

IMMUCELL CORP /DE/
Form 10-Q
November 10, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2016

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, 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 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

The number of shares of the Registrant’s common stock outstanding at November 8, 2016 was 4,847,390.

ImmuCell Corporation

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ImmuCell Corporation**PART 1. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****(Unaudited Condensed)****BALANCE SHEETS**

	As of September 30, 2016	As of December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 4,408,415	\$ 1,573,328
Short-term investments	5,199,000	4,464,000
Accounts receivable, net	677,155	718,103
Inventory	1,766,396	870,207
Prepaid expenses and other current assets	693,461	256,698
Total current assets	12,744,427	7,882,336
PROPERTY, PLANT AND EQUIPMENT, net	7,238,391	5,718,814
LONG-TERM INVESTMENTS	0	487,000
DEFERRED TAX ASSET	290,074	452,117
INTANGIBLE ASSETS, NET	175,731	0
GOODWILL	95,557	0
OTHER ASSETS, NET	34,264	0
TOTAL ASSETS	\$ 20,578,444	\$ 14,540,267
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 888,857	\$ 662,165
Current portion of bank debt	131,397	130,780
Deferred revenue	33,856	0
Total current liabilities	1,054,110	792,945
LONG-TERM LIABILITIES:		
Bank debt, net of current portion	2,913,448	3,054,977
Interest rate swaps	203,160	78,525

Total long-term liabilities	3,116,608	3,133,502
TOTAL LIABILITIES	4,170,718	3,926,447

CONTINGENT LIABILITIES AND COMMITMENTS (See Note 15)

STOCKHOLDERS' EQUITY:

Common stock, \$0.10 par value per share, 10,000,000 and 8,000,000 shares authorized, 4,384,958 and 3,261,148 shares issued, as of September 30, 2016 and December 31, 2015, respectively	438,496	326,115
Additional paid-in capital	15,414,361	10,150,190
Retained earnings	1,116,835	638,672
Treasury stock, at cost, 197,448 and 206,114 shares as of September 30, 2016 and December 31, 2015, respectively	(431,943)	(450,901)
Accumulated other comprehensive loss	(130,023)	(50,256)
Total stockholders' equity	16,407,726	10,613,820
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 20,578,444	\$ 14,540,267

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

ImmuCell Corporation**(Unaudited Condensed)****STATEMENTS OF INCOME**

	For the Three-Month		For the Nine-Month	
	Periods Ended		Periods Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Product sales	\$1,968,122	\$2,472,428	\$7,330,143	\$7,534,281
Costs of goods sold	763,495	860,526	3,128,095	2,940,881
Gross margin	1,204,627	1,611,902	4,202,048	4,593,400
Sales and marketing expenses	483,709	381,740	1,365,017	1,086,928
Administrative expenses	362,730	301,566	1,075,538	941,417
Product development expenses	307,721	301,746	990,598	904,170
Operating expenses	1,154,160	985,052	3,431,153	2,932,515
NET OPERATING INCOME	50,467	626,850	770,895	1,660,885
Other expenses, net	26,510	15,111	81,195	27,059
INCOME BEFORE INCOME TAXES	23,957	611,739	689,700	1,633,826
Income tax (benefit) expense	(10,913)	260,447	211,537	709,394
NET INCOME	\$34,870	\$351,292	\$478,163	\$924,432
Weighted average common shares outstanding:				
Basic	4,182,529	3,052,175	4,065,243	3,038,111
Diluted	4,302,280	3,188,349	4,179,181	3,162,620
NET INCOME PER SHARE:				
Basic	\$0.01	\$0.12	\$0.12	\$0.30
Diluted	\$0.01	\$0.11	\$0.11	\$0.29

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

ImmuCell Corporation

(Unaudited Condensed)

STATEMENTS OF COMPREHENSIVE INCOME

	For the Three-Month		For the Nine-Month	
	Periods Ended September 30,		Periods Ended September 30,	
	2016	2015	2016	2015
Net income	\$34,870	\$351,292	\$478,163	\$924,432
Other comprehensive income:				
Interest rate swaps, before taxes	24,255	(81,767)	(124,635)	(79,956)
Income tax applicable to interest rate swaps	(8,732)	32,620	44,868	31,897
Other comprehensive income (loss), net of taxes	15,523	(49,147)	(79,767)	(48,059)
Total comprehensive income	\$50,393	\$302,145	\$398,396	\$876,373

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

ImmuCell Corporation**(Unaudited Condensed)****STATEMENTS OF CASH FLOWS**

	For the Nine-Month Periods Ended September 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$478,163	\$924,432
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	569,081	378,475
Amortization	21,676	2,074
Deferred income taxes	206,911	680,087
Stock-based compensation	50,312	17,825
Loss (Gain) on disposal of fixed assets	2,109	(3,984)
Provision for uncollectible accounts	2,225	1,898
Changes in:		
Accounts receivable, gross	38,723	214,180
Inventory	(783,190)	81,311
Prepaid expenses and other current assets	(471,027)	(127,160)
Accounts payable and accrued expenses	(100,697)	(92,332)
Deferred revenue	33,856	(6,690)
Net cash provided by operating activities	48,142	2,070,116
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1,794,755)	(1,772,091)
Acquisition of certain business assets	(368,219)	0
Maturities of investments	3,968,000	2,489,000
Purchases of investments	(4,216,000)	(3,711,000)
Proceeds from sale of fixed assets	0	66,215
Net cash used for investing activities	(2,410,974)	(2,927,876)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from public offering, net	5,313,223	0
Proceeds from debt issuance	0	2,500,000
Debt principal repayments	(100,545)	(136,339)
Debt issuance costs	(46,734)	(32,759)
Proceeds from exercise of stock options	31,975	120,210
Tax benefits related to stock options	0	25,707
Net cash provided by financing activities	5,197,919	2,476,819
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,835,087	1,619,059

BEGINNING CASH AND CASH EQUIVALENTS	1,573,328	850,028
ENDING CASH AND CASH EQUIVALENTS	\$4,408,415	\$2,469,087

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

CASH PAID FOR:

Income taxes	\$125,125	\$3,600
Interest expense	\$115,682	\$38,324

NON-CASH ACTIVITIES:

Change in capital expenditures included in accounts payable and accrued expenses	\$163,635	\$(213,418)
Net change in fair value of interest rate swaps	\$79,767	\$48,059
Fixed asset disposals, gross	\$58,714	\$279,111

See Note 8 for non-cash activities related to a 2016 business acquisition

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

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements

1. BUSINESS OPERATIONS

ImmuCell Corporation (the “Company”, “we”, “us”, “our”) is a growing animal health company whose purpose is to create scientifically-proven and practical products that improve animal health and productivity in the dairy and beef industries. The Company was originally incorporated in Maine in 1982 and reincorporated in Delaware in 1987, in conjunction with its initial public offering of common stock. We market products that provide immediate immunity to newborn dairy and beef cattle. We are developing product line extensions of our existing products and are in the late stages of developing a novel product that addresses mastitis, the most significant cause of economic loss to the dairy industry. These products help reduce the need to use traditional antibiotics in food producing animals. The Company is subject to certain risks associated with its stage of development including dependence on key individuals, competition from other larger companies, the successful sale of existing products and the development and acquisition of additional commercially viable products with appropriate regulatory approvals, where applicable. These and other risks to our company are further detailed under **PART II-OTHER INFORMATION: ITEM 1A- RISK FACTORS**.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

We have prepared the accompanying unaudited condensed financial statements reflecting all adjustments that are, in our opinion, necessary in order to ensure that the financial statements are not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP in these footnotes are to the FASB *Accounting Standards Codification*TM (Codification). As described below, certain prior year accounts have been reclassified to conform with the 2016 financial statement presentation. Certain information and footnote disclosures normally included in the annual financial statements have been condensed or omitted. Accordingly, we believe that although the disclosures are adequate to ensure that the information presented is not misleading, these unaudited condensed financial statements should be read in conjunction with the financial statements for the year ended December 31, 2015 and the notes thereto, contained in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission (SEC).

(b) Cash, Cash Equivalents, Short-Term Investments and Long-Term Investments

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash

balances in excess of Federal Deposit Insurance Corporation (FDIC) limits of \$250,000 per financial institution per depositor are maintained in money market accounts at financial institutions that are secured, in part, by the Securities Investor Protection Corporation. Amounts in excess of these FDIC limits per bank that are not invested in securities backed by the U.S. government aggregated \$3,908,115 and \$1,073,028 as of September 30, 2016 and December 31, 2015, respectively. We account for marketable securities in accordance with Codification Topic 320, *Investments - Debt and Equity Securities*. Short-term investments are classified as held to maturity and are comprised principally of certificates of deposit that mature in more than three months from their purchase dates and not more than twelve months from the balance sheet date. Long-term investments are classified as held to maturity and are comprised principally of certificates of deposit that mature in more than twelve months from the balance sheet date. Short-term and long-term investments are held at different financial institutions that are insured by the FDIC, within the FDIC limits per financial institution. See Note 3.

(c) Inventory

Inventory includes raw materials, work-in-process and finished goods and is recorded at the lower of cost, on the first-in, first-out method, or net realizable value (determined as the estimated selling price in the normal course of business, less reasonably predictable costs of completion, disposal and transportation). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. See Note 4.

(d) Accounts Receivable

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful collection and product returns. Management determines the allowance for doubtful accounts on a monthly basis by identifying troubled accounts and by using historical experience applied to an aging of accounts. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded as income when received. Accounts receivable are considered to be past due if any portion of the receivable balance is outstanding for more than 30 days. Interest is charged on past due accounts receivable.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

(e) Property, Plant and Equipment

We depreciate property, plant and equipment on the straight-line method by charges to operations in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The facility we are constructing to produce the active ingredient, Nisin, for **Mast Out**® will be depreciated over its useful life beginning when that facility is placed into service, which could be before the Food and Drug Administration (FDA) approval of the product is achieved. This facility is not yet placed in service. We are evaluating the estimated useful lives of the assets associated with this facility. Repairs to fixed assets that benefit more than a current period are capitalized and depreciated over their useful lives. See Note 7.

(f) Intangible Assets and Goodwill

We amortize intangible assets on the straight-line method by charges to operations in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. We have recorded intangible assets related to customer contracts, customer relationships, non-compete agreements, and technology, each with defined useful lives. We have classified as goodwill the amounts paid in excess of fair value of the net assets (including tax attributes) of assets acquired in purchase transactions. We continually assess that these assets are realizable in accordance with the impairment provisions of Codification Topic 360, *Accounting for the Impairment or Disposal of Long-Lived Assets*. We assess the impairment of intangible assets and goodwill that have indefinite lives on an annual basis (as of December 31st) and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We would record an impairment charge if such an assessment were to indicate that the fair value of such assets was less than their carrying values. Judgement is required in determining whether an event has occurred that may impair the value of identifiable intangible assets or goodwill. Factors that could indicate that an impairment may exist include significant under-performance relative to plan or long-term projections, significant changes in business strategy, significant negative industry or economic trends. Although we believe intangible assets and goodwill are appropriately stated in the accompanying financial statements, changes in strategy or market conditions could significantly impact these judgements and require an adjustment to the recorded balance. See Notes 2(h), 8 and 9 for additional disclosures.

(g) Fair Value Measurements

In determining fair value measurements, we follow the provisions of Codification Topic 820, *Fair Value Measurements and Disclosures*. Codification Topic 820 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. The topic provides a consistent definition of fair value which focuses on an exit price, which is the price that would be received to sell an asset or paid

to transfer a liability in an orderly transaction between market participants at the measurement date. The topic also prioritizes, within the measurement of fair value, the use of market-based information over entity-specific information and establishes a three-level hierarchy for fair value measurements based on the nature of inputs used in the valuation of an asset or liability as of the measurement date. At September 30, 2016 and December 31, 2015, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, other assets, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The three-level hierarchy is as follows:

- Level 1 - Pricing inputs are quoted prices available in active markets for identical assets or liabilities as of the measurement date.
- Level 2 - Pricing inputs are quoted prices for similar assets or liabilities, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data.
- Level 3 - Pricing inputs are unobservable for the assets or liabilities, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the asset or liability.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, an asset's or liability's level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement in its entirety requires judgement, and considers factors specific to the investment.

Our held to maturity securities are comprised of investments in bank certificates of deposit. The value of these securities is disclosed in Note 3. We also hold money market mutual funds in a brokerage account, which are classified as cash equivalents and measured at fair value. The fair value of these investments is based on their closing published net asset value.

