

IMMUCELL CORP /DE/
Form 10-Q
November 13, 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 September 30, 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 November 5, 2018 was 5,484,728.

ImmuCell Corporation

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

	As of September 30, 2018	As of December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 2,393,263	\$ 3,798,811
Trade accounts receivable, net	853,972	1,344,022
Inventory	2,249,942	2,049,732
Prepaid expenses and other current assets	720,851	314,667
Total current assets	6,218,028	7,507,232
PROPERTY, PLANT AND EQUIPMENT, net	26,472,454	26,069,689
DEFERRED TAX ASSETS, net	-	472,726
INTANGIBLE ASSETS, net	138,504	152,832
GOODWILL	95,557	95,557
INTEREST RATE SWAPS	98,390	-
OTHER ASSETS	212,467	920
TOTAL ASSETS	\$ 33,235,400	\$ 34,298,956
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 1,060,684	\$ 1,723,270
Current portion of bank debt	842,637	316,629
Deferred revenue	24,100	24,100
Total current liabilities	1,927,421	2,063,999
LONG-TERM LIABILITIES:		
Bank debt, net of current portion	8,634,854	8,639,021
Interest rate swaps	-	996
Total long-term liabilities	8,634,854	8,640,017
TOTAL LIABILITIES	10,562,275	10,704,016
CONTINGENT LIABILITIES AND COMMITMENTS (Note 16)		

STOCKHOLDERS' EQUITY:

Common stock, \$0.10 par value per share, 11,000,000 and 8,000,000 shares authorized, 5,662,645 and 5,662,645 shares issued and 5,484,728 and 5,476,197 shares outstanding, as of September 30, 2018 and December 31, 2017, respectively	566,265	566,265
Additional paid-in capital	22,712,753	22,458,219
(Accumulated deficit) retained earnings	(290,469)	978,973
Treasury stock, at cost, 177,917 and 186,448 shares as of September 30, 2018 and December 31, 2017, respectively	(389,217)	(407,879)
Accumulated other comprehensive income (loss)	73,793	(638)
Total stockholders' equity	22,673,125	23,594,940
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 33,235,400	\$ 34,298,956

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

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

	During the Three-Month Periods Ended		During the Nine-Month Periods Ended	
	September 30, 2018	2017	September 30, 2018	2017
Product sales	\$2,153,750	\$2,004,961	\$8,049,481	\$7,298,496
Costs of goods sold	1,202,783	1,069,110	4,251,863	3,289,361
Gross margin	950,967	935,851	3,797,618	4,009,135
OPERATING EXPENSES (INCOME):				
Product development expenses	908,793	585,834	2,253,620	1,312,456
Sales and marketing expenses	494,703	446,733	1,501,833	1,361,653
Administrative expenses	396,611	385,695	1,262,868	1,164,533
Gain on sale of assets	(700,000)	-	(700,000)	-
Operating activities, net	1,100,107	1,418,262	4,318,321	3,838,642
NET OPERATING (LOSS) INCOME	(149,140)	(482,411)	(520,703)	170,493
Other expenses, net	106,414	49,238	301,664	115,877
(LOSS) INCOME BEFORE INCOME TAXES	(255,554)	(531,649)	(822,367)	54,616
Income tax (benefit) expense	(5,598)	(192,303)	447,075	28,108
NET (LOSS) INCOME	\$(249,956)	\$(339,346)	\$(1,269,442)	\$26,508
Basic weighted average common shares outstanding	5,483,880	4,992,803	5,481,095	4,896,782
Basic (loss) income per share	\$(0.05)	\$(0.07)	\$(0.23)	\$0.01
Diluted weighted average common shares outstanding	5,483,880	4,992,803	5,481,095	4,999,245
Diluted (loss) income per share	\$(0.05)	\$(0.07)	\$(0.23)	\$0.01

STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

	During the Three-Month Periods Ended		During the Nine-Month Periods Ended	
	September 30, 2018	2017	September 30, 2018	2017
Net (loss) income	\$(249,956)	\$(339,346)	\$(1,269,442)	\$26,508
Other comprehensive income:				
Interest rate swaps, before taxes	19,107	2,850	99,386	5,342

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Income tax applicable to interest rate swaps	(4,777)	(1,026)	(24,956)	(1,923)
Other comprehensive income, net of taxes	14,330	1,824	74,430	3,419
Total comprehensive (loss) income	\$(235,626)	\$(337,522)	\$(1,195,012)	\$29,927

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

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

	During the Nine-Month Periods Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	\$(1,269,442)	\$26,508
Adjustments to reconcile net (loss) income to net cash (used for) provided by operating activities:		
Depreciation	938,416	627,141
Amortization	14,328	14,328
Non-cash interest expense	12,612	11,120
Deferred income taxes	447,770	9,112
Stock-based compensation	257,697	148,035
Gain on sale of assets	(700,000)	-
Gain on disposal of fixed assets	-	(3,663)
Recovery of uncollectible accounts, net	-	(17,643)
Changes in:		
Trade accounts receivable, gross	490,050	141,114
Accrued interest income	-	24,013
Inventory	(200,210)	(605,126)
Prepaid expenses and other current assets	(156,185)	242,683
Other assets	(11,547)	(920)
Accounts payable and accrued expenses	(58,545)	262,270
Deferred revenue	-	(33,856)
Net cash (used for) provided by operating activities	(235,056)	845,116
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1,931,146)	(13,079,386)
Payment of contingent royalties related to 2016 acquisition	(14,077)	(8,661)
Maturities of investments	-	5,699,000
Purchases of investments	-	(249,000)
Proceeds from sale of assets	250,000	-
Proceeds from sale of fixed assets	-	45,000
Net cash used for investing activities	(1,695,223)	(7,593,047)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from private placement, net	-	1,037,164
Proceeds from debt issuance	693,640	3,024,343
Debt principal repayments	(183,887)	(111,981)
Debt issuance costs	(522)	(63,358)
Proceeds from exercise of stock options	15,500	16,500

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Tax benefits related to stock options	-	183
Net cash provided by financing activities	524,731	3,902,851
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,405,548)	(2,845,080)
BEGINNING CASH AND CASH EQUIVALENTS	3,798,811	5,150,344
ENDING CASH AND CASH EQUIVALENTS	\$2,393,263	\$2,305,264

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

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ImmuCell Corporation

(Unaudited Condensed)

STATEMENTS OF CASH FLOWS

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

	During the Nine-Month Periods Ended September 30,	
	2018	2017
CASH PAID FOR:		
Income taxes	\$4,222	\$4,000
Interest	\$294,728	\$123,034
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable and accrued expenses	\$(589,964)	\$1,286,289
Net change in fair value of interest rate swaps	\$(74,430)	\$(3,419)
Fixed asset disposals, gross	\$18,554	\$1,500

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 and third party providers of critical goods and services, 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*TM (Codification). Accordingly, we believe that the disclosures are adequate to ensure that the information presented is not misleading.

(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 \$2,140,960 and \$3,546,529 as of September 30, 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 monthly 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. 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 when practicable. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. 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 September 30, 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 began depreciating the equipment for our Nisin production facility when it was placed in service during the third quarter of 2018. Approximately 89% of these assets are being depreciated over ten years. Significant repairs to fixed assets that benefit more than a current year 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 nine-month period ended September 30, 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 September 30, 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 nine-month period ended September 30, 2018 and the year ended December 31, 2017, there were no transfers between levels. As of September 30, 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 September 30, 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 September 30, 2018 or December 31, 2017.

	As of September 30, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and money market accounts	\$2,393,263	\$-	\$ -	\$2,393,263
Interest rate swaps	\$-	\$98,390	\$ -	\$98,390

	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)

(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 nine-month period ended September 30, 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:

	During the Three-Month		During the Nine-Month	
	Periods Ended September 30,		Periods Ended September 30,	
	2018	2017	2018	2017
Animal Health International, Inc.	50 %	44 %	42 %	42 %
MWI Animal Health	23 %	22 %	22 %	23 %
ANIMART LLC	*	10 %	10 %	*

*Amount is less than 10%.

