

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, 2020

001-12934
(Commission file number)

ImmuCell Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State of Incorporation)

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

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

04103
(Zip Code)

(207) 878-2770
(Registrant's telephone number)

Securities registered pursuant to Section 12(b) of the Exchange Act: None

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 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 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

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 October 30, 2020 was 7,212,919.

ImmuCell Corporation
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ImmuCell Corporation
PART 1. FINANCIAL INFORMATION
ITEM 1. UNAUDITED FINANCIAL STATEMENTS
BALANCE SHEETS

	(Unaudited)	
	As of	As of
	September 30,	December 31,
	2020	2019
	<u> </u>	<u> </u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,918,157	\$ 6,293,293
Short-term investments	1,992,538	2,480,753
Trade accounts receivable, net	1,542,545	1,637,165
Inventory	2,090,817	2,518,256
Prepaid expenses and other current assets	393,160	259,566
Total current assets	<u>9,937,217</u>	<u>13,189,033</u>
PROPERTY, PLANT AND EQUIPMENT, net	27,180,040	25,265,738
RESTRICTED CASH	1,401,970	—
OPERATING LEASE RIGHT-OF-USE ASSET	1,246,866	—
INTANGIBLE ASSETS, net	100,296	114,624
GOODWILL	95,557	95,557
OTHER ASSETS	25,262	26,884
TOTAL ASSETS	<u>\$ 39,987,208</u>	<u>\$ 38,691,836</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 992,484	\$ 1,220,566
Current portion of debt obligations	711,906	1,274,790
Current portion of operating lease liability	97,458	—
Total current liabilities	<u>1,801,848</u>	<u>2,495,356</u>
LONG-TERM LIABILITIES:		
Debt obligations, net of current portion	9,004,402	7,146,676
Operating lease liability, net of current portion	1,160,297	—
Interest rate swaps	—	58,526
Total long-term liabilities	<u>10,164,699</u>	<u>7,205,202</u>
TOTAL LIABILITIES	11,966,547	9,700,558
CONTINGENT LIABILITIES AND COMMITMENTS (See Note 11)		
STOCKHOLDERS' EQUITY:		
Common stock, \$0.10 par value per share, 15,000,000 and 11,000,000 shares authorized, 7,299,009 shares issued and 7,212,919 shares outstanding, as of September 30, 2020 and December 31, 2019, respectively	729,901	729,901
Additional paid-in capital	31,328,328	31,131,893
Accumulated deficit	(3,849,232)	(2,638,285)
Treasury stock, at cost, 86,090 shares as of September 30, 2020 and December 31, 2019	(188,336)	(188,336)
Accumulated other comprehensive loss	—	(43,895)
Total stockholders' equity	<u>28,020,661</u>	<u>28,991,278</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 39,987,208</u>	<u>\$ 38,691,836</u>

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

ImmuCell Corporation
Unaudited
STATEMENTS OF OPERATIONS

	During the Three- Month Periods Ended September 30,		During the Nine- Month Periods Ended September 30,	
	2020	2019	2020	2019
Product sales	\$3,722,517	\$2,970,496	\$11,598,858	\$10,090,977
Costs of goods sold	<u>2,000,066</u>	<u>1,519,151</u>	<u>6,357,068</u>	<u>5,189,353</u>
Gross margin	1,722,451	1,451,345	5,241,790	4,901,624
Product development expenses	1,123,144	984,728	3,184,198	2,715,149
Sales and marketing expenses	459,117	497,654	1,507,538	1,628,534
Administrative expenses	<u>391,788</u>	<u>398,779</u>	<u>1,296,043</u>	<u>1,269,384</u>
Operating expenses	1,974,049	1,881,161	5,987,779	5,613,067
NET OPERATING LOSS	(251,598)	(429,816)	(745,989)	(711,443)
Other expenses, net	<u>71,290</u>	<u>65,280</u>	<u>479,590</u>	<u>241,897</u>
LOSS BEFORE INCOME TAXES	(322,888)	(495,096)	(1,225,579)	(953,340)
Income tax expense (benefit)	<u>—</u>	<u>7,439</u>	<u>(14,632)</u>	<u>31,796</u>
NET LOSS	<u>\$ (322,888)</u>	<u>\$ (502,535)</u>	<u>\$ (1,210,947)</u>	<u>\$ (985,136)</u>
Basic weighted average common shares outstanding	7,212,919	7,209,595	7,212,919	6,687,037
Basic net loss per share	\$ (0.04)	\$ (0.07)	\$ (0.17)	\$ (0.15)
Diluted weighted average common shares outstanding	7,212,919	7,209,595	7,212,919	6,687,037
Diluted net loss per share	\$ (0.04)	\$ (0.07)	\$ (0.17)	\$ (0.15)

