IMMUCELL CORP /DE/
Form 10-Q
November 13, 2017

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, 2017

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, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 6, 2017 was 5,051,390.

ImmuCell Corporation

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September 30, 2017

PART I: FINANCIAL INFORMATION

ImmuCell Corporation

PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

(Unaudited Condensed)

BALANCE SHEETS

	As of September 30, 2017	As of December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,305,264	$ 5,150,344
Short-term investments	-	5,474,013
Accounts receivable, net	868,919	992,390
Inventory	2,732,025	2,126,899
Prepaid expenses and other current assets	361,799	604,482
Total current assets	6,268,007	14,348,128
PROPERTY, PLANT AND EQUIPMENT, net	23,543,490	9,846,293
DEFERRED TAX ASSETS	189,968	201,003
INTANGIBLE ASSETS, net	157,608	171,936
GOODWILL	95,557	95,557
OTHER ASSETS, net	35,184	34,264
TOTAL ASSETS	$ 30,289,814	$ 24,697,181
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 3,431,661	$ 1,891,763
Current portion of bank debt	145,016	133,269
Deferred revenue	-	33,856
Total current liabilities	3,576,677	2,058,888
LONG-TERM LIABILITIES:		
Bank debt, net of current portion	5,727,182	2,878,805
Interest rate swaps	32,005	37,346

Total long-term liabilities	5,759,187	2,916,151
TOTAL LIABILITIES	9,335,864	4,975,039
CONTINGENT LIABILITIES AND COMMITMENTS (See Note 15)		
STOCKHOLDERS' EQUITY:		
Common stock, $0.10 par value per share, 8,000,000 and 8,000,000 shares authorized, 5,244,838 and 5,044,838 shares issued and 5,051,390 and 4,847,390 shares outstanding, as of September 30, 2017 and December 31, 2016, respectively	524,484	504,484
Additional paid-in capital	19,699,514	18,526,383
Retained earnings	1,173,628	1,147,120
Treasury stock, at cost, 193,448 and 197,448 shares as of September 30, 2017 and December 31, 2016, respectively	(423,193)	(431,943)
Accumulated other comprehensive loss	(20,483)	(23,902)
Total stockholders' equity	20,953,950	19,722,142
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 30,289,814	$ 24,697,181

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

ImmuCell Corporation

(Unaudited Condensed)

STATEMENTS OF (LOSS) INCOME

	For the Three-Month Periods Ended September 30,		For the Nine-Month Periods Ended September 30,	
	2017	2016	2017	2016
Product sales	$ 2,004,961	$1,968,122	$7,298,496	$7,330,143
Costs of goods sold	1,069,110	763,495	3,289,361	3,128,095
Gross margin	935,851	1,204,627	4,009,135	4,202,048
Sales and marketing expenses	446,733	483,709	1,361,653	1,365,017
Product development expenses	585,834	307,721	1,312,456	990,598
Administrative expenses	385,695	362,730	1,164,533	1,075,538
Operating expenses	1,418,262	1,154,160	3,838,642	3,431,153
NET OPERATING (LOSS) INCOME	(482,411)	50,467	170,493	770,895
Other expenses, net	49,238	26,510	115,877	81,195
(LOSS) INCOME BEFORE INCOME TAXES	(531,649)	23,957	54,616	689,700
Income tax (benefit) expense	(192,303)	(10,913)	28,108	211,537
NET (LOSS) INCOME	($339,346)	$34,870	$26,508	$478,163
Weighted average common shares outstanding:				
Basic	4,992,803	4,182,529	4,896,782	4,065,243
Diluted	4,992,803	4,302,280	4,999,245	4,179,181
NET (LOSS) INCOME PER SHARE:				
Basic	($0.07)	$0.01	$0.01	$0.12
Diluted	($0.07)	$0.01	$0.01	$0.11

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

ImmuCell Corporation

(Unaudited Condensed)

STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

	For the Three-Month Periods Ended September 30,		**For the Nine-Month Periods Ended September 30,**	
	2017	2016	2017	2016
Net (loss) income	($339,346)	$34,870	$26,508	$478,163
Other comprehensive income (loss):				
Interest rate swaps, before taxes	2,850	24,255	5,342	(124,635)
Income tax applicable to interest rate swaps	(1,026)	(8,732)	(1,923)	44,868
Other comprehensive income (loss), net of taxes	1,824	15,523	3,419	(79,767)
Total comprehensive (loss) income	($337,522)	$50,393	$29,927	$398,396

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, 2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$26,508	$478,163
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	627,141	569,081
Amortization	14,328	15,309
Non-cash interest expense	11,120	6,367
Deferred income taxes	9,112	206,911
Stock-based compensation	148,035	50,312
(Gain) loss on disposal of fixed assets	(3,663)	2,109
(Recovery of) provision for uncollectible accounts, net	(17,643)	2,225
Changes in:		
Accounts receivable, gross	141,114	38,723
Accrued interest income	24,013	(10,843)
Inventory	(605,126)	(783,190)
Prepaid expenses and other current assets	242,683	(460,184)
Other assets	(920)	-
Accounts payable and accrued expenses	262,270	891
Deferred revenue	(33,856)	33,856
Net cash provided by operating activities	845,116	149,730
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(13,079,386)	(1,794,755)
Acquisition of certain business assets	(8,661)	(469,807)
Maturities of investments	5,699,000	3,968,000
Purchases of investments	(249,000)	(4,216,000)
Proceeds from sale of fixed assets	45,000	-
Net cash used for investing activities	(7,593,047)	(2,512,562)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from public offering, net	-	5,313,223
Proceeds from private placement, net	1,037,164	-
Proceeds from debt issuance	3,024,343	-
Debt principal repayments	(111,981)	(100,545)

Debt issuance costs	(63,358)	(46,734)
Proceeds from exercise of stock options	16,500	31,975
Tax benefits related to stock options	183	-
Net cash provided by financing activities	3,902,851	5,197,919
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,845,080)	2,835,087
BEGINNING CASH AND CASH EQUIVALENTS	5,150,344	1,573,328
ENDING CASH AND CASH EQUIVALENTS	$2,305,264	$4,408,415

See Note 8 for additional disclosures about cash and non-cash activities related to the 2016 business acquisition.

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

ImmuCell Corporation

(Unaudited Condensed)

STATEMENTS OF CASH FLOWS

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

	For the Nine-Month Periods Ended September 30,	
	2017	2016
CASH PAID FOR:		
Income taxes	$ 4,000	$125,125
Interest expense	$ 123,034	$115,682
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable and accrued expenses	$ 1,286,289	$163,635
Net change in fair value of interest rate swaps	($3,419)	$79,767
Fixed asset disposals, gross	$ 1,500	$58,714

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 an animal health company whose purpose is to create scientifically-proven and practical products that improve the health and productivity of dairy and beef cattle. 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. The $20,803,000 investment we are making in a Nisin production facility is being funded from available cash and bank debt, together with cash flows from ongoing operations. As we complete the investment in our Nisin production facility and draw down the remaining bank debt that is available to us, we are reducing our cash reserves to a lower than normal level. We are going to be reliant on positive cash flows during our peak selling season (first quarter) to begin to re-build these cash reserves. Based on our best estimates and projections, we believe that we have sufficient capital resources to continue operations for at least twelve months. 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*™ (Codification). 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, 2016 and the notes thereto, contained in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission (SEC). Certain prior year accounts have been reclassified to conform with the 2017 financial statement presentation.

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

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. 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 $2,052,985 and $4,650,044 as of September 30, 2017 and December 31, 2016, respectively. We account for investments in 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. Short-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.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

(d) Accounts Receivable

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful collection. 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 a portion of the receivable balance is outstanding for more than 30 days. Past due accounts receivable are subject to an interest charge. See Note 5.

(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 pharmaceutical ingredient, Nisin, will be depreciated over its useful life beginning when that facility is placed into service, which will likely 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. Significant 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 relationships, non-compete agreements, and developed 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) acquired in purchase transactions.

We assess the impairment of intangible assets and goodwill that have indefinite lives at the reporting unit level 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 the carrying value. Judgement is required in determining whether an event has occurred that may impair the value of goodwill or identifiable intangible assets. 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 and 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. No goodwill impairments were recorded during the nine-month period ended September 30, 2017 or the year ended December 31, 2016. 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, 2017 and December 31, 2016, 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 amount outstanding under our bank debt facilities is measured at carrying value in our accompanying balance sheets. Our bank debt facilities are valued using Level 2 inputs. The estimated fair value of our bank debt facilities approximates their carrying value. 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, 2017 and the year ended December 31, 2016, there were no transfers between levels. As of September 30, 2017 and December 31, 2016, our Level 1 assets measured at fair value by quoted prices in active markets consisted of bank savings accounts and money market funds. As of September 30, 2017 and December 31, 2016, our bank certificates of deposit were classified as Level 2 and were measured by significant other observable inputs. As of September 30, 2017 and December 31, 2016, our interest rate swaps were classified as Level 2 and were measured by observable market data in combination with expected cash flows for each instrument. There were no assets or liabilities measured at fair value on a nonrecurring basis as of September 30, 2017 or December 31, 2016.

	As of September 30, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and money market accounts	$2,305,264	-	-	$2,305,264
Liabilities:				
Interest rate swaps	-	$32,005	-	$32,005

	As of December 31, 2016			
	Level 1	Level 2	Level 3	Total

Assets:				
Cash and money market accounts	$5,150,344	-	-	$5,150,344
Bank certificates of deposit	-	$5,474,013	-	$5,474,013
Liabilities:				
Interest rate swaps	-	$37,346	-	$37,346

(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 nine-month period ended September 30, 2017 or the year ended December 31, 2016.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

(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:

	For the Three-Month Periods Ended September 30,		**For the Nine-Month Periods Ended September 30,**	
	2017	2016	2017	2016
Patterson Companies, Inc.	44 %	40 %	42 %	39 %
AmerisourceBergen Corporation	22 %	18 %	23 %	20 %
ANIMART LLC [1]	10 %	11 %	*	*

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, 2017	**As of December 31, 2016**
Patterson Companies, Inc.	52 %	31 %
AmerisourceBergen Corporation	20 %	33 %

[1] 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 when four criteria are met. 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 do not bill for or collect sales tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We generally have experienced an immaterial amount of product returns. However, during the nine-month period ended September 30, 2017, we experienced returns with an aggregated sales value of approximately $10,720, which costs were accounted for as an increase to costs of goods sold.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

(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 $47,863 and $88,017 during the nine-month periods ended September 30, 2017 and 2016, 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.