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

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

	As of		As of	
	September 30,		December 31,	
	2018		2017	
Animal Health International, Inc.	58	%	40	%
MWI Animal Health	25	%	29	%

(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 Accounting Standards Codification (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 beginning on January 1, 2018, 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.

(l) Expense Recognition

In 2018, we 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 \$3,900 and \$15,526 during the three-month periods ended September 30, 2018 and 2017 and \$26,895 and \$47,863 during the nine-month periods ended September 30, 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 the amended provisions of ASC 340-40 did not have a material impact on our financial statements.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

(m) Income Taxes

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. During the second quarter of 2018, we assessed our historical and near-term future profitability and decided to record \$563,252 in non-cash income tax expense to create a full valuation allowance against our net deferred tax assets (which consist largely of net operating loss carryforwards and federal and state tax credits). We have incurred a net loss for six consecutive quarters and have not been profitable on a year-to-date basis since the nine-month period ended September 30, 2017 and project additional net losses for some period going forward before returning to profitability. During the third quarter of 2018, we increased this valuation allowance by \$315,725 to \$878,977. We will continue to assess the need for the valuation allowance at each quarter and in the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to adjust our valuation allowance. 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 September 30, 2018 or December 31, 2017. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 15.

(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 \$89,706 and \$46,922 during the three-month periods ended September 30, 2018 and 2017 and \$257,697 and \$148,035 during the nine-month periods ended September 30, 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:

	During the Three-Month Periods Ended September 30,		During the Nine-Month Periods Ended September 30,	
	2018	2017	2018	2017
Weighted average number of shares outstanding	5,483,880	4,992,803	5,481,095	4,896,782
Effect of dilutive stock options	-	-	-	102,463
Diluted number of shares outstanding	5,483,880	4,992,803	5,481,095	4,999,245
Outstanding stock options not included in the calculation because the effect would be anti-dilutive	489,000	367,000	489,000	63,000

(p) Use of Estimates

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

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

(q) New Accounting Pronouncements

In 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 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.

In August 2017, the FASB issued ASU 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*. The new guidance is intended to more closely align hedge accounting with entities' hedging strategies, simplify the application of hedge accounting and increase the transparency of hedging programs. ASU 2017-12 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. For cash flow and net investment hedges existing at the date of adoption, ASU 2017-12 must be applied through a cumulative-effect adjustment. The amended presentation and disclosure guidance is required only prospectively. We are currently evaluating the impact of the adoption of this guidance on our financial statements. The adoption of ASU 2017-12 is not expected to have a material impact on our financial statements.

3. CASH AND CASH EQUIVALENTS

Cash and cash equivalents consisted of the following:

	As of	As of
	September 30,	December 31,
	2018	2017
Cash and cash equivalents	\$ 2,393,263	\$ 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	As of
	September 30,	December 31,
	2018	2017
Raw materials	\$ 416,139	\$ 483,329
Work-in-process	1,310,526	1,349,649
Finished goods	523,277	216,754
Total	\$ 2,249,942	\$ 2,049,732

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of	As of
	September 30,	December 31,
	2018	2017
Other receivables ⁽¹⁾	\$ 390,207	\$ 149,590
Prepaid expenses	296,380	130,813
Security deposits ⁽²⁾	34,264	34,264
Total	\$ 720,851	\$ 314,667

⁽¹⁾This amount includes \$250,000 due from a third party for the sale of assets. See Note 13.

⁽²⁾ This amount consists of the current portion of escrow funds held against certain construction performance requirements for our Nisin production facility.

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ImmuCell Corporation**Notes to Unaudited Condensed Financial Statements (Continued)****6. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consisted of the following:

	Estimated Useful Lives (in years)	As of September 30, 2018	As of December 31, 2017
Laboratory and manufacturing equipment	3-10	\$ 15,042,596	\$ 5,511,452
Building and improvements	10-39	17,006,716	16,966,728
Office furniture and equipment	3-10	734,887	698,877
Construction in progress		34,786	8,315,436
Land		516,867	518,999
Property, plant and equipment, gross		33,335,852	32,011,492
Accumulated depreciation		(6,863,398)	(5,941,803)
Property, plant and equipment, net		\$ 26,472,454	\$ 26,069,689

As of December 31, 2017, construction in progress consisted principally of payments for equipment to be used in our Nisin production facility. Approximately \$18,554 and \$435,448 of property, plant and equipment, gross, was disposed of during the nine-month period ended September 30, 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 1TM 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 \$10,000 and \$18,000 as of September 30, 2018 and December 31, 2017, respectively, which was recorded in accounts payable and accrued expenses as of those dates. Royalty expense of \$12,046 and \$6,836 was incurred for sales recorded during the nine-month periods ended September 30, 2018 and 2017, 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 September 30, 2018 and 2017 and \$14,328 during the nine-month periods ended September 30, 2018 and 2017. The net value of these intangibles was \$138,504 and \$152,832 as of September 30, 2018 and December 31, 2017, respectively. A summary of intangible amortization expense estimated for the periods subsequent to September 30, 2018 is as follows:

Period	Amount
Three-month period ending December 31, 2018	\$4,776
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	\$138,504

Intangible assets as of September 30, 2018 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	\$ 184,100	\$ (50,628)	\$ 133,472
Customer relationships	1,300	(357)	943
Non-compete agreements	5,640	(1,551)	4,089
Total	\$ 191,040	\$ (52,536)	\$ 138,504

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

Accumulated

	Gross Carrying	Amortization	Net Book
	Value		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	As of
	September 30, 2018	December 31, 2017
Accounts payable – capital	\$ 51,426	\$ 641,389
Accounts payable – trade	515,785	580,456
Accrued payroll	281,036	254,743
Accrued professional fees	95,575	64,200
Accrued other	116,862	182,482
Total	\$ 1,060,684	\$ 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 September 30, 2018, \$579,485 was outstanding under this first note (Loan #1). Proceeds from a \$2,500,000 second mortgage on our 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 September 30, 2018, \$2,256,028 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 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 was 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 4.35% for the one-month period beginning October 1, 2018) through September 2018, at which time the loan converted to a seven-year term loan facility at the same variable interest rate with monthly principal and interest payments due based on a seven-year amortization schedule. As of September 30, 2018, \$3,940,000 was outstanding under this third note. 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 was 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 4.35% for the one-month period beginning October 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 \$1,408,000 will be due during the first quarter of 2027. As of September 30, 2018, \$2,496,000 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 4.31% for the one-month period beginning September 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 \$206,000 will be due during the first quarter of 2027. As of September 30, 2018, \$323,333 was outstanding under this fifth note. We are required by bank debt covenant to maintain at least \$2,000,000 of otherwise unrestricted cash, cash equivalents and short-term investments.

We hedged our interest rate exposures on Loan #1 and Loan #2 with interest rate swap agreements that effectively converted floating interest rates based on the one-month LIBOR plus a margin of 3.25% and 2.25% to the fixed rates of 6.04% and 4.38%, respectively. As of September 30, 2018, the variable rates on these two mortgage notes were approximately 5.40% and 4.43%, respectively. All derivatives are recognized on the balance sheet at their fair value. At the time of the closings and thereafter, the agreements were determined to be highly effective in hedging the variability of the identified cash flows and have been designated as cash flow hedges of the variability in the hedged interest payments. Changes in the fair value of the interest rate swap agreements are recorded in other comprehensive income, 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 \$2,835,513 as of September 30, 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*.