STATEMENTS OF COMPREHENSIVE LOSS

	During the Three- Month Periods Ended September 30,		During the Nine- Month Periods Ended September 30,	
	2020	2019	2020	2019
Net loss	\$ (322,888)	\$ (502,535)	\$ (1,210,947)	\$ (985,136)
Other comprehensive (loss) income:				
Interest rate swaps, before taxes	—	(29,757)	58,527	(127,182)
Income tax applicable to interest rate swaps	<u>—</u>	<u>7,439</u>	<u>(14,632)</u>	<u>31,795</u>
Other comprehensive (loss) income, net of taxes	<u>—</u>	<u>(22,318)</u>	<u>43,895</u>	<u>(95,387)</u>
Total comprehensive loss	<u>\$ (322,888)</u>	<u>\$ (524,853)</u>	<u>\$ (1,167,052)</u>	<u>\$ (1,080,523)</u>

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

ImmuCell Corporation
Unaudited
STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock				Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Additional paid-in capital	Accumulated Deficit	Shares	Amount		
During the Three-Month Period Ended September 30, 2020:								
BALANCE,								
June 30, 2020	7,299,009	\$729,901	\$31,265,931	(\$3,526,344)	86,090	(\$188,336)	\$—	\$28,281,152
Net loss	—	—	—	(322,888)	—	—	—	(322,888)
Stock-based compensation	—	—	62,397	—	—	—	—	62,397
BALANCE,								
September 30, 2020	<u>7,299,009</u>	<u>\$729,901</u>	<u>\$31,328,328</u>	<u>(\$3,849,232)</u>	<u>86,090</u>	<u>(\$188,336)</u>	<u>\$—</u>	<u>\$28,020,661</u>
During the Three-Month Period Ended September 30, 2019:								
BALANCE,								
June 30, 2019	7,299,009	\$729,901	\$30,978,936	(\$1,825,298)	89,414	(\$195,608)	(\$42,912)	\$29,645,019
Net loss	—	—	—	(502,535)	—	—	—	(502,535)
Other comprehensive loss, net of taxes	—	—	—	—	—	—	(22,318)	(22,318)
Stock-based compensation	—	—	68,653	—	—	—	—	68,653
BALANCE,								
September 30, 2019	<u>7,299,009</u>	<u>\$729,901</u>	<u>\$31,047,589</u>	<u>(\$2,327,833)</u>	<u>89,414</u>	<u>(\$195,608)</u>	<u>(\$65,230)</u>	<u>\$29,188,819</u>
During the Nine-Month Period Ended September 30, 2020:								
BALANCE,								
December 31, 2019	7,299,009	\$729,901	\$31,131,893	(\$2,638,285)	86,090	(\$188,336)	(\$43,895)	\$28,991,278
Net loss	—	—	—	(1,210,947)	—	—	—	(1,210,947)
Other comprehensive income, net of taxes	—	—	—	—	—	—	43,895	43,895
Stock-based compensation	—	—	196,435	—	—	—	—	196,435
BALANCE,								
September 30, 2020	<u>7,299,009</u>	<u>\$729,901</u>	<u>\$31,328,328</u>	<u>(\$3,849,232)</u>	<u>86,090</u>	<u>(\$188,336)</u>	<u>\$—</u>	<u>\$28,020,661</u>
During the Nine-Month Period Ended September 30, 2019:								
BALANCE,								
December 31, 2018	5,662,645	\$566,265	\$22,695,557	(\$1,342,698)	93,683	(\$204,947)	\$30,157	\$21,744,334
Net loss	—	—	—	(985,135)	—	—	—	(985,135)
Other comprehensive loss, net of taxes	—	—	—	—	—	—	(95,387)	(95,387)
Public offering of common stock, net of \$696,566 of offering costs	1,636,364	163,636	8,139,800	—	—	—	—	8,303,436
Exercise of stock options	—	—	(9,337)	—	(4,269)	9,339	—	2
Stock-based compensation	—	—	221,569	—	—	—	—	221,569
BALANCE,								
September 30, 2019	<u>7,299,009</u>	<u>\$729,901</u>	<u>\$31,047,589</u>	<u>(\$2,327,833)</u>	<u>89,414</u>	<u>(\$195,608)</u>	<u>(\$65,230)</u>	<u>\$29,188,819</u>

