IMMUCELL CORP /DE/
Form 10-Q
May 14, 2018

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 March 31, 2018

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 May 8, 2018 was 5,480,157.

ImmuCell Corporation

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March 31, 2018

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

(Unaudited Condensed)

BALANCE SHEETS

	As of March 31, 2018	As of December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$3,060,470	$3,798,811
Accounts receivable, net	999,899	1,344,022
Inventory	1,929,927	2,049,732
Prepaid expenses and other current assets	401,739	314,667
Total current assets	6,392,035	7,507,232
PROPERTY, PLANT AND EQUIPMENT, net	26,428,756	26,069,689
DEFERRED TAX ASSETS, net	504,236	472,726
INTANGIBLE ASSETS, net	148,056	152,832
GOODWILL	95,557	95,557
INTEREST RATE SWAPS	57,628	-
OTHER ASSETS	5,831	920
TOTAL ASSETS	$33,632,099	$34,298,956
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$928,450	$1,723,270
Current portion of bank debt	454,550	316,629
Deferred revenue	24,100	24,100
Total current liabilities	1,407,100	2,063,999
LONG-TERM LIABILITIES:		
Bank debt, net of current portion	8,732,119	8,639,021
Interest rate swaps	-	996
Total long-term liabilities	8,732,119	8,640,017
TOTAL LIABILITIES	10,139,219	10,704,016

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, 5,662,645 and 5,662,645 shares issued and 5,480,157 and 5,476,197 shares outstanding, as of March 31, 2018 and December 31, 2017, respectively	566,265	566,265
Additional paid-in capital	22,524,760	22,458,219
Retained earnings	757,851	978,973
Treasury stock, at cost, 182,488 and 186,448 shares as of March 31, 2018 and December 31, 2017, respectively	(399,217)	(407,879)
Accumulated other comprehensive income (loss)	43,221	(638)
Total stockholders' equity	23,492,880	23,594,940
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$33,632,099	$34,298,956

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

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ImmuCell Corporation

(Unaudited Condensed)

STATEMENTS OF OPERATIONS

	For the Three-Month Periods Ended March 31,	
	2018	2017
Product sales	$2,881,185	$3,543,930
Costs of goods sold	1,521,444	1,391,997
Gross margin	1,359,741	2,151,933
Product development expenses	582,934	339,616
Sales and marketing expenses	531,905	514,475
Administrative expenses	423,057	379,633
Operating expenses	1,537,896	1,233,724
NET OPERATING (LOSS) INCOME	(178,155)	918,209
Other expenses, net	92,116	30,242
(LOSS) INCOME BEFORE INCOME TAXES	(270,271)	887,967
Income tax (benefit) expense	(49,148)	303,725
NET (LOSS) INCOME	$(221,123)	$584,242
Weighted average common shares outstanding:		
Basic	5,477,921	4,847,557
Diluted	5,477,921	4,940,293
NET (LOSS) INCOME PER SHARE:		
Basic	$(0.04)	$0.12
Diluted	$(0.04)	$0.12

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 March 31,	
	2018	2017
Net (loss) income	$(221,123)	$584,242
Other comprehensive income:		
Interest rate swaps, before taxes	58,625	15,735
Income tax applicable to interest rate swaps	(14,766)	(5,665)
Other comprehensive income, net of taxes	43,859	10,070
Total comprehensive (loss) income	$(177,264)	$594,312

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

ImmuCell Corporation

(Unaudited Condensed)

STATEMENTS OF CASH FLOWS

	For the Three-Month Periods Ended March 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	$(221,123)	$584,242
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation	279,896	213,466
Amortization	4,776	4,776
Non-cash interest expense	4,204	2,941
Deferred income taxes	(46,276)	252,912
Stock-based compensation	71,048	46,763
Gain on disposal of fixed assets	-	(3,663)
Provision for uncollectible accounts	-	1,080
Changes in:		
Accounts receivable	344,123	(20,352)
Accrued interest income	-	13,658
Inventory	119,806	27,965
Prepaid expenses and other current assets	(87,072)	33,584
Other assets	(4,911)	-
Accounts payable and accrued expenses	(214,809)	131,838
Deferred revenue	-	(33,856)
Net cash provided by operating activities	249,662	1,255,354
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1,213,252)	(4,932,828)
Payment of contingent royalties related to 2016 acquisition	(5,723)	(3,769)
Maturities of investments	-	2,731,000
Purchases of investments	-	(249,000)
Proceeds from sale of fixed assets	-	45,000
Net cash used in investing activities	(1,218,975)	(2,409,597)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from debt issuance	267,141	340,000
Debt principal repayments	(39,803)	(35,295)
Payments of debt issuance costs	(522)	(54,036)
Proceeds from exercise of stock options	4,156	5,250
Net cash provided by financing activities	230,972	255,919
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(738,341)	(898,324)
BEGINNING CASH, CASH EQUIVALENTS AND RESTRICTED CASH	3,798,811	5,150,344

ENDING CASH, CASH EQUIVALENTS AND RESTRICTED CASH	$3,060,470	$4,252,020

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 Three-Month Periods Ended March 31,	
	2018	2017
CASH PAID FOR:		
Income taxes	$-	$-
Interest expense	$89,313	$36,556
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable and accrued expenses	$(574,288)	$(399,541)
Net change in fair value of interest rate swaps	$(43,859)	$(10,070)
Fixed asset disposals, gross	$3,430	$431,970

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. Based on our best estimates and projections, we believe that we have sufficient capital resources to continue operations for at least twelve months from the date of this filing. These and other risks to our Company are further detailed under **Part II, Item 1A** – “Risk Factors” of this Quarterly Report.

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 the disclosures are adequate to ensure that the information presented is not misleading. Certain prior year accounts have been reclassified to conform with the 2018 financial statement presentation and had no effect on previously reported results.

(b) Cash and Cash Equivalents

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 $2,808,182 and $3,546,529 as of March 31, 2018 and December 31, 2017, respectively. We account for investments in marketable securities in accordance with Codification Topic 320, *Investments – Debt and Equity Securities*. 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. At each balance sheet date, we evaluate our ending inventories for excess quantities and obsolescence. Inventories that we consider excess or obsolete are reserved. Once inventory is written down and a new cost basis is established, it is not written back up if demand increases. See Note 4.

(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 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. Accounts receivable are written off when deemed uncollectible. The amount of accounts receivable written off during all periods reported was immaterial. Recoveries of accounts receivable previously written off are recorded as income when received. As of March 31, 2018, we determined that no allowance for doubtful accounts was necessary.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

(e) Property, Plant and Equipment

We depreciate property, plant and equipment on the straight-line method by charges to operations in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The facility we have constructed to produce the active pharmaceutical ingredient, Nisin, is being depreciated over 39 years from when a certificate of occupancy was issued during the fourth quarter of 2017. We are evaluating the estimated useful lives of the assets included in construction in progress since they were not placed in service as of March 31, 2018. Significant repairs to fixed assets that benefit more than a current period are capitalized and depreciated over their useful lives. Insignificant repairs are expensed when incurred. See Note 6.

(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. Judgment 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 judgments and require an adjustment to the recorded balance. No impairments were recorded during the three-month period ended March 31, 2018 or the year ended December 31, 2017. See Notes 2(h), 7 and 8 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. As of March 31, 2018 and December 31, 2017, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, other assets, accounts payable, deferred revenue 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 based on similar instruments with similar maturities. 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.

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 judgment, and considers factors specific to the investment. We 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.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

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 three-month period ended March 31, 2018 and the year ended December 31, 2017, there were no transfers between levels. As of March 31, 2018 and December 31, 2017, 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 March 31, 2018 and December 31, 2017, 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 March 31, 2018 or December 31, 2017.