We assess the levels of the investments at each measurement date, and transfers between levels are recognized on the actual date of the event or change in circumstances that caused the transfer in accordance with our accounting policy regarding the recognition of transfers between levels of the fair value hierarchy. During the nine-month period ended September 30, 2016 and the year ended December 31, 2015, there were no transfers between levels. As of September 30, 2016 and December 31, 2015, our interest rate swap agreements and bank certificates of deposit were classified as Level 2. As of September 30, 2016 and December 31, 2015, the Level 1 assets measured at fair value consisted of bank savings accounts and money market funds valued at \$4,408,415 and \$1,573,328, respectively, and our Level 2 assets measured at fair value consisted of bank certificates of deposit of \$5,199,000 and \$4,951,000, respectively. There were no assets or liabilities measured at fair value on a nonrecurring basis as of September 30, 2016, or December 31, 2015.

(h) Valuation of Long-Lived Assets

We periodically evaluate our long-lived assets, consisting principally of fixed assets and amortizable intangible assets for potential impairment. In accordance with the applicable accounting guidance for the treatment of long-lived assets, we review the carrying value of our long-lived assets or asset group that is held and used, including intangible assets subject to amortization, for impairment whenever events and circumstances indicate that the carrying value of the assets may not be recoverable. Under the held and used approach, the asset or asset group to be tested for impairment should represent the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities. We evaluate our long-lived assets whenever events or circumstances suggest that the carrying amount of an asset or group of assets may not be recoverable from the estimated undiscounted future cash flows. No impairment was recognized during the three-month or nine-month periods ended September 30, 2016 or 2015.

(i) Concentration of Risk

Concentration of credit risk with respect to accounts receivable is principally limited to certain customers to whom we make substantial sales. To reduce risk, we routinely assess the financial strength of our customers and, as a consequence, believe that our accounts receivable credit risk exposure is limited. We maintain an allowance for potential credit losses, but historically we have not experienced significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

	Three-Month Periods Ended September 30, 2016		2015		Nine-Month Periods Ended September 30, 2016		2015	
Patterson Companies, Inc. ⁽¹⁾	40	%	39	%	39	%	41	%
AmerisourceBergen Corporation ⁽²⁾	18	%	22	%	20	%	21	%
ANIMART LLC ⁽³⁾	11	%	*		*		*	

ImmuCell Corporation**Notes to Unaudited Condensed Financial Statements (continued)**

Accounts receivable due from significant customers amounted to the percentages of total trade accounts receivable as detailed in the following table:

	As of September 30, 2016		As of December 31, 2015	
Patterson Companies, Inc. ⁽¹⁾	42	%	26	%
ANIMART LLC ⁽³⁾	15	%	11	%
AmerisourceBergen Corporation ⁽²⁾	14	%	27	%

⁽¹⁾ During June 2015, Patterson Companies, Inc. (NASDAQ: PDCO) acquired Animal Health International, Inc.

⁽²⁾ During March 2015, AmerisourceBergen Corporation (NYSE: ABC) acquired MWI Animal Health.

⁽³⁾ Assumes that the acquisition of Animal Medic by ANIMART LLC (which closed during the third quarter of 2016) had occurred as of the beginning of the periods being reported.

*Amount is less than 10%.

We believe that supplies and raw materials for the production of our products are available from more than one vendor or farm. Our policy is to maintain more than one source of supply for the components used in our products. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies.

(j) Interest Rate Swap Agreements

All derivatives are recognized on the balance sheet at their fair value. We entered into interest rate swap agreements in 2010 and 2015. On the dates the agreements were entered into, we designated the derivatives as hedges of the variability of cash flows to be paid related to our long-term debt. The agreements have been determined to be highly effective in hedging the variability of identified cash flows, so changes in the fair market value of the interest rate swap agreements are recorded as comprehensive income (loss), until earnings are affected by the variability of cash flows (e.g. when periodic settlements on a variable-rate asset or liability are recorded in earnings). We formally documented the relationship between the interest rate swap agreements and the related hedged items. We also

formally assess, both at the interest rate swap agreements' inception and on an ongoing basis, whether the agreements are highly effective in offsetting changes in cash flow of hedged items. See Note 11.

(k) Revenue Recognition

We sell products that provide immediate immunity to newborn dairy and beef cattle. We recognize revenue in accordance with Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition". SAB No. 104 requires that four criteria are met before revenue is recognized. These include i) persuasive evidence that an arrangement exists, ii) delivery has occurred or services have been rendered, iii) the seller's price is fixed and determinable and iv) collectability is reasonably assured. We recognize revenue at the time of shipment (including to distributors) for substantially all products, as title and risk of loss pass to the customer on delivery to the common carrier after concluding that collectability is reasonably assured. We offer a 50% credit on **First Defense**® product that is returned to us past its expiration date, which is generally two years past its date of manufacture. We generally experience a minimal amount of product returns.

(l) Expense Recognition

Advertising costs are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to \$50,079 and \$27,545 during the three-month periods ended September 30, 2016 and 2015 and \$88,017 and \$72,539 during the nine-month periods ended September 30, 2016 and 2015, respectively. All product development expenses are expensed as incurred, as are all related patent costs. We capitalize costs to produce inventory during the production cycle, and these costs are charged to costs of goods sold when the inventory is sold to a customer.

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Notes to Unaudited Condensed Financial Statements (continued)

(m) Income Taxes

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. We believe it is more likely than not that the deferred tax assets will be realized through future taxable income and 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. Codification Topic 740-10 clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position must meet before being recognized in the financial statements. In the ordinary course of business, there are transactions and calculations where the ultimate tax outcome is uncertain. In addition, we are subject to periodic audits and examinations by the Internal Revenue Service and other taxing authorities. Our tax returns for the years 2013 through 2015 are subject to audit. We have evaluated the positions taken on our filed tax returns. We have concluded that no uncertain tax positions exist as of September 30, 2016. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 14.

(n) Stock-Based Compensation

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model. Accordingly, we recorded compensation expense pertaining to stock-based compensation of \$21,360 and \$6,342 during the three-month periods ended September 30, 2016 and 2015 and \$50,312 and \$17,825 during the nine-month periods ended September 30, 2016 and 2015, respectively, which resulted in a decrease to income before income taxes of less than \$0.01 per share during each of the periods reported.

(o) Net Income Per Common Share

Net income per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*. The basic net income per share has been computed by dividing net income by the weighted average number of common shares outstanding during this period. The diluted net income per share has been computed by dividing net income by the weighted average number of shares outstanding during the period plus all outstanding stock options with an exercise price that is less than the average market price of the common stock during the period less the number of shares that could have been repurchased at this average market price with the proceeds from the hypothetical stock option exercises. The weighted average and diluted number of shares outstanding consisted of the

following:

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2016	2015	2016	2015
Weighted average number of shares outstanding	4,182,529	3,052,175	4,065,243	3,038,111
Effect of dilutive stock options	119,751	136,174	113,938	124,509
Diluted number of shares outstanding	4,302,280	3,188,349	4,179,181	3,162,620
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	20,000	0	22,000	3,000

(p) Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Although we regularly assess these estimates, actual amounts could differ from those estimates. Changes in estimates are recorded during the period in which they become known. Significant estimates include our inventory, goodwill, accrued expenses and costs of goods sold accounts as well as amortization of our intangible assets.

(q) New Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. ASU 2014-09 was initially to become effective for the Company on January 1, 2017. Early application was not permitted. In July 2015, the FASB approved a one-year deferral in the effective date to January 1, 2018, with the option of applying the standard on the original effective date. ASU 2014-09 permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect that ASU 2014-09 would have on our financial statements and related disclosures.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

In April 2015, the FASB issued ASU No. 2015-03, *Interest-Imputation of Interest*, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This update is effective for the annual reporting periods beginning after December 15, 2015. During the first quarter of 2016, we adopted ASU 2015-03 and reclassified \$40,792 of debt issuance costs (net) from other assets to a reduction in our bank debt liability as of December 31, 2015. In August 2015, the FASB confirmed that ASU No. 2015-03 did not address the presentation or subsequent measurement of debt issuance costs related to line-of-credit arrangements. For line-of-credit arrangements, borrowers have the option of presenting debt issuance costs as an asset which is subsequently amortized ratably over the term of the line-of-credit arrangement, regardless of whether there are any related outstanding borrowings. ASU No. 2015-03 did not have a material impact on our financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory*, which simplifies the existing guidance which requires entities to subsequently measure inventory at the lower of cost or market value. Under ASU No. 2015-11, an entity should measure inventory valued using a first-in, first-out or average cost method at the lower of cost or net realizable value, which is defined as the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This update is effective for public business entities during fiscal years beginning after December 15, 2016. We adopted ASU 2015-11 during the third quarter of 2016, and it did not have a material impact on our financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes*, which simplifies the existing guidance which requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. Under ASU No. 2015-17, an entity should classify all deferred tax liabilities and assets as one noncurrent deferred tax liability or asset (net) within the statement of financial position. The amendments apply to all entities that present a classified statement of financial position and are effective for the public business entities for annual periods beginning after December 15, 2016, including interim periods therein. Earlier application is permitted. During the first quarter of 2016, we adopted ASU No. 2015-17 early and reclassified \$19,588 of current deferred tax liabilities to long-term, which amount was netted against our long-term deferred tax asset, as of December 31, 2015. ASU No. 2015-17 did not have a material impact on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which requires lessees to put most leases on their balance sheet but recognize expenses on their income statements in a manner similar to today's accounting. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods therein. Early adoption is permitted. We are not subject to material lease obligations, and we do not expect ASU 2016-02 to have a material impact on our financial statements.

3. CASH, CASH EQUIVALENTS, SHORT-TERM INVESTMENTS AND LONG-TERM INVESTMENTS

Cash, cash equivalents, short-term investments and long-term investments (at cost) consisted of the following:

	As of	As of	Increase
	September 30,	December 31,	(Decrease)
	2016	2015	
Cash and cash equivalents	\$ 4,408,415	\$ 1,573,328	\$2,835,087
Short-term investments ⁽¹⁾	5,199,000	4,464,000	735,000
Subtotal	9,607,415	6,037,328	3,570,087
Long-term investments ⁽¹⁾	0	487,000	(487,000)
Total	\$ 9,607,415	\$ 6,524,328	\$3,083,087

⁽¹⁾ We accrued \$20,065 and \$9,221 in interest income on these investments as of September 30, 2016 and December 31, 2015, respectively, which was recorded in other receivables.

ImmuCell Corporation**Notes to Unaudited Condensed Financial Statements (continued)**

Held to maturity securities are carried at amortized cost. The cost of securities sold is determined based on the specific identification method. Realized gains and losses, and declines in value judged to be other than temporary, are included in investment income. As of September 30, 2016, held to maturity securities consisted of the following:

		Gross Unrealized		Estimated
	Cost	Gains	Losses	Fair Value
Certificates of deposit	\$5,199,000	\$5,642	\$ 0	\$5,204,642

4. INVENTORY

Inventory consisted of the following:

	As of September 30, 2016	As of December 31, 2015	Increase
Raw materials	\$ 422,271	\$ 284,331	\$ 137,940
Work-in-process	749,033	452,024	297,009
Finished goods	595,092	133,852	461,240
Total	\$ 1,766,396	\$ 870,207	\$ 896,189

5. ACCOUNTS RECEIVABLE

Accounts receivable consisted of the following:

	As of September 30, 2016	As of December 31, 2015	(Decrease)
Trade accounts receivable, gross	\$ 697,472	\$ 736,195	\$ (38,723)

Accumulated allowance for bad debt	(20,317)	(18,092)	(2,225)
Trade accounts receivable, net	\$ 677,155	\$ 718,103	\$ (40,948)

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of September 30, 2016	As of December 31, 2015	Increase
Prepaid expenses and other current assets ⁽¹⁾	\$ 197,259	\$ 183,396	\$ 13,863
Other receivables	164,411	36,001	128,410
Security deposits	331,791	37,301	294,490
Total	\$ 693,461	\$ 256,698	\$ 436,763

⁽¹⁾ During the first quarter of 2016, we paid \$20,500 for an option to purchase additional land nearby to our Portland facility that could be used to construct an additional facility should we decide to exercise the option before the end of 2016 for an additional \$184,500.

ImmuCell Corporation**Notes to Unaudited Condensed Financial Statements (continued)****7.PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consisted of the following, at cost:

	Estimated Useful Lives	As of September 30, 2016	As of December 31, 2015	Increase (Decrease)
Laboratory and manufacturing equipment	5-10	\$ 5,435,652	\$ 3,766,556	\$ 1,669,096
Building and improvements	10-25	5,027,812	4,716,204	311,608
Office furniture and equipment	5-10	652,100	568,188	83,912
Construction in progress ⁽¹⁾		1,038,731	1,084,924	(46,193)
Land		347,115	333,486	13,629
Property, plant and equipment, gross		12,501,410	10,469,358	2,032,052
Accumulated depreciation		(5,263,019)	(4,750,544)	(512,475)
Property, plant and equipment, net		\$ 7,238,391	\$ 5,718,814	\$ 1,519,577

⁽¹⁾ As of September 30, 2016, construction in progress included \$650,733 in payments related to the construction of our commercial-scale Nisin plant. As of December 31, 2015, construction in progress consisted principally of partial payments towards new manufacturing equipment related to expanding our production capacity for **First Defense**®.