	During the Three-Month		During the Nine-Month	
	Periods Ended September 30,		Periods Ended September 30,	
	2018	2017	2018	2017
Payments required by interest rate swaps	\$1,391	\$8,115	\$9,499	\$29,834
Other comprehensive income, net of taxes	\$14,330	\$1,824	\$74,430	\$3,419

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 September 30, 2018 and 2017 are reflected in the following table by loan:

	During the Three-Month Periods Ended			
	September 30, 2018		September 30, 2017	
	Proceeds from	Debt Principal	Proceeds from	Debt Principal
	Debt Issuance	Repayments	Debt Issuance	Repayments
Loan #1	\$-	\$ (16,219)	\$-	\$ (15,264)
Loan #2	-	(21,279)	-	(20,343)
Loan #3	426,499	-	2,184,343	-
Loan #4	-	(32,000)	-	-
Loan #5	-	(2,640)	-	(2,802)
Total	\$426,499	\$ (72,138)	\$2,184,313	\$ (38,409)

Debt proceeds received and principal repayments made during the nine-month periods ended September 30, 2018 and 2017 are reflected in the following table by loan:

	During the Nine-Month Periods Ended			
	September 30, 2018		September 30, 2017	
	Proceeds from	Debt Principal	Proceeds from Debt	Debt Principal
	Debt Issuance	Repayments	Issuance	Repayments
Loan #1	\$-	\$ (47,995)	\$-	\$ (45,168)
Loan #2	-	(63,837)	-	(61,029)
Loan #3	426,499	-	2,684,343	-
Loan #4	267,141	(64,000)	-	-
Loan #5	-	(8,055)	340,000	(5,784)
Total	\$693,640	\$ (183,887)	\$3,024,343	\$ (111,981)

Principal payments (net of debt issuance costs) due under bank loans outstanding as of September 30, 2018 (excluding our \$500,000 line of credit) are reflected in the following table by the year that payments are due:

	Three-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	\$ 16,881	\$ 68,908	\$ 493,696	\$ -	\$ -	\$-	\$ 579,485
Loan #2	22,260	89,997	94,005	98,538	103,077	1,848,151	2,256,028
Loan #3 ⁽¹⁾	140,714	562,857	562,857	562,857	562,857	1,547,858	3,940,000
Loan #4 ⁽¹⁾	32,000	128,000	128,000	128,000	128,000	1,952,000	2,496,000
Loan #5 ⁽²⁾	2,874	11,812	12,332	12,874	13,441	270,000	323,333
Total	\$ 214,729	\$ 861,574	\$ 1,290,890	\$ 802,269	\$ 807,375	\$ 5,618,009	\$ 9,594,846
Debt Issuance							(117,355)
Costs							
Total							\$ 9,477,491

These notes bear interest at a variable rate equal to the one-month LIBOR plus a margin of 2.25%. Figures in this (1)table are estimated using an interest rate of approximately 4.35%. The actual interest rate and principal payments will be different.

This note bears interest at a variable rate equal to the one-month LIBOR plus a margin of 2.25%. Figures in this (2)table are estimated using an interest rate of approximately 4.31%. 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 September 30, 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.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

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).

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. At the June 14, 2018 Annual Meeting of Stockholders, our stockholders voted to approve an amendment to the Company's Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 8,000,000 to 11,000,000.

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

In June 2010, our stockholders approved the 2010 Stock Option and Incentive Plan (the "2010 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at 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.

ImmuCell Corporation

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	-	44,500	122,500	\$ 7.39	
Terminations	-	(15,000)	(11,000)	\$ 6.55	
Exercises	(10,000)	(2,000)	-	\$ 3.38	
Outstanding at September 30, 2018	107,500	270,000	111,500	\$ 5.47	\$1,400,530
Vested at September 30, 2018	107,500	36,500	-	\$ 2.59	\$827,070
Vested and expected to vest at September 30, 2018	107,500	270,000	111,500	\$ 5.47	\$1,400,530
Reserved for future grants	-	1,000	188,500		

⁽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 nine-month period ended September 30, 2018, five employees exercised stock options covering 12,000 shares. Four thousand of these options were exercised for cash, resulting in total proceeds of \$15,490, and 8,000 of these options were exercised by the surrender of 3,469 shares of common stock with a fair market value of \$25,040 at

the time of exercise and \$10 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 September 30, 2018 was approximately five years and six months. The weighted average remaining life of the options exercisable under these plans as of September 30, 2018 was approximately nine months. The exercise prices of the options outstanding as of September 30, 2018 ranged from \$1.70 to \$8.90 per share. The 167,000 stock options granted during the nine-month period ended September 30, 2018 had exercise prices between \$6.81 and \$8.43 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 \$46,790 and \$43,470, respectively. The weighted-average grant date fair values of options granted during 2018 and 2017 were \$4.21 and \$3.51 per share, respectively. As of September 30, 2018, total unrecognized stock-based compensation related to non-vested stock options aggregated \$795,891, which will be recognized over a weighted average period of one year and eleven months. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, for the purpose discussed in Note 2(n), with the following weighted-average assumptions for the three-month and nine-month periods ended September 30, 2018 and for the year ended December 31, 2017:

	During the Three-Month	During the Nine-Month	During the Year
	Period Ended September 30, 2018	Period Ended September 30, 2018	Ended December 31, 2017
Risk-free interest rate	2.5	% 2.6	% 1.9
Dividend yield	0	% 0	% 0
Expected volatility	57	% 57	% 61
Expected life	6.5 years	6.5 years	6.5 years

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

ImmuCell Corporation

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 as well as subsequently issued shares of such common stock. 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.

At various times over the years, our Board of Directors has voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date, which is currently September 19, 2022. Our Board of Directors also has voted to authorize amendments to increase the ownership threshold for determining “Acquiring Person” status to 20%. During the second quarter of 2015, our Board of Directors also voted to authorize an amendment to remove 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. Each time that we made such amendments we entered into amendments to the Rights Agreement with the Rights Agent reflecting such extensions, threshold increases or provision changes. 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 to prevent scours in newborn calves. 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. We do sell into select international regions and may expand this international reach in the future. The demand for animal protein, that must be produced efficiently while insuring food quality and safety, increases as the human population grows. Our products help address the growing human health concern about using less antibiotics in food-producing animals. There were no material changes between the allocation and timing of revenue recognition during the three-month and nine-month periods ended September 30, 2018 (under ASC 606) and the three-month and nine-month periods ended September 30, 2017 (under ASC 605). We do not have any contract assets such as contracts for which we have satisfied the performance obligations but do not yet have the right to bill for or contract liabilities such as customer advances. All trade receivables on our balance sheet are from contracts with customers. We incur no material costs to obtain contracts. As of March 31, 2018, we had a backlog of orders (representing purchase orders received from customers which were not fulfilled or paid) worth approximately \$1,245,000 for the First Defense[®] product line. Before June 30, 2018 we cleared all of this backlog that was related to orders for our bivalent formats of the First Defense[®] product line (which will be re-branded as Dual-Force[™] First Defense[®]). As of September 30, 2018, we had a backlog of orders for Tri-Shield First Defense[®] worth approximately \$301,000. We do not have any contract assets such as contracts for which we have satisfied the performance obligations but do not yet have the right to bill for 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.

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

The following table presents our product sales disaggregated by geographic area:

	During the Three-Month	During the Nine-Month
	Period Ended September 30, 2018	Period Ended September 30, 2018
United States	\$ 1,893,483	\$ 7,033,232
Other	260,267	1,016,249
Total product sales	\$ 2,153,750	\$ 8,049,481

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

	During the Three-Month	During the Nine-Month
	Period Ended September 30, 2018	Period Ended September 30, 2018
First Defense⁰ product line	\$ 2,118,655	\$ 7,783,006
Other animal health	35,095	266,475
Total product sales	\$ 2,153,750	\$ 8,049,481

13. GAIN ON SALE OF ASSETS

During the third quarter of 2018, we sold the assets underlying our water diagnostic product for \$700,000. This sale of assets was recognized as an operating activity at that time in accordance with ASC 610: *Other Income* and ASC 810: *Consolidation*. An upfront payment of \$250,000 was received upon closing, a second payment of \$250,000 (which was recorded in prepaid expenses and other current assets) is due during the third quarter of 2019 and a third payment of \$200,000 (which was recorded in other assets) is due during the fourth quarter of 2019.