	As of March 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and money market accounts	$3,060,470	$-	$ -	$3,060,470
Interest rate swaps	-	57,628	-	57,628
Total	$3,060,470	$57,628	$ -	$3,118,098

	As of December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and money market accounts	$3,798,811	$-	$ -	$3,798,811
Liabilities:				
Interest rate swaps	-	(996)	-	(996)
Total	$3,798,811	$(996)	$ -	$3,797,815

(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 for use 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. No impairment was recognized during the three-month period ended March 31, 2018 or the year ended December 31, 2017.

(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 when deemed necessary, 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 March 31,	
	2018	2017
Animal Health International, Inc.	34 %	40 %
MWI Animal Health	24 %	26 %
ANIMART LLC	11 %	*

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

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

	As of March 31, 2018		As of December 31, 2017	
MWI Animal Health	25	%	29	%
Animal Health International, Inc.	20	%	40	%
Robert J. Matthews Company	15	%	*	
ANIMART LLC	14	%	*	

*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 10.

(k) Revenue Recognition

We sell products that provide immediate immunity to newborn dairy and beef cattle. For periods ended on and before December 31, 2017, we recognized revenue in accordance with ASC 605 when four criteria were met. These included i) persuasive evidence that an arrangement existed, ii) delivery had occurred, iii) our price was fixed and determinable and iv) collectability was reasonably assured. For periods ending after December 31, 2017, we recognize revenue in accordance with ASC 606, *Revenue from Contracts with Customers*. ASC 606 is a single comprehensive model for companies to use in accounting for revenue arising from contracts with customers. The core principle is that we recognize the amount of revenue to which we expect to be entitled for the transfer of promised goods or services to customers when a customer obtains control of promised goods or services in an amount that reflects the consideration we expect to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASC 606 replaces most existing revenue recognition guidance in U.S. GAAP. We evaluated the new standard against our existing accounting policies and practices, including reviewing distributor agreements, purchase orders, invoices, shipping forms, and conducting questionnaires with our sales team. We adopted the standard using the modified retrospective transition method, and the adoption did not have a material impact on our financial statements as of the date of adoption (January 1, 2018). Comparative prior periods have not been adjusted and continue to be reported under ASC 605. We conduct our business with customers through valid purchase orders or sales orders which are considered contracts and are not interdependent on one another. A performance obligation is a promise in a contract to transfer a distinct product to the customer. The transaction price is the amount of consideration we expect to receive under the arrangement. Revenue is measured based on consideration specified in a contract with a customer. The transaction price of a contract is allocated to each distinct performance obligation and recognized when or as the customer receives the benefit of the performance obligation. Product transaction prices on a purchase or sale order are discrete and stand-alone. We recognize revenue when we satisfy a performance obligation in a contract by transferring control over a product to a customer when product delivery occurs. Consideration is typically paid approximately 30 days from the time control is transferred. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost in costs of goods sold. We have enhanced disclosures related to disaggregation of revenue sources and accounting policies prospectively as a result of adopting these standards. 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. See Note 12.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

(l) Expense Recognition

We also adopted ASC 340-40, *Accounting for Other Assets and Deferred Costs*, which requires sales commissions and other third party acquisition costs resulting directly from securing contracts with customers to be recognized as an asset when incurred and to be expensed over the associated contract term or estimated customer life depending on the nature of the underlying contract. We do not incur costs that are eligible for capitalization. Advertising costs are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to $21,766 and $29,057 during the three-month periods ended March 31, 2018 and 2017, 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. Adoption of ASC 340-40 did not have a material impact on our financial statements.

(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. Deferred tax assets and liabilities are recorded net as long term. 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 2014 through 2017 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 March 31, 2018 or December 31, 2017. 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 $71,048 and $46,763 during the three-month periods ended March 31, 2018 and 2017, 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 March 31,	
	2018	2017
Weighted average number of shares outstanding	5,477,921	4,847,557
Effect of dilutive stock options	-	92,736
Diluted number of shares outstanding	5,477,921	4,940,293
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	477,000	184,000

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

(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.

(q) New Accounting Pronouncements

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 statement in a manner similar to existing accounting practices. 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. We adopted this guidance during the year ended December 31, 2017. The adoption of this guidance did not 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 adopted this guidance during the three-month period ended March 31, 2018. The adoption of this guidance did not have a material impact on our financial statements.

3. CASH AND CASH EQUIVALENTS

Cash and cash equivalents consisted of the following:

	As of March 31, 2018	As of December 31, 2017
Cash and cash equivalents	$3,060,470	$ 3,798,811

Short-term investments were liquidated during 2017 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. We are required by bank debt covenant to maintain at least $2,000,000 of otherwise unrestricted cash, cash equivalents and short-term investments.

4. INVENTORY

Inventory consisted of the following:

	As of March 31, 2018	As of December 31, 2017
Raw materials	$438,864	$ 483,329
Work-in-process	1,425,611	1,349,649
Finished goods	65,452	216,754
Total	$1,929,927	$ 2,049,732

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of March 31, 2018	As of December 31, 2017
Prepaid expenses	$223,696	$ 130,813
Other receivables	143,779	149,590
Security deposits [1]	34,264	34,264
Total	$401,739	$ 314,667

[1] This amount consists of the current portion of escrow funds held against certain construction performance requirements.

6. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

	Estimated Useful Lives (in years)	As of March 31, 2018	As of December 31, 2017
Laboratory and manufacturing equipment	3-10	$5,525,018	$5,511,452
Building and improvements	10-39	17,002,112	16,966,728
Office furniture and equipment	3-10	698,877	698,877
Construction in progress		8,902,019	8,315,436
Land		518,999	518,999
Property, plant and equipment, gross		32,647,025	32,011,492
Accumulated depreciation		(6,218,269)	(5,941,803)
Property, plant and equipment, net		$26,428,756	$26,069,689

As of March 31, 2018 and December 31, 2017, construction in progress consisted principally of payments for equipment to be used in our Nisin production facility. Approximately $3,430 and $435,448 of property, plant and equipment was disposed of during the three-month period ended March 31, 2018 and the year ended December 31, 2017, respectively.

7. 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). The formulation was developed for us and has been sold as a feed product without disease claims since 2012. **Tri-Shield™ First Defense®** is being sold in this format because the additional antibodies do 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 $18,000 as of March 31, 2018 and December 31, 2017, which was recorded in accounts payable and accrued expenses as of those dates. Royalty payments of $10,615 and $8,200 were made for sales recorded during the years ended December 31, 2017 and 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.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

8. INTANGIBLE ASSETS

The intangible assets described in Note 7 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 during the three-month periods ended March 31, 2018 and 2017. The net value of these intangibles was $148,056 and $152,832 as of March 31, 2018 and December 31, 2017, respectively. A summary of intangible amortization expense estimated for the periods subsequent to March 31, 2018 is as follows:

Period	Amount
Nine months ending December 31, 2018	$14,328
Year ending December 31, 2019	19,104
Year ending December 31, 2020	19,104
Year ending December 31, 2021	19,104
Year ending December 31, 2022	19,104
After December 31, 2022	57,312
Total	$148,056

Intangible assets as of March 31, 2018 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	$ 184,100	$ (41,422)	$142,678
Customer relationships	1,300	(293)	1,007
Non-compete agreements	5,640	(1,269)	4,371
Total	$ 191,040	$ (42,984)	$148,056

Intangible assets as of December 31, 2017 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	$ 184,100	$ (36,820)	$147,280
Customer relationships	1,300	(260)	1,040

Non-compete agreements	5,640	(1,128)	4,512
Total	$ 191,040	$ (38,208)	$152,832

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of March 31, 2018	As of December 31, 2017
Accounts payable – capital	$67,101	$ 641,389
Accounts payable – trade	362,685	580,456
Accrued payroll	252,495	254,743
Accrued professional fees	60,265	64,200
Accrued other	185,904	182,482
Total	$928,450	$ 1,723,270

