4,600	1,208
Total revenues	1,635,624	1,461,487
COSTS AND EXPENSES:		
Product costs	813,799	739,719
Product development expenses	332,036	432,485
General and administrative expenses	249,096	233,655
Product selling expenses	171,719	128,099
Total costs and expenses	1,566,650	1,533,958
Net operating income (loss)	68,974	(72,471)
Interest income	59,690	35,414
Other income (expense), net	(108)	593
Net interest and other income	59,582	36,007
INCOME (LOSS) BEFORE INCOME TAXES	128,556	(36,464)
INCOME TAX EXPENSE (BENEFIT)	50,897	(1,835)
NET INCOME (LOSS)	$ 77,659	$ (34,629)
NET INCOME (LOSS) PER COMMON SHARE:		
Basic	$ 0.03	$ (0.01)
Diluted	$ 0.03	$ (0.01)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic	2,892,476	2,922,519
Diluted	2,965,036	2,922,519

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

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STATEMENTS OF STOCKHOLDERS EQUITY

(Unaudited)

FOR THE THREE-MONTH PERIOD ENDED MARCH 31, 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 income				77,659			77,659
Stock-based compensation			26,021				26,021
BALANCE, March 31, 2008	3,261,148	$ 326,115	$ 9,694,893	$ 942,588	368,672	$ (802,945)	$ 10,160,651

FOR THE THREE-MONTH PERIOD ENDED MARCH 31, 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				(34,629)			(34,629)
Exercise of Stock Options			(66,508)		(76,000)	166,258	99,750
Stock-based compensation			32,023				32,023
Tax benefits related to stock options			921				921
BALANCE, March 31, 2009	3,261,148	$ 326,115	$ 9,689,403	$ 361,743	290,496	$ (635,495)	$ 9,741,766

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

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STATEMENTS OF CASH FLOWS FOR THE THREE-MONTH PERIODS

ENDED MARCH 31, 2008 AND 2009

(Unaudited)

	Three-Month Periods Ended March 31,	
	2008	2009
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 77,659	$ (34,629)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation	89,824	94,246
Amortization	10,131	7,536
Deferred income taxes	28,000	20,988
Stock-based compensation	26,021	32,023
Loss on disposal of fixed assets	41,352	
Changes in:		
Receivables	2,326	(92,510)
Income taxes receivable/payable	107,667	(23,804)
Inventories	186,642	48,058
Prepaid expenses and other assets	(52,386)	(17,843)
Accrued expenses	(40,535)	(85,973)
Accounts payable	81,087	56,544
Net cash provided by operating activities	557,788	4,636
CASH FLOWS FROM INVESTING ACTIVITES :		
Purchase of property, plant and equipment	(102,416)	(19,074)
Maturities of short-term investments	967,679	385,000
Purchases of short-term investments	(875,000)	(396,000)
Net cash used for investing activities	(9,737)	(30,074)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Tax benefits related to stock options		921
Proceeds from exercise of stock options		99,750
Net cash provided by financing activities		100,671
NET INCREASE IN CASH AND CASH EQUIVALENTS	548,051	75,233
BEGINNING CASH AND CASH EQUIVALENTS	1,192,637	1,199,929
ENDING CASH AND CASH EQUIVALENTS	$ 1,740,688	$ 1,275,162
INCOME TAXES REFUNDED (PAID), NET	$ 84,347	$ (30)
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Change in capital expenditures included in accounts payable		$ 36,393

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NOTES TO UNAUDITED FINANCIAL STATEMENTS

March 31, 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. Certain information and footnote disclosures normally included in the annual financial statements which are prepared in accordance with accounting principles generally accepted in the United States of America 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.

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 deposits 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) within FDIC limits. The Emergency Economic Stabilization Act of 2008 increased these insurance limits from $100,000 to $250,000 per institution for the period from October 3, 2008 to December 31, 2009.