(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 2016 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, 2017 or December 31, 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 $46,922 and $21,360 during the three-month periods ended September 30, 2017 and 2016, respectively, and $148,035 and $50,312 during the nine-month periods ended September 30, 2017 and 2016,

respectively.

(o) Net (Loss) Income Per Common Share

Net (loss) income per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share.* The net (loss) per share has been computed by dividing the net (loss) by the weighted average number of common shares outstanding during the period. All stock options have been excluded from the denominator in the calculation of dilutive earnings per share when we are in a loss position, as the inclusion would be anti-dilutive. The basic net income per share has been computed by dividing net income by the weighted average number of common shares outstanding during the 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:

	For the Three-Month Periods Ended September 30,		**For the Nine-Month Periods Ended September 30,**	
	2017	2016	2017	2016
Weighted average number of shares outstanding	4,992,803	4,182,529	4,896,782	4,065,243
Effect of dilutive stock options	-	119,751	102,463	113,938
Diluted number of shares outstanding	4,992,803	4,302,280	4,999,245	4,179,181
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	367,000	20,000	63,000	22,000

(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 valuation, valuation of goodwill and long-lived assets, accrued expenses, costs of goods sold, and useful lives of intangible assets.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (continued)

(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 full or modified retrospective method. We intend to utilize the modified retrospective method and have made a preliminary evaluation of the effect that ASU 2014-09 would have on our financial statements and related disclosures and do not expect ASU 2014-09 to 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. Based on our current lease agreements, 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.

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill And Other (Topic 350)*: *Simplifying The Test For Goodwill Impairment*, in an effort to simplify the subsequent measurement of goodwill and the associated procedures to determine fair value. The guidance eliminates Step 2 from the goodwill impairment test. Instead, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of the reporting unit with its carrying amount, and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, not to exceed the total amount of goodwill allocated to the reporting unit. This guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within that reporting period. The adoption of this guidance is not expected to have a material impact on our financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718) Scope of Modification Accounting* to provide clarity and reduce both diversity in practice and cost complexity when applying the guidance in Topic 718 to a change to the terms and conditions of a stock-based payment award. ASU 2017-09 also provides guidance about the types of changes to the terms or conditions of a share-based payment award that require an entity

to apply modification accounting in accordance with Topic 718. The standard is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted. We are currently evaluating the effect this standard will have on our financial statements and related disclosures, but we do not expect the impact to be significant.

3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash, cash equivalents and short-term investments (at amortized cost plus accrued interest) consisted of the following:

	As of September 30, 2017	**As of December 31, 2016**	(Decrease)
Cash and cash equivalents	$ 2,305,264	$ 5,150,344	($ 2,845,080)
Short-term investments	-	5,474,013	(5,474,013)
Total	$ 2,305,264	$ 10,624,357	($ 8,319,093)

Held to maturity securities (certificates of deposit) are carried at amortized cost. Short-term investments were liquidated to finance the investment in our Nisin production facility. 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.

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Notes to Unaudited Condensed Financial Statements (continued)

The fair value of held to maturity securities consisted of the following:

	As of September 30, 2017	As of December 31, 2016	(Decrease) Increase
Amortized cost	-	$ 5,450,000	($5,450,000)
Accrued interest	-	24,013	(24,013)
Gross unrealized gains	-	2,073	(2,073)
Gross unrealized losses	-	(59)	59
Estimated fair value	-	$ 5,476,027	($5,476,027)

4. INVENTORY

Inventory consisted of the following:

	As of September 30, 2017	As of December 31, 2016	Increase (Decrease)
Raw materials	$ 507,606	$ 318,443	$ 189,163
Work-in-process	1,602,861	968,810	634,051
Finished goods	621,558	839,646	(218,088)
Total	$ 2,732,025	$ 2,126,899	$ 605,126

5. ACCOUNTS RECEIVABLE

Accounts receivable consisted of the following:

	As of September 30, 2017	As of December 31, 2016	(Decrease) Increase
Trade accounts receivable, gross	$ 872,602	$ 1,013,716	($ 141,114)
Allowance for bad debt and product returns	(3,683)	(21,326)	17,643
Trade accounts receivable, net	$ 868,919	$ 992,390	($ 123,471)

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of September 30, 2017	As of December 31, 2016	Increase (Decrease)
Prepaid expenses	$ 190,678	$ 126,523	$ 64,155
Other receivables	125,691	144,848	(19,157)
Security deposits[(1)]	45,430	333,111	(287,681)
Total	$ 361,799	$ 604,482	($ 242,683)

[(1)] As of September 30, 2017 and December 31, 2016, this amount is comprised of $45,430 and $308,375, respectively, related to the current portion of escrow funds held against certain construction performance requirements.

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Notes to Unaudited Condensed Financial Statements (continued)

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

	Estimated Useful Lives (in years)	As of September 30, 2017	As of December 31, 2016	(Decrease) Increase
Laboratory and manufacturing equipment	3-10	$ 5,512,098	$ 5,562,938	($ 50,840)
Building and improvements	10-33	5,387,614	5,037,512	350,102
Office furniture and equipment	3-10	697,585	653,462	44,123
Construction in progress		17,111,445	3,694,509	13,416,936
Land		518,998	347,114	171,884
Property, plant and equipment, gross		29,227,740	15,295,535	13,932,205
Accumulated depreciation		(5,684,250)	(5,449,242)	(235,008)
Property, plant and equipment, net		$ 23,543,490	$ 9,846,293	$ 13,697,197

Construction in progress consisted principally of costs incurred in connection with the building and equipping of our Nisin production plant. Approximately $431,970 and $0 of property, plant and equipment was disposed of during the nine-month periods ended September 30, 2017 and 2016, respectively.

8. BUSINESS ACQUISITION

On January 4, 2016, we acquired certain business assets and processes 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. Additionally, subject to USDA approval, our new product, **First Defense®Tri-Shield™**, will be sold in this

format because the additional antibodies would not fit in the bolus. 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. There are also royalty payments owed based on a percentage of sales made through December 31, 2018, which are due semi-annually in January and July. There is no limit to the royalty amount. As of January 4, 2016, we estimated the aggregate royalties to be paid would be approximately $67,000, which was recorded in accounts payable and accrued expenses. The amount due was estimated to be approximately $25,000 and $30,000 as of September 30, 2017 and December 31, 2016, respectively, which was recorded in accounts payable and accrued expenses as of those dates. Royalty payments of $4,892 and $8,200 were made for sales recorded during the six-month period ended June 30, 2017 and the year ended December 31, 2016, respectively. The estimated fair values of the assets purchased in this transaction included inventory of approximately $113,000, machinery and equipment of approximately $132,000, a developed technology intangible of approximately $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 approximately $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 assets acquired in accordance with our policies. The impact of the acquisition on our pro forma prior year operations is not material. As of December 31, 2016, we vacated the rented facility in Minnesota that had been used to produce the gel solution format of our product and certain other related private-label products. This resulted in the termination of employment of four employees, as these production functions were consolidated into our Portland facility, which enables us to better utilize existing infrastructure and larger scale equipment to improve operating efficiencies.

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Notes to Unaudited Condensed Financial Statements (continued)

9. INTANGIBLE ASSETS

The intangible assets described in Note 8 are being amortized to cost of goods sold over their useful lives, which are estimated to be 10 years. Intangible amortization expense was $4,776 and ($133) during the three-month periods ended September 30, 2017 and 2016 and $14,328 and $15,309 during the nine-month periods ended September 30, 2017 and 2016, respectively. The net value of these intangibles was $157,608 as of September 30, 2017. A summary of intangible amortization expense estimated for the periods subsequent to September 30, 2017 is as follows:

Period	**Amount**
Three months ending December 31, 2017	$4,776
Year ending December 31, 2018	19,104
Year ending December 31, 2019	19,104
Year ending December 31, 2020	19,104
Year ending December 31, 2021	19,104
After December 31, 2021	76,416
Total	$157,608

Intangible assets as of September 30, 2017 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	**Net Book Value**
Developed technology	$184,100	$ (32,218)	$151,882
Customer relationships	1,300	(227)	1,073
Non-compete agreements	5,640	(987)	4,653
Total	$191,040	$ (33,432)	$157,608

Intangible assets as of December 31, 2016 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	**Net Book Value**
Developed technology	$184,100	$ (18,410)	$165,690
Customer relationships	1,300	(130)	1,170
Non-compete agreements	5,640	(564)	5,076
Total	$191,040	$ (19,104)	$171,936

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of September 30, 2017	**As of December 31, 2016**	**Increase**
Accounts payable – capital	$ 2,536,151	$ 1,249,862	$1,286,289
Accounts payable – trade	300,167	257,397	42,770
Accrued payroll	233,045	200,477	32,568
Accrued professional fees	106,525	82,500	24,025
Accrued other	255,773	101,527	154,246
Total	$ 3,431,661	$ 1,891,763	$1,539,898

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Notes to Unaudited Condensed Financial Statements (continued)