14. OTHER EXPENSES, NET

Other expenses, net, consisted of the following:

	During the Three-Month		During the Nine-Month	
	Periods Ended September 30,		Periods Ended September 30,	
	2018	2017	2018	2017
Interest expense	\$109,651	\$53,168	\$311,934	\$136,563
Interest income	(3,237)	(2,983)	(10,270)	(15,358)
Other gains	-	(947)	-	(5,328)
Other expenses, net	\$106,414	\$49,238	\$301,664	\$115,877

15. INCOME TAXES

Our income tax benefit aggregated \$5,598 and \$192,303 (amounting to 2% and 36% of our (loss) before income taxes, respectively) for the three-month periods ended September 30, 2018 and 2017, respectively. Our income tax expense aggregated \$447,075 and \$28,108 (amounting to 54% and 51% of our (loss) income before income taxes, respectively) for the nine-month periods ended September 30, 2018 and 2017, respectively. As of September 30, 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.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

The Tax Cuts and Jobs Act was signed into law in December 2017. This legislation made 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 prior 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.

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. During the second quarter of 2018, we recorded a valuation allowance of \$563,252 against these deferred tax assets because we have incurred a net loss for six consecutive quarters and have not been profitable on a year-to-date basis since the nine-month period ended September 30, 2017 and project additional net losses for some period going forward before returning to profitability. During the third quarter of 2018, we increased this valuation allowance by \$315,725 to \$878,977. 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.

16. CONTINGENT LIABILITIES AND COMMITMENTS

Our bylaws, as amended, in effect provide that the Company will indemnify its officers and directors to the maximum extent permitted by Delaware law. In addition, we make similar indemnity undertakings to each director through a separate indemnification agreement with that director. The maximum payment that we may be required to make under such provisions is theoretically unlimited and is impossible to determine. We maintain directors' and officers' liability insurance, which may provide reimbursement to the Company for payments made to, or on behalf of, officers and directors pursuant to the indemnification provisions. Our indemnification obligations were grandfathered under the provisions of Codification Topic 460, *Guarantees*. Accordingly, we have recorded no liability for such obligations as of September 30, 2018. Since our incorporation, we have had no occasion to make any indemnification payment to or on behalf of to any of our officers or directors for any reason.

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

We enter into agreements with third parties in the ordinary course of business under which we are obligated to indemnify such third parties from and against various risks and losses. The precise terms of such indemnities vary with the nature of the agreement. In many cases, we limit the maximum amount of our indemnification obligations, but in some cases those obligations may be theoretically unlimited. We have not incurred material expenses in discharging any of these indemnification obligations, and based on our analysis of the nature of the risks involved, we believe that the fair value of the liabilities potentially arising under these agreements is minimal. Accordingly, we have recorded no liabilities for such obligations as of September 30, 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 December 17, 2019 and the contract counter party were to exercise its right to terminate the agreement, we would be liable for a \$100,000 termination fee under one of such agreements and would need to identify and reach agreement with another party to perform these services for us, unless we make an investment to perform these services for ourselves.

ImmuCell Corporation

Notes to Unaudited Condensed Financial Statements (Continued)

During the second quarter of 2009, we entered into an exclusive and perpetual license (unless terminated for cause) 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**[®]. A milestone payment of \$150,000 was 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. Royalties of \$7,500 were accrued as of September 30, 2018.

We have committed \$682,000 to the purchase of inventory, \$77,000 to capital expenditures and \$142,000 to other obligations as of September 30, 2018.

17. SEGMENT INFORMATION

We principally operate in the business segment described in Note 1. Pursuant to Codification Topic 280, *Segment Reporting*, we operate in one reportable business segment, that being the development, acquisition, manufacture and sale of products that improve the health and productivity of dairy and beef cattle. Almost all of our internally funded product development expenses are in support of such products. The significant accounting policies of this segment are described in Note 2. Our single operating segment is defined as the component of our business for which financial information is available and evaluated regularly by our chief operating decision-maker in deciding how to allocate resources and in assessing performance. Our chief operating decision-maker is our President and CEO.

Sales of the **First Defense**[®] product line aggregated 98% of our total product sales during the three-month periods ended September 30, 2018 and 2017, and 97% and 94% of our total product sales during the nine-month periods ended September 30, 2018 and 2017, respectively. Our primary customers for the majority of our product sales (88% and 87% during the three-month periods ended September 30, 2018 and 2017, respectively, and 87% and 83% during the nine-month periods ended September 30, 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 12% and 13% of our total product sales during the three-month periods ended September 30, 2018 and 2017, respectively, and 13% and 15% of our total product sales during the nine-month periods ended September 30, 2018 and 2017, respectively.

18. 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 \$392,308 and \$465,670 of products from us during the nine-month periods ended September 30, 2018 and 2017, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of \$11,405 and \$3,168 to these affiliated companies during the nine-month periods ended September 30, 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 \$15,177 and \$14,176 as of September 30, 2018 and December 31, 2017, respectively.

19. 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 \$25,644 and \$21,083 into the plan for the three-month periods ended September 30, 2018 and 2017, respectively, and \$79,655 and \$64,105 for the nine-month periods ended September 30, 2018 and 2017, respectively.

20. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of filing on November 13, 2018, the date we have issued this Quarterly Report on Form 10-Q. As of such date, there were no material, reportable subsequent events.

ImmuCell Corporation

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

Cautionary Note Regarding Forward-Looking Statements (Safe Harbor Statement)

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. 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: our plans and strategies for our business; projections of future financial performance; the value of our deferred tax assets; 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 continuing availability to us on reasonable terms of third party providers of critical products or services; the robustness 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 interest rate exposure 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 could reduce the export of dairy products, which could weaken the price received by our customers for their products; our effectiveness in competing against competitors within both our existing and our anticipated product markets; the cost-effectiveness of additional sales and marketing expenditures and resources; 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”, “seeks” 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 involve risks and uncertainties and 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.

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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, during the years ended December 31, 2015 and 2016 and during the nine-month period ended September 30, 2017. We have not been profitable since then largely because of our decision to invest in an elevated level of product development expense to bring new products to market. The table below summarizes the changes in selected, key accounts (in thousands, except for percentages):

	As of September 30, 2018	As of December 31, 2017	(Decrease) Increase	
			Amount	%
Cash and cash equivalents	\$ 2,393	\$ 3,799	\$(1,406)	(37)%
Net working capital	\$ 4,291	\$ 5,443	\$(1,153)	(21)%
Total assets	\$ 33,235	\$ 34,299	\$(1,064)	(3)%
Stockholders' equity	\$ 22,673	\$ 23,595	\$(922)	(4)%
Common shares outstanding	5,485	5,476	9	- %

Net cash (used for) operating activities was (\$235,000) during the nine-month period ended September 30, 2018 in contrast to net cash provided by operating activities of \$845,000 during the nine-month period ended September 30, 2017. Cash paid for capital expenditures totaled \$1.9 million during the nine-month period ended September 30, 2018 in comparison to capital expenditures of \$13.1 million during the nine-month period ended September 30, 2017, reflecting the completion of our Nisin production facility. We are required to make a statement about the adequacy of our capital resources. Accordingly, we comment that we believe we have sufficient capital resources to continue operations for at least twelve months from the date of this filing.

We currently have the production capacity to increase annual sales of the **First Defense[®]** product line by approximately 50% to approximately \$17 million. We would need to invest approximately \$3.5 million to increase our liquid processing capacity by 100% and our freeze drying capacity by 50% to meet sales in excess of that level.

During 2017 and 2016, we raised gross proceeds of approximately \$13.5 million (net proceeds were approximately \$12.2 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 at \$5.25 per share, 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 at \$5.25 per share, raising net proceeds of just over \$1.0 million. During the fourth quarter of 2017, we issued 417,807 shares of common stock at \$7.30 per share, raising net proceeds of approximately \$2.7 million.