8.BUSINESS ACQUISITION

On January 4, 2016, we acquired certain business assets from DAY 1™ Technology, LLC of Minnesota. The acquired rights and know-how are primarily related to formulating our bovine antibodies into a gel solution for an oral delivery option to newborn calves via a syringe (or tube). This product format offers customers an alternative delivery option to the bolus (the standard delivery format of the bivalent **First Defense**® product since first approval by the U.S. Department of Agriculture (USDA) and product launch in 1991) and could allow more market penetration. The formulation was developed for us and has been sold as a feed product without disease claims since 2012. This purchase also includes certain other related private-label products. The total purchase price was approximately \$532,000. Approximately \$368,000 of this amount was paid as of the closing date. A technology transfer payment of \$97,000 was made during the third quarter of 2016, and the remaining estimated balance of approximately \$67,000 will be paid as a royalty on related product sales through December 31, 2018. There is no limit on the amount of the royalty, but it is proportional to sales of related product. That amount is reported in accounts payable and accrued

expenses on the accompanying balance sheet. The estimated fair values of the assets purchased in this transaction included inventory of \$113,000, machinery and equipment of \$132,000, a developed technology intangible of \$191,000 (which includes an immaterial amount of value associated with customer relationships and a non-compete agreement, and was valued using the relief from royalty method) and goodwill of \$96,000. The intangible assets and goodwill are deductible for tax return purposes. The goodwill arising from the acquisition consists largely of the estimated value of anticipated growth opportunities arising from synergies and efficiencies. The measurement period for the transaction was closed as of June 30, 2016, and we continue to assess any impairment of these acquired assets quarterly. The impact of the acquisition on our proforma prior year operations is not significant.

ImmuCell Corporation**Notes to Unaudited Condensed Financial Statements (continued)****9. INTANGIBLE ASSETS**

The intangible assets described in Note 8 are being amortized over their useful lives, which are estimated to be 10 years. Intangible amortization expense was (\$133) and \$15,309 during the three-month and nine-month periods ended September 30, 2016, respectively. The immaterial credit to amortization expense during the three-month period ended September 30, 2016 resulted from an adjustment to correct an immaterial over-recognition of this expense during the six-month period ended June 30, 2016. The net value of these intangibles was \$175,731 as of September 30, 2016. A summary of intangible amortization expense estimated for the five years beginning January 1, 2016 and thereafter is as follows:

Period	Amount
Three months ending December 31, 2016	\$9,847
Year ending December 31, 2017	39,387
Year ending December 31, 2018	39,387
Year ending December 31, 2019	12,444
Year ending December 31, 2020	12,444
After December 31, 2020	62,222
Total	\$175,731

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of	As of	Increase
	September 30,	December 31,	(Decrease)
	2016	2015	
Accounts payable – capital	\$ 165,145	\$ 1,510	\$ 163,635
Accounts payable – trade	412,376	199,105	213,271
Accrued payroll	188,112	242,690	(54,578)
Accrued clinical studies	0	68,428	(68,428)
Accrued professional fees	94,250	56,450	37,800
Accrued other	28,974	93,982	(65,008)
Total	\$ 888,857	\$ 662,165	\$ 226,692

11.BANK DEBT

During the first quarter of 2016, we entered into a bank debt agreement covering certain additional credit facilities with TD Bank N.A. aggregating approximately \$4.5 million comprised of: (a) a \$2.5 million construction loan, drawable over an 18-month period at up to 80% of the cost of equipment installed in the to be constructed commercial-scale production facility for **Mast Out**[®], during which interest only will be payable at a variable rate equal to the 30-day LIBOR plus 2.25%, which converts to a seven-year term loan facility at the end of construction at the same interest rate with monthly principal and interest payments based on a seven-year amortization schedule and (b) a \$2.0 million construction loan, drawable over a 12-month period at up to 75% of the appraised value of the to be constructed commercial-scale production facility for **Mast Out**[®], during which interest only will be payable at a variable rate equal to the 30-day LIBOR plus 2.25%, which converts to a nine-year term loan facility at the end of construction at the same interest rate with monthly principal and interest payments based on a twenty-year amortization schedule. There were no amounts outstanding under these facilities as of September 30, 2016. These credit facilities are to be secured by substantially all of our assets and are subject to certain financial covenants.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

Additionally, we have in place certain credit facilities with TD Bank N.A., which are secured by substantially all of our assets and are subject to certain financial covenants. Proceeds from the \$1,000,000 mortgage note were received during the third quarter of 2010. Based on a 15-year amortization schedule, a balloon principal payment of approximately \$451,885 will be due during the third quarter of 2020. Proceeds from the \$2,500,000 mortgage note were received during the third quarter of 2015. Based on a 20-year amortization schedule, a balloon principal payment of approximately \$1,550,007 will be due during the third quarter of 2025. Principal payments due under debt outstanding as of September 30, 2016 (excluding any debt proceeds to be drawn under the credit facilities entered into during the first quarter of 2016) are reflected in the following table by the year that payments are due:

Period	\$1,000,000 Mortgage Note	\$2,500,000 Mortgage Note	Debt Issuance Costs	Total
Three months ending December 31, 2016	\$ 14,952	\$ 20,343	(\$2,525)	\$ 32,770
Year ending December 31, 2017	61,056	82,308	(10,095)	133,269
Year ending December 31, 2018	64,876	86,097	(10,095)	140,878
Year ending December 31, 2019	68,908	89,997	(10,095)	148,810
Year ending December 31, 2020	493,696	94,005	(9,462)	578,239
After December 31, 2020	0	2,049,766	(38,887)	2,010,879
Total	\$ 703,488	\$ 2,422,516	(\$81,159)	\$ 3,044,845

We hedged our interest rate exposure on these mortgage notes with interest rate swap agreements that effectively converted floating interest rates based on the one-month LIBOR plus a bank profit margin of 3.25% and 2.25% to the fixed rates of 6.04% and 4.38%, respectively. As of September 30, 2016, the variable rates on these two mortgage notes were 3.78% and 2.79%, respectively. All derivatives are recognized on the balance sheet at their fair value. At the time of the closings and thereafter, the agreements were determined to be highly effective in hedging the variability of the identified cash flows and have been designated as cash flow hedges of the variability in the hedged interest payments. Changes in the fair value of the interest rate swap agreements are recorded in other comprehensive income (loss), net of taxes. The original notional amounts of the interest rate swap agreements of \$1,000,000 and \$2,500,000 amortize in accordance with the amortization of the mortgage notes. The notional amount of the interest rate swaps was \$3,126,004 as of September 30, 2016. Payments required by the interest rate swaps totaled \$14,470 and \$5,112 during the three-month periods ended September 30, 2016 and 2015, and \$44,653 and \$15,549 during the nine-month periods ended September 30, 2016 and 2015, respectively. As the result of our decision to hedge this interest rate risk, we recorded other comprehensive income (loss), net of taxes, in the amount of \$15,523 and (\$49,147) during the three-month periods ended September 30, 2016 and 2015, and (\$79,767) and (\$48,059) during the nine-month periods ended September 30, 2016 and 2015, respectively, which reflects the change in the fair value of the interest rate swap (liabilities), net of taxes. The fair values of the interest rate swaps have been determined using observable market-based inputs or unobservable inputs that are corroborated by market data. Accordingly, the interest rate swaps are classified as level 2 within the fair value hierarchy provided in Codification Topic 820, *Fair Value Measurements and Disclosures*.

In connection with the credit facilities entered into during the third quarters of 2010 and 2015 and the first quarter of 2016, we incurred debt issue costs of \$26,489, \$34,125 and \$46,734, respectively, which costs are being recorded as a component of other expenses over the terms of the credit facilities.

Proceeds from a \$600,000 note bearing interest at 4.25% were received during the first quarter of 2011. This note was repaid during the third quarter of 2015.

The \$500,000 line of credit with TD Bank N.A. was first entered into during the third quarter of 2010 and has been renewed approximately annually since then and is available as needed and has been extended through May 31, 2017 and is renewable annually thereafter. The line of credit was unused as of September 30, 2016 and December 31, 2015. Interest on any borrowings against the line of credit would be variable at the higher of 4.25% per annum or the one-month LIBOR plus 3.5% per annum.

12.STOCKHOLDERS' EQUITY

On October 28, 2015, we filed a registration statement on Form S-3 with the SEC for the potential issuance of up to \$10,000,000 in equity (subject to certain limitations). This registration statement became effective on November 10, 2015. Under this form of registration statement, we were limited to raising gross proceeds of no more than one-third of the market capitalization of our common stock (as determined by the high price within the preceding 60 days leading up to a sale of securities) held by non-affiliates (non-insiders) of the Company within a twelve-month period. This limit was approximately \$5,958,000, based on the closing price of \$8.08 per share as of January 6, 2016. On February 3, 2016, we sold 1,123,810 shares of common stock at a price to the public of \$5.25 per share in an underwritten public offering, raising gross proceeds of approximately \$5,900,000, resulting in net proceeds of approximately \$5,313,000 (after deducting underwriting discounts and offering expenses) to the Company.

ImmuCell Corporation**Notes to Unaudited Condensed Financial Statements (continued)**

At the June 15, 2016 Annual Meeting of Stockholders, our stockholders voted to approve an amendment to the Company's Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 8,000,000 to 10,000,000.

In June 2000, our stockholders approved the 2000 Stock Option and Incentive Plan (the "2000 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at i) no less than fair market value on the date of grant in the case of incentive stock options and ii) no less than 85% of fair market value on the date of grant in the case of non-qualified stock options. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. Originally, 250,000 shares of common stock were reserved for issuance under the 2000 Plan. The stockholders of the Company approved an increase in this number to 500,000 shares in June 2001. All options granted under the 2000 Plan expire no later than ten years from the date of grant. The 2000 Plan expired in February 2010, after which date no further options could be granted under the 2000 Plan. However, outstanding options under the 2000 Plan may be exercised in accordance with their terms.

In June 2010, our stockholders approved the 2010 Stock Option and Incentive Plan (the "2010 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at i) no less than fair market value on the date of grant in the case of incentive stock options and ii) no less than 85% of fair market value on the date of grant in the case of non-qualified stock options. At that time, 300,000 shares of common stock were reserved for issuance under the 2010 Plan and subsequently no additional shares have been reserved for the 2010 Plan. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. All options granted under the 2010 Plan expire no later than ten years from the date of grant.

Activity under the stock option plans described above was as follows:

	2000 Plan	2010 Plan	Weighted Average Exercise	Aggregate Intrinsic Value
Outstanding at December 31, 2014	157,500	95,500	\$ 3.42	\$ 364,000
Grants	0	16,000	\$ 7.40	
Terminations	0	(3,000)	\$ 4.95	
Exercises	(26,000)	(2,000)	\$ 4.29	
Outstanding at December 31, 2015	131,500	106,500	\$ 3.57	\$ 945,000

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Grants	0	44,000	\$ 6.98	
Terminations	0	(5,000)	\$ 6.19	
Exercises	0	(16,000)	\$ 5.59	
Outstanding at September 30, 2016	131,500	129,500	\$ 3.97	\$ 981,000
Exercisable at September 30, 2016	131,500	25,500	\$ 2.62	\$ 802,000
Reserved for future grants	0	150,500		

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ImmuCell Corporation**Notes to Unaudited Condensed Financial Statements (continued)**

During the nine-month period ended September 30, 2016, one employee and one director exercised stock options covering the aggregate of 16,000 shares, of which 15,000 were exercised during the three-month period ended September 30, 2016. Six thousand of these options were exercised for cash, resulting in total proceeds of \$31,900, and 10,000 of these options were exercised by the surrender of 7,334 shares of common stock with a fair market value of \$57,425 at the time of exercise and \$75 in cash. During the year ended December 31, 2015, eleven employees exercised stock options covering the aggregate of 28,000 shares, of which 14,000 were exercised during the three-month period ended September 30, 2015. These options were exercised for cash, resulting in total proceeds of \$120,210. At September 30, 2016, 261,000 shares of common stock were reserved for future issuance under all outstanding stock options described above, and an additional 150,500 shares of common stock were reserved for the potential issuance of stock option grants in the future under the 2010 Plan. The weighted average remaining life of the options outstanding under the 2000 Plan and the 2010 Plan as of September 30, 2016 was approximately four years and seven months. The weighted average remaining life of the options exercisable under these plans as of September 30, 2016 was approximately two years and six months. The exercise prices of the options outstanding as of September 30, 2016 ranged from \$1.70 to \$8.21 per share. The 44,000 stock options granted during the first nine months of 2016 had exercise prices between \$6.70 and \$8.21 per share. The 16,000 stock options granted during 2015 had exercise prices between \$6.05 and \$7.54 per share. The aggregate intrinsic value of options exercised during 2016 and 2015 approximated \$32,000 and \$110,000, respectively. The weighted-average grant date fair values of options granted during 2016 and 2015 were \$4.16 and \$3.46 per share, respectively. As of September 30, 2016, total unrecognized stock-based compensation related to non-vested stock options aggregated \$238,047. That cost is expected to be recognized at a declining rate through the second quarter of 2023 (the remaining vesting period of the outstanding non-vested stock options), including \$25,270 during remainder of 2016. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, for the purpose discussed in Note 2(n), with the following weighted-average assumptions for the three-month and nine-month periods ended September 30, 2016 and for the year ended December 31, 2015:

	2016		2015	
Risk-free interest rate	1.2	%	2.0	%
Dividend yield	0	%	0	%
Expected volatility	63	%	47	%
Expected life	6.5 years		6 years	

The risk-free interest rate is based on U.S. Treasury yields for a maturity approximating the expected option term, while the other assumptions are derived from averages of our historical data.