11. BANK DEBT

We have in place five credit facilities and a line of credit with TD Bank N.A. The first note (Loan #1) is not to exceed 80% of the appraised value of our corporate headquarters and production and research facility at 56 Evergreen Drive in Portland. Proceeds of $1.0 million were received during the third quarter of 2010 with monthly principal and interest payments due for ten years. Based on a fifteen-year amortization schedule, a balloon principal payment of $451,885 will be due during the third quarter of 2020. As of September 30, 2017, $643,368 was outstanding under this first note. Proceeds from a $2.5 million second mortgage on this first note (Loan #2) were received during the third quarter of 2015 with monthly principal and interest payments due for ten years. Based on a twenty-year amortization schedule, a balloon principal payment of approximately $1.55 million will be due during the third quarter of 2025. As of September 30, 2017, $2,341,144 was outstanding under Loan #2. During the first quarter of 2016, we entered into two additional credit facilities aggregating up to approximately $4.5 million. As a result of loan amendments entered into the during the first quarter of 2017, these two credit facilities were increased to up to $6.5 million, subject to certain restrictions set forth in the agreements. The third note (Loan #3) is comprised of a construction loan of up to $3.94 million and not to exceed 80% of the cost of the equipment to be installed in our commercial-scale Nisin production facility at 33 Caddie Lane in Portland. As amended, interest only will be payable at a variable rate equal to the one-month LIBOR plus a margin of 2.25% (which was equal to 3.485% as of September 30, 2017) through September 2018, at which time the loan converts to a seven-year term loan facility at the same variable interest rate with monthly principal and interest payments due based on a seven-year amortization schedule. As of September 30, 2017, $2,684,343 was outstanding under this third note, and $1,255,657 was available to be drawn generally at the same time as when the remaining project disbursements are made. The fourth note (Loan #4) is comprised of a construction loan of up to $2.56 million and not to exceed 80% (75% prior to the 2017 amendments) of the appraised value of our commercial-scale Nisin production facility. As amended, interest only will be payable at a variable rate equal to the one-month LIBOR plus a margin of 2.25% (which was equal to 3.485% as of September 30, 2017) through March 2018, at which time the loan converts to a term loan facility at the same variable interest rate with monthly principal and interest payments due for ten years. Based on a twenty-year amortization schedule, a balloon principal payment of approximately $1.62 million will be due during the first quarter of 2027. As of September 30, 2017, there were no proceeds outstanding under this fourth note, and $2.56 million was available to be drawn generally at the same time as when the remaining project disbursements are made. The fifth note (Loan #5) is a mortgage that is secured by the 4,114 square foot warehouse and storage facility we acquired adjacent to our Nisin production facility. Proceeds of $340,000 were received during the first quarter of 2017. This note bears interest at a variable rate equal to the one-month LIBOR plus a margin of 2.25% (which was equal to 3.485% as of September 30, 2017) with monthly principal and interest payments due for ten years. Based on a twenty-year amortization schedule, a balloon principal payment of approximately $199,000 will be due during the first quarter of 2027. As of September 30, 2017, $334,216 was outstanding under this fifth note.

We hedged our interest rate exposures on Loan #1 and Loan #2 with interest rate swap agreements that effectively converted floating interest rates based on the one-month LIBOR plus a margin of 3.25% and 2.25% to the fixed rates of 6.04% and 4.38%, respectively. As of September 30, 2017, the variable rates on these two mortgage notes were 4.49% and 3.49%, 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 (loss) income, 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 $2,984,512 as of September 30, 2017. 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*.

	For the Three-Month Periods Ended September 30,	
	2017	2016
Payments required by interest rate swaps	$8,115	$14,470
Other comprehensive income, net of taxes	$1,824	$15,523

	For the Nine-Month Periods Ended September 30,	
	2017	2016
Payments required by interest rate swaps	$29,834	$ 44,653
Other comprehensive income (loss), net of taxes	$3,419	($79,767)

In connection with the credit facilities entered into during the third quarters of 2010 and 2015, we incurred debt issue costs of $26,489 and $34,125, respectively. In connection with the credit facilities entered into during the first quarters of 2016 and 2017, we incurred debt issue costs of $46,734 and $63,358, respectively. The 2017 amendments to the 2016 agreements were accounted for as modifications. All debt issuance costs are being recorded as a component of other expenses and are being amortized over the terms of the respective credit facilities.

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Notes to Unaudited Condensed Financial Statements (continued)

These five credit facilities are secured by substantially all of our assets and are subject to certain restrictions and financial covenants. Principal payments (net of debt issuance costs) due under bank loans outstanding as of September 30, 2017 (excluding our $500,000 line of credit) are reflected in the following table by the year that payments are due:

	Three-month period ending 12/31/2017	**Year ending 12/31/2018**	**Year ending 12/31/2019**	**Year ending 12/31/2020**	**Year ending 12/31/2021**	**After 12/31/2021**	Total
Loan #1	$ 15,888	$ 64,876	$ 68,908	$ 493,696	-	-	$643,368
Loan #2	21,279	86,097	89,997	94,005	98,538	1,951,228	2,341,144
Loan #3[(1)]	-	85,036	347,638	359,949	372,695	1,519,025	2,684,343
Loan #4	-	-	-	-	-	-	-
Loan #5[(1)]	3,005	12,283	12,718	13,169	13,635	279,406	334,216
Debt Issuance Costs	(4,122)	(16,489)	(16,489)	(15,855)	(14,841)	(63,077)	(130,873)
	$ 36,050	$ 231,803	$ 502,772	$ 944,964	$ 470,027	$3,686,582	$5,872,198

[(1)] These notes bear interest at a variable rate equal to the one-month LIBOR plus a margin of 2.25%. Figures in this table are estimated using an interest rate of approximately 3.485%. The actual interest rate and principal payments will be different.

During the third quarter of 2010, we entered into a $500,000 line of credit with TD Bank N.A., which is secured by substantially all of our assets and is subject to certain restrictions and financial covenants. This line of credit has been renewed approximately annually since then and is available as needed and has been extended through May 31, 2018. There was no outstanding balance under this line of credit as of September 30, 2017 or December 31, 2016. Interest on borrowings against the line of credit are 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 (File No. 333-207635) with the Securities and Exchange Commission (SEC) for the potential issuance of up to $10,000,000 in equity securities (subject to certain limitations). This registration statement became effective on November 10, 2015. Under this form of registration statement, we are limited within a twelve-month period to raising gross proceeds of no more than one-third of the market capitalization of our common stock (as determined by the high price or our common stock within the preceding 60 days leading up to a sale of securities) held by non-affiliates (non-insiders) of the Company.

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 pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately $5,900,000 and resulting in net proceeds to the Company of approximately $5,313,000 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

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 approximately $3,464,000 and resulting in net proceeds to the Company of approximately $3,161,000 (after deducting placement agent fees and other expenses incurred in connection with the equity financing).

On July 27, 2017, we issued 200,000 shares of our common stock at a price of $5.25 per share to two related investors pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of $1,050,000 and resulting in net proceeds of approximately $1,037,000 (after deducting estimated expenses incurred in connection with the equity financing).

At the June 15, 2016 Annual Meeting of Stockholders, we reported that 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. After careful consideration, we determined that the method of voting instructions described in our Proxy Statement was not consistent with the way the votes were actually recorded in accordance with stock exchange rules. Therefore, during the second quarter of 2017, we elected to treat the amendment as ineffective, and there was no increase in our authorized common stock. As of September 30, 2017, we had 8,000,000 authorized shares of common stock.

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Notes to Unaudited Condensed Financial Statements (continued)

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. The 2010 Plan expires in June 2020, after which date no further options could be granted under the 2010 Plan. However, options outstanding under the 2010 Plan at that time could be exercised in accordance with their terms.

In June 2017, our stockholders approved the 2017 Stock Option and Incentive Plan (the "2017 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 2017 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 2017 Plan expire no later than ten years from the date of grant. The 2017 Plan expires in March 2027, after which date no further options could be granted under the 2017 Plan. However, options outstanding under the 2017 Plan at that time could be exercised in accordance with their terms. Activity under the stock option plans described above was as follows:

	2000 Plan	2010 Plan	2017 Plan	Weighted Average Exercise Price	Aggregate Intrinsic Value[1]
Outstanding at December 31, 2015	131,500	106,500	-	$ 3.57	$ 945,000
Grants	-	46,000	-	$ 6.98	
Terminations	(5,000)	(12,000)	-	$ 6.16	
Exercises	-	(16,000)	-	$ 5.59	
Outstanding at December 31, 2016	126,500	124,500	-	$ 3.89	$ 517,000
Grants	-	138,000	-	$ 5.85	
Terminations	(5,000)	(13,000)	-	$ 5.58	
Exercises	(3,000)	(1,000)	-	$ 4.13	
Outstanding at September 30, 2017	118,500	248,500	-	$ 4.54	$ 718,000
Vested at September 30, 2017	118,500	42,500	-	$ 2.64	$ 621,000
Vested and expected to vest at September 30, 2017	118,500	248,500	-	$ 4.54	$ 718,000
Reserved for future grants	-	30,500	300,000		

[1] Intrinsic value is the difference between the fair market value as of the date indicated and as of the date of the option grant.

During the nine-month period ended September 31, 2017, three employees exercised stock options covering 4,000 shares for cash, resulting in total proceeds of $16,500. During the year ended December 31, 2016, one employee and one director exercised stock options covering the aggregate of 16,000 shares, of which 6,000 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. As of September 30, 2017, 367,000 shares of common stock were reserved for future issuance under all outstanding stock options described above, an additional 30,500 shares of common stock were reserved for the potential issuance of stock option grants in the future under the 2010 Plan and an additional 300,000 shares of common stock were reserved for the potential issuance of stock option grants in the future under the 2017 Plan.

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Notes to Unaudited Condensed Financial Statements (continued)

The weighted average remaining life of the options outstanding under the 2000 Plan and the 2010 Plan as of September 30, 2017 was approximately five years and eight months. The weighted average remaining life of the options exercisable under these plans as of September 30, 2017 was approximately one year and nine months. The exercise prices of the options outstanding as of September 30, 2017 ranged from $1.70 to $8.21 per share. The 138,000 stock options granted during the nine-month period ended September 30, 2017 had exercise prices between $5.33 and $6.23 per share. The 46,000 stock options granted during 2016 had exercise prices between $6.27 and $8.21 per share. The aggregate intrinsic value of options exercised during 2017 and 2016 approximated $7,340 and $32,000, respectively. The weighted-average grant date fair values of options granted during 2017 and 2016 were $3.47 and $4.16 per share, respectively. As of September 30, 2017, total unrecognized stock-based compensation related to non-vested stock options aggregated $484,575, which will be recognized over a weighted average period of two years and six months. 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, 2017 and for the year ended December 31, 2016:

	For the Three-Month Period Ended September 30, 2017	**For the Nine-Month Period Ended September 30, 2017**	**For the Year Ended December 31, 2016**
Risk-free interest rate	1.9%	1.9%	1.2%
Dividend yield	0%	0%	0%
Expected volatility	61%	61%	63%
Expected life	6.5 years	6.5 years	6.5 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.