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

ImmuCell Corporation
Unaudited
STATEMENTS OF CASH FLOWS

	During the Nine-Month Periods Ended September 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (1,210,947)	\$ (985,136)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation	1,719,393	1,691,049
Amortization of intangible assets	14,328	14,328
Amortization and write-off of debt issuance costs	101,077	12,732
Deferred income taxes	(14,632)	31,796
Stock-based compensation	196,435	221,569
Loss on disposal of fixed assets	3,266	2,469
Non-cash rent expense	10,889	—
Changes in:		
Trade accounts receivable	94,620	45,593
Accrued interest income	27,215	(52,947)
Inventory	427,439	(349,402)
Prepaid expenses and other current assets	(133,594)	(116,456)
Other assets	1,622	(16,292)
Accounts payable and accrued expenses	(77,781)	(219,170)
Net cash provided by operating activities	<u>1,159,330</u>	<u>280,133</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(3,787,860)	(700,017)
Maturities of investments	2,453,000	2,976,000
Purchases of investments	(1,992,000)	(10,123,000)
Proceeds from sale of fixed assets	600	—
Payment of contingent royalties related to 2016 acquisition	—	(8,914)
Proceeds from sale of assets	—	250,000
Net cash used for investing activities	<u>(3,326,260)</u>	<u>(7,605,931)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from public offering, net	—	8,303,436
Proceeds from debt issuance	10,037,700	—
Line of credit repayment	—	(500,000)
Debt principal repayments	(8,804,147)	(644,129)
Payments of debt issuance costs	(39,789)	—
Proceeds from exercise of stock options	—	2
Net cash provided by financing activities	<u>1,193,764</u>	<u>7,159,309</u>
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(973,166)	(166,489)
BEGINNING CASH, CASH EQUIVALENTS AND RESTRICTED CASH	<u>6,293,293</u>	<u>2,521,050</u>
ENDING CASH, CASH EQUIVALENTS AND RESTRICTED CASH	<u>\$ 5,320,127</u>	<u>\$ 2,354,561</u>

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

ImmuCell Corporation
Unaudited
STATEMENTS OF CASH FLOWS
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

	During the Nine-Month Periods Ended September 30,	
	2020	2019
CASH PAID FOR:		
Income taxes	\$ 4,700	\$ 4,700
Interest expense	\$ 408,131	\$ 325,343
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable and accrued expenses	\$ (150,295)	\$ (55,200)
Net change in fair value of interest rate swaps, net of taxes	\$ (43,895)	\$ 95,387
Fixed asset disposals, gross	\$ 100,390	\$ 11,164
Operating lease right-of-use asset and operating lease liability	\$ 1,313,698	\$ —
	As of	As of
	September	September
	30, 2020	30, 2019
Cash and cash equivalents	<u>\$ 3,918,157</u>	<u>\$ 2,354,561</u>
Restricted cash	1,401,970	—
Cash, cash equivalents and restricted cash ⁽¹⁾	<u><u>\$ 5,320,127</u></u>	<u><u>\$ 2,354,561</u></u>

⁽¹⁾This amount does not include \$1,992,538 and \$7,199,947 of short-term investments as of September 30, 2020 and 2019, respectively.

