

IMMUCELL CORP /DE/
Form 10-Q
November 04, 2008
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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, 2008

.. **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)

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Delaware
(State of incorporation)

01-0382980
(I.R.S. Employer Identification No.)

56 Evergreen Drive, Portland, ME
(Address of principal executive office)

04103
(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 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

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

As of November 4, 2008, the registrant had 2,894,652 shares of Common Stock, par value \$0.10 per share, outstanding.

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	December 31, 2007	(Unaudited) September 30, 2008
<u>ASSETS</u>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,192,637	\$ 940,722
Short-term investments	4,218,880	4,135,080
Trade accounts receivable, net of allowance for doubtful accounts of \$10,000 at December 31, 2007 and September 30, 2008	712,224	461,348
Income taxes receivable	126,872	335,495
Other receivables	80,858	51,893
Inventories	588,609	703,994
Prepaid expenses	70,215	139,889
Current portion of deferred tax asset	75,066	78,066
Total current assets	7,065,361	6,846,487
PROPERTY, PLANT AND EQUIPMENT, at cost:		
Laboratory and manufacturing equipment	2,249,866	2,469,390
Building and improvements	2,335,895	2,399,357
Office furniture and equipment	188,245	187,165
Construction in progress	42,388	60,534
Land	50,000	50,000
	4,866,394	5,166,446
Less - accumulated depreciation	1,926,008	2,187,138
Net property, plant and equipment	2,940,386	2,979,308
LONG-TERM PORTION OF DEFERRED TAX ASSET	340,037	325,037
PRODUCT RIGHTS AND OTHER ASSETS , net of accumulated amortization of \$1,269,000 and \$1,297,000 at December 31, 2007 and September 30, 2008, respectively	66,704	39,181
TOTAL ASSETS	\$ 10,412,488	\$ 10,190,013
<u>LIABILITIES AND STOCKHOLDERS EQUITY</u>		
CURRENT LIABILITIES:		
Accrued expenses	\$ 237,181	\$ 194,565
Accounts payable	118,336	283,944
Total current liabilities	355,517	478,509
STOCKHOLDERS EQUITY:		
Common stock, Par value-\$0.10 per share		

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Authorized-8,000,000 shares, Issued-3,261,148 shares at December 31, 2007 and September 30, 2008	326,115	326,115
Capital in excess of par value	9,668,872	9,750,781
Accumulated surplus	864,929	436,361
Treasury stock at cost 368,672 and 366,496 shares at December 31, 2007 and September 30, 2008, respectively	(802,945)	(801,753)
Total stockholders equity	10,056,971	9,711,504
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 10,412,488	\$ 10,190,013

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

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STATEMENTS OF OPERATIONS FOR THE

THREE AND NINE-MONTH PERIODS ENDED SEPTEMBER 30, 2007 AND 2008

(Unaudited)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2007	2008	2007	2008
REVENUES:				
Product sales	\$ 982,839	\$ 923,969	\$ 3,282,559	\$ 3,381,113
Technology licensing revenue	931,263		1,247,550	
Royalty income	17,739	33	36,246	4,814
Total revenues	1,931,841	924,002	4,566,355	3,385,927
COSTS AND EXPENSES:				
Product costs	476,493	621,364	1,617,847	1,881,925
Product development expenses	589,322	485,323	1,149,272	1,240,571
General and administrative expenses	215,488	222,263	616,970	715,616
Product selling expenses	113,243	144,800	367,382	423,413
Total costs and expenses	1,394,546	1,473,750	3,751,471	4,261,525
Net operating income (loss)	537,295	(549,748)	814,884	(875,598)
Interest income	66,953	49,081	212,482	164,158
Other income (expense), net	281	700	1,513	1,490
Net interest and other income	67,234	49,781	213,995	165,648
INCOME (LOSS) BEFORE INCOME TAXES	604,529	(499,967)	1,028,879	(709,950)
INCOME TAX EXPENSE (BENEFIT)	250,640	(231,522)	438,467	(281,382)
NET INCOME (LOSS)	\$ 353,889	\$ (268,445)	\$ 590,412	\$ (428,568)
NET INCOME (LOSS) PER COMMON SHARE:				
Basic	\$ 0.12	\$ (0.09)	\$ 0.20	\$ (0.15)
Diluted	\$ 0.12	\$ (0.09)	\$ 0.19	\$ (0.15)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic	2,896,950	2,894,652	2,899,177	2,893,246
Diluted	3,013,024	2,894,652	3,048,561	2,893,246