Common Stock Rights Plan

In September 1995, our Board of Directors adopted a Common Stock Rights Plan (the “Rights Plan”) and declared a dividend of one common share purchase right (a “Right”) for each of the then outstanding shares of the common stock of the Company. Each Right entitles the registered holder to purchase from the Company one share of common stock at an initial purchase price of $70.00 per share, subject to adjustment. The description and terms of the Rights are set

forth in a Rights Agreement between the Company and American Stock Transfer & Trust Co., as Rights Agent.

The Rights (as amended) become exercisable and transferable apart from the common stock upon the earlier of i) 10 days following a public announcement that a person or group (Acquiring Person) has, without the prior consent of the Continuing Directors (as such term is defined in the Rights Agreement), acquired beneficial ownership of 20% or more of the outstanding common stock or ii) 10 days following commencement of a tender offer or exchange offer the consummation of which would result in ownership by a person or group of 20% or more of the outstanding common stock (the earlier of such dates being called the Distribution Date).

Upon the Distribution Date, the holder of each Right not owned by the Acquiring Person would be entitled to purchase common stock at a discount to the initial purchase price of $70.00 per share, effectively equal to one half of the market price of a share of common stock on the date the Acquiring Person becomes an Acquiring Person. If, after the Distribution Date, the Company should consolidate or merge with any other entity and the Company were not the surviving company, or, if the Company were the surviving company, all or part of the Company's common stock were changed or exchanged into the securities of any other entity, or if more than 50% of the Company's assets or earning power were sold, each Right would entitle its holder to purchase, at the Rights' then-current purchase price, a number of shares of the acquiring company's common stock having a market value at that time equal to twice the Right's exercise price.

At any time after a person or group becomes an Acquiring Person and prior to the acquisition by such person or group of 50% or more of the outstanding common stock, the Board of Directors of the Company may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of common stock per Right (subject to adjustment). At any time prior to 14 days following the date that any person or group becomes an Acquiring Person (subject to extension by the Board of Directors), the Board of Directors of the Company may redeem the then outstanding Rights in whole, but not in part, at a price of $0.005 per Right, subject to adjustment.

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Notes to Unaudited Condensed Financial Statements (continued)

On June 8, 2005, our Board of Directors voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years, to September 19, 2008. As of June 30, 2005, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. On June 6, 2008 our Board of Directors voted to authorize an amendment of the Rights Agreement to extend the Final Expiration Date by an additional three years, to September 19, 2011 and to increase the ownership threshold for determining "Acquiring Person" status from 15% to 18%. As of June 30, 2008, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase. On August 5, 2011, our Board of Directors voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2014 and to increase the ownership threshold for determining "Acquiring Person" status from 18% to 20%. As of August 9, 2011, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension and threshold increase. On June 10, 2014, our Board of Directors voted to authorize an amendment to the Rights Agreement to extend the Final Expiration Date by an additional three years to September 19, 2017. As of June 16, 2014, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. During the second quarter of 2015, we amended our Common Stock Rights Plan by removing a provision that prevented a new group of directors elected following the emergence of an Acquiring Person (an owner of more than 20% of our stock) from controlling the Rights Plan by maintaining exclusive authority over the Rights Plan with pre-existing directors. We did this because such provisions have come to be viewed with disfavor by Delaware courts. On June 15, 2017, our Board of Directors voted to authorize an amendment to the Rights Agreement to extend the Final Expiration Date by an additional five years to September 19, 2022. As of August 10, 2017, we entered into an amendment to the Rights Agreement with the Rights Agent reflecting such extension. No other changes have been made to the terms of the Rights or the Rights Agreement.

13. OTHER EXPENSES, NET

Other expenses, net, consisted of the following:

	For the Three-Month Periods Ended September 30,		**For the Nine-Month Periods Ended September 30,**	
	2017	2016	2017	2016
Interest expense	$53,168	$41,452	$136,563	$123,292

Interest income	(2,983)	(16,980)	(15,358)	(43,725)
Other gains	(947)	2,038	(5,328)	1,628
Other expenses, net	$49,238	$26,510	$115,877	$81,195

14. INCOME TAXES

Our income tax (benefit) aggregated ($192,303) and ($10,913) (amounting to 36% and 46% of our (loss) income before income taxes, respectively) for the three-month periods ended September 30, 2017 and 2016, respectively. Our income tax expense aggregated $28,108 and $211,537 (amounting to 51% and 31% of our income before income taxes, respectively) for the nine-month periods ended September 30, 2017 and 2016, respectively. As of September 30, 2017, we had federal general business tax credit carryforwards of approximately $285,000 that expire in 2032 through 2037 (if not utilized before then) and state tax credit carryforwards of approximately $184,000 that expire in 2023 through 2037 (if not utilized before then). The $965,000 licensing payment that we made during the fourth quarter of 2004 was treated as an intangible asset and is being amortized over 15 years, for tax return purposes only. Approximately $1,112,000 of our investment in a small-scale facility to produce the Drug Substance (our Active Pharmaceutical Ingredient, Nisin) was expensed as incurred for our books. Included in this amount is approximately $820,000 that was capitalized and is being depreciated over statutory periods for tax return purposes only.

The provision for income taxes is determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the estimated future tax effects of temporary differences between book and tax treatment of assets and liabilities and carryforwards to the extent they are realizable. We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. While we consider future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of the net recorded amount, a reduction of the valuation allowance would increase income in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax asset in the future, a reduction to the deferred tax asset would be charged to income in the period such determination was made.

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Notes to Unaudited Condensed Financial Statements (continued)

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 2013. 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.

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, 2017. 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 are aware of no such claims against us as of the date of this filing. We feel that we have reasonable levels of liability insurance to support our operations.

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, 2017.

We are committed to purchasing certain key parts (syringes) and services (formulation, filling and packaging of Drug Product) pertaining to our mastitis product 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 under one of such agreements.

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 (**First Defense® Tri-Shield™**) that is under development. This perpetual license (if not terminated for cause) is subject to a milestone payment of $150,000 due within 90 days of regulatory approval and a royalty equal to 4% of sales above current sales of our bivalent product plus a growth assumption.

During the third quarter of 2016, we initiated construction of our Nisin production facility. The estimated total cost of the Nisin facility is approximately $20,803,000. As of September 30, 2017, we had incurred approximately $17,106,000 of capital expenditures related to this project, of which $14,570,000 had been paid as of the end of the quarter. The majority of the remainder of this investment is expected to be paid during the three-month period ending December 31, 2017. As of September 30, 2017, we had committed $4,516,000 of the remaining $6,233,000 expected to be paid on this project. Approximately $2,605,000 of these capital expenditures is committed under a guaranteed maximum price contract with our construction management firm, net of payments made. 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. We expect to fund the remaining costs in excess of our current cash and investments with borrowings under the credit facilities described in Note 11. In addition to the commitments related to our Nisin production facility discussed above, we had committed $441,000 to the production of inventory and $134,000 to other obligations as of September 30, 2017.

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Notes to Unaudited Condensed Financial Statements (continued)

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 dairy and beef cattle. 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. Our single operating segment is defined as the component of our business for which financial information is available and evaluated regularly by our chief operating decision-maker in deciding how to allocate resources and in assessing performance. Our chief operating decision-maker is our President and CEO.

Sales of the **First Defense®** product line aggregated 98% and 93% of our total product sales during the three-month periods ended September 30, 2017 and 2016, respectively, and 94% and 93% of our total product sales during the nine-month periods ended September 30, 2017 and 2016, respectively. Our primary customers for the majority of our product sales (87% and 83% during the three-month periods ended September 30, 2017 and 2016, respectively, and 83% and 85% during the nine-month periods ended September 30, 2017 and 2016, 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 13% and 17% of our total product sales during the three-month periods ended September 30, 2017 and 2016, respectively, and 15% and 14% of our total product sales during the nine-month periods ended September 30, 2017 and 2016, 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®** and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased $465,670 and $476,311 of products from ImmuCell during the nine-month periods ended September 30, 2017 and 2016, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of $3,168 and $2,925 to these affiliate companies during the nine-month periods ended September 30, 2017 and 2016, respectively, that were expensed as incurred. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated $27,909 and $3,221 as of September 30, 2017 and December 31, 2016, respectively.

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 $21,083 and $17,642 into the plan during the three-month periods ended September 30, 2017 and 2016, respectively, and $64,105 and $55,209 during the nine-month periods ended September 30, 2017 and 2016, respectively.

19. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of filing on November 13, 2017, 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 November 13, 2017, we announced that we achieved regulatory approval of **First Defense® Tri-Shield™**, our new trivalent scours preventative product.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed financial statements and the related notes and other financial information included in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. One should review **Part II -**"Other Information", **Item 1A -**"Risk Factors" of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Liquidity and Capital Resources

We have funded most of our product development and other operating expenses principally from our gross margin on product sales. We were profitable during the six-month period ended December 31, 2014 and during the years ended December 31, 2015 and 2016 and during the nine-month period ended September 30, 2017. The table below summarizes the changes in selected, key accounts (in thousands, except for percentages):

	As of September 30, 2017	As of December 31, 2016	(Decrease) Increase Amount	%
Cash, cash equivalents and short-term investments	$ 2,305	$ 10,624	$(8,319)	(78)%
Net working capital	$ 2,691	$ 12,289	$(9,598)	(78)%
Total assets	$ 30,290	$ 24,697	$5,593	23 %
Stockholders' equity	$ 20,954	$ 19,722	$1,232	6 %
Common shares outstanding	5,051	4,847	204	4 %

Net cash provided by operating activities amounted to $845,000 during the nine-month period ended September 30, 2017 in comparison to net cash provided by operating activities of $150,000 during the nine-month period ended September 30, 2016. Capital investments totaled $13.1 million during the nine-month period ended September 30, 2017 compared to capital investments of $1.8 million (which amount did not include approximately $470,000 related to a business acquisition) during the nine-month period ended September 30, 2016.

During the first and fourth quarters of 2016, we issued an aggregate of approximately 1.8 million shares of common stock, raising net proceeds of approximately $8.5 million in two separate transactions. During the third quarter of 2017, we issued 200,000 shares of common stock, raising net proceeds of just over $1.0 million.