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

	December 31, 2008	March 31, 2009	Increase
Cash and cash equivalents	$ 1,200	$ 1,275	$ 75
Short-term investments	3,854	3,865	11
	$ 5,054	$ 5,140	$86

3. INVENTORIES

Inventories consist of the following (in thousands):

	December 31, 2008	March 31, 2009
Raw materials	$ 180	$ 282
Work-in-process	292	223
Finished goods	124	43
	$ 596	$ 548

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NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2009

4. INCOME TAXES

Effective January 1, 2007, we implemented the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertainties in Income Taxes, which did not have a material impact on our financial condition, results of operations, earnings per share or cash flows. We account for income taxes in accordance with Statement of Financial Accounting Standards (SFAS) No. 109, *Accounting for Income Taxes*. This statement 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. Our income tax expense aggregated $51,000 (40% of income before income taxes) during the three-month period ended March 31, 2008 in contrast to an income tax benefit of $2,000 (5% of the loss before income taxes) during the three-month period ended March 31, 2009.

5. NET INCOME (LOSS) PER COMMON SHARE

The net income (loss) per common share has been computed in accordance with SFAS No. 128, *Earnings Per Share*. During the three-month period ended March 31, 2008, the basic net income per common share has been computed by dividing the net income by the weighted average number of common shares outstanding during the period, and the diluted net income per common share reflects the potential dilution from outstanding stock options as shown in the table below. During the three-month period ended March 31, 2009, 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.

	Three-Month Periods Ended March 31,	
	2008	2009
Weighted average number of shares outstanding during the period	2,892,476	2,922,519
Dilutive stock options	179,000	
Shares that could have been repurchased with the proceeds from the dilutive stock options	(106,440)	
Diluted number of shares outstanding during the period	2,965,036	2,922,519
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	287,000	387,000

6. EMPLOYEE STOCK-BASED COMPENSATION

In December 2004, the FASB issued Revised SFAS No. 123, *Share-Based Payments* (SFAS 123R), revising FASB Statements No. 123, *Accounting for Stock-Based Compensation*, and No. 95, *Statement of Cash Flows*. SFAS 123R eliminates the ability to account for stock-based compensation transactions using Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. We implemented SFAS 123R effective beginning January 1, 2006. Accordingly, we recorded compensation expense pertaining to stock-based compensation of approximately $26,000 and $32,000 during the three-month periods ended March 31, 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 387,000 stock options outstanding as of March 31, 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 our Annual Report on Form 10-K for the year ended December 31, 2008. As of March 31, 2009, total unrecognized compensation costs related to non-vested stock-based compensation arrangements aggregated approximately $181,000. That cost is expected to be recognized through the fourth quarter of 2011, which represents the remaining vesting period of the outstanding, non-vested stock options.

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NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 2009

7. SEGMENT AND SIGNIFICANT CUSTOMER INFORMATION

Pursuant to 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 Company s Annual Report on Form 10-K for the year ended December 31, 2008.

Our primary customers for the majority (80% and 76% for the three-month periods ended March 31, 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 20% and 24% of product sales for the three-month periods ended March 31, 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 March 31,	
	2008	2009
Animal Health International, Inc.	28%	28%
Lextron, Inc.	14%	15%

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

	As of	
	December 31, 2008	March 31, 2009
Animal Health International, Inc.	37%	35%
Lextron, Inc.	*	15%
MWI Veterinary Supply Co.	14%	*

* Amount is less than 10%.

8. 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 a 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. As of June 30, 2005, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. 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 UNAUDITED FINANCIAL STATEMENTS (Continued)

March 31, 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 $98,000 and $99,000 of products from ImmuCell during the three-month periods ended March 31, 2008 and 2009, respectively.

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

RESULTS OF OPERATIONS FOR THE THREE-MONTH PERIOD ENDED MARCH 31, 2009

Product Sales

Product sales decreased by approximately 10%, or $171,000, to $1,460,000 during the three-month period ended March 31, 2009 in comparison to $1,631,000 during the same period in 2008. If we had shipped our backlog of orders aggregating approximately $48,000 as of March 31, 2009, our products sales would have been down by 8%, or $123,000. The backlog of orders as of March 31, 2009 was shipped to customers in April 2009. We are making significant investments to expand our production capacity in order to address this inventory shortage.

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 declining 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. However, sales of this product decreased 11% during the three-month period ended March 31, 2009 in comparison to the same period in 2008. 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 **Wipe Out® Dairy Wipes** decreased by 16% during the three-month period ended March 31, 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 small producers out of business.