13. OTHER EXPENSES, NET

Other expenses, net, consisted of the following:

	Three-Month Periods		Nine-Month Periods	
	Ended September 30,		Ended September 30,	
	2016	2015	2016	2015
Interest expense	\$38,928	\$15,084	\$116,925	\$41,039
Interest income	(16,980)	(4,461)	(43,725)	(10,634)
Debt issuance amortization	2,524	636	6,367	2,074
Other gains	2,038	3,852	1,628	(5,420)
Other expenses, net	\$26,510	\$15,111	\$81,195	\$27,059

14.INCOME TAXES

Our income tax (benefit) expense aggregated (\$10,913) and \$260,447 for the three-month periods ended September 30, 2016 and 2015, respectively. Our income tax expense aggregated \$211,537 and \$709,394 for the nine-month periods ended September 30, 2016 and 2015, respectively. In 2015, we utilized approximately \$1,700,000 of net operating loss carryforwards to offset otherwise taxable income. As of December 31, 2015, we had federal net operating loss carryforwards of approximately \$115,000 that we expect to utilize against taxable income in 2016. Additionally, we have federal general business tax credit carryforwards of approximately \$262,000 that expire in 2027 through 2034, if not utilized before then, as well as approximately \$78,000 of state tax credits.

Deferred tax assets are recognized only when it is probable that sufficient taxable income will be available in future periods against which deductible temporary differences and credits may be utilized. However, the amount of the deferred tax asset could be reduced if projected income is not achieved due to various factors, such as unfavorable business conditions. If projected income is not expected to be achieved, we would decrease the deferred tax asset to the amount that we believe can be realized.

Net operating loss carryforwards, credits, and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service. Section 382 of the Internal Revenue Code contains provisions that could place annual limitations on the future utilization of net operating loss carryforwards and credits in the event of a change in ownership of the Company, as defined.

The Company files income tax returns in the U.S. federal jurisdiction and several state jurisdictions. With few exceptions, the Company is no longer subject to income tax examinations by tax authorities for years before 2012. We currently have no tax examinations in progress. We also have not paid additional taxes, interest or penalties as a result of tax examinations nor do we have any unrecognized tax benefits for any of the periods in the accompanying financial statements.

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ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

15. CONTINGENT LIABILITIES AND COMMITMENTS

Our bylaws, as amended, in effect provide that the Company will indemnify its officers and directors to the maximum extent permitted by Delaware law. In addition, we make similar indemnity undertakings to each director through a separate indemnification agreement with that director. The maximum payment that we may be required to make under such provisions is theoretically unlimited and is impossible to determine. We maintain directors' and officers' liability insurance, which may provide reimbursement to the Company for payments made to, or on behalf of, officers and directors pursuant to the indemnification provisions. Our indemnification obligations were grandfathered under the provisions of Codification Topic 460, *Guarantees*. Accordingly, we have recorded no liability for such obligations as of September 30, 2016. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

The development, manufacturing and marketing of animal health care products entails an inherent risk that liability claims will be asserted against us during the normal course of business. We feel that we have reasonable levels of liability insurance to support our operations. We are aware of no such claims against us as of the date of this filing.

We enter into agreements with third parties in the ordinary course of business under which we are obligated to indemnify such third parties from and against various risks and losses. The precise terms of such indemnities vary with the nature of the agreement. In many cases, we limit the maximum amount of our indemnification obligations, but in some cases those obligations may be theoretically unlimited. We have not incurred material expenses in discharging any of these indemnification obligations, and based on our analysis of the nature of the risks involved, we believe that the fair value of the liabilities potentially arising under these agreements is minimal. Accordingly, we have recorded no liabilities for such obligations as of September 30, 2016.

We are committed to purchasing certain key parts (syringes) and services (formulation, filling and packaging of Drug Product) pertaining to **Mast Out**[®] exclusively from two contractors. If we do not commercialize the product by the end of 2019, we would be liable for a \$100,000 termination fee.

During the second quarter of 2009, we entered into an exclusive license with the Baylor College of Medicine covering the underlying rotavirus vaccine technology used to generate the specific antibodies for our product line extension that is under development. This perpetual license (if not terminated for cause) is subject to a milestone payment of \$150,000 upon regulatory approval and a royalty based on sales related to this technology.

As of September 30, 2016, we had committed approximately \$417,000 to capital expenditures, \$541,000 to the production of inventory and an additional \$159,000 to other obligations. Additionally, during the third quarter of 2016, we entered into a guaranteed maximum price contract with our construction management firm in the amount of approximately \$5,000,000 covering construction costs for the new production facility for **Mast Out**®. This contract includes provisions that could reduce the amount of the commitment generally by the amount not expended or committed by the construction manager at the time of an unexpected and unlikely early termination.

16.SEGMENT INFORMATION

We principally operate in the business segment described in Note 1. Pursuant to Codification Topic 280, *Segment Reporting*, we operate in one reportable business segment, that being the development, acquisition, manufacture and sale of products that improve the health and productivity of cows for the dairy and beef industries. Almost all of our internally funded product development expenses are in support of such products. The significant accounting policies of this segment are described in Note 2. Sales of the **First Defense**® product line aggregated 93% and 88% of our total product sales during the three-month periods ended September 30, 2016 and 2015 and 93% and 92% of our total product sales during the nine-month periods ended September 30, 2016 and 2015, respectively.

Our primary customers for the majority of our product sales (83% and 85% for the three-month periods ended September 30, 2016 and 2015 and 85% and 83% for the nine-month periods ended September 30, 2016 and 2015, respectively) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 17% and 6% of our total product sales for the three-month periods ended September 30, 2016 and 2015 and 14% and 13% of our total product sales for the nine-month periods ended September 30, 2016 and 2015, respectively.

17.RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone Inc. (formerly Stearns Veterinary Outlet, Inc.), a domestic distributor of ImmuCell products (**First Defense**®, **Wipe Out**® **Dairy Wipes**, and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased \$144,365 and \$157,350 of products from ImmuCell during the three-month periods ended September 30, 2016 and 2015 and \$476,311 and \$452,207 of products from ImmuCell during the nine-month periods ended September 30, 2016 and 2015, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of \$2,925 and \$3,222 to these affiliated companies during the nine-month periods ended September 30, 2016 and 2015, respectively. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated \$65,484 and \$36,528 as of September 30, 2016 and December 31, 2015, respectively.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

18.EMPLOYEE BENEFITS

We have a 401(k) savings plan (the Plan) in which all employees completing one month of service with the Company are eligible to participate. Participants may contribute up to the maximum amount allowed by the Internal Revenue Service. Since August 2012, we have matched 100% of the first 3% of each employee's salary that is contributed to the Plan and 50% of the next 2% of each employee's salary that is contributed to the Plan. Under this matching plan, we paid \$17,642 and \$17,102 into the Plan during the three-month periods ended September 30, 2016 and 2015, and \$55,209 and \$54,157 during the nine-month periods ended September 30, 2016 and 2015, respectively.

19.SUBSEQUENT EVENTS

We have adopted the disclosure provisions of Codification Topic 855-10-50-1, *Subsequent Events*, which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued. Entities are required to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. Codification Topic 855-10-50-1 requires additional disclosures only, and therefore did not have an impact on our financial condition, results of operations, earnings per share or cash flows. Public entities must evaluate subsequent events through the date that financial statements are issued. Accordingly, we have evaluated subsequent events through the time of filing on November 10, 2016, the date we have issued this Quarterly Report on Form 10-Q. As of such date, except as described below, there were no material, reportable subsequent events.

On October 21, 2016, we closed on a private placement of 659,880 shares of common stock to nineteen institutional and accredited investors at \$5.25 per share, raising gross proceeds of \$3,464,000. The net proceeds were approximately \$3,164,000 after deducting placement agent fees and other estimated expenses incurred in connection with the equity financing.

We expect to close down the rented facility in Minnesota that has been used to produce the gel solution format of our product and the certain other related private-label products by year end. This will result in the termination of employment of four employees for us, as these production functions are consolidated into our Portland facility. Consolidation of this product line in Portland enables us to leverage existing infrastructure and larger scale equipment to improve operating efficiencies.

ImmuCell Corporation

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

Financial Condition

Our strategy is focused on developing and selling products that improve animal health and productivity in the dairy and beef industries. We aim to capitalize on the significant growth in sales of **First Defense**® and to revolutionize the mastitis treatment paradigm. We have funded most of our product development expenses principally from our gross margin on product sales. As anticipated, we incurred a net loss during the year ended December 31, 2014 due to an unusually large investment in a pilot plant for **Mast Out**®. After completing this investment, we did return to profitability, as planned, during the six-month period ended December 31, 2014 and continued this profitability throughout 2015 and for the nine-month period ended September 30, 2016. The table below summarizes the changes in selected, key accounts (in thousands, except for percentages):

	As of September 30, 2016	As of December 31, 2015	Increase	
			Amount	%
Cash, cash equivalents, short-term investments and long-term investments	\$ 9,607	(1) \$ 6,524	\$3,083	47 %
Net working capital	\$ 11,690	\$ 7,089	\$4,601	65 %
Total assets	\$ 20,578	\$ 14,540	\$6,038	42 %
Stockholders' equity	\$ 16,408	\$ 10,614	\$5,794	55 %
Common shares outstanding	4,188	3,055	1,132	37 %

(1) This balance does not include approximately \$343,000 being held temporarily in escrow against certain construction performance requirements related to our production facility for **Mast Out**®.

Net cash provided by operating activities amounted to \$48,000 during the nine-month period ended September 30, 2016 in comparison to net cash provided by operating activities of \$2,070,000 during the nine-month period ended September 30, 2015. Capital investments totaled \$1,795,000 during the nine-month period ended September 30, 2016 compared to capital investments of \$1,772,000 during the nine-month period ended September 30, 2015. As we progress our investment in the production facility for **Mast Out**® described below, we expect these investments of cash to increase. Together with gross margin earned from ongoing product sales, 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.

During the third quarters of 2010 and 2015, we agreed to terms of certain credit facilities with TD Bank, N.A., which are secured by substantially all of our assets including our building, which was independently appraised at \$4,180,000 in connection with the 2015 financing. As of September 30, 2016, our outstanding bank debt balance was approximately \$3,126,000. We have a \$500,000 line of credit that is available as needed. These credit facilities are subject to certain financial covenants and are secured by substantially all of our assets. Based on our unaudited results, we are in compliance with all applicable covenants as of September 30, 2016.

During the first quarter of 2016, we entered into a bank debt agreement covering certain additional credit facilities with TD Bank N.A. aggregating approximately \$4.5 million comprised of: (a) a \$2.5 million construction loan, drawable over an 18-month period at up to 80% of the cost of equipment installed in the to be constructed commercial-scale production facility for **Mast Out**[®], which converts to a seven-year term loan facility at the end of construction with monthly principal and interest payments based on a seven-year amortization schedule and (b) a \$2.0 million construction loan, drawable over a 12-month period at up to 75% of the appraised value of the to be constructed commercial-scale production facility for **Mast Out**[®], which converts to a nine-year term loan facility at the end of construction with monthly principal and interest payments based on a twenty-year amortization schedule. As of September 30, 2016, we had not drawn proceeds under either of these credit facilities. These credit facilities are subject to certain financial covenants and are secured by substantially all of our assets. We are in compliance with all applicable covenants as of September 30, 2016. At this point, we anticipate drawing funds under the \$2.5 million construction loan during the second quarter of 2017 and drawing funds under the \$2.0 million construction loan during the first quarter of 2017. These credit facilities may be effectively converted to fixed rate loans when proceeds are drawn (at our option) by entering into interest rate swap agreements.