During 2017 and 2016, we secured debt financing from TD Bank N.A. in the form of three different facilities aggregating up to approximately \$6.8 million. This debt is in addition to two mortgage loans entered into during 2010 and 2015 that aggregated \$3.5 million at inception, also with TD Bank N.A. As of September 30, 2018, \$9.6 million was outstanding under these five facilities. 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 September 30, 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 September 30, 2018. We are required by bank debt covenant to maintain at least \$2 million of otherwise unrestricted cash, cash equivalents and short-term investments, thus reducing the effective availability of our liquid assets for operational needs by that amount. We are negotiating with the bank to return to an acceptable covenant based on income statement performance in order to regain access to these liquid assets.

During the third quarter of 2016, we initiated construction of our Nisin production facility, and we completed that construction 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 and completed that installation during the third quarter of 2018 and began depreciating these equipment costs at that time. 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 amount and timing of this investment on a cash-paid basis:

Period	Amount Paid
Paid through December 31, 2016	\$2,080,000 ⁽¹⁾
Paid during the year ended December 31, 2017	17,161,000 ⁽²⁾
Paid during the nine-month period ended September 30, 2018	1,595,000 ⁽³⁾
Estimated total cost of investment	\$20,836,000 ⁽⁴⁾

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

⁽²⁾ This amount includes approximately \$1,250,000 that was capitalized as of December 31, 2016 but paid during the first quarter of 2017. This amount does not include approximately \$641,000 that was capitalized as of December 31, 2017 but not paid until the first quarter of 2018.

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This amount includes approximately \$641,000 that was capitalized as of December 31, 2017 but paid during the (3)first quarter of 2018. This amount does not include approximately \$1,000 that was capitalized as of September 30, 2018 but not paid until the fourth quarter of 2018.

(4) This figure does not include approximately \$40,000 worth of equipment that we intend to purchase to complete the project.

Our capital expenditures paid 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:

Project Description	Paid during the years ended December 31,				Total
	2014	2015	2016	2017	
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
Purchase of warehouse building	-	-	-	472,000	472,000
Other capital expenditures	495,000	463,000	320,000	74,000	(1) 1,352,000
Total	\$1,536,000	\$2,719,000	\$3,586,000	\$17,760,000	\$25,601,000

(1) This amount is net of a credit of approximately \$61,000 for a returned fixed asset that was acquired during 2016.

During the nine-month period ended September 30, 2018, we invested approximately \$1,595,000 in the Nisin production facility and related equipment and \$336,000 in other routine capital expenditures. As of October 1, 2018, we had additional authorization from our Board of Directors to invest up to approximately \$359,000 through December 31, 2018 in routine and necessary capital expenditures.

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 beginning on July 1, 2017 and ending June 30, 2028 and by 30% during the twelve-month period 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 assessed value of \$1.7 million as of April 1, 2017, the TIF reduced our property taxes by approximately \$22,000 during the twelve-month period ended June 30, 2018 (the first year of the

TIF benefit). Based on the assessed value of \$4 million as of April 1, 2018, the TIF has reduced our property taxes by approximately \$58,000 during the twelve-month period ending June 30, 2019 (the second year of the TIF benefit). 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.

Results of Operations

2018 Compared to 2017

Product Sales

Total product sales during the three-month period ended September 30, 2018 increased by 7%, or \$149,000, to \$2.2 million, from \$2.0 million during the same period in 2017, with domestic sales increasing by 8%, or \$143,000, and international sales increasing by 2%, or \$5,000, in comparison to the same period during 2017. Approximately 88% of our sales during the third quarter of 2018 were domestic. Total product sales during the nine-month period ended September 30, 2018 increased by 10%, or \$751,000, to \$8 million from \$7.3 million during the same period in 2017, with domestic sales increasing by 15%, or \$903,000, and international sales decreasing by 13%, or \$152,000, in comparison to the same period in 2017. The final sales of the discontinued topical wipes product line aggregating approximately \$97,000 were recorded during the three-month period ended March 31, 2017. Approximately 87% of our sales during the nine-month period ended September 30, 2018 were domestic. The sales increases during the three-month and nine-month periods ended September 30, 2018 were largely the result of sales of our new product, **Tri-Shield First Defense**^Ø. Total product sales during the rolling twelve-month period ended September 30, 2018 increased by 18%, or \$1.7 million, to \$11.2 million from \$9.5 million during the same period ended September 30, 2017. Sales of the discontinued topical wipes product line aggregated approximately \$0 and \$175,000 during the rolling twelve-month periods ended September 30, 2018 and 2017, respectively. The sales increases during the rolling twelve-month period ended September 30, 2018 were largely the result of strong results from the **First Defense**^Ø product line. The rolling twelve-month figures are a non-GAAP disclosure and are derived from taking sales during the year ended December 31st less sales during the nine months ended September 30th of the prior year plus sales during the nine months ended September 30th of the current year.

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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 value of the 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, as sales demand for the bivalent bolus, tube and bulk powder formats of the **First Defense⁰** product line exceeded available inventory. As of March 31, 2018, we had a backlog of orders for **Dual-ForceTM** worth approximately \$901,000, which we filled during the second quarter of 2018. 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. In order to produce more doses quickly to clear the 2015/2016 order backlog, we significantly increased the quantity of our supply of colostrum. The 2018 backlog problem was largely caused by a reduction in the biological yield from this new colostrum supply. 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 we rebuild target inventory levels of the **Dual-ForceTM**, we are confident that we will again consistently supply product to the market because of the improved production methods to increase yields and the enhanced manufacturing redundancies that we have implemented.

Our new product line extension, **Tri-Shield First Defense⁰**, 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 bivalent product with a guaranteed level of rotavirus antibody in one preventative dose in a gel tube delivery format. 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. Because it is possible that all farms may not have a prevalent rotavirus problem, we are continuing to sell the bivalent formats of the **First Defense⁰** product line 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 believe 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. We believe that the variability in a cow's immune response to vaccines (that can impact our costs of goods sold when we immunize our source cows to produce the antibodies used in our production process) creates a sales opportunity for our product. 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 Vaccination⁰**, suggests that by delivering immediate immunity directly to the calf via **Tri-Shield⁰**, 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-Shield⁰**, 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.

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Soon after regulatory approval of **Tri-Shield First Defense**[®] was obtained during the fourth quarter of 2017, we ran out of inventory of this product format. 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 commercial scale. Simply put, the complex vaccine production process used to obtain regulatory approval required significant additional process development work and optimization to meet large-scale production needs. As of March 31, 2018, the backlog of orders for this new product increased to approximately \$344,000. While the backlog of orders is worth approximately \$301,000 as of September 30, 2018, we do not think this is a meaningful figure because currently we are not actively soliciting all orders possible for **Tri-Shield**[®] given the short supply situation and because we believe many distributors are holding off on placing orders until we have the supply situation under better control. 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. 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 instead working with distribution partners to allocate the limited supply to influential end-users and veterinarians capable of collecting field data that could help us re-launch **Tri-Shield**[®] as soon as production issues are resolved and adequate inventory is on hand, which is anticipated to be during the middle of 2019. 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**[®] were approximately \$250,000, \$236,000, \$216,000 and \$252,000 during the fourth quarter of 2017, the first quarter of 2018, the second quarter of 2018 and the third quarter of 2018, respectively. We expect to have approximately \$500,000 worth of **Tri-Shield**[®] available for sale during the fourth quarter of 2018. We are satisfied that we are successfully addressing the vaccine and biological yield issues pertaining to the production of this new product.