Other Revenues

Royalty income decreased to $1,000 during the three-month period ended March 31, 2009 in comparison to $5,000 during the three-month period ended March 31, 2008, as the result of lower sales reported by the firm that has licensed our milk protein purification technology.

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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 March 31,		Decrease	
	2008	2009	Amount	%
Gross margin	$ 817	$ 721	$ 96	12%
Percent of product sales	50%	49%	1%	2%

	Twelve-Month Periods Ended March 31,		Decrease	
	2008	2009	Amount	%
Gross margin	$ 2,442	$ 1,973	$ 469	19%
Percent of product sales	50%	44%	6%	12%

We now experience lower gross margin percentages in comparison to those achieved in the past. The gross margin as a percentage of product sales was 49% and 50% during the three-month periods ended March 31, 2009 and 2008, respectively. The gross margin as a percentage of product sales was 44% and 50% during the twelve-month periods ended March 31, 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. Our current annual target for gross margin percentage is 50%, a level consistent with our experience for the year ended December 31, 2007 and for the twelve-month period ended March 31, 2008. 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. 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®**.

Product Development and Licensing

Product development expenses increased by approximately 30%, or $100,000, to $432,000 during the three-month period ended March 31, 2009 in comparison to the same period in 2008. Product development expenses aggregated 30% and 20% of total revenues during the three-month periods ended March 31, 2009 and 2008, respectively. The increased expenses during the three-month period ended March 31, 2009 principally reflect the costs of funding the development of **Mast Out®** internally.

In April 2000, we acquired an exclusive license from Nutrition 21, Inc. to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Mast Out®**. In November 2004, we paid Nutrition 21 approximately $965,000 to buy out this royalty and milestone-based license to Nisin, thereby acquiring control of the animal health applications of Nisin. Nisin, the same active ingredient contained in **Wipe Out® Dairy Wipes**, is an antibacterial peptide 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 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,

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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, 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.

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 (three doses at three consecutive milkings) demonstrated a 58% efficacy rate in eliminating infection in lactating cows with culture-confirmed mastitis (compared to a placebo cure rate of 10%). This efficacy rate represents a blended average of results from cows with mastitis caused by several different pathogens. For example, **Mast Out®** achieved a statistically significant 100% efficacy rate in *Streptococcus agalactiae* cases (compared to a placebo cure rate of 25%), where antibiotics are commonly used effectively, and a statistically significant 28% efficacy rate in *Staphylococcus aureus* cases (compared to a placebo cure rate of 0%), where antibiotics are often not effective.

In December 2004, we entered into a product development and marketing agreement with Pfizer Animal Health, a division of Pfizer, Inc. covering **Mast Out®**. In July 2007, we received notice from Pfizer that it had elected to terminate the product development and marketing agreement. Since then, Pfizer has 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®**. 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.

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 all at once, 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 using starter development and improvement programs that 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 for sale in the U.S. We believe that such a product has significant sales potential in the U.S. dairy 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 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 pivotal effectiveness study. We are working with more than a dozen investigators across the U.S. to complete this study. As of the end of April 2009, we had enrolled approximately 85% of the qualified cases required to reach our targeted study size. It has taken longer than we first estimated to achieve the enrollment of the total number of cases meeting our clinical requirements, but we believe the extra time invested at this stage will provide us with more robust results. We expect to complete this study during the first half of 2009. Upon completion of the treatment phase, it will take approximately two to three months to close out all clinical sites, perform statistical analysis of the data and discuss the results with the FDA before a public announcement of study results can be made.