During 2016, we issued the aggregate of 1,783,690 shares of common stock raising net proceeds of approximately \$8,477,000 in two separate equity transactions. During the first quarter of 2016, we sold 1,123,810 shares of common stock at a price to the public of \$5.25 per share in an underwritten public offering, raising gross proceeds of approximately \$5,900,000. The net proceeds from this first equity financing were approximately \$5,313,000 after deducting underwriting discounts and offering expenses. During the fourth quarter of 2016, we sold 659,880 shares of common stock at \$5.25 per share in a private placement to nineteen institutional and accredited investors, raising gross proceeds of approximately \$3,464,000. The net proceeds from this second equity financing were approximately \$3,164,000 after deducting placement agent fees and other estimated expenses.

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During the third quarter of 2016, we initiated construction of our pharmaceutical facility to produce Nisin, the active ingredient in **Mast Out**®. The estimated total cost of the Nisin facility is approximately \$20,000,000. The spend on this project is heavily weighted to the nine-month period ending June 30, 2017. We expect to fund remaining costs in excess of our current cash and investments with cash to be generated from operations during 2016 to 2018, borrowings under the credit facilities described above and possibly some incremental bank debt (as to which we do not presently have binding lending commitments in place). These costs are being capitalized on our balance sheet as construction in progress. Depreciation of these costs is expected to begin when the facility is placed into service, which could be before FDA approval of the product is achieved. The following table details the amount and timing of the expected investment:

Period	Amount
Nine-month period ended September 30, 2016	\$651,000 ⁽¹⁾
Estimated investment required to complete	19,349,000 ⁽²⁾
Estimated total investment	\$20,000,000

⁽¹⁾ We expect most of this investment to be disbursed during the nine-month period ending June 30, 2017.

⁽²⁾ This budget estimate does not include approximately \$278,000 that was invested in land for the facility, which was acquired during the fourth quarter of 2015.

During the third quarter of 2016, the City of Portland approved a Tax Increment Financing (TIF) credit enhancement package that reduces our real estate taxes on the **Mast Out**® facility that we are constructing by 65% over the first eleven years and by 30% during the 12th year, after which time the rebate expires. The TIF is still subject to standard approvals by the State's Department of Economic and Community Development. The aggregate financial benefit was originally estimated to be approximately \$400,000 based on the then current \$3,000,000 building cost estimate calculated during 2015 before the detailed design work and construction bidding was complete. Significant process-directed requirements to the building have since increased the estimated construction costs to approximately \$11,000,000. We believe the cost per square foot as currently estimated for a facility of this purpose is competitive and that the increase is largely the result of the preliminary engineering estimate from 2015 for a building shell being for much less of a structure that would not have satisfied our regulatory and Nisin production capacity needs. The value of the tax savings would increase in proportion to the increase in the cost of the building as assessed for city real estate tax purposes. The actual savings will be based on the assessed value of the building after construction is complete, which is likely to be less than its cost of construction, but significantly more than \$3,000,000. For example, an assessed value of \$7,000,000 could generate a tax rebate of approximately \$1,200,000 over the life of the TIF.

During the 18-month period ended June 30, 2016, we invested approximately \$3,600,000 in capital expenditures including the completion of a 7,100 square foot facility addition (described below) and installation of a second freeze

dryer, among other investments. We completed the investment to increase our liquid processing capacity by 50% during the fourth quarter of 2015 and the investment to increase our freeze-drying capacity by 100% at the end of the first quarter of 2016. These investments were necessary to increase our manufacturing capacity to fill the backlog of **First Defense**® orders and to meet the increased sales demand that we are anticipating. These investments do not include cash budgeted for construction of the commercial-scale production facility for **Mast Out**® described above. As of October 1, 2016, we had additional authorization from our Board of Directors to spend up to approximately \$715,000 for new manufacturing equipment and other routine and necessary capital expenditures and to prepare for the launch of a trivalent product format of **First Defense**®.

During the third quarter of 2013, our Board of Directors approved the aggregate investment of approximately \$3,000,000 in two projects. The first investment involved acquiring processing equipment and modifying a portion of our facility to create a pilot production plant for the **Mast Out**® product development initiative. These expenses were not capitalized because this plant was not expected to support commercial sales. Construction of the facility addition was substantially completed during the third quarter of 2014. This specifically targeted increase in product development expenses resulted in a net loss during the first six months of 2014. The second investment involved acquiring manufacturing equipment and constructing a two-story addition to our facility, providing us with approximately 7,100 square feet of cold storage, production and warehouse space to increase our commercial production capacity for **First Defense**® and other products. Construction of the facility addition was initiated at the end of the third quarter of 2014 and was substantially completed during the first quarter of 2015. These expenses have been capitalized as they support the commercial sale of our existing products. The following table details the spending on these two projects, which were completed on budget:

Period	Expenses	Capital Expenditures	Total Expenses and Capital Expenditures
Three-month period ended December 31, 2013	\$ 110,000	\$ 21,000	\$ 131,000
Year ended December 31, 2014	973,000	1,492,000	2,465,000
Nine-month period ended September 30, 2015	9,000	414,000	423,000
Total investment	\$ 1,092,000	\$ 1,927,000	\$ 3,019,000

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Results of Operations

Product Sales

Product sales during the three-month period ended September 30, 2016 decreased by 20%, or \$504,000, to \$1,968,000 from \$2,472,000 during the three-month period ended September 30, 2015. Product sales during the nine-month period ended September 30, 2016 decreased by 3%, or \$204,000, to \$7,330,000 from \$7,534,000 during the nine-month period ended September 30, 2015. While sales decreased by \$504,000 and \$204,000 during the three-month and nine-month periods ended September 30, 2016, respectively, (in comparison to the same periods during the prior year), there are many other important factors that should be considered when assessing the long-term health of our business. Product sales during the twelve-month period ended September 30, 2016 increased by 3%, or \$285,000, to \$10,025,000 from \$9,740,000 during the twelve-month period ended September 30, 2015. During the nine-month period ended September 30, 2016, domestic product sales decreased by less than 1%, or \$46,000, and international sales decreased by 13%, or \$158,000, in comparison to the same period in 2015. The decrease in international sales was more a result of how we chose to allocate scarce product than a factor of reduced demand. After a prolonged period of order backlog, we had no backlog of orders as of September 30, 2016 in comparison to backlogs of the following:

As of	Backlog Amount
March 31, 2015	\$1,284,000
June 30, 2015	\$1,452,000
September 30, 2015	\$1,554,000
December 31, 2015	\$381,000
March 31, 2016	\$1,660,000
June 30, 2016	\$365,000

The prolonged period of order backlog (which began early in 2015 and extended through the middle of 2016) created a significant disruption in our sales shipment pattern. Sales for the year ended December 31, 2015 were up 35% in comparison to the year ended December 31, 2014. This strong growth trend has not continued into the second half of 2016, in comparison to the respective period during 2015, but sales for the nine-month period ended September 30, 2016 were 36% greater than sales during the nine-month period ended September 30, 2014 (skipping over the same period in 2015), demonstrating a positive longer-term sales trend. We believe the sales declines in the current periods are largely related to the short-term negative impact related to emerging from the backlog situation, and we remain optimistic about the long-term health of our business.

We continue to make significant progress on several product development objectives that may help us increase sales. We have obtained concurrence from the USDA that we have been granted disease claims against bovine rotavirus for our new product, which would be the first calf level product to offer this unique breadth of claims. We are now working to complete the other laboratory and manufacturing objectives required for product license approval, which we hope to earn in 2017. We are currently working to establish USDA claims for our gel tube formulation of **First Defense Technology™** and to add a *C. perfringens* claim to our product line. With our increased production capacity, we have begun to seek additional distributor partnerships to bring **First Defense®** into new international territories. These long-term growth plans could more than offset recent market dynamics that are significantly impacting our financial results during the second half of 2016, such as:

Customer order patterns were disrupted during the prolonged period of order backlog from first quarter of 2015 until the early part of the third quarter of 2016.

After completing a significant investment to double **First Defense®** production capacity during early 2016, the distribution chain was re-supplied with product largely during the second quarter of 2016.

When customers were unable to secure supply of **First Defense®**, some moved to other products (with and without claims), and some opted to use no scours preventative at all.

ImmuCell Corporation

A competitive product, that experienced interrupted supply to the market during late 2014 and through the first half of 2015, has returned to the market. Some customers have reverted back to using this product.

The Company's sales team needs to regain momentum lost when it was not able to focus on acquiring new customers during the period of scarce product supply.

Based on our informal survey of market sources, the value of a bull calf has dropped from approximately \$450 last year to about \$50 to \$200 presently.

The average Class III milk price has declined from \$15.80 per hundred pounds during 2015 (compared to \$22.34 for 2014) to \$14.38 during the first nine months of 2016. The average price of \$13.48 during the first six months of the year increased to \$16.18 during the third quarter of 2016.

During the first quarter of 2016, we completed an investment to double our production capacity of **First Defense**[®]. This doubling allowed us to fill a backlog of orders that had persisted since the first quarter of 2015. Having now re-set distributor inventory levels after a long period of order backlog and as we compare current results to a 2015 period during which a competitor was largely out of the market, we do not expect to experience sales growth during the fourth quarter of 2016. Our lead product, **First Defense**[®], continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent bovine enteritis (scours) in newborn calves. Now that we are building stocks of inventory held available for shipment, our increased investment in sales and marketing expenses will be valuable as we work to re-engage lost customers and introduce **First Defense**[®] to new customers. We are selling new product applications of **First Defense**[®] under the description **First Defense Technology**[™], which is a unique whey protein concentrate that is processed utilizing our proprietary milk protein purification methods, for the nutritional and feed supplement markets in different formats without the claims of our USDA-licensed product. During the first quarter of 2011, we initiated sales of **First Defense Technology**[™] in a bulk powder format (no capsule), which is delivered with a scoop and mixed with colostrum for feeding to calves. During the fourth quarter of 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start[®] 150 Plus and certain similar private label products, which are colostrum replacers with **First Defense Technology**[™] **Inside**. During the first quarter of 2012, we launched a tube delivery format of our **First Defense Technology**[™] in a gel solution. Sales of the **First Defense**[®] product line aggregated 93% and 88% of our total sales during the three-month periods ended September 30, 2016 and 2015 and 93% and 92% of our total sales during the nine-month periods ended September 30, 2016 and 2015, respectively. Sales of the **First Defense**[®] product line decreased by 16%, or \$339,000, during the three-month period ended September 30, 2016 in comparison to the same period in 2015. Despite a decline during the third quarter, sales of the **First Defense**[®] product line increased by 2% during the six-month period ended September 30, 2016 compared to the six-month period ended September 30, 2015. Sales of the **First Defense**[®] product line decreased by 2%, or \$143,000, during the nine-month period ended September 30, 2016 in comparison to the same period in 2015. Sales of the **First Defense**[®] product line increased by 4%, or \$317,000, during the twelve-month period ended September 30, 2016 in comparison to the same period ended September 30, 2015. Sales of the **First Defense**[®] product line increased by 36%, 27% and 14% during the years ended December 31, 2015, 2014 and 2013, respectively, in comparison to the prior years. We have realized positive sales growth of the **First Defense**[®] product line for twenty-one of the last twenty-four quarters, in comparison to the same quarters of the prior year. This new level of sales demand for **First Defense**[®] exceeded our production capacity and available inventory.

We believe that the long-term growth in sales of the **First Defense**[®] product line may reflect, at least in part, the success of our strategic decision initiated in 2010 to invest in additional sales and marketing efforts. Our sales and marketing team currently consists of a vice president, five regional managers and an inside sales and customer service representative. Our facility manager processes all shipments. We launched a new communications campaign at the end of 2010 that continues to emphasize how the unique ability of **First Defense**[®] to provide **Immediate Immunity**[™] generates a dependable return on investment for dairy and beef producers. Preventing newborn calves from becoming sick helps them to reach their genetic potential.

Competition for resources that dairy producers allocate to their calf enterprises has increased due to the many new products that have been introduced to the calf market. Our sales are normally seasonal, with higher sales expected during the first quarter and lower sales expected during the second and third quarters. Such seasonality is heavily influenced by the beef calving season. Warm and dry weather reduces the producer's perception of the need for a disease preventative product like **First Defense**[®], but heat stress on calves caused by extremely hot summer weather can increase the incidence of scours. Harsher winter weather benefits our sales. The animal health distribution segment has been aggressively consolidating over the last few years. Larger distributors have been acquiring smaller distributors. Beef herd numbers were reduced because of the 2012 drought conditions in many parts of North America. This resulted in an increase in the value of newborn calves, as producers re-build their herd levels. Such an upswing increased a producer's likelihood to invest in **First Defense**[®] for their calf crop.