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

10. BANK DEBT

We have in place five credit facilities and a line of credit with TD Bank N.A. that are secured by substantially all of our assets and are subject to certain restrictions and financial covenants. 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 $1,000,000 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 March 31, 2018, $611,592 was outstanding under this first note. Proceeds from a $2,500,000 second mortgage on this corporate headquarters (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 $1,550,000 will be due during the third quarter of 2025. As of March 31, 2018, $2,298,586 was outstanding under Loan #2. During the first quarter of 2016, we entered into two additional credit facilities (Loans #3 and #4) aggregating up to approximately $4,500,000. As a result of loan amendments entered into the during the first quarter of 2017, these two credit facilities were increased to up to $6,500,000, subject to certain restrictions set forth in the agreements. The third note (Loan #3) is comprised of a construction loan of up to $3,940,000 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 (adjusted at each monthly payment date) plus a margin of 2.25% (which was equal to approximately 4.14% for the one-month period beginning April 1, 2018) 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 March 31, 2018, $3,513,501 was outstanding under this third note, and $426,499 was remaining and available to be drawn. The fourth note (Loan #4) is comprised of a construction loan of up to $2,560,000 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 (adjusted at each monthly payment date) plus a margin of 2.25% (which was equal to approximately 4.14% for the one-month period beginning April 1, 2018) through March 2018, at which time the loan converted 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 $1,620,000 will be due during the first quarter of 2027. As of March 31, 2018, $2,560,000 was outstanding under this fourth note. 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 (adjusted at each monthly payment date) plus a margin of 2.25% (which was equal to approximately 4.04% for the one-month period beginning March 16, 2018) 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 March 31, 2018, $328,751 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 March 31, 2018, the variable rates on these two mortgage notes were approximately 5.00% and 4.09%, 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 $2,910,178 as of March 31, 2018. 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 March 31,	
	2018	2017
Payments required by interest rate swaps	$5,285	$11,676
Other comprehensive income, net of taxes	$43,859	$10,070

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 and amendments thereto entered into during the first quarters of 2016 and 2017, we incurred debt issue costs of $46,734 and $66,622, respectively. The 2017 amendments to the 2016 agreements were accounted for as modifications. The amortization of debt issuance costs is being recorded as a component of other expenses and is being amortized over the terms of the respective credit facilities.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

Debt proceeds received and principal repayments made during the three-month periods ended March 31, 2018 and 2017 are reflected in the following table by year and by loan:

	For the Three-Month Period Ended March 31, 2018		For the Three-Month Period Ended March 31, 2017	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	$-	$(15,888)	$-	$(14,952)
Loan #2	-	(21,279)	-	(20,343)
Loan #3	-	-	-	-
Loan #4	267,141	-	-	-
Loan #5	-	(2,636)	340,000	-
Total	$267,141	$(39,803)	$340,000	$(35,295)

Principal payments (net of debt issuance costs) due under bank loans outstanding as of March 31, 2018 (excluding our $500,000 line of credit) are reflected in the following table by the year that payments are due:

	Nine-Months ending 12/31/2018	Year ending 12/31/2019	Year ending 12/31/2020	Year ending 12/31/2021	Year Ending 12/31/2022	After 12/31/2022	Total
Loan #1	$ 48,988	$ 68,908	$493,696	$ -	$ -	$-	$611,592
Loan #2	64,818	89,997	94,005	98,538	103,077	1,848,151	2,298,586
Loan #3[1]	108,778	446,518	465,345	484,965	505,412	1,502,483	3,513,501
Loan #4[1]	62,717	86,702	90,358	94,168	98,138	2,127,917	2,560,000
Loan #5[2]	8,766	12,109	12,607	13,125	13,665	268,479	328,751
Total	$ 294,067	$ 704,234	$1,156,011	$ 690,796	$ 720,292	$5,747,030	$9,312,430
Debt Issuance Costs							(125,761)
Total							$9,186,669

(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 4.14%. The actual interest rate and principal payments will be different.

(2) This note bears 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 4.04%. 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 has been renewed approximately annually since then and is available as needed and has been extended through May 31, 2020. There was no outstanding balance under this line of credit as of March 31, 2018 or December 31, 2017. Interest on borrowings against the line of credit is variable at the higher of 4.25% per annum or the one-month LIBOR plus 3.5% per annum.

11. 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 were 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 of 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).

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

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 $1,034,000 (after deducting expenses incurred in connection with the equity financing).

On December 21, 2017, we sold 417,807 shares of common stock at a price to the public of $7.30 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately $3,050,000 and resulting in net proceeds to the Company of approximately $2,734,000 (after deducting underwriting discounts and offering 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 March 31, 2018, we had 8,000,000 authorized shares of common stock. We have recommended that our stockholders vote 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 11,000,000 at the June 14, 2018 Annual Meeting of Stockholders.

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 no less than fair market value on the date of grant. 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.

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Notes to Unaudited Condensed Financial Statements (Continued)

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 no less than fair market value on the date of grant. 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, 2016	126,500	124,500	-	$ 3.89	$516,990
Grants	-	141,000	-	$ 5.92	
Terminations	(5,000)	(16,000)	-	$ 5.68	
Exercises	(4,000)	(7,000)	-	$ 3.47	
Outstanding at December 31, 2017	117,500	242,500	-	$ 4.58	$1,513,980
Grants	-	34,500	102,500	$ 7.38	
Terminations	-	(9,000)	(5,000)	$ 6.27	
Exercises	(5,000)	(1,000)	-	$ 3.19	
Outstanding at March 31, 2018	112,500	267,000	97,500	$ 5.36	$783,750
Vested at March 31, 2018	112,500	36,500	-	$ 2.59	$656,460
Vested and expected to vest at March 31, 2018	112,500	267,000	97,500	$ 5.36	$783,750
Reserved for future grants	-	5,000	202,500		

(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 three-month period ended March 31, 2018, two employees exercised stock options covering 6,000 shares. One thousand of these options were exercised for cash, resulting in total proceeds of $4,150, and 5,000 of these options were exercised by the surrender of 2,040 shares of common stock with a fair market value of $14,994 at the

time of exercise and $6 in cash. During the year ended December 31, 2017, six employees exercised stock options covering 11,000 shares for cash, resulting in total proceeds of $49,560.

The weighted average remaining life of the options outstanding under the 2000 Plan, the 2010 Plan and the 2017 Plan as of March 31, 2018 was approximately five years and nine months. The weighted average remaining life of the options exercisable under these plans as of March 31, 2018 was approximately one year and three months. The exercise prices of the options outstanding as of March 31, 2018 ranged from $1.70 to $8.90 per share. The 137,000 stock options granted during the three-month period ended March 31, 2018 had exercise prices between $7.08 and $7.80 per share. The 141,000 stock options granted during the year ended December 31, 2017 had exercise prices between $5.33 and $8.90 per share. The aggregate intrinsic value of options exercised during 2018 and 2017 approximated $24,800 and $43,470, respectively. The weighted-average grant date fair values of options granted during 2018 and 2017 were $4.22 and $3.51 per share, respectively. As of March 31, 2018, total unrecognized stock-based compensation related to non-vested stock options aggregated $915,479, which will be recognized over a weighted average period of two years and five 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 period ended March 31, 2018 and for the year ended December 31, 2017:

	For the Three-Month Period Ended March 31, 2018		**For the Year Ended December 31, 2017**	
Risk-free interest rate	2.5	%	1.9	%
Dividend yield	0	%	0	%
Expected volatility	57	%	61	%
Expected life	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.

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Notes to Unaudited Condensed Financial Statements (Continued)

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.

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.