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

Table of Contents**IMMUCELL CORPORATION****STATEMENTS OF STOCKHOLDERS EQUITY**

(Unaudited)

FOR THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2007

	Common Stock \$0.10 Par Value		Capital in Excess of Par Value	Accumulated Surplus	Treasury Stock		Total Stockholders Equity
	Shares	Amount			Shares	Amount	
BALANCE,							
December 31, 2006	3,261,148	\$ 326,115	\$ 9,565,738	\$ 202,791	365,454	\$ (762,630)	\$ 9,332,014
Net income				590,412			590,412
Exercise of stock options			13,077		(12,000)	25,135	38,212
Stock-based compensation			65,664				65,664
Tax benefits related to stock options			822				822
Acquisition of treasury stock					15,218	(65,450)	(65,450)
BALANCE,							
September 30, 2007	3,261,148	\$ 326,115	\$ 9,645,301	\$ 793,203	368,672	\$ (802,945)	\$ 9,961,674

FOR THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2008

	Common Stock \$0.10 Par Value		Capital in Excess of Par Value	Accumulated Surplus	Treasury Stock		Total Stockholders Equity
	Shares	Amount			Shares	Amount	
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

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

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STATEMENTS OF CASH FLOWS FOR THE NINE-MONTH PERIODS

ENDED SEPTEMBER 30, 2007 AND 2008

(Unaudited)

	Nine-Month Periods Ended September 30,	
	2007	2008
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	\$ 590,412	\$ (428,568)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation	216,057	269,745
Amortization	469,678	27,798
Deferred income taxes	368,203	12,000
Stock-based compensation	65,664	83,099
Loss on disposal of fixed assets	70	31,708
Changes in:		
Receivables	158,691	279,841
Income taxes receivable/payable	(340,574)	(208,623)
Inventories	112,367	(115,385)
Prepaid expenses and other assets	(52,848)	(69,949)
Accrued expenses	(177,813)	(42,616)
Accounts payable	90,101	165,608
Deferred revenue	(1,247,550)	
Net cash provided by operating activities	252,458	4,658
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1,411,817)	(358,677)
Insurance recovery on fixed asset loss		18,302
Maturities of short-term investments	4,604,024	4,230,903
Purchases of short-term investments	(3,348,162)	(4,147,103)
Net cash used for investing activities	(155,955)	(256,575)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Tax benefits related to stock options	822	
Proceeds from exercise of stock options, net	38,212	2
Acquisition of treasury stock	(65,450)	
Net cash (used for) provided by financing activities	(26,416)	2
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	70,087	(251,915)
BEGINNING CASH AND CASH EQUIVALENTS	1,348,854	1,192,637
ENDING CASH AND CASH EQUIVALENTS	\$ 1,418,941	940,722
CASH PAID FOR INCOME TAXES	\$ 409,152	\$ 892
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Change in capital expenditures included in accounts payable	\$ (138,176)	

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NOTES TO UNAUDITED FINANCIAL STATEMENTS

September 30, 2008

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, 2007 and the notes thereto, contained in our Annual Report on Form 10-KSB 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 of \$100,000 each. The Emergency Economic Stabilization Act of 2008 increased these insurance limits to \$250,000 each 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, 2007	September 30, 2008	Decrease
Cash and cash equivalents	\$ 1,193	\$ 941	\$ 252
Short-term investments	4,219	4,135	84
	\$ 5,412	\$ 5,076	\$ 336