During the first quarter of 2008, we implemented a modest increase to the selling price of **First Defense**[®]. We did not implement another price increase for **First Defense**[®] until the third quarter of 2014. During 2015, we implemented an increase to the selling price of **First Defense Technology**[™]. The selling price for **Wipe Out Dairy Wipes** was increased effective January 1, 2016. Effective for orders placed after April 1, 2016, we implemented a price increase of approximately 5% for **First Defense**[®].

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We sell topical wipes that are pre-moistened with a Nisin-based formulation (our second leading source of product sales) in two product formats. Since 1999, we have been selling **Wipe Out® Dairy Wipes** for use in preparing the teat area of a cow for milking. We are competing against less expensive products and alternative teat sanitizing methods. We believe that sales growth potential for **Wipe Out® Dairy Wipes** is limited because most of our sales of this product tend to be to smaller dairies that are under continued financial pressures, forcing many small dairy producers out of business. While our product is a high quality tool, there are less expensive ways to sanitize a cow's udder prior to milking, and many producers opt for a less expensive solution. During the first quarter of 2013, we initiated sales of Nisin-based wipes for pets in a 120-count canister (Preva™ wipes) to Bayer HealthCare Animal Health of St. Joseph, Missouri for commercial sales to pet owners. Sales of the topical wipes product line (both product formats) decreased by 49%, or \$54,000, during the three-month period ended September 30, 2016 in comparison to the same period in 2015. Sales of the topical wipes product line increased by 10%, or \$24,000, during the nine-month period ended September 30, 2016 in comparison to the same period in 2015. Sales of the topical wipes product line aggregated 3% and 4% of total sales during the three-month periods ended September 30, 2016 and 2015 and 4% and 3% of total product sales during the nine-month periods ended September 30, 2016 and 2015, respectively.

Sales of the new private label products (our third leading source of product sales during 2016) that we acquired in January 2016 aggregated 2% and 3% of our total sales during the three-month and nine-month periods ended September 30, 2016, respectively. These products generally are comprised of nutritional feed ingredients delivered via a tube or capsule.

Sales of our **California Mastitis Test (CMT)** aggregated approximately 2% and 1% of total sales during the three-month periods ended September 30, 2016 and 2015 and 1% and 2% of total sales during the nine-month periods ended September 30, 2016 and 2015, respectively.

We make and sell bulk reagents for Isolate™ (formerly known as Crypto-Scan®), which is a drinking water test that is sold by our distributor in Europe. No sales of Isolate™ were made during the first nine months of 2016. Sales of Isolate™ aggregated 7% and 3% of total sales during the three-month and nine-month periods ended September 30, 2015, respectively.

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		(Decrease)	
		September 30,			
		2016	2015	Amount	%
Gross margin		\$1,205	\$1,612	\$(407)	(25 %)
Percent of product sales		61 %	65 %	(4 %)	(6 %)

		Six-Month Periods Ended		(Decrease)	
		September 30,			
		2016	2015	Amount	%
Gross margin		\$2,444	\$2,742	\$(298)	(11 %)
Percent of product sales		56 %	62 %	(6 %)	(9 %)

		Nine-Month Periods Ended		(Decrease)	
		September 30,			
		2016	2015	Amount	%
Gross margin		\$4,202	\$4,593	\$(391)	(9 %)
Percent of product sales		57 %	61 %	(4 %)	(6 %)

		Twelve-Month Periods Ended		(Decrease)	
		September 30,			
		2016	2015	Amount	%
Gross margin		\$5,860	\$5,936	\$(77)	(1 %)
Percent of product sales		58 %	61 %	(2 %)	(4 %)

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The gross margin as a percentage of product sales decreased to 61% during the three-month period ended September 30, 2016 from 65% during the three-month period ended September 30, 2015. The gross margin increased to 61% during the three-month period ended September 30, 2016 from 52% during the three-month period ended June 30, 2016. The gross margin decreased to 56% during the six-month period ended September 30, 2016 from 62% during the six-month period ended September 30, 2015. The gross margin decreased to 57% during the nine-month period ended September 30, 2016 from 61% during the nine-month period ended September 30, 2015. The gross margin decreased to 58% during the twelve-month period ended September 30, 2016 from 61% during the twelve-month period ended September 30, 2015. The gross margin was 61% and 59% during the years ended December 31, 2015 and 2014, respectively. This compares to gross margin percentages of 51% and 57% during the years ended December 31, 2013 and 2012, respectively. Our objective has been to maintain the full-year gross margin percentage over 50%, and we have achieved this annual objective since 2009. Going forward, we may be able to increase this target to approximately 55%. A number of factors account for the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter. The gross margin on **First Defense**[®] is affected by biological yields from our raw material, which do vary over time. We have contracted with many new farms to buy more colostrum to increase our production output. Like most U.S. manufacturers, we have been experiencing increases in the cost of raw materials that we purchase. The costs for production of **First Defense**[®] and **Wipe Out**[®] **Dairy Wipes** have increased due to increased labor costs and other expenses associated with our efforts to sustain compliance with current Good Manufacturing Practices (cGMP) regulations in our production processes. We have been able to minimize the impact of these cost increases by implementing yield improvements. Product mix also affects gross margin in that we earn a higher gross margin on **First Defense**[®] and a much lower gross margin on **Wipe Out**[®] **Dairy Wipes**.

Sales and Marketing Expenses

Sales and marketing expenses increased by approximately 27%, or \$102,000, to \$484,000 during the three-month period ended September 30, 2016, in comparison to \$382,000 during the three-month period ended September 30, 2015, aggregating 25% and 15% of product sales, respectively. Sales and marketing expenses increased by approximately 26%, or \$278,000, to \$1,365,000 during the nine-month period ended September 30, 2016, in comparison to \$1,087,000 during the nine-month period ended September 30, 2015, aggregating 19% and 14% of product sales, respectively. We continue to leverage the efforts of our small sales force by using veterinary distributors. These expenses have increased due principally to a strategic decision to invest more to support **First Defense**[®] sales. This investment may have created, at least in part, our recent increase in product sales. Our current budgetary objective in 2016 is to invest 18% or less of product sales in sales and marketing expenses on an annual basis. We are currently running above that level as we hold our investment at the planned level, despite the drop in sales, in effort to get sales back on a positive track after a prolonged period of order backlog.

Administrative Expenses

Administrative expenses increased by approximately 20%, or \$61,000, to \$363,000 during the three-month period ended September 30, 2016, in comparison to \$302,000 during the three-month period ended September 30, 2015. Administrative expenses increased by approximately 14%, or \$134,000, to \$1,076,000 during the nine-month period ended September 30, 2016, in comparison to \$941,000 during the nine-month period ended September 30, 2015. We strive to be efficient with these expenses while funding costs associated with complying with the Sarbanes-Oxley Act of 2002 and other costs associated with being a publicly-held company. Prior to 2014, we had limited our investment in investor relations spending. Beginning in the second quarter of 2014, we initiated an investment in a more actively managed investor relations program. Additionally, we continue to provide full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as in Current Reports on Form 8-K when legally required or deemed appropriate by management. Additional information about management and our business is available in our annual Proxy Statement. All of these reports are filed with the SEC and are available on-line or upon request to the Company.

Product Development Expenses

Product development expenses increased by 2%, or \$6,000, to \$308,000 during the three-month period ended September 30, 2016 compared to \$302,000 during the three-month period ended September 30, 2015. These expenses aggregated 16% and 12% of product sales during these three-month periods, respectively. Product development expenses increased by 10%, or \$86,000, to \$991,000 during the nine-month period ended September 30, 2016 compared to \$904,000 during the nine-month period ended September 30, 2015. These expenses aggregated 14% and 12% of product sales during these nine-month periods, respectively. From January 1, 1999 (the year we first re-focused our business strategy on **First Defense**® and other products for the dairy and beef industries) to September 30, 2016, we invested the aggregate of approximately \$22,975,000 in product development expenses, averaging approximately \$1,294,000 per year during this period. Approximately \$4,130,000 of this investment was offset by product licensing revenues, technology sales and grant income, most of which was earned from 1999 to 2007.

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The majority of our product development spending is focused on the development of **Mast Out**[®], our Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows. During the 16.75 year period that began on January 1, 2000 (the year we began the development of **Mast Out**[®]) and ended on September 30, 2016, we invested the aggregate of approximately \$12,271,000 in the development of **Mast Out**[®]. This estimated allocation to **Mast Out**[®] reflects only direct expenditures and includes no allocation of product development or administrative overhead expenses. Approximately \$2,891,000 of this investment was offset by product licensing revenues and grant income related to **Mast Out**[®], most of which was earned from 2001 to 2007.

During 2000, we acquired an exclusive license from Nutrition 21, Inc. (formerly Applied Microbiology Inc. or AMBI) to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Mast Out**[®]. In 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 our topical wipe products, is an antibacterial peptide known to be effective against most Gram-positive and some Gram-negative bacteria. In our pivotal effectiveness study, statistically significant **Mast Out**[®] cure rates were associated with a statistically significant reduction in milk somatic cell count, which is an important measure of milk quality. Nisin is a well characterized substance, having been used in food preservation applications for over 50 years. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes methods to achieve pharmaceutical-grade purity.

It is generally current practice to treat mastitis only when the disease has progressed to the clinical stage where the milk from an infected cow cannot be sold. The use of all mastitis drugs currently on the market is permitted only if the milk from treated cows is discarded during treatment and for a period of time thereafter to allow the antibiotic residues to clear from milk that is to be consumed by humans. We have estimated that the cost of this discarded milk may be approximately \$300 million per year. Because milk from cows with subclinical infections can be sold, this disease is largely left untreated to avoid the milk discard penalty. Subclinical mastitis is associated with reduced milk production (some have estimated approximately 1,500 pounds of lost milk, or about \$240 at \$16.00 per hundredweight, per infected cow), reduced milk premiums, reproduction inefficiencies and an increased incidence of clinical mastitis. We intend to introduce the first mastitis treatment that is not subject to milk discard or meat withhold requirements, which would be a significant competitive advantage for our product.

In 2004, we entered into a product development and marketing agreement with Pfizer Animal Health (doing business as Zoetis since 2013) covering **Mast Out**[®]. Zoetis elected to terminate the agreement in 2007. We believe that this decision was not based on any unanticipated efficacy or regulatory issues. Rather, we believe the decision was primarily driven by a marketing concern relating to their fear that the milk from treated cows could interfere with the manufacture of certain cultured dairy products. Due to the zero milk discard feature, there is a risk that Nisin from the milk of cows treated with **Mast Out**[®] could interfere with the manufacture of certain (but not all) commercial cultured dairy products, such as some kinds of cheese and yogurt, if a process tank contains a high enough percentage of milk from treated cows. The impact of this potential interference ranges from a delay in the manufacturing process, which

does happen at times for other reasons, to the less likely stopping of a cheese starter culture. Milk from cows that have been treated with **Mast Out**[®] that is sold exclusively for fluid milk products presents no such risk. We worked with scientists and mastitis experts to conduct a formal risk assessment to quantify the impact that milk from treated cows may have on cultured dairy products. This study concluded that the dilution of milk from treated cows through comingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when **Mast Out**[®] is used in accordance with the product label. We do not believe that a premium-priced product such as **Mast Out**[®] will be used as part of a whole herd (“blitz”) treatment protocol, which reduces the risk of cheese interference. We do not see this as a significant problem as modern “precision dairying” practices support reducing the indiscriminate use of drug treatments.

Commercial introduction of **Mast Out**[®] in the United States is subject to approval of our New Animal Drug Application (NADA) by the Food and Drug Administration (FDA), which approval cannot be assured. Foreign regulatory approvals would be required for sales in key markets outside of the United States, which would involve some similar and some different requirements. The NADA is comprised of five principal Technical Sections and one administrative submission that are subject to the FDA’s phased review. By statute, each Technical Section submission is generally subject to a six-month review cycle by the FDA. Each Technical Section can be reviewed and approved separately. Upon review and assessment by the FDA that all requirements for a Technical Section have been met, the FDA may issue a Technical Section Complete Letter. The current status of our work on these submissions to the FDA is as follows:

1) Environmental Impact: During the third quarter of 2008, we received the Environmental Impact Technical section Complete Letter from the FDA.

2) Target Animal Safety: During the second quarter of 2012, we received the Target Animal Safety Technical Section Complete Letter from the FDA.

3) Effectiveness: During the third quarter of 2012, we received the Effectiveness Technical Section Complete Letter from the FDA. The draft product label carries claims for the treatment of subclinical mastitis associated with *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, and coagulase-negative staphylococci in lactating dairy cattle.