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 98% of our total product sales during the three-month periods ended September 30, 2018 and 2017. Sales of the **First Defense**[®] product line during the three-month period ended September 30, 2018 increased by 8% in comparison to the same period during 2017, with domestic sales increasing by 9% and international sales increasing by 2%, in comparison to the same period during 2017. Sales of the **First Defense**[®] product line aggregated 97% and 94% of our total product sales during the nine-month periods ended September 30, 2018 and 2017, respectively. Sales of the **First Defense**[®] product line during the nine-month period ended September 30, 2018 increased by 14% in comparison to the same period during 2017, with domestic sales increasing by 17% and international sales decreasing by 5%, in comparison to the same period in 2017. Sales of the **First Defense**[®] product line aggregated 96% and 94% of our total product sales during the rolling twelve-month periods ended September 30, 2018 and 2017, respectively. Sales of the **First Defense**[®] product line during the rolling twelve-month period ended September 30, 2018 increased by 20% in comparison to the same period ended September 30, 2017, with domestic sales increasing by 20% and international sales increasing by 19% in comparison to the same period ended September 30, 2017.

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 the **First Defense**[®] bolus and have not increased the selling price again since then. Going forward, we anticipate making more frequent (but not more than annual) price increases in line with current rates of inflation.

Sales of products other than the **First Defense**[®] product line decreased by 26% during the three-month period ended September 30, 2018 in comparison to the same period in 2017. Sales of these other products decreased by 40% during the nine-month period ended September 30, 2018 in comparison to the same period in 2017. Sales of these other products decreased by 23% during the rolling twelve-month period ended September 30, 2018 in comparison to the same period ended September 30, 2017. Sales of these other products aggregated 2% of our total product sales during the three-month periods ended September 30, 2018 and 2017, and 3% and 6% of our total product sales during the nine-month periods ended September 30, 2018 and 2017, respectively, and 4% and 6% of our total product sales during the rolling twelve-month periods ended September 30, 2018 and 2017, respectively. Because our Nisin-based topical wipes product line (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 spaces, we discontinued the production and sale of this product line during the first quarter of 2017. We acquired several other private label products (our second leading source of product sales during 2017 and during the first nine months of 2018) in connection with our January 2016 acquisition of certain gel formulation technology. These products contribute a lower gross margin percentage than the **First Defense**[®] product line. We sell our own **California Mastitis Test (CMT)** (our fourth leading source of product sales during 2017 and our third leading source of product sales during the first nine months of 2018), which is used to detect somatic cell counts in milk. We make and sell bulk reagents for **Isolate**[™] (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. No sales of this product have been recorded during 2018. Because this product is non-core to our strategic focus, we sold the underlying cell line assets and intellectual property to a distributor during the third quarter of 2018 for \$700,000. We expect to make one final sale of this product to this distributor for approximately \$125,000 during the first quarter of 2019. We have retained the rights to all animal health, diagnostic, feed and nutritional applications of this technology.

ImmuCell Corporation*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):

	During the Three-Month		Increase	
	Periods Ended		(Decrease)	
	September 30,			
	2018	2017	Amount	%
Gross margin	\$ 951	\$ 936	\$ 15	2 %
Percent of Product sales	44 %	47 %	(3)%	(5)%

	During the Nine-Month		(Decrease)	
	Periods Ended		(Decrease)	
	September 30,			
	2018	2017	Amount	%
Gross margin	\$3,798	\$4,009	\$(212)	(5)%
Percent of Product sales	47 %	55 %	(8)%	(14)%

	During the Rolling Twelve-Month		(Decrease)	
	Periods Ended		(Decrease)	
	September 30,			
	2018	2017	Amount	%
Gross margin	\$5,010	\$5,228	\$(218)	(4)%
Percent of Product sales	45 %	55 %	(10)%	(18)%

The figures in the above tables compare to gross margin percentages of 50% and 57% during the years ended December 31, 2017 and 2016, 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 decreases that led to the 2018 backlog

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. We believe we understand the cause of this significant biological variance and are correcting for it going forward. 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 are incurring extra labor and materials costs to further develop the vaccine manufacturing process and to produce small batches of **Tri-Shield**[®]. 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 of approximately 50% after the initial launch of new products. We have achieved this annual objective during all of the years ended from December 31, 2009 to 2017 but not in the 2018 periods, largely for the reasons discussed above. 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 for delivery to the newborn calf. This impacts our costs of goods sold but ensures 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.

ImmuCell Corporation*Product Development Expenses*

Product development expenses increased by 55%, or \$323,000, to \$909,000 during the three-month period ended September 30, 2018 in comparison to \$586,000 during the same period in 2017, as we invested to gain regulatory approval to launch our new products. Product development expenses aggregated 42% and 29% of product sales during the three-month periods ended September 30, 2018 and 2017, respectively. Product development expenses increased by 72%, or \$941,000, to \$2.3 million during the nine-month period ended September 30, 2018 in comparison to \$1.3 million during the same period ended September 30, 2017. Product development expenses aggregated 28% and 18% of product sales during the nine-month periods ended September 30, 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 the 18.75-year period that began on January 1, 2000 (the year we began the development of our mastitis drug) and ended on September 30, 2018, we invested the aggregate of approximately \$36.3 million in the development of this product. This figure includes approximately \$15.1 million of product development expenses (not including depreciation expense related to the production facility and equipment), approximately \$20.8 million of capital expenditures for the production facility and equipment and \$329,000 for land. This estimated allocation of product development expenses reflects only direct expenditures and includes no allocation of product development or administrative overhead expenses. Approximately \$2.9 million of this investment was offset by product licensing revenues and grant outcome.

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, as well as cost and other economic considerations, support reducing the indiscriminate use of drug treatments.

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 phased review by the Center for Veterinary Medicine, U.S. Food & Drug Administration (FDA). 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): During the third quarter of 2018, we received the Human Food Safety Technical Section Complete Letter from the FDA confirming, among other things, a zero milk discard period and a zero meat withhold period during and after treatment with our product.
- 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)

conduct product stability studies, iv) optimize process yields and v) verify the cost of production. We believe these efforts have reduced the risk associated with our investment of approximately \$21 million in the commercial-scale production facility.

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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 the 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 completed the installation and qualification 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 before year end. A second phased submission, which includes responses to the first phased review and detailed information about the manufacturing process and controls for the sterile Nisin Drug Product, is expected to be filed in the middle 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. Our timeline supports obtaining FDA approval for the Nisin product during late 2019 or the first half of 2020, subject to specific FDA review and requests. With respect to the 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.

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 manufacturer. They will conduct 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 December 17, 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 as well as exploring potential alternative providers of these services (as required by the contract).

U.S. Patent No. 10,023,617 entitled “Methods and Systems of Producing Pharmaceutical Grade Lantibiotics”, which covers key, novel and proprietary aspects of our manufacturing process for preparing pharmaceutical-grade Nisin, was issued during the third quarter of 2018.

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. We achieved product license approval and initiated market launch of this product, **Tri-Shield First Defense[®]**, during the fourth quarter of 2017. During the third quarter of 2018, we obtained approval from the Canadian Food Inspection Agency to sell **Tri-Shield[®]** in Canada. We expect to initiate sales in Canada after domestic demand is met. The balance of our product development efforts have been primarily focused on other improvements, extensions or additions to our **First Defense[®]** product line. We are currently working to establish USDA claims for our bivalent gel tube (expected by the end of 2018) and bivalent bulk powder (expected during the first quarter of 2019) formulations of **First Defense Technology[®]**, which will then be re-branded, together with the bolus format, as **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 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 11%, or \$48,000, to \$495,000 during the three-month period ended September 30, 2018 in comparison to \$447,000 during the same period in 2017, amounting to 23% and 22% of product sales during the three-month periods ended September 30, 2018 and 2017, respectively. Sales and marketing expenses increased by approximately 10%, or \$140,000, to \$1.5 million during the nine-month period ended September 30, 2018 in comparison to approximately \$1.4 million during the same period in 2017, amounting to 19% of product sales during the nine-month periods ended September 30, 2018 and 2017. We continue to leverage the efforts of our small sales force by using animal health distributors. Our current budgetary objective for the full year of 2018 and for 2019 is to invest less than 20% of product sales in sales and marketing expenses on an annual basis. With the new equity proceeds raised during the fourth quarter of 2017, we have increased our sales team by two new employees.