3. INVENTORIES

Inventories consist of the following (in thousands):

	December 31, 2007	September 30, 2008
Raw materials	\$ 182	\$ 297
Work-in-process	396	288
Finished goods	11	119
	\$ 589	\$ 704

4. LICENSING AND TECHNOLOGY LICENSING REVENUE

Revenue of \$2,375,000 paid by Pfizer in connection with a product development and marketing agreement covering **Mast Out**[®] was deferred when the cash was received and recognized as technology licensing revenue from December 2004 to July 2007, while this technology was licensed to Pfizer. In July 2007, Pfizer elected to terminate the product development and marketing agreement. The product rights and related data have been returned to us, and we are continuing the product development effort. During the third quarter of 2007, we recognized the remaining deferred income and wrote off the remaining unamortized cost of associated technology rights. Technology licensing revenue included the recognition of the related deferred revenue amounting to approximately \$931,000 and \$1,248,000 during the three and nine-month periods ended September 30, 2007, respectively. Product development expenses included amortization of associated technology rights amounting to approximately \$329,000 and \$439,000 during the three and nine-month periods ended September 30, 2007, respectively.

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NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2008

5. INCOME TAXES

Effective January 1, 2007, we implemented the provisions of Financial Accounting Standards Board 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 \$251,000 (41% of income before income taxes) during the three-month period ended September 30, 2007 in contrast to an income tax benefit of \$232,000 (46% of the loss before income taxes) during the three-month period ended September 30, 2008. Our income tax expense aggregated \$438,000 (43% of income before income taxes) during the nine-month period ended September 30, 2007 in contrast to an income tax benefit of \$281,000 (40% of the loss before income taxes) during the nine-month period ended September 30, 2008.

6. 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 and nine-month periods ended September 30, 2007, 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 and nine-month periods ended September 30, 2008, 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 September 30,		Nine-Month Periods Ended September 30,	
	2007	2008	2007	2008
Weighted average number of shares outstanding during the period	2,896,950	2,894,652	2,899,177	2,893,246
Dilutive stock options	281,872		362,205	
Shares that could have been repurchased with the proceeds from the dilutive stock options	(165,798)		(212,821)	
Diluted number of shares outstanding during the period	3,013,024	2,894,652	3,048,561	2,893,246
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	166,666	418,000	90,222	418,000

7. EMPLOYEE STOCK-BASED COMPENSATION

In December 2004, the Financial Accounting Standards Board (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 \$22,000 and \$29,000 during the three-month periods ended September 30, 2007 and 2008, respectively, and \$66,000 and \$83,000 during the nine-month periods ended September 30, 2007 and 2008, respectively. Half of this expense is allocated to general and administrative expenses and half to product development expenses.

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The exercise price of the 418,000 stock options outstanding as of September 30, 2008 ranged from \$1.31 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-KSB for the year ended December 31, 2007. As of September 30, 2008, 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 2011, which represents the remaining vesting period of the outstanding, non-vested stock options.

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NOTES TO UNAUDITED FINANCIAL STATEMENTS (Continued)

September 30, 2008

8. 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 2 to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2007.

Our primary customers for the majority (88% and 94% for the three-month periods ended September 2007 and 2008, 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 12% and 4% of product sales for the three-month periods ended September 30, 2007 and 2008, respectively.

Our primary customers for the majority (84% and 88% for the nine-month periods ended September 30, 2007 and 2008, 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 16% and 11% of product sales for the nine-month periods ended September 30, 2007 and 2008, 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,	
	2007	2008	2007	2008
Animal Health International, Inc.	25%	19%	25%	21%
Lextron, Inc./Vet Pharm, Inc.(1)	24%	18%	18%	17%
MWI Veterinary Supply Co.	10%	13%	*	11%

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

	As of	
	December 31, 2007	September 30, 2008
Animal Health International, Inc.	33%	33%
Lextron, Inc./Vet Pharm, Inc.(1)	12%	13%
TCS Biosciences, Ltd.	16%	*
MWI Veterinary Supply Co.	*	18%

* Amount is less than 10%.