12. REVENUE

We primarily offer the **First Defense®** product line to dairy and beef producers. Generally, our products are promoted to veterinarians and dairy and beef producers by our sales team and then sold through distributors. Our primary market is North America, but we are beginning to expand into other geographic territories around the world. The **First Defense®** product line prevents scours in newborn calves. The demand for animal protein, that must be produced efficiently while insuring food quality and safety, increases as the human population grows. There were no material changes between the allocation and timing of revenue recognition during the three-month period ended March 31, 2018 (under ASC 606) and the three-month period ended March 31, 2017 (under ASC 605). We do not have any contract assets such as work-in-process or contract liabilities such as customer advances. All trade receivables on our condensed financial statements are from contracts with customers. We incur no material costs to obtain a contract. As of March 31, 2018, we had a backlog of orders, which represents purchase orders received from customers which were not fulfilled or paid, worth approximately $1,245,000 that we expect to fulfill by December 31, 2018.

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Notes to Unaudited Condensed Financial Statements (Continued)

The following table presents our revenue disaggregated by geographic area:

	For the Three-Month Periods Ended March 31,	
	2018	2017
United States	$2,595,616	$2,796,176
Other	285,569	747,754
Total	$2,881,185	$3,543,930

The following table presents our revenue disaggregated by major product category:

	For the Three-Month Periods Ended March 31,	
	2018	2017
First Defense® product line	$2,780,869	$3,243,704
Other animal health	100,316	203,826
Other	-	96,400
Total	$2,881,185	$3,543,930

13. OTHER EXPENSES, NET

Other expenses, net, consisted of the following:

	For the Three-Month Periods Ended March 31,

	2018	2017
Interest expense	$96,015	$39,902
Interest income	(3,824)	(5,957)
Other gains	(75)	(3,703)
Other expenses, net	$92,116	$30,242

14. INCOME TAXES

Our income tax (benefit) expense aggregated ($49,148) and $303,725 (amounting to (18%) and 34% of our (loss) income before income taxes, respectively) for the three-month periods ended March 31, 2018 and 2017, respectively. As of March 31, 2018, we had federal net operating loss carryforwards of approximately $1,700,000 that expire in 2034 through 2037 (if not utilized before then) and state net operating loss carryforwards of approximately $429,000 that expire in 2037 (if not utilized before then). Additionally, we had federal general business tax credit carryforwards of approximately $335,000 that expire in 2027 through 2037 (if not utilized before then) and state tax credit carryforwards of approximately $294,000 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 from 2013 to 2015. Included in this amount is approximately $820,000 that was capitalized and is being depreciated over statutory periods for tax return purposes only.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act. This legislation makes significant change in the U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from the current rate of 34% to 21%. As a result of the enacted law, we were required to revalue deferred tax assets and liabilities at the enacted rate in 2017.

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Notes to Unaudited Condensed Financial Statements (Continued)

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 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, an increase to the valuation allowance would be charged to income in the period such determination was made.

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 2014. 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 March 31, 2018. 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 March 31, 2018.

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 achieve regulatory approval 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, **Tri-Shield™ First Defense®**. This perpetual license (if not terminated for cause) is subject to a milestone payment of $150,000 due upon regulatory approval of the product, which was achieved during the fourth quarter of 2017. This amount was accrued at December 31, 2017 and paid in January 2018. The license is also subject to a royalty equal to 4% of the sales realized above the average of the sales of our bivalent product line for the years ended December 31, 2016 and 2015, plus a growth assumption of 6%. Earned royalties due are subject to annual minimums of $5,000, $10,000, $15,000, $20,000 and $25,000 for the years ending December 31, 2017, 2018, 2019, 2020, and 2021 (and thereafter), respectively. Royalties of $5,000 were accrued at December 31, 2017 and paid in January 2018.

During the third quarter of 2016, we initiated construction of our Nisin production facility. The estimated total cost of the Nisin facility is approximately $21,000,000. As of March 31, 2018, we had incurred approximately $20,501,000 of capital expenditures related to this project, of which $20,451,000 had been paid as of March 31, 2018. The majority of the remainder of this investment is expected to be paid during the second quarter of 2018. In addition to the commitments related to our Nisin production facility discussed above, we had committed $255,000 to the purchase of inventory, $95,000 to capital expeditures and $41,000 to other obligations as of March 31, 2018.

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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 97% and 92% of our total product sales during the three-month periods ended March 31, 2018 and 2017, respectively. Our primary customers for the majority of our product sales (90% and 77% during the three-month periods ended March 31, 2018 and 2017, 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 10% and 18% of our total product sales during the three-month periods ended March 31, 2018 and 2017, 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 (the **First Defense®** product line and **CMT**) and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased $209,633 and $196,708 of products from ImmuCell during the three-month periods ended March 31, 2018 and 2017, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of $10,383 and $1,177 to these affiliated companies during the three-month periods ended March 31, 2018 and 2017, respectively, that were expensed as incurred. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated $56,588 and $14,176 as of March 31, 2018 and December 31, 2017, 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. We currently match 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 $24,646 and $18,709 into the plan for the three-month periods ended March 31, 2018 and 2017, respectively.

19. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of filing on May 14, 2018, the date we have issued this Quarterly Report on Form 10-Q. As of such date, there were no material, reportable subsequent events.

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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 operations principally from our gross margin on product sales and equity and debt financings. 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 unaudited nine-month period ended September 30, 2017. The table below summarizes the changes in selected, key accounts (in thousands, except for percentages):

	As of March 31, 2018	As of **December 31, 2017**	**(Decrease) Increase** Amount	%
Cash and cash equivalents	$3,060	$ 3,799	$(738)	(19)%
Net working capital	$4,985	$ 5,443	$(458)	(8)%
Total assets	$33,632	$ 34,299	$(667)	(2)%
Stockholders' equity	$23,493	$ 23,595	$(102)	(-)%
Common shares outstanding	5,480	5,476	4	- %

Net cash provided by operating activities decreased to $250,000 during the three-month period ended March 31, 2018 from $1.3 million during the three-month period ended March 31, 2017 primarily as a result of the order backlog,

discussed more fully below. Cash paid for capital expenditures totaled $1.2 million during the three-month period ended March 31, 2018 in comparison to capital expenditures of $4.9 million during the three-month period ended March 31, 2017, reflecting the near completion of our Nisin production facility. We believe that we have sufficient capital resources to continue operations for at least twelve months from the date of this filing.

During 2017 and 2016, we raised net proceeds of approximately $12.24 million (gross proceeds were approximately $13.46 million) from four different common equity transactions. 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. During the fourth quarter of 2017, we issued 417,807 shares of common stock, raising net proceeds of approximately $2.73 million.

During 2017 and 2016, we secured debt financing from TD Bank N.A. in the form of three different facilities aggregating up to $6.84 million. This debt is in addition to two mortgage loans entered into during 2010 and 2015 aggregating $3.5 million at inception, also with TD Bank N.A. As of March 31, 2018, $9.31 million was outstanding under these five facilities and approximately $426,000 was available to be drawn. We also have a $500,000 line of credit with TD Bank N.A. that is available as needed through May 31, 2020 and subject to extension by the bank after that date. No amounts were outstanding under the line of credit as of March 31, 2018. These credit facilities are subject to certain restrictions and financial covenants and are secured by substantially all of our assets, including our facility at 56 Evergreen Drive in Portland, which was independently appraised at $4.2 million in connection with the 2015 financing. We are in compliance with all applicable covenants as of March 31, 2018.

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During the third quarter of 2016, we initiated construction of our Nisin production facility. We completed construction of the building during the fourth quarter of 2017 and began depreciating these construction costs at that time. We began equipment installation during the third quarter of 2017. These costs are being capitalized on our balance sheet as construction in progress. Depreciation of these costs is expected to begin when the equipment is placed into service for its intended purpose (which is to produce Nisin), which will likely be during 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 year ended December 31, 2017	17,161,000	(2)
Paid during the three-month period ended March 31, 2018	1,209,000	(3)
Estimate to be paid after March 31, 2018	550,000	(4)
Estimated total cost of investment	$21,000,000	

(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 $641,000 that was capitalized as of December 31, 2017 but not paid until the first quarter of 2018.