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

ImmuCell Corporation
Notes to Unaudited Financial Statements

1. BUSINESS OPERATIONS

ImmuCell Corporation (the “Company”, “we”, “us”, “our”) was originally incorporated in Maine in 1982 and reincorporated in Delaware in 1987, in conjunction with our initial public offering of common stock. We are 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. We manufacture and market the **First Defense**[®] product line for the prevention of scours in newborn dairy and beef calves. We are developing improved formulations of this product line providing **Immediate Immunity**[™] to newborn calves and are in the late stages of developing **Re-Tain**[™], a treatment for cows with subclinical 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. We are subject to certain risks associated with this 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

We have prepared the accompanying unaudited financial statements reflecting all adjustments (which are of a normal recurring nature) that are, in our opinion, necessary in order to ensure that the financial statements are not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP in these footnotes are to the FASB *Accounting Standards Codification*[™] (Codification). Accordingly, we believe that the disclosures are adequate to ensure that the information presented is not misleading. You should read these unaudited financial statements in conjunction with our audited financial statements on Form 10-K for the year ended December 31, 2019.

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

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits of \$250,000 per financial institution per depositor are maintained in money market accounts at financial institutions that are secured, in part, by the Securities Investor Protection Corporation. Amounts in excess of these FDIC limits per bank that are not invested in securities backed by the U.S. government aggregated \$0 and \$5,792,993 as of September 30, 2020 and December 31, 2019, respectively. Short-term investments are classified as held to maturity and are comprised of certificates of deposit that mature in more than three months from their purchase dates and not more than twelve months from the balance sheet date. Short-term investments are held at different financial institutions that are insured by the FDIC, within the FDIC limits per financial institution. We account for investments in marketable securities in accordance with Codification Topic 320, *Investments — Debt and Equity Securities*. See Note 3.

(c) Trade Accounts Receivable, net

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful collection when applicable. 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, 2020 and December 31, 2019, we determined that no allowance for doubtful accounts was necessary. See Note 4.

(d) Inventory

Inventory includes raw materials, work-in-process and finished goods and is recorded at the lower of cost, on the first-in, first-out method, or net realizable value (determined as the estimated selling price in the normal course of business, less reasonably predictable costs of completion, disposal and transportation). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. At each balance sheet date, we evaluate our ending inventories for excess quantities and obsolescence. Inventories that we consider excess or obsolete are written down to estimated net realizable value. 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

ImmuCell Corporation
Notes to Unaudited Financial Statements (continued)

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 feasible. See Note 5.

(e) Property, Plant and Equipment, net

We depreciate property, plant and equipment on the straight-line method by charges to operations and costs of goods sold 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 Nisin Drug Substance for **Re-Tain™** 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 Drug Substance facility when it was placed in service during the third quarter of 2018. Approximately 88% of these assets are being depreciated over ten years. We began depreciating the leasehold improvements to our new **First Defense®** production facility at 175 Industrial Way over the remainder of the ten-year lease term beginning when a certificate of occupancy was issued during the second quarter of 2020. Significant repairs to fixed assets that benefit more than a current period are capitalized and depreciated over their useful lives. Insignificant repairs are expensed when incurred. See Note 7.

(f) Intangible Assets and Goodwill

We amortize intangible assets on the straight-line method by charges to costs of goods sold 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 properly 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 goodwill impairments were recorded during the nine-month period ended September 30, 2020 or the year ended December 31, 2019. See Notes 2(h) 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, 2020 and December 31, 2019, the carrying amounts of cash and cash equivalents, short-term investments, accounts receivable, inventory, other assets, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The amount outstanding under our bank debt facilities is measured at carrying value in our accompanying balance sheets. Our bank debt facilities are valued using Level 2 inputs. The estimated fair value of our bank debt facilities approximates their carrying value 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, the level of an asset or liability 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

ImmuCell Corporation
Notes to Unaudited Financial Statements (continued)

and considers factors specific to the investment. From time to time, we also hold money market mutual funds in a brokerage account, which are classified as cash equivalents and measured at fair value. The fair value of these investments is based on their closing published net asset value.