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4) Human Food Safety (HFS): The HFS Technical Section submission was made during the fourth quarter of 2010. This Technical Section includes several subsections such as: a) toxicology, b) total metabolism, c) effects of drug residues in food on human intestinal microbiology, d) effects on bacteria of human health concern (antimicrobial resistance) and e) pivotal residue chemistry. During the second quarter of 2011, we announced that the FDA had accepted the subsections described above and granted **Mast Out**® a zero milk discard period and a zero meat withhold period during and after treatment. Before we can obtain this Technical Section Complete Letter, we must transfer our analytical method that measures Nisin residues in milk to a government laboratory. Due to unexpected regulatory demands and review delays, completion of the HFS Technical Section is currently anticipated during the middle of 2017.

5) Chemistry, Manufacturing and Controls (CMC): Obtaining FDA approval of the CMC Technical Section defines the critical path to FDA approval and to initial commercial sales. During the third quarter of 2014, we completed an investment in facility modifications and processing equipment necessary to produce the Drug Substance (the Active Pharmaceutical Ingredient, which is our pharmaceutical-grade Nisin) at small-scale. This small-scale facility has been used to i) expand our process knowledge and controls, ii) establish operating ranges for critical process parameters, iii) optimize process yields and iv) verify the cost of production. We believe these efforts will reduce risk as we invest in the commercial-scale production facility.

Accessing Nisin production at commercial scale is the most critical action in front of us on our path to regulatory approval. Our initial plan was to have Nisin produced for us under a Development and Manufacturing Agreement with Lonza Sales, Ltd. of Basel, Switzerland, in order to avoid the investment in a manufacturing facility. By the end of 2011, we determined that the required minimum volumes were too large to permit efficient, continuous production and that the cost of goods under this contract would not be commercially feasible. This contract was terminated during the fourth quarter of 2014 by mutual consent. We presented this product development opportunity to a variety of large and small animal health companies. During the second quarter of 2013, we received a non-refundable \$250,000 exclusive license option fee from a prospective partner that considered manufacturing our Nisin in a plant of their own. During the third quarter of 2013, this prospective partner decided not to execute a development and marketing license because it had determined that, in its opinion, it could not cost-effectively commercialize the product. While such a corporate partnership could have allowed us to avoid the large investment in a commercial-scale production facility, the partnership would have taken a large share of the gross margin from all future product sales. We are encouraged by the regulatory and marketing feedback from prospective partners, following their due diligence, that our novel mastitis treatment can achieve FDA approval and have a significant, positive impact on the dairy industry. During the fourth quarter of 2015, we acquired land nearby to our existing Portland facility for the construction of our own facility for the commercial-scale production of Nisin. During the third quarter of 2016, we broke ground for this facility. We plan to complete construction by the third quarter of 2017 and installation and qualification of equipment by the first quarter of 2018. To gain regulatory approval of this product, validation batches must be produced at commercial scale, and a detailed CMC Technical Section prepared and submitted to the FDA. We expect that two, six-month reviews of the CMC Technical Section by the FDA will be required. Additionally, successful FDA site inspections must be achieved.

After preparing materials responsive to other administrative requirements, the administrative NADA submission will be assembled for review by the FDA. This final administrative submission is subject to a statutory sixty-day review period. Adherence to this timeline sets us up for anticipated regulatory approval in 2019.

We are party to a long-term, exclusive supply agreement with Plas-Pak Inc. of Norwich, Connecticut covering the proprietary syringe that was developed specifically for treating cows with **Mast Out**[®]. These syringes were used for all pivotal studies of **Mast Out**[®]. During the fourth quarter of 2015, this contract was extended through December 31, 2020.

Since 2010, we have been party to a long-term, exclusive Contract Manufacture Agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved Drug Product (filled and packaged syringes) manufacturer, covering the formulating and sterile-filling of the Drug Substance into Drug Product for **Mast Out**[®]. Norbrook provided these services for clinical material used in all pivotal studies of **Mast Out**[®]. During the fourth quarter of 2015, we entered into a revised agreement with Norbrook covering the final development and commercial-scale (but not at small-scale) launch of **Mast Out**[®] after FDA approval.

In addition to our work on **Mast Out**[®], we are actively developing further improvements, extensions or additions to our current **First Defense**[®] product line. For example, we currently are developing treatments that could prevent calf scours caused by enteric pathogens in addition to *E. coli* K99 and bovine coronavirus (the current disease claims for **First Defense**[®]). In connection with that effort, during the second quarter of 2009 we entered into an exclusive license with the Baylor College of Medicine covering the underlying rotavirus vaccine technology used to generate the specific antibodies. This perpetual license (if not terminated for cause) is subject to milestone and royalty payments. If approved, this would be the first passive antibody product on the market with USDA-approved disease claims providing immediate immunity against the three leading causes of calf scours, *E. coli*, coronavirus and rotavirus. Results from pilot studies completed during the first quarter of 2009 justified continued product development. We initiated a second pivotal effectiveness study at Cornell University College of Veterinary Medicine during the second quarter of 2014 and announced positive effectiveness results from this pivotal study during the first quarter of 2015. During the third quarter of 2015, we obtained concurrence from the USDA that we have been granted disease claims against bovine rotavirus for our product. We are now working to complete the other laboratory and manufacturing objectives required for product license approval. This could position us to achieve product licensure and market launch with the expanded claims during 2017. We intend to continue selling the bivalent formats of **First Defense**[®] as options for customers after launch of the trivalent product. We are currently working to establish USDA claims for our gel tube formulation of **First Defense Technology**[™] and to add a *C. perfringens* claim to our product line. At the same time, we are working to expand our product development pipeline of bacteriocins that can be used as alternatives to traditional antibiotics. During the second quarter of 2015, we entered into an exclusive option agreement to license new bacteriocin technology from the University of Massachusetts Amherst. This technology focuses on bacteriocins having activity against Gram-negative infections for use in combating mastitis in dairy cattle. Subject to the availability of needed financial and other resources, we intend to begin new development projects that are aligned with our core competencies and market focus. We also remain interested in acquiring, on suitable terms, other new products and technologies that fit with our sales focus on the dairy and beef industries.

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Net Operating Income

Net operating income during the three-month period ended September 30, 2016 of \$50,000 compares to \$627,000 during the three-month period ended September 30, 2015. Net operating income during the nine-month period ended September 30, 2016 of \$771,000 compares to \$1,661,000 during the nine-month period ended September 30, 2015. We have now reported positive net operating income for nine consecutive quarters.

Other expenses, net

Interest expense increased by approximately \$24,000 to \$39,000 during the three-month period ended September 30, 2016, in comparison to \$15,000 during the three-month period ended September 30, 2015. Interest income increased by approximately \$13,000 to \$17,000 during the three-month period ended September 30, 2016, in comparison to \$4,000 during the three-month period ended September 30, 2015. Other expenses, net, aggregated \$27,000 and \$15,000 during the three-month periods ended September 30, 2016 and 2015, respectively.

Interest expense increased by approximately \$76,000 to \$117,000 during the nine-month period ended September 30, 2016, in comparison to \$41,000 during the nine-month period ended September 30, 2015. Interest income increased by approximately \$33,000 to \$44,000 during the nine-month period ended September 30, 2016, in comparison to \$11,000 during the nine-month period ended September 30, 2015. Other expenses, net, aggregated \$81,000 and \$27,000 during the nine-month periods ended September 30, 2016 and 2015, respectively.

Income Before Income Taxes and Net Income

Our income before income taxes was \$24,000 during the three-month period ended September 30, 2016 in comparison to income before income taxes of \$612,000 during the three-month period ended September 30, 2015. We recorded income tax (benefit) expense of (46%) and 43% of the income before income taxes during the three-month periods ended September 30, 2016 and 2015, respectively. The income tax benefit during the three-month period ended September 30, 2016 resulted from a lowering of our estimated state tax obligations. Our net income was \$35,000, or \$0.01 per diluted share, during the three-month period ended September 30, 2016 in comparison to net income of \$351,000, or \$0.11 per diluted share, during the three-month period ended September 30, 2015.

Our income before income taxes was \$690,000 during the nine-month period ended September 30, 2016 compared to income before income taxes of \$1,634,000 during the nine-month period ended September 30, 2015. We recorded income tax expense of 31% and 43% of the income before income taxes during the nine-month periods ended September 30, 2016 and 2015, respectively. The lower tax rate in 2016 is principally related to lower state taxes. Our net income was \$478,000, or \$0.11 per diluted share, during the nine-month period ended September 30, 2016 compared to net income of \$924,000, or \$0.29 per diluted share, during the nine-month period ended September 30, 2015. The decrease in earnings per diluted share was the result of a \$446,000 drop in net income and there being more shares outstanding during most of the first nine months of 2016.

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of September 30, 2016, there have been no significant changes in market risk exposures that materially affected the quantitative and qualitative disclosures as described in Item 7A to our Annual Report on Form 10-K.

ITEM 4 - CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. Our management, with the participation of the individual who serves as our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. 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 is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting. The individual who serves as our principal executive and principal financial officer periodically evaluates any change in internal control over financial reporting which has occurred during the prior fiscal quarter. Management has concluded that there was no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2016 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

None

ITEM 1A - RISK FACTORS

Safe Harbor Statement

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: projections of future financial performance; the scope and timing of future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis; future market share of and revenue generated by products still in development; future sources of financial support for our product development, manufacturing and marketing efforts; the future adequacy of our own manufacturing facilities or those of third parties with which we have contractual relationships to meet demand for our products on a timely basis; the amount and timing of future investments in facility modifications and production equipment; the future adequacy of our working capital and the availability of third party financing; timing and future costs of a facility to produce the Drug Substance (active pharmaceutical ingredient) for **Mast Out**[®]; the timing and outcome of pending or anticipated applications for future regulatory approvals; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; future realization of deferred tax assets; costs associated with sustaining compliance with cGMP regulations in our current operations and attaining such compliance for the facility to produce the Drug Substance for **Mast Out**[®]; factors that may affect the dairy and beef industries and future demand for our products; the cost-effectiveness of additional sales and marketing expenditures and resources; the accuracy of our understanding of our distributors’ ordering patterns; anticipated changes in our manufacturing capabilities and efficiencies; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as “expects”, “may”, “anticipates”, “aims”, “intends”, “would”, “could”, “should”, “will”, “plans”, “believes”, “estimates”, “targets”, “projects”, “forecasts” and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate. 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, alignment between our manufacturing resources and product

demand, the uncertainties associated with product development and Drug Substance manufacturing, our potential reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making by regulatory authorities, possible dilutive impacts on existing stockholders from any equity financing transactions in which we may engage, currency fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized below and uncertainties otherwise referred to in this Quarterly Report.

Projection of net income: Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Weaker than expected sales of **First Defense**® or extended shortfalls in production relative to the growing product sales demand could lead to less profits or an operating loss. Large investments in product development (or cost overruns) can result in a net loss. We expect the recent profitability trend to continue.

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*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 (including part of the cost of our expansion to support the commercialization of **Mast Out**[®]). Our business would not have been profitable during the nine consecutive years in the period ended December 31, 2007, or during the years ended December 31, 2012, 2013 and 2015 or during the first nine months of 2016 without the gross margin that we earned on sales of **First Defense**[®], which accounted for 93% of our product sales during both the first nine months of 2016 and the year ended December 31, 2015.

Product risks generally: The sale of our products is subject to financial, efficacy, regulatory, competitive and other market risks. Elevated standards to achieve regulatory compliance required to sell our products continue to evolve. 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 low enough cost to result in a sufficient gross margin to justify their continued manufacture and sale.

Product liability: The manufacture and sale of our products entails a risk of product liability. Our exposure to product liability is mitigated to some extent by the fact that our products are principally directed towards the animal health market. We have maintained product liability insurance in an amount which we believe is reasonable in relation to our potential exposure in this area. We have no history of claims of this nature being made.

*Regulatory requirements for **First Defense**[®]:* **First Defense**[®] is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the “Reference Standard”). Due to the unique nature of the **First Defense**[®] label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product. Similar regulatory oversight risks exist in territories outside of the United States where we sell our products.