We have in place five credit facilities and a line of credit with TD Bank N.A. During the third quarters of 2010 and 2015, we agreed to terms of two credit facilities. As of September 30, 2017, approximately $3.0 million was outstanding under these two loan agreements. During the first quarter of 2016, we entered into two additional bank debt agreements covering two additional credit facilities aggregating up to approximately $4.5 million. During the first quarter of 2017, we amended these two agreements to increase the total amount of debt available to up to approximately $6.5 million. As of September 30, 2017, approximately $2.7 million was outstanding under these two loan agreements, and approximately $3.8 million was available to be drawn generally at the same time as when the remaining project disbursements are made. During the first quarter of 2017, we acquired a 4,114 square foot warehouse and storage facility that is adjacent to our Nisin production facility. We financed the purchase price of $465,500, in part, with a mortgage loan in the amount of $340,000. As of September 30, 2017, approximately $334,000 was outstanding under this loan agreement. We have a $500,000 line of credit that is available as needed through May 31, 2018 and subject to extension by the bank after that date. No amounts were outstanding under the line of credit as of September 30, 2017. These credit facilities are subject to certain restrictions and financial covenants and are secured by substantially all of our assets, including our corporate headquarters and production and research facility at 56 Evergreen Drive in Portland, which was independently appraised at $4.2 million in connection with the 2015 financing. Based on our unaudited results, we are in compliance with all applicable covenants as of September 30, 2017.

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During the third quarter of 2016, we initiated construction of our Nisin production facility. The estimated total cost of the Nisin facility is approximately $20.8 million. This cost estimate has increased by approximately 4% from the $20 million estimate as of September 30, 2016 and by approximately 3% from the most recent cost estimate as of June 30, 2017. While we negotiate to control cost increases at every opportunity, such increases are to be expected on an investment of this size as project requirements are finalized. Expenditures on this project are heavily weighted to the six-month period ending December 31, 2017. We are substantially complete with construction of the building shell and have made significant progress on the interior of the building. We began equipment installation during the third quarter of 2017. We expect to fund the estimated costs to complete the project of approximately $6.2 million that are in excess of our current cash and investments (which was equal to approximately $2.3 million as of September 30, 2017) with available borrowings (aggregating up to approximately $4.3 million) under the credit facilities and line of credit, described above. 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 for its intended purpose (which is to produce Nisin), which will likely be by the second quarter of 2018. We anticipate that depreciation expense, while not affecting our cash flows from operations, will result in net operating losses until product sales increase sufficiently to offset these non-cash expenses. The following table details the expected amount and timing of this investment:

Period	Amount
Paid through December 31, 2016	$2,080,000 (1)
Paid during the nine-month period ended September 30, 2017	12,489,000 (2)
Estimate to be paid after September 30, 2017	6,234,000 (3)
Estimated total cost of investment	$20,803,000 (4)

(1) This amount does not include approximately $1,250,000 that was capitalized as of December 31, 2016 but not paid until the first quarter of 2017.

(2) This amount includes approximately $1,250,000 that was capitalized as of December 31, 2016 but paid during the first quarter of 2017. This amount does not include approximately $2,536,000 that was capitalized as of September 30, 2017 but not paid until the fourth quarter of 2017.

(3) This amount includes approximately $2,536,000 that was capitalized as of September 30, 2017 but paid during the fourth quarter of 2017.

(4) 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.

Our capital expenditure investments from January 1, 2014 through September 30, 2017 have been larger than our historical norm due to investments to increase our production capacity for the **First Defense®** product line and to

construct and equip our Nisin production facility. During the nine-month period ended September 30, 2017, we invested approximately $121,000 in routine and necessary capital expenditures, which does not include payments pertaining to the Nisin production facility, described above. As of October 1, 2017, we had additional authorization from our Board of Directors to invest up to approximately $29,000 through December 31, 2017 in routine and necessary capital expenditures, which is in addition to payments made pertaining to the Nisin production facility, described above. We believe that our cash, together with gross margin to be earned from ongoing product sales and available bank debt, is sufficient to meet our working capital and capital expenditure requirements and to finance our ongoing business operations during at least the next twelve months.

During the early part of 2015, we invested $644,000 to complete a 7,100 square foot addition to our Portland facility, providing cold storage, production and warehouse space required to increase our manufacturing capacity. Construction of the facility addition was initiated at the end of the third quarter of 2014. The total cost of this project was $1,914,000. We completed an investment to increase our liquid processing capacity by 50% during the fourth quarter of 2015 and an investment to increase our freeze-drying capacity by 100% at the end of the first quarter of 2016. During 2015, we invested $1,379,000 in these production capacity increases and $430,000 in other capital expenditures. During 2016, we invested $1,161,000 to complete these production capacity increases and $345,000 in other capital expenditures.

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 Nisin production facility that we are constructing by 65% over the eleven-year period ending June 30, 2028 and by 30% during the year ending June 30, 2029, at which time the rebate expires. During the second quarter of 2017, the TIF was approved 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 assessed value of approximately $1,651,000 as of April 1, 2017 for the building in process of being completed, the TIF will reduce our property taxes by approximately $23,000 for the year ending June 30, 2018. The value of the tax savings would increase in proportion to the increase in the assessment of the building 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.

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Results of Operations

Product Sales

Total product sales during the three-month period ended September 30, 2017 increased by 2%, or $37,000, to $2,005,000 from $1,968,000 during the same period in 2016, with domestic product sales increasing by 7%, or $121,000, and international product sales decreasing by 25%, or $85,000, in comparison to the same period during 2016. Sales of the discontinued topical wipes product line aggregated approximately $57,000 during the three-month period ended September 30, 2016. Sales during the third quarter of 2016 included the shipments of orders worth $365,000 that were in backlog as of June 30, 2016, as the backlog of orders at that time was being cleared. Since the third quarter of 2016, we have had sufficient available inventory and are shipping in accordance with the current demand of our distributors. We believe that the 25% decrease (only $85,000 on a dollar basis) in international sales during the third quarter was largely a timing difference, as most of our international orders tend to be received in larger amounts less frequently. Total product sales during the nine-month period ended September 30, 2017 decreased by less than 1%, or $32,000, to $7,298,000 from $7,330,000 during the same period in 2016, with domestic product sales decreasing by 3%, or $172,000, and international product sales increasing by 14%, or $140,000, in comparison to the same period during 2016. Sales of the discontinued topical wipes product line aggregated approximately $97,000 and $271,000 during the nine-month periods ended September 30, 2017 and 2016, respectively. Sales during the first nine months of 2016 included the shipments of orders worth $381,000 that were in backlog as of December 31, 2015. Total product sales during the twelve-month period ended September 30, 2017 decreased by 5%, or $512,000, to $9,512,000 from $10,025,000 during the same period ended September 30, 2016, with domestic sales decreasing by 5%, or $436,000, and international sales decreasing by 5%, or $76,000, in comparison to the same period ended September 30, 2016. Sales of the discontinued topical wipes product line aggregated approximately $175,000 and $368,000 during the twelve-month periods ended September 30, 2017 and 2016, respectively. We do expect to record positive sales growth during the three-month period ending December 31, 2017 in comparison to the same period during the prior year.

The **First Defense®**product line (our lead product), continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent scours (diarrhea) in newborn calves. Sales of the **First Defense®**product line aggregated 98% and 93% of our total product sales during the three-month periods ended September 30, 2017 and 2016, respectively. Sales of the **First Defense®** product line during the three-month period ended September 30, 2017 increased by 7% in comparison to the same period during 2016 with domestic sales increasing by 14% and international sales decreasing by 25%, in comparison to the same period during 2016. Sales of the **First Defense®** product line aggregated 94% and 93% of our total product sales during the nine-month periods ended September 30, 2017 and 2016, respectively. Sales of the **First Defense®** product line during the nine-month period ended September 30, 2017 increased by 1% in comparison to the same period during 2016 with domestic sales increasing by less than 1% and international sales increasing by 4%, in comparison to the same period during 2016. Sales of the **First**

Defense® product line aggregated 94% and 93% of our total product sales during the twelve-month periods ended September 30, 2017 and 2016, respectively. Sales of the **First Defense®** product line during the twelve-month period ended September 30, 2017 decreased by 4% in comparison to the same period ended September 30, 2016 with domestic sales decreasing by 3% and international sales decreasing by 12%, in comparison to the same period ended September 30, 2016.

We have significantly increased our supply of colostrum, and we completed the investments necessary to increase our liquid processing capacity by 50% during the fourth quarter of 2015 and our freeze drying capacity by 100% during the first quarter of 2016. The prolonged period of order backlog (which began early in 2015 and extended through the middle of 2016) disrupted normal shipping patterns. During this period when demand outpaced our production capacity, we were forced to allocate product to customers, and more product was allocated to domestic distributors. With our production capacity expanded, current demand now has been fully met, and we are working to grow sales.

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 to help us introduce the expanding **First Defense®**product line to new customers. Our sales and marketing team currently consists of one vice president, six regional managers and one inside sales and marketing employee. We launched a 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 and competitive return on investment for dairy and beef producers. Preventing newborn calves from becoming sick helps them to reach their genetic potential and reduces the need to use treatment antibiotics later in life. We are expanding this message by suggesting that producers can go **Beyond Vaccination™** to prevent scours with our new product, **First Defense® Tri-Shield™**, which is expected to launch (subject to USDA approval) during the fourth quarter of 2017. This product enables producers to prevent scours at the calf-level without needing a dam-level scours vaccine. By our estimates, in certain cases, when our product replaces all costs associated with dam-level scours vaccination programs, the producer can experience a positive return on investment and more consistent calf protection.