(3) This amount includes approximately $641,000 that was capitalized as of December 31, 2017 but paid during the first quarter of 2018. This amount does not include approximately $50,000 that was capitalized as of March 31, 2018 but not paid until the second quarter of 2018.

(4) This amount includes approximately $50,000 that was capitalized as of March 31, 2018 but paid during the second quarter of 2018.

Our capital expenditures from January 1, 2014 through December 31, 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, as detailed in the following table:

	Paid during the years ended December 31,				
Project Description	2014	2015	2016	2017	Total
Facility addition at 56 Evergreen Drive	$1,041,000	$914,000	$-	$-	$1,955,000
Production capacity increase	-	1,077,000	1,173,000	-	2,250,000
Land for Nisin production facility	-	265,000	13,000	53,000	331,000

Nisin production facility and equipment	-	-	2,080,000	17,161,000	19,241,000
Other capital expenditures	495,000	463,000	320,000	546,000 (1)	1,824,000
Total	$1,536,000	$2,719,000	$3,586,000	$17,760,000	$25,601,000

(1) This amount includes approximately $472,000 paid for the purchase of a warehouse building adjacent to our Nisin production facility and is net of a credit of approximately $61,000 for a returned fixed asset acquired during 2016.

During the three-month period ended March 31, 2018, we invested approximately $618,000 in the Nisin production facility and equipment and $21,000 in other capital expenditures. As of April 1, 2018, we had additional authorization from our Board of Directors to invest up to approximately $725,000 through December 31, 2018 in routine and necessary capital expenditures, which is in addition to the payments expected to be made to complete the Nisin production facility, described in the tables above.

During the third quarter of 2016, the City of Portland approved a Tax Increment Financing (TIF) credit enhancement package that reduces the real estate taxes on our Nisin production facility by 65% over the eleven-year period ending June 30, 2028 and by 30% during the twelve months ending June 30, 2029, at which time the rebate expires. During the second quarter of 2017, the TIF was approved by the Maine Department of Economic and Community Development. The aggregate financial benefit was originally estimated to be approximately $400,000. Based on the $1.6 million increase in the assessed value as of April 1, 2017 for the building in process of being completed, the TIF has reduced our property taxes by approximately $22,000 for the twelve months ending June 30, 2018. The value of the tax savings will increase in proportion to any 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

2018 Compared to 2017

Product Sales

Total product sales during the three-month period ended March 31, 2018 decreased by 19%, or $663,000, to $2.9 million, from $3.5 million during the same period in 2017, with domestic sales decreasing by 7%, or $201,000, and international sales decreasing by 62%, or $462,000, in comparison to the same period during 2017. Sales of the discontinued topical wipes product line aggregated approximately $0 and $97,000 during the three-month periods ended March 31, 2018 and 2017, respectively. Total product sales during the rolling twelve months ended March 31, 2018 decreased by 3%, or $333,000, to $9.8 million from $10.1 million during the same period ended March 31, 2017, with domestic sales increasing by less than 1%, or $57,000, and international sales decreasing by 23%, or $390,000, in comparison to 2017. Sales of the discontinued topical wipes product line aggregated approximately $0 and $354,000 during the rolling twelve months ended March 31, 2018 and 2017, respectively.

The sales results based on product we shipped to customers during the first quarter of 2018 compared to the record first quarter of 2017 are below expectations. The inventory supply problem that caused a large order backlog is discussed below. Sales demand from our customers appears to remain very strong despite the supply challenges. If we had sufficient inventory to fulfill all orders on hand as of March 31, 2018, sales would have been up 16% and 9% during the three-month and the rolling twelve months ended March 31, 2018, respectively, in comparison to the same periods ended March 31, 2017. The estimated value of this backlog is calculated by multiplying the number of units for which customer orders had been received but were not shipped at the end of the period by the expected selling price. The rolling twelve-month figures were derived from taking the year ended December 31, 2017 less the three months ended March 31, 2017 plus the three months March 31, 2018.

The prolonged period of order backlog we experienced (which began early in 2015 and extended through the middle of 2016) disrupted our normal product shipping patterns for the first time. In response, we completed 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. This expanded production capacity has the potential to produce product with an annual sales value of approximately $17 million. The actual production output will vary subject to product yields, selling price and product format mix. Since the third quarter of 2016 and through most of 2017, we had sufficient available inventory and were shipping in accordance with the current demand of our distributors. However,

during the first quarter of 2018, we incurred a backlog of orders for the second time. We quickly sold out of our initial launch quantities of **Tri-Shield™ First Defense®** soon after regulatory approval was obtained during the fourth quarter of 2017, which led to a backlog of orders worth approximately $168,000 as of December 31, 2017. During the first quarter of 2018, market demand for **Tri-Shield™** quickly exceeded our available inventory. Production has not kept pace with demand primarily because of the difficulty in producing enough of the new, complex rotavirus vaccine that is used to immunize our source cows at large scale. As of March 31, 2018, the backlog of orders for this new product increased to approximately $344,000, which we expect to fulfill during the next nine months. While this backlog is a problem and could adversely impact customer relations and result in lost sales, it is also a positive indication that the market is accepting our new product offering. We are scaling up production and expect to have inventory in line with anticipated sales during the fourth quarter of 2018. Given this shortage of supply, we have had to change our market launch strategy for **Tri-Shield™**. We have pivoted away from a mass-market launch and are working with distribution partners to allocate the limited supply to influential end-users and veterinarians capable of collecting field data that could help with a re-launch around year end assuming the production issues have been resolved and adequate inventory is on hand. During the first quarter of 2018, sales demand for the bivalent bolus and tube formats of the **First Defense®** product line also exceeded available inventory. As of March 31, 2018, we had a backlog of orders for these other formats of the **First Defense®** product line worth approximately $901,000, which we expect to fulfill during the second quarter of 2018. In order to produce more doses quickly to clear the first order backlog, we significantly increased the quantity of our supply of colostrum. The current backlog problem is largely caused by a reduction in the biological yield from this new milk supply and other factors discussed below with respect to the gross margin analysis. To address the inherent variability in our biological yields, among other process improvements, we are working to optimize the mix of early milk that is rich with antibodies and later milk that contains less antibodies. As of May 11, 2018, we had reduced the backlog of orders for the bivalent bolus and tube formats of the **First Defense®** product line by approximately 41% to approximately $536,000. We expect to clear this order backlog during the second quarter of 2018 and begin building adequate inventory levels. We are confident that once this backlog is cleared, we will again produce a reliable supply of the **First Defense®** product line because of the improved quality control processes, the modified production methods to increase yields and the enhanced manufacturing redundancies that we are implementing.

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Going forward, we do not expect to provide disclosures about sales by individual product format because we believe the important metric to watch is total sales of the **First Defense®** product line as a whole. However, to provide some insight into the new product launch, sales of **Tri-Shield™ First Defense®** were approximately $250,000 and $236,000 during the fourth quarter of 2017 and first quarter of 2018, respectively. Due to the production limitations, discussed above, we expect to have a similar amount of product available for sale during the second and third quarters of 2018. We now have some good market feedback about the initial customer demand for our product. We are satisfied that we are successfully addressing the vaccine and biological yield issues pertaining to the production of this new product. By and during the fourth quarter of 2018, we expect to be able to produce product with a sales value of approximately $500,000 to $750,000.

The **First Defense®** product line 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 97% and 92% of our total product sales during the three-month periods ended March 31, 2018 and 2017, respectively. Sales of the **First Defense®** product line during the three-month period ended March 31, 2018 decreased by 14% in comparison to the same period during 2017, with domestic sales decreasing by 4% and international sales decreasing by 56%, in comparison to the same period during 2017. Sales of the **First Defense®** product line aggregated 96% and 93% of our total product sales during the rolling twelve months ended March 31, 2018 and 2017, respectively. Sales of the **First Defense®** product line during the rolling twelve months ended March 31, 2018 decreased by less than 1% in comparison to 2017, with domestic sales increasing by 5% and international sales decreasing by 24% in comparison to the same period ended March 31, 2017.