*Regulatory requirements for **Wipe Out**[®]**Dairy Wipes**:* While the FDA regulates the manufacture and sale of **Wipe Out**[®]**Dairy Wipes**, this type of product is permitted to be sold without a NADA approval, in accordance with the FDA’s Compliance Policy Guide 7125.30 (“Teat Dips and Udder Washes for Dairy Cows and Goats”). This policy guide could be withdrawn at the FDA’s discretion, in which case we would likely discontinue sales of the product. The manufacture of **Wipe Out**[®]**Dairy Wipes** is subject to Part 211 of the cGMP regulations. As a result, our operations are subject to inspection by the FDA. During the second quarter of 2007, the FDA inspected our facilities and operations and issued a Warning Letter to us, citing deficiencies in specific areas of the cGMP regulations. We filed an initial response to the FDA during the second quarter of 2007, and we responded to a request for additional information during the second quarter of 2008. During the first quarter of 2013, the FDA again inspected our facilities

and operations. The report from this inspection was favorable, and we responded to the few, minor observations that were noted. During the third quarter of 2016, the FDA again inspected our facilities and operations. The preliminary report from this inspection noted five observations. We submitted our responses to the observations that were noted, and subsequently were informed that the FDA had closed its inspection. 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 FDA approval for this product. Completing the development of **Mast Out**[®] through to the submission of the administrative NADA to the FDA involves risk. While three Technical Sections have been approved and the Human Food Safety Technical Section is near completion, the development process timeline has been extensive (16 years) and has involved multiple commercial production strategies. As such, the Chemistry, Manufacturing and Controls Technical Section has not yet been submitted for the Nisin Drug Substance or the Drug Product. To minimize this risk, we have met with the FDA to align on filing strategy and requirements. It presently is uncertain when or if this approval will be achieved, but we have disclosed a timeline of events that could lead to approval during 2019. We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Mast Out**[®], who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. International regulatory approvals would be required for sales outside of the United States, such as Canada. European regulatory authorities are not expected to approve a product with a zero milk discard claim, which would remove a significant competitive advantage of **Mast Out**[®] in that territory. However, the assigned milk discard period may be shorter for **Mast Out**[®] than it is for other products on the market in Europe.

Concentration of sales: Approximately 99% and 96% of our product sales were made to customers in the dairy and beef industries throughout the world during the first nine months of 2016 and 2015, respectively. Approximately 85% and 83% of our product sales were made to customers in the U.S. dairy and beef industries during the first nine months of 2016 and 2015, respectively. A large portion of our product sales (59% and 63% during the first nine months of 2016 and 2015, respectively) was made to two large distributors. A large portion of our trade accounts receivable (56% and 52% as of September 30, 2016 and December 31, 2015, respectively) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us.

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Economics of the dairy and beef industries:

All cattle and calves in the United States as of January 1, 2016 totaled 92,000,000, which is 3.3% higher than January 1, 2015. Prior to January 1, 2015, the January count of cattle inventory had steadily declined from 97,000,000 as of January 1, 2007.

All cattle and calves in the United States as of July 1, 2015 totaled 98,400,000, which is 2.2% higher than July 1, 2014. This was the first increase in the July count of cattle inventory since 2006, suggesting the rebuilding of the U.S. herd has begun. The July 1, 2014 amount of 96,300,000 was the lowest inventory count as of July 1st in decades. The USDA has suspended its reporting of this data point, and no such data is available as of July 1, 2016.

From 1998 through 2015, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 (2004) to the high of 9,317,000 (2015). The 2015 level exceeded the previous high during this eighteen-year period of 9,314,000 in 2008. During the first nine months of 2016, this average increased slightly to 9,327,000.

While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk, demand for milk is also influenced by very volatile international demand for milk products. The Class III milk price (an industry benchmark that reflects the value of product used to make cheese) is an important indicator because it defines our customers' revenue level. This annual average milk price level (measured in dollars per hundred pounds of milk) for 2014 of \$22.34 (peaking at \$24.60 in September 2014) was the highest level since these records were first reported in 1980. This strong price level declined to the average of \$15.80 during 2015. This average price decreased further to \$14.38 during the first nine months of 2016. However, the average during the third quarter of 2016 of \$16.18 was higher than the average of \$13.48 during the first six months of 2016. The recent annual fluctuations in this milk price level are demonstrated in the following table:

Average Class			
III Milk Price Increase			
for the			
year ended (Decrease)			
December 31,			
2012	2013		
\$17.44	\$17.99	3	%

2013	2014		
\$17.99	\$22.34	24	%

2014	2015		
\$22.34	\$15.80	(29)	%

The actual level of milk prices may be less important than its level relative to feed costs. One measure of this relationship is known as the milk-to-feed price ratio, which represents the amount of feed that one pound of milk can buy. The annual average for this ratio of 1.52 in 2012 was the lowest recorded since this ratio was first reported in 1985. The highest annual average this ratio has reached since 1985 was 3.64 in 1987. Since this ratio reached 3.24 in 2005, it has not exceeded 3.0. The annual average of 2.54 for 2014 was the highest this ratio has been since it was 2.81 in 2007. This ratio dropped to an annual average of 2.12 during 2015 and increased slightly to 2.14 during the first nine months of 2016. The following table demonstrates the annual volatility and the low values of this ratio recently:

Average Milk-To-Feed Price Ratio for the year ended December 31,		Increase (Decrease)	
2012	2013		
1.52	1.75	15	%

2013	2014	
1.75	2.54	45%

2014	2015	
2.54	2.12	(16%)

An increase in feed costs also has a negative impact on the beef industry. Widespread severe drought conditions in key U.S. agricultural regions during 2012 drove feed costs higher and the inventory of all cattle and calves lower. The positive trend in these market indices during 2013 and 2014 resulted in an increase in the value of milk cows. The 2014 annual average price for a milk cow increased by 32% to \$1,835 in comparison to 2013. Previously, this annual average price since 1970 was only higher when it reached \$1,840 in 2007 and \$1,953 in 2008. This annual average price for 2015 increased by 9% to \$1,993 in comparison to 2014, but this average price has declined by 11% to \$1,768 during 2016. The industry data referred to above is compiled from USDA databases. The value of newborn bull calves had risen to the unusually high level of approximately \$300 to \$400, but this value has decreased recently, currently ranging from \$50 to \$200 depending on region. Given our focus on the dairy and beef industries, the volatile market conditions and the resulting financial insecurities of our primary end users are risks to our ability to maintain and grow sales at a profitable level. These factors also heighten the challenge of selling premium-priced animal health products (such as **Mast Out**[®]) into the dairy market.

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Product development risks: The development of new products is subject to financial, scientific, regulatory and market risks. Our current business growth strategy relies heavily on the development of **Mast Out**[®], which requires (and will continue to require) a substantial investment. Our efforts will be subject to inspection and approval by the FDA. There is no assurance whether or when we will obtain all of the data necessary to support regulatory approval for this product.

*Risks associated with **Mast Out**[®] funding strategy:* The construction of and the financing for the commercial-scale Drug Substance production facility is the most critical action in front of us on our path to U.S. regulatory approval for **Mast Out**[®]. Proceeds from a bank financing covering a \$4.5 million debt facility entered into during the first quarter of 2016 have not yet been drawn. We believe our current cash and investments, together with the \$4.5 million debt facility and cash to be generated from operations and possibly some incremental bank debt, will be adequate financing to complete the project. However, due to the risks described herein, we could fail to generate sufficient cash to fully fund that project, and we could experience cost overruns or delays.

Uncertainty of market size and product sales estimates: Estimating the size of the market for **Mast Out**[®] is subject to numerous uncertainties. Some of the uncertainties surrounding our product include market acceptance, the development of the subclinical mastitis treatment market, the effect of a premium selling price on market penetration, cost of manufacture and integration of milk from treated cows with susceptible cheese starter cultures.

Competition from others: Many of our competitors are significantly larger and more diversified in the relevant markets than we are and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. Zoetis, Elanco, Boehringer Ingelheim and Merck, among other companies, sell products that compete directly with **First Defense**[®] in preventing scours in newborn calves. The product sold by Elanco (which has a similar selling price to our product) experienced a lack of supply in the market during late 2014 and into the middle of 2015, but is now back on the market. The product sold by Zoetis does carry a rotavirus claim (which we do not yet have), but it does not have an *E. coli* claim (which we do have), and it sells for approximately half the price of our product. The market for the treatment of mastitis in dairy cows is highly competitive, and presently is dominated by large companies such as Zoetis, Merck and Boehringer Ingelheim. There is no assurance that **Mast Out**[®] will compete successfully in this market. We may not be aware of other companies that compete with us or intend to compete with us in the future.

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 that we obtain from third parties. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. The loss of farms from which we buy raw material for **First Defense**[®] could make it difficult for us to produce enough inventory. We are dependent on our manufacturing facility

and operations at 56 Evergreen Drive in Portland for the production of **First Defense**® and our topical wipes and will be dependent on the facility we are constructing for the production of **Mast Out**® when that product begins commercial sales. The specific antibodies that we purify from colostrum for **First Defense**® and the Nisin we produce by fermentation for our topical wipes are not readily available from other sources. We expect to be dependent on Plas-Pak for the supply of the syringes used for **Mast Out**®. We expect to be dependent on Norbrook for the sterile-filling and final packaging of our Drug Substance into Drug Product. Given the requirement that such a facility be inspected and approved by the FDA, it could be costly and time-consuming to find an adequate alternative source for these services. Any significant damage to or other disruption in the services at these facilities (including due to regulatory non-compliance) could adversely affect the production of inventory and result in significant added expenses and loss of future sales.

Small size; dependence on key personnel: We are a small company with 46 employees (including 5 part-time employees). As such, we rely on certain key employees to support different operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained. Our competitive position will be highly influenced by our ability to attract and retain key scientific, managerial and sales and marketing personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products, maintain compliance with current 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.

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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 operational safeguards and contractual agreements. Reliance upon trade secret, rather than patent, protection may cause us to be vulnerable to competitors who successfully replicate our manufacturing techniques and processes. Additionally, there can be no assurance that others may not independently develop similar trade secrets or technology or obtain access to our unpatented trade secrets or proprietary technology. Other companies may have filed patent applications and may have been issued patents involving products or technologies potentially useful to us or necessary for us to commercialize our products or achieve our business goals. There can be no assurance that we will be able to obtain licenses to such patents on terms that are acceptable. There is also a risk that competitors could challenge the claims in patents that have been issued to us.

Certain provisions might discourage, delay or prevent a change in control of our Company or changes in our management: Provisions of our certificate of incorporation, our bylaws, our Common Stock Rights Plan or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

limitations on the removal of directors; advance notice requirements for stockholder proposals and nominations; the ability of our Board of Directors to alter or repeal our bylaws; the ability of our Board of Directors to refuse to redeem rights issued under our Common Stock Rights Plan or otherwise to limit or suspend its operation that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors; and Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could depress the trading price of our common stock or limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood of obtaining a premium for our common stock in an acquisition.

Cost burdens of our reporting obligations as a public company: Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws and the provisions of the Sarbanes-Oxley Act

of 2002.

Exposure to risks associated with the financial downturn and global economic crisis: The U.S. economy has technically come out of a recession, which was caused principally by the housing, credit and financial crises that began around 2008. However, such recent positive indications could prove temporary and further downturn could occur. The credit markets continue to be very turbulent and uncertain. Some observers believe that the housing market remains problematic for the overall U.S. economy, the United States has taken on too much national debt and the equity markets are overvalued. This extraordinary period of instability in the U.S. economy and the financial markets has been troubling for nearly all Americans. The European economy remains sluggish and precarious. Certain emerging markets also show signs of slower growth or, in some areas, downturns in economic performance. While we do price our products in U.S. dollars for all export markets, the strength of the dollar against weakening foreign currencies could reduce product demand in international markets. A combination of the conditions, trends and concerns summarized above could have a corresponding negative effect on our business and operations, including the demand for our products in the U.S. market and our ability to penetrate international markets.

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 United States 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 (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 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.

Stock market valuation: Our common stock trades on The Nasdaq Stock Market (NasdaqCM: ICCC). Our average daily trading volume (although it has increased recently) is lower than the volume for most other companies and the bid/ask stock price spread can be larger, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire. There are companies in the animal health sector with market capitalization values that greatly exceed our current market capitalization of approximately \$32,000,000 as of September 30, 2016. Some of these companies have little or no product sales. We currently have annual product sales of over \$10,000,000. Before gross margin from the sale of new products is achieved, our market capitalization may be heavily dependent on the perceived potential for growth from our products under development.

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No expectation to pay any dividends or repurchase stock for the foreseeable future: We do not anticipate paying any dividends to, or repurchasing stock from, our stockholders for the foreseeable future. Instead, we expect to use cash to fund product development costs and investments in our facility and production equipment and to reduce debt. Stockholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, contractual restrictions, restrictions imposed by applicable laws, current and anticipated needs for liquidity and other factors our Board of Directors deems relevant.

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

None

ITEM 3 - DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4 - MINE SAFETY DISCLOSURES

None

ITEM 5 - OTHER INFORMATION

None

ITEM 6 - EXHIBITS

Exhibit 10.1 Standard Form of Agreement between the Company (as owner) and Construction Manager (as constructor) between the Company and Consigli Construction Co., Inc. dated as of September 27, 2016.

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.

101.INS XBRL Instance Document.

101.SCH XBRL Taxonomy Extension Schema Document.

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB XBRL Taxonomy Extension Label Linkbase Document.

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

ImmuCell Corporation

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ImmuCell Corporation
Registrant

Date: November 10, 2016 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer
and Principal Financial Officer