Administrative Expenses

Administrative expenses increased by approximately 3%, or \$11,000, to \$397,000 during the three-month period ended September 30, 2018 in comparison to \$386,000 during the same period in 2017. Administrative expenses increased by approximately 8%, or \$98,000, to \$1.3 million during the nine-month period ended September 30, 2018 in comparison to \$1.2 million during the same period in 2017. The year-to-date increase is due largely to a \$40,000 increase in stock-based compensation expense (non-cash), together with increases in legal, board of directors and consulting expenses. 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.

Gain on Sale of Assets

During the third quarter of 2018, we sold the assets underlying our water diagnostic product for \$700,000. This sale of assets was recognized as an operating activity at that time. An upfront payment of \$250,000 was received upon

closing, a second payment of \$250,000 is due during the third quarter of 2019 and a third payment of \$200,000 is due during the fourth quarter of 2019.

Net Operating (Loss) Income

Our net operating (loss) during the three-month period ended September 30, 2018 of (\$149,000) was in comparison to a net operating (loss) of (\$482,000) during the same period in 2017. Our net operating (loss) during the nine-month period ended September 30, 2018 of (\$521,000) was in contrast to net operating income of \$170,000 during the same period in 2017. The swing in the year-to-date results from an operating profit to loss is primarily the result of a \$941,000 increase in product development expenses and a \$140,000 increase in sales and marketing expenses with \$212,000 less gross margin earned from product sales, offset in part by a \$700,000 gain from the sale of assets.

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Other Income (Expenses), net

During the three-month period ended September 30, 2018, interest expense (including amortization of debt issuance costs of approximately \$4,000 during the three-month periods ended September 30, 2018 and 2017) increased by approximately 106%, or \$56,000, to \$110,000 in comparison to \$53,000 during the same period in 2017, due to higher levels of outstanding debt at modestly higher interest rates on the variable rate credit facilities. Interest income was approximately \$3,000 during both the three-month periods ended September 30, 2018 and 2017. Other expenses, net, aggregated \$106,000 and \$49,000 during the three-month periods ended September 30, 2018 and 2017, respectively.

During the nine-month period ended September 30, 2018, interest expense (including amortization of debt issuance costs of approximately \$13,000 and \$11,000 during the nine-month periods ended September 30, 2018 and 2017, respectively) increased by approximately 128%, or \$175,000, to \$312,000 in comparison to \$137,000 during the same period in 2017, due to higher levels of outstanding debt at modestly higher interest rates on the variable rate credit facilities. Interest expense is anticipated to be approximately \$407,000 during the year ending December 31, 2018. This estimate assumes an interest rate of 4.5% under the variable rate credit facilities. Actual interest expense will be charged at 2.25% over the one-month LIBOR. The one-month LIBOR was approximately 2.26% as September 30, 2018. Interest income decreased by approximately 33%, or \$5,000, to \$10,000 during the nine-month period ended September 30, 2018, in comparison to \$15,000 during the same period in 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 \$302,000 and \$116,000 during the nine-month periods ended September 30, 2018 and 2017, respectively.

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

Our (loss) before income taxes of (\$256,000) during the three-month period ended September 30, 2018 was in comparison to a (loss) before income taxes of (\$532,000) during the same period in 2017. We recorded an income tax (benefit) of (2%) and (36%) of the (loss) before income taxes during the three-month periods ended September 30, 2018 and 2017, respectively. Our net (loss) of (\$250,000), or (\$0.05) per share, during the three-month period ended September 30, 2018 is in comparison to net (loss) of (\$339,000), or (\$0.07) per share, during the same period ended September 30, 2017. The tax benefit rate in 2018 was a result of recording a full valuation allowance against our deferred tax assets.

Our (loss) before income taxes of (\$822,000) during the nine-month period ended September 30, 2018 was in contrast to income before income taxes of \$55,000 during the same period in 2017. We recorded an income tax expense of 54% and 51% of the (loss) income before income taxes during the nine-month periods ended September 30, 2018 and 2017, respectively. During the second quarter of 2018, we assessed our historical and near-term future profitability and determined the need to record non-cash income tax expense of approximately \$563,000 to create a full valuation allowance against our net deferred tax assets (which consist largely of net operating loss carryforwards and federal and state tax credits). We remain confident that we will be able to realize these deferred tax assets to offset future taxable income before they expire, but we do not believe that will be soon enough to avoid the need for this valuation allowance, based on applicable current accounting standards and practices. Therefore, because we had incurred a net loss for three consecutive quarters and anticipate additional net losses for some period going forward before returning to profitability, it was determined, based on such accounting standards and practices, that this valuation allowance was necessary. We will continue to assess the need for the valuation allowance at each quarter and, in the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to adjust our valuation allowance. On December 22, 2017, the Tax Cuts and Jobs Act was signed into law. This legislation made 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 prior rate of 34% to 21%. Our net (loss) of (\$1.3 million), or (\$0.23) per share, during the nine-month period ended September 30, 2018 is in contrast to net income of \$27,000, or \$0.01 per diluted share, during the same period in 2017.

Certain non-cash expenses aggregating \$1,223,000 (comprised of \$965,000 of depreciation and amortization and \$258,000 of stock-based compensation) during the nine-month period ended September 30, 2018 increased by 53%, or \$422,000, from \$801,000 (comprised of \$653,000 of depreciation and amortization and \$148,000 of stock-based compensation) during the nine-month period ended September 30, 2017. We began depreciating our Nisin production facility during the fourth quarter of 2017, and we began depreciating the related production equipment during the third quarter of 2018. For tax return purposes only, our total depreciation and amortization expense during 2017 was approximately \$2.4 million, which will be available to offset future taxable income. Our preliminary estimate of total depreciation and amortization expense for book purposes for the year ending December 31, 2018 is approximately \$1,558,000. This figure is a preliminary estimate only and actual depreciation expense will vary from this estimate. This depreciation expense (which is far larger than what we have incurred historically) may contribute to a net loss for the year ending December 31, 2018. Amortization and stock-based compensation are two other non-cash expenses included in our operating results. Because of the increasing amount of depreciation and stock-based compensation 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 to the accompanying unaudited condensed financial statements) to assess the cash generating ability of our operations going forward. Net cash (used for) provided by operating activities (which does not include investing or financing activities) was (\$235,000) and \$845,000 during the nine-month periods ended September 30, 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 financing activities from our Statements of Cash Flows (see page 4 to the accompanying unaudited condensed financial statements).

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Critical Accounting Policies

The financial statements are presented on the basis of accounting principles that are generally accepted in the United States. All professional accounting standards that were effective and applicable to us as of September 30, 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 in accordance with the five step model in ASC 606. 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 September 30, 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 September 30, 2018. Based on this evaluation, that officer concluded that our disclosure controls and procedures were not effective as of September 30, 2018, due to the fact that we are not yet able to conclude that the material weakness described below has been remediated by the changes we have made to our internal controls. 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.

Management's Report on Internal Control Over Financial Reporting. The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. We conducted an evaluation of the effectiveness of the internal controls over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. This evaluation included a review of the documentation of controls, evaluation of the design effectiveness of controls, testing the operating effectiveness of the controls and a conclusion on this evaluation. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on management's assessment, we concluded that our internal control over financial reporting is not effective as of September 30, 2018, because we identified a material weakness during the second quarter of 2018, which has not yet been remediated. We had an inadequate review of the calculation of our income tax provision and related disclosures, specifically our evaluation of the need for and the adequacy of a valuation allowance against our net deferred tax assets (which consist largely of net operating loss carryforwards and federal and state tax credits). We are implementing some changes to our internal controls over financial reporting, including the scheduling of more formal communications between ourselves and our tax consultant regarding our income tax provision and related 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. We have concluded that there was no material change in our internal control over financial reporting that occurred during the quarter ended September 30, 2018 that has materially affected, or is

reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1 - LEGAL PROCEEDINGS

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

ITEM 1A - RISK FACTORS

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 years ended December 31, 2015 and 2016 and during the nine-month period ended September 30, 2017. During the four quarters since then, we have incurred net losses largely due to facility start-up and development costs related to our Nisin product development program. Depreciation expenses related to the Nisin production facility are expected to contribute to reported net losses until and unless product sales increase to offset these non-cash expenses.