(1) Figures reported reflect the August 2007 acquisition of Vet Pharm, Inc. by Lextron, Inc. as if the transaction had been completed as of January 1, 2007.

9. COMMON STOCK

In April 2003, we announced that our Board of Directors had approved a plan to repurchase up to 100,000 shares of our common stock as market conditions warrant. The maximum of 100,000 shares represented approximately 3.7% of our outstanding common stock as of March 31, 2003. Repurchases under the plan were made from time to time at the discretion of management. In August 2007, our Board of Directors voted

to discontinue the plan, determining that the funds available

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for repurchases could be better utilized to support increased product development activities at this time. Before this plan was terminated, we repurchased an aggregate of 52,025 shares of our common stock at a total cost of approximately \$233,749 (average purchase price of \$4.49 per share). During the nine-month period ended September 30, 2007, we repurchased an aggregate of 15,218 shares of our common stock at a total cost of approximately \$65,450 (average purchase price of \$4.30 per share).

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) 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.

10. 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**[®] and **Wipe Out**[®] Dairy Wipes and of J-t Enterprises of Melrose, Inc., an exporter of **First Defense**[®]. His affiliated companies purchased approximately \$165,000 and \$164,000 of products from ImmuCell during the nine-month periods ended September 30, 2007 and 2008, respectively.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS
RESULTS OF OPERATIONS FOR THE THREE AND NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2008*Product Sales*

Product sales decreased by approximately 6%, or \$59,000, to \$924,000 during the three-month period ended September 30, 2008 in comparison to \$983,000 during the same period in 2007. Product sales increased by approximately 3%, or \$99,000, to \$3,381,000 during the nine-month period ended September 30, 2008 in comparison to \$3,283,000 during the same period in 2007. Sales of our products may be influenced by the price of milk, heifers 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 2007 was \$18.04 per 100 pounds, which represents a 52% increase over the 2006 average of \$11.89. During the first nine months of 2008, this average price level was \$17.93, which represented a 2% increase over the first nine months of 2007. For a point of reference, this price level was \$10.42 in 2002, which approximates the price level experienced during the 1970 s. While an increase in the sales value of milk is good for our customers, some of this benefit has been offset by increases in the costs to produce milk. 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 2007, this ratio averaged 2.80. The monthly average during the first nine months of 2008 dropped to 2.01, representing a 28% decrease compared to the first nine months of 2007. A ratio of 2.01 means that a dairy producer can buy 2.01 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 2007, this price is estimated to have increased to approximately \$1,840, which is a 6% increase over 2006. In 2008, this price averaged approximately \$1,953, which represents a 6% increase over 2007. 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.

Our lead product, **First Defense**[®], continues to benefit from wide acceptance as an effective tool to prevent bovine enteritis (scours) in newborn calves. Sales of this product increased 2% during the nine-month period ended September 30, 2008 in comparison to the same period in 2007. We launched this product in 1991 after receiving USDA approval for its sale. During the first quarter of 2008, we sold our 8,000,000th dose of **First Defense**[®]. Sales are normally seasonal, with higher sales expected during the first and fourth quarters and lower sales expected during the

second and third quarters.

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During the second quarter of 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** increased by 3% during the nine-month period ended September 30, 2008 in comparison to the same period in 2007. 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

Given the termination of a product development and marketing agreement covering **Mast Out**[®] during the third quarter of 2007, no technology licensing revenue was recorded during the three and nine-month periods ended September 30, 2008, respectively, in contrast to \$931,000 and \$1,248,000 during the three and nine-month periods ended September 30, 2007, respectively. Royalty income decreased to \$33 and \$5,000 during the three and nine-month periods ended September 30, 2008, respectively, in comparison to \$18,000 and \$36,000 during the same periods in 2007, respectively, as the result of lower sales reported by the firm that has licensed our milk protein purification technology.