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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. 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. While positive results from a pivotal effectiveness study are necessary to support continued development of **Mast Out®**, the approval of several additional Technical Sections under the FDA s phased review of a NADA is also required. Included among the additional Technical Sections required for NADA final approval are: 1) Environmental Impact, 2) Target Animal Safety, 3) Human Food Safety, 4) Chemistry, Manufacturing and Controls (CMC) and 5) several administrative requirements. During the third quarter of 2008, we received the Environmental Impact Technical Section Complete Letter from the FDA. Work required for the Target Animal Safety Technical Section has been initiated, and critical studies are planned for 2009. The Human Food Safety data will determine if a milk discard period will not be required. The Human Food Safety 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 under FDA review), effects on bacteria of human health concern or antimicrobial resistance (which is complete) and toxicology (which is complete). Toxicology studies establish an Acceptable Daily Intake (ADI) level for humans, and the toxicological ADI for Nisin supports a zero milk and meat withhold claim. The toxicology studies were similar to the studies performed by others that affirmed the Generally Regarded As Safe (GRAS) status of Nisin for use as a food preservative. All of these subsections must be completed before the Human Food Safety Technical Section Complete Letter establishing a zero milk discard or a milk withhold period can be issued by the FDA.

Before the CMC Technical Section can be completed, a commercial scale manufacturing site for the Active Pharmaceutical Ingredient (API) that is compliant with current Good Manufacturing Practice (cGMP) regulations must be identified. This site will be subject to FDA approval and inspection. As the result of work we have done with outside companies to examine manufacturing options, we have recently determined that contracting for the manufacture of the API may require investments that could potentially deplete all of our available cash. We are not prepared to take that risk at this time without a partner. We do have a commercial 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. We intend to complete all the Technical Sections pertaining to the safety, effectiveness and zero milk discard claims during 2009. Subject to achieving these critical development milestones, it is our objective to enter into an alliance with a partner that could help underwrite the commercial manufacturing costs and complete the CMC Technical Section and subsequently optimize the launch, distribution and sales of **Mast Out®.**

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 2006 we obtained an option to an exclusive license from Baylor College of Medicine covering certain rotavirus vaccine technology. We anticipate converting this option into a license during the second quarter of 2009. Additionally, during the second quarter of 2007, we acquired an option to an exclusive license from Ohio State University covering certain rotavirus technology. Results from recently completed pilot studies justify conducting a pivotal effectiveness study in 2009. This study could position us for USDA approval of a product effective against scours caused by rotavirus in 2010. 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. As additional opportunities arise to commercialize our own technology, or licensable technology, we may begin new development projects.

We believe that market opportunities for growth of **First Defense®** sales exist in foreign territories. Regulatory authorities in some foreign territories may require that our manufacturing operations be compliant with cGMP regulations. 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.). 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.

Over the past three years, we have initiated efforts to become compliant with current Good Manufacturing Practice (cGMP) regulations in our manufacturing operations. Compliance with cGMP regulations will require a sustained investment. We believe that cGMP standards will further increase 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.

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General and Administrative Expenses

During the three-month period ended March 31, 2009, general and administrative expenses decreased by 6%, or $15,000, to $234,000 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 March 31, 2009, product selling expenses decreased by 25%, or $44,000, to $128,000, as compared to the same period in 2008, aggregating 9% and 11% of product sales during the three-month periods ended March 31, 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) Income Before Income Taxes and Net (Loss) Income

Our loss before income taxes of $(36,000) during the three-month period ended March 31, 2009 contrasts to income before income taxes of $129,000 during the three-month period ended March 31, 2008. Our income tax benefit was 5% of our loss before income taxes during the three-month period ended March 31, 2009 in contrast to income tax expense of 40% of our income before income taxes during the three-month period ended March 31, 2008. Our net loss for the three-month period ended March 31, 2009 was $(35,000) (or $(0.01) per share) in contrast to net income of $78,000 (or $0.03 per share) during the three-month period ended March 31, 2008.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and short-term investments increased by 2%, or $86,000, to $5,140,000 at March 31, 2009 from $5,054,000 at December 31, 2008. Net cash provided by operating activities amounted to $5,000 during the three-month period ended March 31, 2009 as compared to $558,000 during the three-month period ended March 31, 2008. Total assets increased by 1%, or $105,000, to $10,233,000 at March 31, 2009 from $10,128,000 at December 31, 2008. We have no outstanding bank debt. Net working capital increased by 2%, or $153,000, to $6,398,000 at March 31, 2009 from $6,245,000 at December 31, 2008. Stockholders equity increased by 1%, or $98,000, to $9,742,000 at March 31, 2009 from $9,644,000 at December 31, 2008, primarily as a result of the net loss being more than offset by an increase in equity from stock option exercises, during the first three months of 2009.