Deferred tax assets: The realizability of our deferred tax assets is a subjective estimate that is contingent upon many variables. During the second quarter of 2018, we recorded a full valuation allowance against our deferred tax assets that significantly increased our net loss in comparison to other periods. This non-cash expense could be reversed in the future. We will continue to assess the need for the valuation allowance at each quarter and in the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to adjust our valuation allowance.

Material weakness in internal control: Our business could be adversely impacted if we have deficiencies in our disclosure controls and procedures or internal controls over financial reporting. Our management identified an internal control material weakness as of June 30, 2018 that remains as of September 30, 2018. A material weakness is a

deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness is in connection with our controls over our review of the calculation of our income tax provision and related disclosures, specifically our evaluation of the adequacy of the valuation allowance against our net deferred tax assets (which consist largely of net operating loss carryforwards and federal and state tax credits). We determined that controls over the valuation of deferred tax assets were not operating effectively and the resulting control deficiency amounted to a material weakness in our internal controls over financial reporting. We have implemented some changes to our internal controls over financial reporting subsequent to June 30, 2018, including the scheduling of more formal communications between ourselves and our tax consultant regarding our income tax provision and related disclosures. However, at this time we cannot conclude that the material weakness has been remediated. We will evaluate our remediation plan again during our year-end audit. Effective internal control over financial reporting and disclosure controls and procedures are necessary in order for us to provide reliable financial and other reports. If we cannot maintain effective internal control or disclosure controls and procedures, or provide reliable financial statements or SEC reports, investors may lose confidence in our reported financial information, our operating results and the trading price of our common stock could suffer and we might become subject to litigation. While our management will continue to review the effectiveness of our internal control over financial reporting and disclosure controls and procedures, there is no assurance that our disclosure controls and procedures or our internal control over financial reporting will be effective in accomplishing all control objectives.

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*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 94% of our total product sales during the nine-month periods ended September 30, 2018 and 2017, respectively.

Concentration of sales: Approximately 100% and 98% of our product sales were made to customers in the dairy and beef industries throughout the world during the nine-month periods ended September 30, 2018 and 2017, respectively. Approximately 87% and 83% of our product sales were made to customers in the U.S. dairy and beef industries during the nine-month periods ended September 30, 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 (65% during the nine-month periods ended September 30, 2018 and 2017) was made to two large distributors. A large portion of our trade accounts receivable (83% as of September 30, 2018 and 69% as of December 31, 2017) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us.

Gross margin on product sales: It is one of our goals to again achieve a gross margin (before related depreciation expenses) as a percentage of total sales of 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. We believe these failures result from exposure to excessive heat conditions. 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 dry ice going forward. 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:* The bolus format of the **First Defense** product line is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991. As such, our operations are subject to periodic inspection by the USDA. 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 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.

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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 four of the five required Technical Sections have been approved, the development process timeline has been extensive (approximately 18 years) and has involved multiple commercial production strategies. As a result, the Chemistry, Manufacturing and Controls Technical Section has not yet been submitted for the Nisin Drug Substance or the Nisin 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 during late 2019 or the first half of 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.

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 nine months of 2018 increased slightly to 9,394,000.

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 nine months of 2018 dropped by 10% to \$14.62. While the September price of \$16.09 is the highest for the year, the low price level so far in 2018 is very problematic to the profitability of our customers. The recent annual fluctuations in this milk price level are

demonstrated in the following table:

Average Class III Milk Price for the Year Ended		Increase (Decrease)
<u>2013</u>	<u>2014</u>	
\$ 17.99	\$ 22.34	24%
<u>2014</u>	<u>2015</u>	
\$ 22.34	\$ 15.80	(29)%
<u>2015</u>	<u>2016</u>	
\$ 15.80	\$ 14.87	(6)%
<u>2016</u>	<u>2017</u>	
\$ 14.87	\$ 16.17	9%

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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 nine months of 2018 dropped by 17% to 2.00. The annual average has not been lower than this level since 2013. An increase in feed costs also has a negative impact on the beef industry. 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)
<u>2013</u>	<u>2014</u>	
1.75	2.54	45%
<u>2014</u>	<u>2015</u>	
2.54	2.13	(16)%
<u>2015</u>	<u>2016</u>	
2.13	2.26	6%
<u>2016</u>	<u>2017</u>	
2.26	2.43	7%

The all-time high value (annual average) for a milk cow was \$1,993 during 2015. Since then, this annual average value declined to \$1,768 during 2016 and further to \$1,623 during 2017 and further to \$1,400 during the first nine months of 2018. The 2018 value represents a 30%, or \$593, decrease from the 2015 high.

The industry data referred to above is compiled from USDA databases. Additionally, 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.

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 of personnel and capital resources. 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. Having completed construction of the production facility described elsewhere in this report at a cost of almost \$21 million, we will continue to incur product development expenses to operate this facility. 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 for our purified Nisin product: 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 have constructed to have production capacity to meet approximately \$10 million in annual 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.

Exposure to debt service obligations and debt covenants: Rising interest rates could negatively affect our operating results due to the large portion of our borrowings that bear interest at variable rates (which were not effectively converted to fixed rate obligations through interest rate swaps) as well as by increasing dairy farmers' operating costs and thus putting further financial pressure on an already stressed business sector. We are required by bank debt covenant to maintain at least \$2 million of otherwise unrestricted cash, cash equivalents and short-term investments. This requirement effectively reduces the availability of our liquid assets for operational needs and creates a risk of non-compliance.

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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. Elanco, Merck 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 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 and are priced lower than what we expect for our product, but all of them involve traditional antibiotics and are 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 December 17, 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 (including a modification to allow for the production and acquisition of commercial inventory before regulatory approval is achieved) and a term extension with Norbrook. There is no assurance that this negotiation will be successful for us. In accordance with this contract, we are evaluating alternative sources for these services (including a potential investment in our own facility to perform these services internally) 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. There can be no assurance that we would be able to identify and reach contractual terms with a duly licensed/certified provider of these services, as applicable, if our relationship with Norbrook were to be terminated or, if we were able to do so, how quickly that could occur and on what terms. Such a shift could result in significant production interruptions, delay in market launch, significantly increased cost of goods sold and reduced margins, the effects of which could be material and adverse. 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.

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 or three 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 will not be able to achieve our production capacity growth objectives on a timely basis.

Small size; dependence on key personnel: We are a small company with 53 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.

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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. 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 dairy market is presently under extreme economic pressure, causing many of our customers to lose money or only earn minimal profits. A small percentage reduction in the export of dairy products results in a significant drop in the domestic price of milk. 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. The **First Defense**[®] product line 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 the **First Defense**[®] product line, although presently we do not anticipate that this will be the case.

Biological terrorism: The threat of biological terrorism is a risk to both the economic health of our customers and our ability to economically acquire and collect good quality raw material from our contract farms. Any act of widespread bioterrorism against the dairy industry could adversely affect our operations.

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: ICCG). 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 \$41,135,000 as of November 5, 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.

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

None

ITEM 3 - DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4 - MINE SAFETY DISCLOSURES

None

ITEM 5 - OTHER INFORMATION

None

ITEM 6 - EXHIBITS

Exhibit 31 Certifications required by Rule 13a-14(a).

Exhibit 32 Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS XBRL Instance Document.

- 101.SCH XBRL Taxonomy Extension Schema Document.
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document.
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document.
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

ImmuCell Corporation

SIGNATURE

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

ImmuCell Corporation
Registrant

Date: November 13, 2018 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer
and Principal Financial Officer