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,		Decrease	
	2007	2008	Amount	%
Gross margin	\$ 506	\$ 303	\$ 203	40%
Percent of product sales	52%	33%	19%	37%
	Nine-Month Periods Ended September 30,		Decrease	
	2007	2008	Amount	%
Gross margin	\$ 1,665	\$ 1,499	\$ 166	10%
Percent of product sales	51%	44%	7%	14%
	Twelve-Month Periods Ended September 30,		Increase (Decrease)	
	2007	2008	Amount	%
Gross margin	\$ 2,203	\$ 2,338	\$ 135	6%
Percent of product sales	51%	48%	(3)%	(6)%

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 33% and 52% during the three-month periods ended September 30, 2008 and 2007, respectively. The gross margin as a percentage of product sales was 44% and 51% during the nine-month periods ended September 30, 2008 and 2007, respectively. The gross margin as a percentage of product sales was 48% and 51% during the twelve-month periods ended September 30, 2008 and 2007, respectively. This compares to gross margin percentages of 52%, 56% and 61% for the years ended December 31, 2007, 2006 and 2005, 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 periods ended September 30, 2008 and 2007. The gross margin percentage was unusually low during the three-month period ended September 30, 2008. We expect some fluctuations in gross margin percentages from quarter to quarter. 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

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higher gross margin on **First Defense**[®] and a lower gross margin on **Wipe Out**[®] **Dairy Wipes**. Because **First Defense**[®] customers are price sensitive, we had held its selling price without significant increase for about 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 decreased by approximately 18%, or \$104,000, to \$485,000 during the three-month period ended September 30, 2008 in comparison to the same period in 2007. Product development expenses aggregated 53% and 31% of total revenues during the three-month periods ended September 30, 2008 and 2007, respectively. Product development expenses increased by approximately 8%, or \$91,000, to \$1,241,000 during the nine-month period ended September 30, 2008 in comparison to the same period in 2007. Product development expenses aggregated 37% and 25% of total revenues during the nine-month periods ended September 30, 2008 and 2007, respectively. During the three and nine-month periods ended September 30, 2007, product development expenses included approximately \$329,000 and \$439,000, respectively, in non-cash amortization expense pertaining to a technology asset that was written off during the third quarter of 2007 when the associated product development and marketing agreement covering **Mast Out**[®] was terminated. The increased cash expenses (excluding the non-cash amortization in the 2007 periods) during the three and nine-month periods ended September 30, 2008 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, it is common practice to treat only clinical cases (cows producing abnormal milk) since that milk already is unsuitable for commercial sale. Because milk from cows with subclinical mastitis (cows with infected udders but still producing normal milk) can be sold, dairy producers generally do not treat subclinical mastitis in order to avoid the milk discard requirement. The safety profile of Nisin and its long history as a food preservative may allow for the sale of **Mast Out**[®] in the U.S. without a milk discard requirement, which would be a significant competitive advantage. No other intramammary mastitis treatment product 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**[®]. Under that agreement (as later 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 other significant progress in the areas of effectiveness, manufacturing and pharmacokinetics. 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**[®].

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We believe that Pfizer's decision to terminate the product development and marketing agreement was not based on any unanticipated efficacy or regulatory issues. Rather, we believe Pfizer's decision was primarily market driven, largely relating to concerns that the use of **Mast Out** may require specific treatment restrictions at the herd level, 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 (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 could 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 would have significant sales potential in the U.S. dairy market.