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 67% during the three-month period ended March 31, 2018 in comparison to the same period during 2017. Sales of these other products decreased by 43% during the rolling twelve months ended March 31, 2018 in comparison to the same period during 2017. Sales of these other products aggregated 3% and 8% of our total product sales during the three-month periods ended March 31, 2018 and 2017, respectively, and 4% and 7% of our total product sales during the rolling twelve months ended March 31, 2018 and 2017, respectively. Sales of our Nisin-based topical wipes (our second leading source of animal health product sales prior to 2017) 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 $3,000 during 2017. We acquired several other private label products (our second leading source of product sales during 2017) in connection with our January 2016 acquisition of certain gel formulation technology. These products contribute less gross margin than the **First Defense®** product line and consume production capacity. We make and sell bulk reagents for Isolate™ (formerly known as Crypto-Scan®) (our third leading source of product sales during 2017), which is a drinking water test that is sold by our distributor in the United Kingdom. Lastly, we sell our own **California Mastitis Test (CMT)** (our fourth leading source of product sales during 2017), which is used to detect somatic cell counts in milk.

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 March 31,		(Decrease)	
	2018	2017	Amount	%
Gross margin	$1,360	$2,152	$(792)	(37)%
Percent of Product sales	47 %	61 %	(14)%	(22)%

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The gross margin as a percentage of product sales was 47% and 61% during the three-month periods ended March 31, 2018 and 2017, respectively. Several events occurred during the first quarter of 2018 that drove our costs of goods sold higher than normal. Due largely to biological yield losses discussed above, the legacy formats of the **First Defense®** product line yielded fewer doses than normal and incurred higher per unit production costs during the first quarter of 2018, in comparison to the same period in 2017. Costs associated with the initial batches of **Tri-Shield™ First Defense®** have yielded fewer doses at a higher cost than we expect going forward when the new product is in full production mode. We believe we understand the cause of this current and significant biological variance and are correcting for it going forward.

	For the Rolling Twelve Months Ended March 31,		**(Decrease)**	
	2018	2017	Amount	%
Gross margin	$4,429	$5,815	$(1,386)	(24)%
Percent of Product sales	45 %	58 %	(12)%	(21)%

The gross margin as a percentage of product sales was 45% and 58% during the rolling twelve months ended March 31, 2018 and 2017, respectively. This compares to gross margin percentages of 50% and 57% during the years ended December 31, 2017 and 2016, respectively. As we evaluate our product costs and selling price, it is one of our goals to continue to achieve a gross margin (before related depreciation expenses) as a percentage of total sales consistent with current results (approximately 50%) after the initial launch of new products. We have achieved this annual objective since 2009. 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 always affected by inherent 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. 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 going forward based on process improvements that we are implementing and are beginning to see positive results during the second quarter of 2018.

Product Development Expenses

Product development expenses increased by 72%, or $243,000, to $583,000 during the three-month period ended March 31, 2018 in comparison to $340,000 during the same period in 2017, as we invested to gain regulatory approval to launch two new products. Product development expenses aggregated 20% and 10% of product sales during the three-month periods ended March 31, 2018 and 2017, respectively. Product development expenses increased by 79%, or $1.0 million, to $2.3 million during the rolling twelve months ended March 31, 2018 in comparison to $1.3 million during the same period ended March 31, 2017. Product development expenses aggregated 23% and 13% of product sales during the rolling twelve months ended March 31, 2018 and 2017, respectively. Since January 1, 2000 (the year we began development of our Nisin-based treatment for subclinical mastitis in lactating dairy cows), the majority of our product development spending has been focused on this product development initiative.

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.

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The New Animal Drug Application (NADA) for our novel mastitis treatment product is comprised of five principal Technical Sections and one administrative submission that are subject to the FDA's phased review. By statute, each Technical Section submission is generally subject to a six-month review cycle by the FDA. Each Technical Section can be reviewed and approved separately. Upon review and assessment by the FDA that all requirements for a Technical Section have been met, the FDA may issue a Technical Section Complete Letter. The current status of our work on these submissions to the FDA is as follows:

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

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

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

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. We submitted the HFS Technical Section to the FDA at the end of the first quarter of 2018. 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 with respect to this submission late in the third 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 was 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 have reduced the risk associated with our $21 million investment 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 of our Nisin product. 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.

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 this facility. Construction of the facility was completed during the fourth quarter of 2017. As anticipated, we began equipment installation during the third quarter of 2017 and expect installation and qualification to be complete during the second quarter of 2018. Three registration batches must be produced at commercial scale, a detailed CMC Technical Section must be completed and submitted to the FDA and successful FDA inspection(s) must be achieved. We anticipate making the first phased Nisin Drug Substance CMC Technical Section submission to the FDA during the middle of 2018. A second phased submission, which includes responses to the first phased review and detailed information on the sterile Nisin Drug Product, is expected to be filed in the first half of 2019. Each submission is subject to a six month review by the FDA. After approval of the CMC section, there is a 60-day administrative review before product license approval can be issued. We expect to achieve earlier approval of the HFS Technical Section. Our timeline supports obtaining FDA approval for the Nisin product by late 2019 to early 2020, subject to specific FDA review and requests. With respect to CMC Technical Section, we intend to disclose the timing of the phased submissions to the FDA and the timing of the responses from the FDA and any revisions to the timeline, as we go forward.

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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 (aseptic filled and packaged syringes) manufacturer, covering the formulation and aseptic filling and final packaging of the Nisin Drug Product. Norbrook provided these services for clinical material used in all of our 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. If we do not achieve FDA approval of the Nisin product by the end of 2019, this agreement may be terminated by Norbrook, in which event we would be liable for a $100,000 termination fee under this agreement. We are presently negotiating certain contract modifications and extensions with Norbrook and identifying and exploring potential alternative providers of these services.

Our second most important product development program (in terms of dollars invested and, we believe, potential market impact) has been 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 for use with animals. This perpetual license (if not terminated for cause) is subject to 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 achieved product license approval and initiated market launch of this product, **Tri-Shield™ First Defense®**, during the fourth quarter of 2017. This is 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 contain only one or two of these label claims. This new product is now available in a gel tube delivery format. Because it is possible that all farms may not have a prevalent rotavirus problem, we are continuing to sell the bivalent formats of **First Defense®** as options for customers. 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 mother cow to increase the antibody level against specific scours-causing pathogens in the colostrum that she produces for her 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 **Tri-Shield™ First Defense®**, producers can reduce stress-causing injections to the cow and save the associated 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 **Tri-Shield™ First Defense®**, 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. This variability in a cow's immune response to vaccines that creates a sales opportunity for our new product also causes a production challenge that can impact our costs of goods sold when we immunize our source cows to produce the antibodies used in our production process.

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 and bulk powder (both expected by the end of 2018) formulations of **First Defense Technology®**, which will then be re-branded **Dual-Force™ First Defense®**. We are also investing in additional studies comparing the **First Defense®** product line 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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Sales and Marketing Expenses

Sales and marketing expenses increased by approximately 3%, or $17,000, to $532,000 during the three-month period ended March 31, 2018 in comparison to $514,000 during the same period in 2017, amounting to 18% and 15% of product sales during the three-month periods ended March 31, 2018 and 2017, respectively. Sales and marketing expenses decreased by approximately 1%, or $17,000, to $1.9 million during the rolling twelve months ended March 31, 2018 in comparison to approximately $1.9 million during the same period ended March 31, 2017, amounting to 20% and 19% of product sales during the rolling twelve months ended March 31, 2018 and 2017, respectively. We continue to leverage the efforts of our small sales force by using animal health distributors. Our current budgetary objective in 2018 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 fourth quarter of 2017, we increased our sales team by one new employee and are presently recruiting to fill one additional position.