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 $1,029,000 for facility modifications and production equipment. In December 2008, our Board of Directors increased the authorized spending limit by $285,000. We have been monitoring the status of the economy and our business as we make decisions pertaining to these investments. As of April 1, 2009, we have authorization from our Board of Directors to spend up to $848,000 on this project, 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 has caused us to increase our spending on product development expenses that are no longer being funded by Pfizer. As previously reported, we expected a net loss in 2008, and we are projecting another net loss for 2009, after the nine consecutive years of profitability that we recorded during the years ended December 31, 1999 to December 31, 2007. We believe that the commercial prospects for **Mast Out®** warrant this level of investment. With approximately $5,140,000 in cash and short-term investments as of March 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable

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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 December 31, 2008. 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.

Internal Controls over Financial Reporting

Management s Annual Report on Internal Control over Financial Reporting. The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company s internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Management periodically evaluates the effectiveness of the internal controls over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. This evaluation includes a review of the documentation of controls, evaluation of the design effectiveness of controls, testing the operating effectiveness of the controls and a conclusion on this evaluation. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As previously reported, management assessed the effectiveness of the Company s internal control over financial reporting as of December 31, 2008. Based on management s assessment and those criteria, management concluded that the internal control over financial reporting as of December 31, 2008 was effective.

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; future costs of development-related efforts; future realization of deferred tax assets; future regulatory requirements relating to our products; factors that may affect the dairy industry and future demand for our products; the scope and timing of future development work and commercialization of our products; anticipated changes in our manufacturing capabilities; the amount of future investments in facility modifications and production equipment; the timing of anticipated applications for future regulatory approvals; anticipated future product development efforts; 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. 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.

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, doing away with health care, 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 dairy industry in the United States has been facing very difficult economic pressures. The number of small dairy producers continues to decrease. The size of the U.S. dairy herd has remained consistently in the range of approximately 9,000,00 to 9,300,000 cows over the last ten years, but a significant decrease in the herd size is expected in 2009. Sales of our products may be influenced by the price 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 three months of 2009, this average price level was $10.18, which represents a 44% decrease from the first

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three months of 2008. For a point of reference, this price level was $10.42 in 2002, which approximates the price level 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. For 2008, this ratio averaged 2.01. The monthly average during the first three months of 2009 dropped to 1.53, representing a 34% decrease compared to the first three months of 2008. A ratio of 1.53 means that a dairy producer can buy 1.53 pounds of feed for every pound of milk sold. Whenever the ratio meets or exceeds 3.0, it is considered profitable to buy feed and produce milk. 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. During the first three months of 2009, this price averaged approximately $1,510, which represents a 23% decrease in comparison to the first three months of 2008. 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 that we buy raw material from could make it difficult for us to produce enough inventory until supply agreements are reached with replacement farms.

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 include subclinical market development, coverage of relevant pathogens, selling price, cost of manufacture, integration of milk from treated cows into cheese starter cultures and market acceptance.

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 quarter of 2009, without the gross margin that we earned from the sale of **First Defense®**.

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 necessary 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, Fort Dodge and Intervet/Schering Plough. There is no assurance that **Mast Out®** will compete successfully in this market.

Competition from others: We may not be aware of competition that we face from other companies. 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.

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Small size: We are a small company with approximately 31 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. As a smaller reporting company, we need to implement additional provisions of the Sarbanes Oxley Act during fiscal year 2009. 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 disruption in the services at this facility could adversely affect the production of inventory.

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.

*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.

*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 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.

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.

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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.

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.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

Exhibit 4.1	Rights Agreement dated as of September 5, 1995, between the Registrant and American Stock Transfer and Trust Co., as Rights Agent, which includes as Exhibit A thereto the Form of Rights Certificate and as Exhibit B thereto the Summary of Rights to Purchase Common Stock.
Exhibit 31	Certifications required by Rule 13a-14(a).
Exhibit 32	Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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SIGNATURE

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

ImmuCell Corporation

Registrant

Date: May 5, 2009

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