Commercial introduction of **Mast Out** in the United States is subject to approval by the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine, which approval cannot be assured. It is our objective to submit the administrative New Animal Drug Application (NADA) to the FDA during the first half of 2010, unless we encounter an unanticipated number of submission-review cycles with the FDA. 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.

In July 2007, we began preparations for the pivotal effectiveness study. Such preparations included the production of registration batches of **Mast Out** drug product to fulfill the pivotal regulatory requirements of effectiveness, target animal safety, and stability. In June 2008, we initiated the pivotal effectiveness study. We are working with more than twelve investigators across the U.S. to complete this study. As of October 2008, we had enrolled approximately 40% of the qualified cases required to reach our targeted study size. Achieving the enrollment of the total number of cases meeting our clinical requirements will take the study into the first half of 2009. Upon completion of the treatment phase, we will commence orderly close out of the clinical sites, analysis of the data and discussion of the results with the FDA before a public announcement can be made.

The approval of several additional Technical Sections under the FDA's phased review of a NADA is also required before any U.S. product sales would be allowed. 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 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 the milk discard period. The Human Food Safety Technical Section includes several subsections such as residue chemistry (which is in progress), total metabolism (which is in progress), 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 under FDA review) 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 are 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 a Human Food Safety Technical Section Complete Letter can be issued by the FDA.

Commercial-scale manufacturing of **Mast Out** will need to comply with current Good Manufacturing Practice (cGMP) regulations and will be subject to FDA approval and inspection. With assistance from outside consultants, we are examining contract manufacturing options for the Active Pharmaceutical Ingredient (API) at this time. We have not yet made a determination of the cost or location of the commercial API manufacturing facility. 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.

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In addition to our work on **Mast Out**[®], we are actively exploring further improvements, extensions or additions to our current product line. For example, we currently are investigating therapies that could prevent scours in calves caused by enteric pathogens other than *E. coli* K99 and 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. Additionally, during the second quarter of 2007, we acquired an option to an exclusive license from Ohio State University covering certain rotavirus technology. If the studies and development that we have planned over the next six months proceed effectively, we could conduct the pivotal effectiveness study in 2009, which could position us for USDA approval by the first half of 2010.

Wipe Out[®] **Dairy Wipes** are manufactured in compliance with cGMP regulations, as required by federal law. We are investing in the process improvements, facility modifications, new equipment, staffing changes and increased documentation required to become compliant with cGMP regulations for our other products, where compliance is not required. We expect that the implementation of these increased standards will result in improved overall quality and consistency in our manufacturing operations. We completed certain related facility renovations and new equipment purchases during 2007 to facilitate this compliance effort. It is our objective to have implemented the process improvements and enhanced process documentation necessary to comply with cGMP regulations across our entire product line by the fourth quarter of 2009. Our initial target date for compliance (the end of 2008) has been extended, consistent with our decision to postpone initiation of a second facility investment project from September 2008 to at least the spring of 2009. See **Liquidity and Capital Resources**, below.

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 Anadis, Ltd. of Australia. Under this agreement, we gained access to relevant production technology and capabilities of Anadis in Australia. We are obligated to pay Anadis a royalty on any sales of **First Defense**[®] manufactured in Australia in collaboration with Anadis.