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Our product carries USDA-claims against *E. coli* and coronavirus. We compete directly at the calf level against products sold by Boehringer Ingelheim (Bar-Guard-99™), Elanco (Bovine Ecolizer®), Merck (BOVILIS® Coronavirus) and Zoetis (Calf-Guard®). The Boehringer product only has claims against *E. coli* and is derived from horse blood. The Elanco product has claims against *E. coli* and *C. perfringens* and is derived from horse blood. The Merck product is an intranasal vaccine that has claims only against coronavirus. The Zoetis product is an oral vaccine that has claims against coronavirus and rotavirus but not *E. coli*. We estimate that the total market for these calf-level products (including sales of our product) is approximately $17 million. With the anticipated additional claim for our new product (**First Defense® Tri-Shield™**) against rotavirus, we intend to also compete against the dam-level vaccine products that are given to the mother cow to improve the quality of the colostrum that she produces. Those products are sold by Elanco (Scour Bos™), Merck (Guardian®) and Zoetis (ScourGuard®). We estimate that the total market for these dam-level products is approximately two times larger than the market for the calf-level products.

Other competition for resources that dairy producers allocate to their calf enterprises has been increased by the many new products (principally feed supplements) that have been introduced to the calf market. Our sales are normally seasonal, with higher sales expected during the first quarter. Warm and dry weather reduces the producer's perception of the need for a disease preventative product like **First Defense®**. However, heat stress on calves caused by extremely hot summer weather can increase the incidence of scours, just as harsher winter weather benefits our sales. Market conditions in the dairy and beef industries, including milk pricing and prices for calves, weakened during 2016 in comparison to 2015. Milk prices have made modest improvements in 2017 over the annual averages for 2016 and 2015. Despite the significant market volatility affecting both milk prices and feed costs, we achieved a record level of product sales during the first quarter of 2017, surpassing the previous high level set during the first quarter of 2015.

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 colostrum (first milk) protein purification methods, for the nutritional and feed supplement markets without the claims of our USDA-licensed product. Through our **First Defense Technology®**, we are selling concentrated whey proteins in different formats. 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. We are working to achieve USDA claims for this product format during 2018. 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 initiated a limited launch of a tube delivery format of our **First Defense Technology®** in a gel solution. We are working to achieve USDA claims for this product format during the first quarter of 2018, which will be sold as **First Defense® Dual Force™**.

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 until the third quarter of 2014. During 2015, we implemented an increase of

approximately 10% to the selling price of the gel tube format of **First Defense Technology®**. During the middle of 2016, we implemented a price increase of approximately 5% for **First Defense®**and have not increased the selling price again since then. This strategy of limiting our price increases recognizes that while selling a premium-priced product, we must be very efficient with our manufacturing costs to maintain a healthy gross margin.

Sales of products other than the **First Defense®** product line decreased by 64% during the three-month period ended September 30, 2017 in comparison to the same period during 2016. Sales of these other products decreased by 18% during the nine-month period ended September 30, 2017 in comparison to the same period during 2016. Sales of these other products decreased by 15% during the twelve-month period ended September 30, 2017 in comparison to the same period during 2016. Sales of these other products aggregated 2% and 7% of our total product sales during the three-month periods ended September 30, 2017 and 2016, respectively, and 6% and 7% of our total product sales during the nine-month periods ended September 30, 2017 and 2016, respectively, and 6% and 7% of our total product sales during the twelve-month periods ended September 30, 2017 and 2016, respectively. Our other product sales are comprised of four different products. First, we began selling **Wipe Out®Dairy Wipes** (a Nisin-based wipe used to prepare the teat area of a cow for milking) in 1999. During the first quarter of 2013, we initiated sales of Nisin-based wipes for pets (Preva™ wipes) to Bayer HealthCare Animal Health of St. Joseph, Missouri for commercial sales to pet owners. Sales of our Nisin-based topical wipes (our second leading source of animal health product sales prior to 2017) aggregated approximately $350,000 during the year ended December 31, 2016. The topical wipes product line contributed very little to our profits and required a significant portion of our production and storage capacity. Because we believed that the sales growth potential for this product line was limited, we discontinued the production and sale of this product line during the first quarter of 2017. In connection therewith, we realized a net gain of $7,000 during the first quarter of 2017. Second, we acquired several other private label products in connection with our January 2016 acquisition of certain gel formulation technology. During the fourth quarter of 2016, we shut down the manufacturing site in Minnesota that had been used to produce these products and moved these operations to our Portland facility. We are realizing reduced labor and overhead expenses and benefiting from certain other operating efficiencies as a result of this consolidation. In connection with the shutdown of the manufacturing site in Minnesota, we realized a net loss of $27,000 during the fourth quarter of 2016. Third, we sell our own **California Mastitis Test (CMT)** which is used to detect somatic cell counts in milk. Fourth, 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.

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Gross Margin

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

	For the Three-Month Periods Ended September 30,		Decrease	
	2017	2016	Amount	%
Gross margin	$936	$1,205	$(269)	(22)%
Percent of Product sales	47 %	61 %	(15) %	(24)%

	For the Nine-Month Periods Ended September 30,		Decrease	
	2017	2016	Amount	%
Gross margin	$4,009	$4,202	$(193)	(5)%
Percent of Product sales	55 %	57 %	(2) %	(4)%

	For the Twelve-Month Periods Ended September 30,		Decrease	
	2017	2016	Amount	%
Gross margin	$5,228	$5,860	$(632)	(11)%
Percent of Product sales	55 %	58 %	(3) %	(6) %

The gross margin as a percentage of product sales was 47% and 61% during the three-month periods ended September 30, 2017 and 2016, respectively, and 55% and 57% during the nine-month periods ended September 30, 2017 and

2016, respectively, and 55% and 58% during the twelve-month periods ended September 30, 2017 and 2016, respectively. The gross margin as a percentage of product sales was 57% and 61% during the years ended December 31, 2016 and 2015, respectively. This compares to gross margin percentages of 59% and 51% during the years ended December 31, 2014 and 2013, respectively. Our current objective is to maintain the gross margin percentage over 55% on an annual basis, and we have achieved this annual objective since 2014. 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 the **First Defense®** product line is affected by biological yields from our raw material, which do vary over time. Just as our customers' cows respond differently to commercial dam-level vaccines depending on time of year and immune competency, our source cows have similar biological variances in response to our proprietary vaccine. The value of our **First Defense®** product line is that we compensate for that variability by standardizing each dose of finished product. This impacts our costs of goods sold but insures that every calf is equally protected, which is something that dam-level commercial scour vaccines cannot offer. Like most U.S. manufacturers, we have also been experiencing increases in the cost of raw materials that we purchase. Our costs have increased due to increased labor costs and other expenses associated with our efforts to sustain compliance with current Good Manufacturing Practice (cGMP) regulations in our production processes. During the third quarter of 2017, we experienced a significant drop in gross margin dollars ($269,000) and a decrease in the gross margin as a percent of sales to 47% from 61% during the third quarter of 2016, due to a cost increase that was largely caused by a drop in the yields from our production process and a scheduled reduction in production output. Over time, we have been able to minimize the impact of cost increases by implementing yield improvements. We anticipate seeing a return to better yields during the fourth quarter of 2017 based on process improvements that we are implementing.

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Sales and Marketing Expenses

Sales and marketing expenses decreased by approximately 8%, or $37,000, to $447,000 during the three-month period ended September 30, 2017 in comparison to $484,000 during the same period in 2016, amounting to 22% and 25% of product sales during the three-month periods ended September 30, 2017 and 2016, respectively. Sales and marketing expenses decreased by less than 1% to $1,362,000 during the nine-month period ended September 30, 2017 in comparison to $1,365,000 during the same period in 2016, amounting to 19% of product sales during the nine-month periods ended September 30, 2017 and 2016. We continue to leverage the efforts of our small sales force by using animal health distributors. These expenses have increased due principally to a strategic decision to invest more to support sales of the **First Defense®** product line. Our current budgetary objective in 2017 is to invest less than 20% of product sales in sales and marketing expenses on an annual basis. With the new equity raised during the third quarter of 2017, we increased our sales team by one new employee in advance of the anticipated product launch of **First Defense®Tri-Shield™**, which could cause us to exceed our budgetary expense ratio temporarily.

Product Development Expenses

Product development expenses increased by 90%, or $278,000, to $586,000 during the three-month period ended September 30, 2017 in comparison to $308,000 during the same period in 2016. Product development expenses aggregated 29% and 16% of product sales during the third quarters of 2017 and 2016, respectively. Product development expenses increased by 32%, or $322,000, to $1,312,000 during the nine-month period ended September 30, 2017 in comparison to $991,000 during the same period in 2016. Product development expenses aggregated 18% and 14% of product sales during the nine-month periods ended September 30, 2017 and 2016, respectively. The majority of our product development spending is focused on the development of our Nisin-based treatment for subclinical mastitis in lactating dairy cows. During the 17.75-year period that began on January 1, 2000 (the year we began this product development initiative) and ended on September 30, 2017, we have invested the aggregate of approximately $13,265,000 in this development. This estimated expense allocation 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 related product licensing revenues and grant income, most of which was earned from 2001 to 2007. Some of the increase in product development expenses during the third quarter of 2017 consisted of final development costs related to the initial production batches of **First Defense® Tri-Shield™**.

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 our novel treatment for subclinical mastitis. 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, is an antibacterial peptide known to be effective against most Gram-positive and some Gram-negative bacteria. In our pivotal effectiveness study, statistically significant 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 processing and purification methods to achieve pharmaceutical-grade purity.

In 2004, we entered into a product development and marketing agreement with Pfizer Animal Health (now known as Zoetis) covering this product. That company 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 treated cows 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 our product 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 the product is used in accordance with the product label. We do not believe that such a premium-priced product 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 our novel mastitis treatment 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.

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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.

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 a zero milk discard period and a zero meat withhold period during and after treatment for our product. 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. This work is complete, and we anticipate that the HFS Technical Section will be submitted to the FDA during the fourth quarter of 2017. This submission is subject to a six-month review by the FDA. As a result, we anticipate making a public disclosure about the response from the FDA during the second quarter of 2018.

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.