Administrative Expenses

Administrative expenses increased by approximately 11%, or $43,000, to $423,000 during the three-month period ended March 31, 2018 in comparison to $380,000 during the same period in 2017. Administrative expenses increased by approximately 5%, or $71,000, to $1.6 million during the rolling twelve months ended March 31, 2018 in comparison to $1.5 million during the same period ended March 31, 2017. We strive to be efficient with these expenses while funding costs associated with complying with the Sarbanes-Oxley Act of 2002 and all the legal, audit and other costs associated with being a publicly-held company. Prior to 2014, we had limited our investment in investor relations spending. Beginning in the second quarter of 2014, we initiated an investment in a more active 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 March 31, 2018 of ($178,000) was in contrast to net operating income of $918,000 during the same period in 2017. Our net operating (loss) during the rolling twelve months ended March 31, 2018 of ($1.3 million) was in contrast to net operating income of $1.1 million during the same period ended March 31, 2017. This decrease was driven primarily by a sales decline due to order backlog issues,

coupled with an increase in cost of goods sold (on similar sales volume) and an increase in product development expenses incurred, as we invested to gain regulatory approval to launch two new products.

Other expenses, net (first quarter)

Interest expense (including amortization of debt issuance costs of approximately $4,000 and $3,000 during the three-month periods ended March 31, 2018 and 2017, respectively) increased by approximately 141%, or $56,000, to $96,000 during the three-month period ended March 31, 2018 in comparison to $40,000 during the same period in 2017, due to higher levels of outstanding debt at modestly higher interest rates on the variable facilities. Interest income decreased by approximately 36%, or $2,000, to $4,000 during the three-month period ended March 31, 2018, in comparison to $6,000 during the same period ended March 31, 2017. Other expenses, net, aggregated $92,000 and $30,000 during the three-month periods ended March 31, 2018 and 2017, respectively.

Other expenses, net (rolling twelve months ended March 31st)

Interest expense (including amortization of debt issuance costs of approximately $17,000 and $11,000 during the rolling twelve months ended March 31, 2018 and 2017, respectively) increased by approximately 67%, or $110,000, to $275,000 during the rolling twelve months ended March 31, 2018 in comparison to $165,000 during the same period ended March 31, 2017, due to higher levels of outstanding debt at modestly higher interest rates on the variable facilities. Assuming that we draw the remaining funds available under our equipment loan during the third quarter of 2018, interest expense would be approximately $441,000 during the year ending December 31, 2018. This estimate assumes an interest rate of 4.5% on the variable rate loan facilities. Actual interest expense will be charged at 2.25% over the one-month LIBOR. The one-month LIBOR was approximately 1.88% as March 31, 2018. Interest income decreased by approximately 69%, or $33,000, to $15,000 during the rolling twelve months ended March 31, 2018, in comparison to $47,000 during the same period ended March 31, 2017. Less interest income was earned during the 2018 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 $258,000 and $139,000 during the rolling twelve months ended March 31, 2018 and 2017, respectively.

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

Our (loss) before income taxes of ($270,000) during the three-month period ended March 31, 2018 was in contrast to income before income taxes of $888,000 during the same period in 2017. We recorded income tax (benefit) expense of (18%) and 34% of the (loss) income before income taxes during the three-month periods ended March 31, 2018 and 2017, respectively. The tax benefit rate during the first quarter of 2018 is unusual because the dollar amount is relatively small, making a relatively small dollar change result in a high percentage change. Our net (loss) of ($221,000), or ($0.04) per share during the three-month period ended March 31, 2018 is in contrast to net income of $584,000, or $0.12 per diluted share, during the three-month period ended March 31, 2017.

During the three-month period ended March 31, 2018 our (loss) before income taxes was ($270,000) (including depreciation and amortization expenses of $285,000), in contrast to income before income taxes of $888,000 (including depreciation and amortization expenses of $218,000) during the three-month period ended March 31, 2017. We began depreciating our Nisin production facility during the fourth quarter of 2017, and we expect to begin depreciating the related production equipment during the second quarter of 2018. Because of the increasing amount of depreciation that is being recorded in our operating results, it is important to consider our net cash provided by operating activities from our Statements of Cash Flows (see page 4 of the accompanying financial statements) to assess the cash generating ability of our operations going forward. Net cash provided by operating activities (which does not include investing or financing activities) was $250,000 and $1.3 million during the three-month periods ended March 31, 2018 and 2017, respectively. Given our increased level of outstanding bank debt, it is also important to consider the amount of our debt principal repayments that is disclosed as part of our net cash provided by (used for) financing activities from our Statements of Cash Flows. During the three-month periods ended March 31, 2018 and 2017, debt principal repayments aggregated approximately $40,000 and $35,000, respectively.

(Loss) Income Before Income Taxes and Net (Loss) Income (rolling twelve months ended March 31st)

Our (loss) before income taxes of ($1.6 million) during the rolling twelve months ended March 31, 2018 was in contrast to income before income taxes of $971,000 during the same period ended March 31, 2017. We recorded an income tax (benefit) expense of (39%) and 34% of the (loss) income before income taxes during the rolling twelve months ended March 31, 2018 and 2017, respectively. On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act. This legislation makes significant changes in the U.S. tax law, including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from the current rate of 34% to 21%. Our net (loss) of ($974,000), or ($0.19) per share, during the rolling twelve months ended March 31, 2018 is in contrast to net income of $640,000, or $0.14 per diluted share, during the rolling twelve months ended March 31,

2017.

During the rolling twelve months ended March 31, 2018, our (loss) before income taxes was ($1.6 million) (including depreciation and amortization expenses of $971,000), in contrast to income before income taxes of $971,000 (including depreciation and amortization expenses of $849,000) during the rolling twelve months ended March 31, 2017. We began depreciating our Nisin production facility during the fourth quarter of 2017, and we expect to begin depreciating the related production equipment during the second quarter of 2018. For tax return purposes only, our depreciation expense for the Nisin production facility during 2017 was approximately $1,492,000, which will be available to offset future taxable income. Our preliminary estimate of depreciation expense for the year ending December 31, 2018 is approximately $2,000,000. This figure is a preliminary estimate only and actual depreciation expense will vary from this estimate. This depreciation expense (that is far larger than what we have incurred historically) may cause, in part, a net loss for the year ending December 31, 2018. Because of the increasing amount of depreciation that is being recorded in our operating results, it is important to consider our net cash provided by operating activities from our Statements of Cash Flows to assess the cash generating ability of our operations going forward. Net cash provided by operating activities (which does not include investing or financing activities) was $170,000 and $1.1 million during the rolling twelve months ended March 31, 2018 and 2017, respectively. Given our increased level of outstanding bank debt, it is also important to consider the amount of our debt principal repayments that is disclosed as part of our net cash provided by (used for) financing activities from our Statements of Cash Flows. During the rolling twelve months ended March 31, 2018 and 2017, debt principal repayments aggregated approximately $156,000 and $138,000, 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 March 31, 2018 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 five criteria are met. These include i) identification of the contract with the customer, ii) identification of the performance obligations in the contract, iii) determination of the transaction price, iv) allocation of the transaction price to the separate performance obligations in the contract and v) recognition of revenue associated with performance obligations as they are satisfied. 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 March 31, 2018, 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, 2017.

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 March 31, 2018. 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 Control 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 were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We implemented internal controls to ensure we adequately evaluate our contracts and properly account for revenue recognition under the new accounting standards. There were no significant changes to our internal control over financial reporting due to the adoption of the new standards.

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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; projections about depreciation expense and its impact on income for book and tax return purposes; 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; estimates about the market size for our products; future market share of and revenue generated by current products and products still in development; our ability to increase production output and reduce costs of goods sold associated with our new product, **Tri-Shield™ First Defense®**; 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 efficiency and effectiveness of our manufacturing processes and related technical issues; estimates about our production capacity; the future adequacy of our working capital and the availability and cost of third party financing; 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; future cost of our variable rate interest expense on most of our bank debt; costs associated with sustaining compliance with current Good Manufacturing Practice (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; implementation of international trade tariffs that could reduce the export of dairy products weakening the price received by our customers for their product; 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; 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”, “b “estimates”, “targets”, “projects”, “forecasts” and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, 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, 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 under **Part II, Item 1A** – “Risk Factors” of this Quarterly Report on Form 10-Q and uncertainties otherwise referred to in this Quarterly Report.