There may be additional animal disease indications for Nisin that we decide to pursue using pharmaceutical-grade Nisin produced under cGMP. During 2006, we completed a collaborative study of Nisin susceptibility in methicillin-resistant canine staphylococcal isolates with investigators at University of Pennsylvania School of Veterinary Medicine. One hundred isolates of methicillin-resistant canine *Staphylococcus aureus* (MRSA), *intermedius* and *schleiferi* were tested and found to be highly susceptible to Nisin's antibacterial activity. These data were presented at the 2007 North American Veterinary Dermatology Forum in Kauai, Hawaii. During the second quarter of 2008, we completed a study in collaboration with the University of Tennessee evaluating the effectiveness of Nisin impregnated wipes used to treat skin infections in dogs. The study consisted of two separate clinical feasibility studies, each of which was defined by the severity of canine skin infections. In the first study, 10 dogs with localized surface skin infections were treated with Nisin impregnated wipes as a stand alone therapy for 2 weeks. The second study consisted of treating 20 dogs that had more severe skin infections generally located in multiple sites on the body. The skin infections in the second study were treated with Nisin impregnated wipes in conjunction with systemic antibiotics. While this study was not designed to show statistical significance, the results do suggest that Nisin could be effective against pyoderma caused by common bacteria, such as methicillin-resistant Staphylococci. The results confirmed our expectation that Nisin is not as effective against fungal and gram negative causes of pyoderma. We continue to evaluate whether further development of this or other Nisin formulations is warranted and remain open to out-licensing this product opportunity to a partner more focused on the companion animal market than we are.

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 maintain relationships with several scientific collaborators who have particular expertise in the areas of strategic interest to us. We occasionally hire outside consultants to assist us with our development work depending upon staff availability, the technical skills required, the nature of the particular project and other considerations. As additional opportunities arise to commercialize our own technology, or licensable technology, we may begin new product development projects. All of our employees are required to execute non-disclosure, non-compete and invention assignment agreements intended to protect our rights in our proprietary products.

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During the three-month period ended September 30, 2008, general and administrative expenses increased by 3%, or \$7,000, to \$222,000 as compared to the same period in 2007. During the nine-month period ended September 30, 2008, general and administrative expenses increased by 16%, or \$99,000, to \$716,000 as compared to the same period in 2007. The increases result, in large part, from increased compensation expense, 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, 2008, product selling expenses increased by 28%, or \$32,000, to \$145,000, as compared to the same period in 2007, aggregating 16% and 12% of product sales during the three-month periods ended September 30, 2008 and 2007, respectively. During the nine-month period ended September 30, 2008, product selling expenses increased by 15%, or \$56,000 to \$423,000, as compared to the same period in 2007, aggregating 13% and 11% of product sales during nine-month periods ended September 30, 2008 and 2007, respectively. 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 \$(500,000) during the three-month period ended September 30, 2008 contrasts to income before income taxes of \$605,000 during the three-month period ended September 30, 2007. We recorded a 46% income tax benefit during the three-month period ended September 30, 2008 in contrast to income tax expense of 41% during the three-month period ended September 30, 2007. Our net loss for the three-month period ended September 30, 2008 was \$(268,000) (or \$(0.09) per share) in contrast to net income of \$354,000 (or \$0.12 per share) during the three-month period ended September 30, 2007. Our loss before income taxes of \$(710,000) during the nine-month period ended September 30, 2008 contrasts to income before income taxes of \$1,029,000 during the nine-month period ended September 30, 2007. We recorded a 40% income tax benefit during the nine-month period ended September 30, 2008 in contrast to income tax expense of 43% during the nine-month period ended September 30, 2007. Our net loss for the nine-month period ended September 30, 2008 was \$(429,000) (or \$(0.15) per share) in contrast to net income for the nine-month period ended September 30, 2007 of \$590,000 (or \$0.19 per diluted share).

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and short-term investments decreased by 6%, or \$336,000, to \$5,076,000 at September 30, 2008 from \$5,412,000 at December 31, 2007. Net cash provided by operating activities amounted to \$5,000 during the nine months ended September 30, 2008 as compared to \$252,000 during the nine months ended September 30, 2007. Total assets decreased by 2%, or \$222,000, to \$10,190,000 at September 30, 2008 from \$10,412,000 at December 31, 2007. We have no outstanding bank debt. Net working capital decreased by 5%, or \$342,000, to \$6,368,000 at September 30, 2008 from \$6,710,000 at December 31, 2007. Stockholders' equity decreased by 3%, or \$345,000, to \$9,712,000 at September 30, 2008 from \$10,057,000 at December 31, 2007, primarily as a result of the net loss during the first nine months of 2008.