Implementing Nisin production at commercial scale is the most critical action in front of us on our path to regulatory approval. We previously entered into an agreement with a multi-national pharmaceutical ingredient manufacturer for our commercial-scale supplies of Nisin. However, we determined in 2014 that that agreement did not offer us the most advantageous supply arrangement in terms of either cost or long-term dependability. We presented this product development opportunity to a variety of large and small animal health companies. While such a corporate partnership could have provided access to a much larger sales and marketing team and allowed us to avoid the large investment in a commercial-scale production facility, the partner would have taken a large share of the gross margin from all future product sales. We are encouraged by the regulatory and marketing feedback that we received 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. We conducted a market research study that estimated that the market potential for this product could grow from approximately $5.8 million to approximately $36.1 million over the first five years after product launch. With a measured approach to expanding our customer-facing staff, it is our near-term objective to double our current product sales through continued growth in sales of the **First Defense®** product line (including **First Defense®Tri-Shield™**) and a successful launch of our novel mastitis treatment as soon as possible. As market penetration is achieved and additional resources are dedicated to sales, marketing and technical services, our longer-term goal is to triple our current sales as soon as possible during the five-year period after the market launch of our new mastitis product. Our financial objective is to maintain our gross margin (before related depreciation expenses) as a percentage of total sales at or above 50%, as we increase the amount of cash we earn from product sales.

During the fourth quarter of 2015, we acquired land nearby to our existing Portland facility for the construction of a new manufacturing facility that would enable us to generate our own Nisin supply at commercial scale. During the third quarter of 2016, we commenced construction of a facility with production capacity to meet approximately $12.6 million in annual sales. The estimated total cost of the Nisin facility is approximately $20.8 million. Our facility is designed to have enough room for a second fermentation and recovery portion of the production line to be purchased and installed at the cost of approximately $7 million to effectively double production output after commercial acceptance of the product is demonstrated. If annual sales of our mastitis product exceed approximately $25 million, we would evaluate all Nisin supply options, factoring in efficiencies and yield improvements. Building an additional Nisin production facility to meet our needs at that time may be the most cost-effective solution. We are substantially complete with construction of the building. As anticipated, we began equipment installation during the third quarter of 2017 and expect installation and qualification to be complete by year end. Three validation batches must be produced at commercial scale, a detailed CMC Technical Section must be prepared and submitted to the FDA and successful FDA site inspections must be achieved. We anticipate making the first submission of the CMC Technical Section to the FDA with three months of product stability data from the three validation batches during the middle of 2018. We anticipate that two submissions will be required. Each submission is subject to a six-month review by the FDA. After approval of this final (being “final” because we expect to achieve earlier approval of the HFS Technical Section) Technical Section, there is a 60-day administrative review before product license approval could be issued. Adherence to this anticipated timeline could lead to potential approval by the end of 2019 with subsequent market launch.

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We are party to a long-term, exclusive supply agreement with Plas-Pak Industries, Inc. (now owned by Nordson Corporation) of Norwich, Connecticut covering the proprietary syringe that was developed specifically for treating cows with our mastitis product. These syringes were used for all pivotal studies. During the third quarter of 2017, this agreement was extended to January 1, 2024.

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 (sterile-filled and packaged syringes) manufacturer, covering the formulation and sterile-filling of the Drug Substance (the active pharmaceutical ingredient) into Drug Product. Norbrook provided these services for clinical material used in all pivotal studies. During the fourth quarter of 2015, we entered into a revised agreement with Norbrook to support the final development and commercial-scale production of our mastitis product after FDA approval.

Our second most important product development program (in terms of dollars invested and, we believe, potential market impact) is an effort to prevent scours in calves caused by rotavirus. 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 a $150,000 milestone payment due within 90 days of USDA approval and ongoing royalty payments. 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 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 of this product, **First Defense® Tri-Shield™**, during the fourth quarter of 2017. This would be the first calf-level, passive antibody product on the market with USDA-approved disease claims providing immediate immunity against each of the three leading causes of calf scours (*E. coli*, coronavirus and rotavirus). The new product combines the *E. coli* and coronavirus antibodies contained in our legacy product with a guaranteed minimum level of rotavirus antibody content in one preventative dose. This unique breadth of claims further differentiates our product from competitive products on the market that have claims against both coronavirus and rotavirus or just *E. coli* or just coronavirus, but not all three. This new product will be available in a gel tube delivery format. Historically, the primary tool to help combat scours has been to vaccinate the cow with a dam-level scours vaccine. With this expanded claim set, we can compete more effectively against these dam-level vaccine products that are given to the cow to improve the quality of her colostrum (first milk) that is fed to the newborn. It is generally believed that only 80% of animals respond to a vaccine, which could leave about 20% of calves unprotected. Additionally, our research suggests that treatment protocols for dam-level scours vaccine programs are not always followed, leaving even more calves compromised. Our new marketing campaign, '**Beyond Vaccination™**', suggests that by delivering immediate immunity directly to the calf via **First Defense® Tri-Shield™**, producers can save needles and labor for vaccines that are more critical to cow health. Reliance on a dam-level scours vaccine requires that money be spent before it is known whether the cow is carrying a viable, valued calf. With **First Defense® Tri-Shield™**, every calf is equally protected and that

investment can be targeted to the calves that are most critical to the operation. This, in turn, can free up space in the cow's vaccination schedule to optimize her immune response to vaccines that are critical to her health. We intend to continue selling the bivalent formats of **First Defense®** as options for customers after the launch of **First Defense® Tri-Shield™**.

The balance of our product development efforts have been primarily focused on other improvements, extensions or additions to our **First Defense®** product line. We are currently working to establish USDA claims for our bivalent gel tube (expected during the first quarter of 2018) and bulk powder (expected during 2018) formulations of **First Defense Technology®**. We are also investing in additional studies comparing **First Defense®** to the competition. 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. During the fourth quarter of 2017, we extended this exclusive option agreement through March 2019. 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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Administrative Expenses

Administrative expenses increased by approximately 6%, or $23,000, to $386,000 during the three-month period ended September 30, 2017 in comparison to $363,000 during the same period in 2016. Administrative expenses increased by approximately 8%, or $89,000, to $1,165,000 during the nine-month period ended September 30, 2017 in comparison to $1,076,000 during the same period in 2016. 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. During 2016, we engaged a new accounting firm for review, audit and tax services. 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 while continuing 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 us 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.

Net Operating (Loss) Income

Our net operating (loss) during the three-month period ended September 30, 2017 of ($482,000) was in contrast to net operating income of $50,000 during the same period in 2016. Our net operating income during the nine-month period ended September 30, 2017 of $170,000 was $600,000 less than our net operating income of $771,000 during the same period in 2016. The decreases in both periods were driven primarily by an increase in cost of goods sold (on similar sales volume) and an increase in product development expenses incurred, as we invest to gain regulatory approval to launch two new products.

Other expenses, net

Interest expense (including amortization of debt issuance costs of approximately $4,000 and $3,000 during the three-month periods ended September 30, 2017 and 2016, respectively) increased by approximately 28%, or $12,000, to $53,000 during the three-month period ended September 30, 2017, in comparison to $41,000 during the same period in 2016. Interest expense (including amortization of debt issuance costs of approximately $11,000 and $6,000 during the nine-month periods ended September 30, 2017 and 2016, respectively) increased by approximately 11%, or $13,000, to $137,000 during the nine-month period ended September 30, 2017, in comparison to $123,000 during the same period in 2016. Interest income decreased by approximately 82%, or $14,000, to $3,000 during the three-month

period ended September 30, 2017, in comparison to $17,000 during the same period in 2016. Interest income decreased by approximately 65%, or $28,000, to $15,000 during the nine-month period ended September 30, 2017, in comparison to $44,000 during the same period in 2016. Less interest income was earned during the 2017 periods because we had less cash and investments on hand and because these funds were held in more liquid investments (that earn a lower rate of interest) during the current periods in order to fund our capital expenditure requirements. Other expenses, net, aggregated $49,000 and $27,000 during the three-month periods ended September 30, 2017 and 2016, respectively. Other expenses, net, aggregated $116,000 and $81,000 during the nine-month periods ended September 30, 2017 and 2016, respectively.

(Loss) Income Before Income Taxes and Net (Loss) Income

Our (loss) before income taxes of ($532,000) during the three-month period ended September 30, 2017 was $556,000 less than our income before income taxes of $24,000 during the same period in 2016. Our income before income taxes of $55,000 during the nine-month period ended September 30, 2017 was $635,000 less than our income before income taxes of $690,000 during the same period in 2016. We recorded an income tax (benefit) of (36%) and (46%) of the (loss) income before income taxes during the three-month periods ended September 30, 2017 and 2016, respectively. We recorded income tax expense of 51% and 31% of the income before income taxes during the nine-month periods ended September 30, 2017 and 2016, respectively. Our net (loss) of ($339,000), or ($0.07) per share, during the three-month period ended September 30, 2017 contrasts to net income of $35,000, or $0.01 per diluted share, during the three-month period ended September 30, 2016. Our net income of $27,000, or $0.01 per diluted share during the nine-month period ended September 30, 2017 compares to net income of $478,000, or $0.11 per diluted share, during the nine-month period ended September 30, 2016. The net loss for the third quarter (driven primarily by higher costs of goods sold and higher product development expenses) reduced our profitability to just over breakeven for the nine-month period ended September 30, 2017.

During the three-month period ended September 30, 2017, our net (loss) was ($339,000) and depreciation and amortization expenses aggregated $215,000. During the three-month period ended September 30, 2016, our net income was $35,000 and depreciation and amortization expenses aggregated $203,000. During the nine-month period ended September 30, 2017, our net income was $27,000 and depreciation and amortization expenses aggregated $653,000. During the nine-month period ended September 30, 2016, our net income was $478,000 and depreciation and amortization expenses aggregated $591,000. During the twelve-month period ended September 30, 2017, our net income was $57,000 and depreciation and amortization expenses aggregated $873,000. During the twelve-month period ended September 30, 2016, our net income was $767,000 and depreciation and amortization expenses aggregated $739,000. Net cash (used for) provided by operating activities (which does not include investing or financing activities) was ($251,000) and ($16,000) during the three-month periods ended September 30, 2017 and 2016, respectively, and $845,000 and $150,000 during the nine-month periods ended September 30, 2017 and 2016, respectively, and $473,000 and $980,000 during the twelve-month periods ended September 30, 2017 and 2016, respectively.

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Critical Accounting Policies

The financial statements are presented on the basis of accounting principles that are generally accepted in the United States. All professional accounting standards that were effective and applicable to us as of September 30, 2017 have been taken into consideration in preparing the financial statements. The preparation of financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, income taxes, contingencies and the useful lives and carrying values of intangible and long lived assets. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have chosen to highlight certain policies that we consider critical to the operations of our business and understanding our financial statements.