Projection of net income (loss): 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 were profitable during the second half of 2014, during the full years of 2015 and 2016 and during the nine-month period ended September 30, 2017. Depreciation expenses related to the Nisin production facility are expected to produce losses until and unless product sales increase to offset these non-cash expenses.

*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 without the gross margin that we earned on sales of the **First Defense®** product line, which accounted for 97% and 92% of our total product sales during the three-month periods ended March 31, 2018 and 2017, respectively.

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Gross margin on product sales: It is one of our goals to continue to achieve a gross margin (before related depreciation expenses) as a percentage of total sales consistent with current results (approximately 50%) after the initial launch of new products. Many factors discussed in this report impact our costs of goods sold. There is a risk that we are not able to achieve our gross margin goals, which could impact our future operating plans.

Product risks: The sale of our products is subject to production, financial, efficacy, regulatory, competitive and other market risks. Elevated standards to achieve and maintain regulatory compliance required to sell our products continue to evolve. Failure to achieve acceptable biological yields from our production processes can increase our costs of goods sold materially and reduce our production output leading to an order backlog. We have experienced customer complaints pertaining to the gel tube format of the **First Defense®** product line about some product that has become compacted and not expressible. This is a risk to achieving and maintaining customer acceptance. The costs associated with replacing defective product are accounted for in costs of goods sold. We believe we have improved our production process to prevent this problem and are incurring added costs to ship this product on ice going forward to insure better quality. There is no assurance that we will continue to achieve market acceptance at a profitable price level or that we can continue to manufacture our products at a low enough cost to result in a sufficient gross margin to justify their continued manufacture and sale.

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

*Regulatory requirements for 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 oversight risks in territories outside of the United States where we sell our products.

Regulatory requirements for our purified Nisin product: 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 (18 years) and has involved multiple commercial production strategies. As a result, the Chemistry, Manufacturing and Controls Technical Section (the approval of which is a precondition to commencement of sales of our mastitis product) 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 late 2019 to early 2020; however, there remains a risk that approval could be delayed or not obtained. 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.

Concentration of sales: Approximately 100% and 96% of our product sales were made to customers in the dairy and beef industries throughout the world during the three-month periods ended March 31, 2018 and 2017, respectively. Approximately 90% and 77% of our product sales were made to customers in the U.S. dairy and beef industries during the three-month periods ended March 31, 2018 and 2017, 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 (58% and 66% during the three-month periods ended March 31, 2018 and 2017, respectively) was made to two large distributors. A large portion of our trade accounts receivable (45% and 69% as of March 31, 2018 and December 31, 2017, respectively) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us.

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Economics of the dairy and beef industries:

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 93,700,000 as of January 1, 2017 and to 94,400,000 as of January 1, 2018, which is 0.7% higher than at January 1, 2017.

From 1998 through 2017, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 (2004) to the high of 9,392,000 (2017). The monthly average for the first quarter of 2018 increased further to 9,407,000.

While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk, demand for milk is also influenced by very volatile international demand for milk products. The Class III milk price (an industry benchmark that reflects the value of product used to make cheese) is an important indicator because it defines our customers' revenue level. This annual average milk price level (measured in dollars per hundred pounds of milk) reached the low point during the fifteen years since 2003 at $11.36 in 2009. The average 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 but increased by 9% to $16.17 during 2017. However, the monthly average for the first quarter of 2018 dropped by 14% to $13.87. 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)**
2013	2014	
$17.99	$22.34	24%
2014	2015	
$22.34	$15.80	(29)%
2015	2016	
$15.80	$14.87	(6)%
2016	2017	
$14.87	$16.17	9%

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 2.13 during 2015 and increased to 2.26 during 2016 and increased further to 2.43 during 2017. The average for the first quarter of 2018 dropped by 15% to 2.06. 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)**
2013	2014	
1.75	2.54	45%
2014	2015	
2.54	2.13	(16)%
2015	2016	
2.13	2.26	6%
2016	2017	
2.26	2.43	7%

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 2017 declined by 8% to $1,623. For January 2018, this price declined further to $1,520. 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 **Tri-Shield™ First Defense®** 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 has required (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 funding strategy for our purified Nisin product: Producing our pharmaceutical-grade Nisin at commercial-scale is the most critical action in front of us on our path to U.S. regulatory approval for this product. We believe our current cash and cash equivalents will be adequate to complete the project. However, due to the risks described herein, we could experience cost overruns and delays that could be difficult to finance. Having substantially completed construction of the production facility described elsewhere in this report at a cost of approximately $21 million, we do not know whether we will receive the necessary regulatory approvals to manufacture and sell the product, or whether the product will achieve market acceptance and profitability. The additional debt we incurred to fund this project will significantly increase our debt service costs going forward. These loans are subject to certain financial covenants. 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, and could eliminate, our expected profitability going forward and significantly reduce our cash flows.

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). We expect the Nisin production facility that we are constructing for approximately $21 million to have annual production capacity to meet approximately $10 million in sales. Our new facility is designed to have enough room to add 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.

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 entrant 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 scours 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 scours product sold by Zoetis sells for approximately half the price of our product, but it does not have an *E. coli* claim (which we do have). 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 mastitis 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 objective 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 to meet customer demand. The specific antibodies that we purify from colostrum for the **First Defense®** product line are not readily available from other sources. We are and will be dependent on our manufacturing facilities and operations in Portland for the production of the **First Defense®** product line and Nisin. We are and will be 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®**, **Tri-Shield™ First Defense®** and our anticipated 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 formulation, aseptic filling and final packaging of our Nisin Drug Substance into Drug Product. If we do not achieve FDA approval of the Nisin product by late 2019, Norbrook would have the right to terminate the agreement, and we would be liable for a $100,000 termination fee. We are currently negotiating certain contract modifications and a term extension with Norbrook but are at risk of non-extension (and termination) of the contract or extension on less favorable terms. We are evaluating alternative sources for these services for potential use post-approval, but 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 facilities (including due to regulatory non-compliance) could adversely affect the production of inventory and result in significant added expenses and potential loss of future sales.

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Production Capacity Constraints: The backlog of orders discussed elsewhere in this report is a risk to our business. Our plan to continue to expand the **First Defense®** product line requires ongoing review of equipment capacity and utilization across the manufacturing value stream at the 56 Evergreen Drive facility as well as assessment of functional obsolescence and reliability of equipment. It is anticipated that we will need to add a third freeze dryer to the equipment train for the **First Defense®** product line over the next two years at a cost of up to $2 million. Our current two freeze dryers are functioning at a utilization rate of approximately 80%. Other ancillary liquid processing equipment may be required. There is a risk that we are not able to achieve our production capacity growth objectives timely.

Small size; dependence on key personnel: We are a small company with 47 employees (including 4 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.

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 economic instability: 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 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 many Americans and businesses. 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 or maintain a profitable presence in international markets.

Bovine diseases: The potential for epidemics of bovine diseases such as Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) presents a risk to us and our customers. Documented cases of BSE in the United States have led to an overall tightening of regulations pertaining to ingredients of animal origin, especially bovine. **First Defense®** is considered a veterinary medicine rather than a feed ingredient, and it is manufactured from bovine milk (colostrum), which is not considered a BSE risk material. Future regulatory action to increase protection of the human food supply could affect **First Defense®**, although presently we do not anticipate that this will be the case.

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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.

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.

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 $42,981,000 as of May 8, 2018. 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

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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.

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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: May 14, 2018 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer and
Principal Financial Officer