As we implement the process improvements necessary to achieve compliance with cGMP regulations across all products, we are investing in personnel, equipment and facility improvements. We have hired personnel in our quality department with experience implementing cGMP regulations. In 2007, we completed a renovation of our company-owned facility which provided approximately 5,000 square feet of new office space and approximately 2,500 square feet of additional warehouse space. These changes will help us segregate and improve our production, quality control and product development processes and facilitate our continued development of **Mast Out**[®]. These investments will be amortized over their useful lives of approximately ten years for equipment, and approximately sixteen years for facility improvements. In June 2008, our Board of Directors authorized the investment of approximately \$775,000 for a facility addition and more production equipment to increase our production capacity by providing greater production and warehouse space, a more efficient loading dock and significantly more on-site cold storage. In September 2008, we decided to postpone most of this project until at least the spring of 2009. This decision will allow us to avoid the added costs of winter construction, while we use the time to finalize the design and permitting, solicit more competitive construction bids and monitor the status of the economy and our business. We pay for investments of this nature with available cash.

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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 expect that expenditures on this program of product development is expected to result in a net loss in 2008 and likely in 2009, ending the nine consecutive years of profitability that we recorded during the years ended December 31, 1999 to December 31, 2007. At this point, we project a loss before income taxes of approximately \$600,000 to \$750,000 for the year ending December 31, 2008. We believe that the commercial prospects for **Mast Out**[®] warrant this level of investment.

With approximately \$5,076,000 in cash and short-term investments as of September 30, 2008, 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. Although we also believe that these cash reserves should be sufficient to fund the internal development of **Mast Out**[®], we remain alert for opportunities to enter into collaborative partnerships with other companies to help share the anticipated costs and risks associated with developing this product and bringing it to market.

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, 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, 2007. Based on management's assessment and those criteria, management concluded that the internal control over financial reporting as of December 31, 2007 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 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 achieving 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-QSB or 10-Q, our Annual Reports on Form 10-KSB or 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.

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 from December 31, 1999 to December 31, 2007 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, resumption of our development work on **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 Schering Plough. There is no assurance that **Mast Out**[®] will compete successfully in this market.

Uncertainty of projections: After nine consecutive years of reporting net income, we expect to report a net loss in 2008, due in large part to our current product development strategy. In our Annual Report on Form 10-KSB for the year ended December 31, 2007, we projected that loss before income taxes would be approximately \$500,000 to \$750,000. Currently, we project the amount of the loss before income taxes at approximately \$600,000 to \$750,000. 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 beyond the current projection 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 do so in 2008 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.

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Uncertainty of market estimates: **Mast Out**[®] has the potential to change the way in which dairy farmers treat mastitis. 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 cited by our outside consultant include subclinical market development, coverage of relevant pathogens, selling price, integration of milk from treated cows into cheese starter cultures and market acceptance.

Small size: We are a small company with approximately 37 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.

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.

Economics of the dairy industry: The dairy industry in the United States has been facing very difficult economic pressures. After declining in 2002 to price levels common in the 1970s, the price of milk increased in 2004 before decreasing in 2005 and further decreasing in 2006. The milk price strengthened significantly in 2007 and held approximately at the 2007 average level during the first nine months of 2008. While an increase in the sales value of milk is good for our customers, some of this benefit has been offset by increases in the costs to produce milk. The number of small dairy farmers continues to decrease. The financial insecurity of our primary customer base is a risk to our ability to maintain and grow sales at a profitable level.

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 **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 would be achieved. Such approval would also require a successful inspection under cGMP standards by the FDA of the facilities used to manufacture the product. We have not identified 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.

*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 are investing in personnel, facility improvements and new equipment to bring our manufacturing operations into 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.

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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 (especially bovine) origin. **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.

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 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

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Date: November 4, 2008

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

and Principal Financial Officer

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