We sell products that provide immediate immunity to newborn dairy and beef cattle. We recognize revenue when four criteria are met. 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 do not bill for or collect sales tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We generally have experienced an immaterial amount of product returns.

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.

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of September 30, 2017, 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 for the year ended December 31, 2016.

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, 2017. 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, 2017 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

In the ordinary course of business, we may become subject to periodic lawsuits, investigations and claims. Although we cannot predict with certainty the ultimate resolution of any such lawsuits, investigations and claims against us, we do not believe that any pending or threatened legal proceedings to which we are or could become a party will have a material adverse effect on our business, results of operations, or financial condition.

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 ongoing and future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis; the expected efficacy of new products; future market share of and revenue generated by current products and 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 future adequacy of our working capital and the availability and cost of third party financing; timing and future costs of a facility to produce the Drug Substance (our active pharmaceutical ingredient, Nisin); the timing and outcome of pending or anticipated applications for regulatory approvals; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; costs associated with sustaining compliance with cGMP regulations in our current operations and attaining such compliance for the facility to produce the Drug Substance; factors that may affect the dairy and beef industries and future demand for our products; our effectiveness in competing against competitors within both our existing and our anticipated product markets; 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 ex

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, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand, the uncertainties associated with product development and Drug Substance manufacturing, actual as compared to expected or estimated costs of expanding our manufacturing facilities, 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 values and 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 the **First Defense®** product line could lead to less profits or an operating loss. Large investments in product development (or cost overruns) can result in a net loss. We have been profitable on an annual basis since the second half of 2014. Depreciation expenses related to the Nisin production facility are expected to produce operating losses until and unless product sales increase to offset these non-cash expenses.

Cash flows/liquidity: As we complete the investment in our Nisin production facility and draw down the remaining bank debt that is available to us, we are reducing our cash reserves to a lower than normal level. We are going to be reliant on positive cash flows during our peak selling season (first quarter) to begin to re-build these cash reserves.

*Reliance on sales of the **First Defense®** product line:* We are heavily reliant on the market acceptance of the **First Defense®** product line to generate product sales and fund our operations. Our business would not have been profitable during the nine consecutive years in the period ended December 31, 2007 or during the years ended December 31, 2012, 2013, 2015 and 2016 or during the nine-month period ended September 30, 2017 without the gross margin that we earned on sales of the **First Defense®** product line, which accounted for 93% of our total product sales during the years ended December 31, 2016 and 2015 and 94% of our total product sales during the nine-month period ended September 30, 2017.

Product risks generally: The sale of our products is subject to financial, efficacy, regulatory, competitive and other market risks. Elevated standards to achieve and maintain 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.

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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 the **First Defense®** product line:* **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. We expect to be subject to similar regulatory risks for our anticipated rotavirus claim, and similar regulatory oversight risks exist in territories outside of the United States where we sell our products.

Regulatory requirements for our Nisin-based treatment for subclinical mastitis: The commercial introduction of this product in the United States will require us to obtain FDA approval. Completing the development 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 (17 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 reduce the risk associated with this process, we have met with the FDA on multiple occasions to align on filing strategy and requirements. We have disclosed a timeline of events that could lead to potential approval by the end of 2019. We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce our mastitis product, 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. European regulatory authorities are not expected to approve a product with a zero milk discard claim, which would remove a significant competitive advantage in that territory. However, the assigned milk discard period may be shorter for our product than it is for other products on the market in Europe.

*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 NADA approval, in accordance with the FDA's Compliance Policy Guide 7125.30 ("Teat Dips and Udder Washes for Dairy Cows and Goats"). 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 inspected our facilities and operations again. The 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. During the first quarter of 2017, we discontinued the manufacture and sale of this product, which reduces our exposure to an adverse action by the FDA in this respect to a minimal level.

Concentration of sales: Approximately 99% and 97% of our product sales were made to customers in the dairy and beef industries throughout the world during the years ended December 31, 2016 and 2015, respectively. Approximately 98% and 99% of our product sales were made to customers in the dairy and beef industries throughout the world during the first nine months of 2017 and 2016, respectively. Approximately 85% and 83% of our product sales were made to customers in the U.S. dairy and beef industries during the years ended December 31, 2016 and 2015, respectively. Approximately 83% and 85% of our product sales were made to customers in the U.S. dairy and beef industries during the first nine months of 2017 and 2016, respectively. The animal health distribution segment has been aggressively consolidating over the last few years with larger distributors acquiring smaller distributors. A large portion of our product sales (60% and 62% during the years ended December 31, 2016 and 2015, respectively, and 65% and 59% during the first nine months of 2017 and 2016, respectively) was made to two large distributors. A large portion of our trade accounts receivable (64% and 52% as of December 31, 2016 and 2015, respectively, and 73% as of September 30, 2017) 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:

The January count of all cattle and calves in the United States had steadily declined from 97,000,000 as of January 1, 2007 to 88,500,000 as of January 1, 2014. Then this figure increased to 89,100,000 as of January 1, 2015 and to 91,900,000 as of January 1, 2016 and to 93,600,000 as of January 1, 2017, which is 1.8% higher than at January 1, 2016.

From 1998 through 2016, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 (2004) to the high of 9,332,000 (2016) and higher to 9,390,000 during the first nine months of 2017. 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 prices were first reported in 1980. This strong price level declined to the average of $15.80 during 2015 and further declined to $14.87 during 2016. However, the average during the nine-month period ended September 30, 2017 improved to $16.12. The recent annual fluctuations in this milk price level are demonstrated in the following table:

Average Class III Milk Price for the Year Ended December 31,		**Increase (Decrease)**
2012	2013	
$17.44	$17.99	3%
2013	2014	
$17.99	$22.34	24%
2014	2015	
$22.34	$15.80	(29)%
2015	2016	
$15.80	$14.87	(6)%

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 to 2.24 during 2016. During the first eight months of 2017, this average improved to 2.41. 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)%
2015	2016	
2.12	2.24	6%

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 declined by 11% to $1,768 during 2016. The average for the first nine months of 2017 declined to $1,627. 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 during 2015 but has declined to very little presently, 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 **First Defense® Tri-Shield™** and our novel mastitis treatment product) 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 our new product to treat subclinical mastitis, 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 our product development funding strategy: The construction and start-up of and the financing for the commercial-scale Nisin production plant is the most critical action in front of us on our path to U.S. regulatory approval. We believe our current cash and investments, together with the available debt facilities of up to approximately $4.3 million, will be adequate financing to complete the project but will not provide us with a large amount of surplus cash. Due to the risks described herein, we could experience cost overruns or delays. We will not know whether we will receive the necessary regulatory approvals, or whether the mastitis product will achieve market acceptance and profitability, until after the construction and qualification of our Nisin production facility, at the presently estimated cost of $20.8 million, is complete. Absent sufficient sales of this new product at a profitable gross margin, we would be required to fund all debt service costs from sales of the **First Defense®** product line which would reduce our expected profitability and adversely affect our liquidity going forward.

Uncertainty of market size and product sales estimates: Estimating the size of the market for any new product 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, competition from existing products sold by substantially larger competitors, the risk of competition from other new products, cost of manufacture and integration of milk from treated cows with susceptible cheese starter cultures. Given what we believe to be reasonable assumptions, we estimate that the market potential for first year sales of our new product could be approximately $5.8 million and could grow to approximately $36.1 million during the fifth year after market launch. The amount of sales that we can capture from this estimated market potential and the timing of when this can be achieved is very difficult to know, and the actual size of the market for our new product may differ materially from our estimates (up or down).

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. Boehringer Ingelheim, Elanco, Merck (a recent entry into this market space) and Zoetis among other companies, sell products that compete directly with the **First Defense®** product line 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 returned to the market in the latter part of 2015 and is regaining sales it had lost during this period. 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 Boehringer Ingelheim, Merck and Zoetis. The products sold by these large companies are well established in the market but are all sold subject to a requirement to discard milk during and for a period of time after treatment. There is no assurance that our product 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 and contract manufacturing services: 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. We have significantly increased the number of farms from which we purchase colostrum. The loss of farms from which we buy raw material for the **First Defense®** product line could make it difficult for us to produce enough inventory. The specific antibodies that we purify from colostrum for the **First Defense®** product line are not readily available from other sources. We are dependent on our manufacturing facility and operations in Portland for the production of the **First Defense®** product line and will be dependent on the facility we are constructing in Portland for the production of Nisin when that product begins commercial sales. We are dependent on Plas-Pak Industries, Inc. (now owned by Nordson Corporation) for the supply of the syringes used for our gel tube format of **First Defense Technology®** and expect to be dependent on this company for the supply of the syringes for **First Defense®Tri-shield™** and our new mastitis product. The supply contract covering the mastitis syringes has been extended to January 1, 2024. We expect to be dependent on a contract with Norbrook for the sterile-filling and final packaging of our Drug Substance into Drug Product. In the event that we do not achieve FDA approval by December 17, 2019, there is a risk that this contract could be terminated. We are negotiating a possible extention to this term. Consistent with provisions in this contract, we are evaluating alternative sources for these services for potential use post-approval. Given the requirement that such a facility be inspected and approved by the FDA, it could be costly and time-consuming to find and qualify an adequate alternative source for these services. Any significant damage to or other disruption in the services at any of these third party or company-owned 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.

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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, manufacturing, managerial and sales and marketing personnel, to develop proprietary technologies and products, to obtain USDA or FDA approval for new products, to maintain regulatory 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.

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 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. Interest rates are trending higher, and a significant portion of our bank debt currently bears interest at variable rates. 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.

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Bovine diseases: The potential for epidemics of bovine diseases such as Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) presents a risk to us and our customers. Documented cases of BSE in the 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 and liquidity: Our common stock trades on The Nasdaq Stock Market (Nasdaq: 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 and prices can be volatile, 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 $42,735,000 as of November 6, 2017. Some of these companies have little or no product sales. We currently have annual product sales of approximately $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.

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 increase our working capital 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 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 13, 2017 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer and
Principal Financial Officer