We assess the levels of the investments at each measurement date, and transfers between levels are recognized on the actual date of the event or change in circumstances that caused the transfer in accordance with our accounting policy regarding the recognition of transfers between levels of the fair value hierarchy. During the nine-month periods ended September 30, 2020 and 2019, there were no transfers between levels. As of September 30, 2020 and December 31, 2019, 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, 2020 and December 31, 2019 our bank certificates of deposit were classified as Level 2 and were measured by other significant observable inputs. As of December 31, 2019, 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, 2020 or December 31, 2019.

	As of September 30, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and money market accounts	\$3,918,157	\$—	\$—	\$3,918,157
Bank certificates of deposit	—	1,992,538	—	1,992,538
Total	\$3,918,157	\$1,992,538	\$—	\$5,910,695

	As of December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and money market accounts	\$6,293,293	\$—	\$—	\$6,293,293
Bank certificates of deposit	—	2,480,753	—	2,480,753
Liabilities:				
Interest rate swaps	—	(58,526)	—	(58,526)
Total, net	\$6,293,293	\$2,422,227	\$—	\$8,715,520

(h) Valuation of Long-Lived Assets

We periodically evaluate our long-lived assets, consisting principally of fixed assets, operating lease right-of-use asset 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, 2020 or the year ended December 31, 2019.

(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:

ImmuCell Corporation
Notes to Unaudited Financial Statements (continued)

	During the Three-Month Periods Ended September 30,		During the Nine-Month Periods Ended September 30,	
	2020	2019	2020	2019
Company A	44%	39%	40%	42%
Company B	27%	29%	30%	27%

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

	As of September 30, 2020	As of December 31, 2019
Company A	38%	28%
Company B	27%	48%

(j) Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification (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. 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. Amounts due are 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 14.

(k) Expense Recognition

We do not incur costs in connection with product sales to customers 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 \$499 and \$9,940 during the three-month periods ended September 30, 2020 and 2019, respectively, and \$24,986 and \$50,563 during the nine-month periods ended September 30, 2020 and 2019, 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.

(l) 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). At that time, we had incurred a net loss for six consecutive quarters, had not been profitable on a year-to-date basis since the nine-month period ended September 30, 2017 and projected additional net losses for some period going forward before returning to profitability. We consider future taxable income and feasible tax planning strategies in assessing the need for a valuation allowance at each quarter end. If we determine that we would be able to realize our deferred tax assets in the future in excess of the net recorded amount over a reasonably short period of time, a reduction of the valuation allowance would increase income in the period such determination was made. Likewise, if we determine that we would not be able to realize all or part of our net deferred tax asset in the

ImmuCell Corporation
Notes to Unaudited Financial Statements (continued)

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

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. With few exceptions, we are no longer subject to income tax examinations by tax authorities for years before 2016. We have evaluated the positions taken on our filed tax returns. We have concluded that no uncertain tax positions existed as of September 30, 2020 or December 31, 2019. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 16.

(m) 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 \$62,397 and \$68,653 during the three-month periods ended September 30, 2020 and 2019, respectively, and \$196,435 and \$221,569 during the nine-month periods ended September 30, 2020 and 2019, respectively.

(n) Net (Loss) Income Per Common Share

Net income (loss) per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*. The weighted average number of shares outstanding was 7,212,919 and 7,209,595 during the three-month periods ended September 30, 2020 and 2019, respectively, and 7,212,919 and 6,687,037 during the nine-month periods ended September 30, 2020 and 2019, respectively. 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 and unrecognized compensation. 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 because their inclusion would be anti-dilutive. Outstanding stock options that were not included in this calculation because the effect would be anti-dilutive amounted to 420,500 and 370,000 as of September 30, 2020 and 2019, respectively.

(o) 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 and are subject to change in the near term. 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, valuation of deferred tax assets, accrued expenses, costs of goods sold and useful lives of intangible assets.

(p) New Accounting Pronouncements Recently Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The guidance in this ASU supersedes the leasing guidance in Topic 840, *Leases*. Under the new guidance, lessees are required to recognize lease assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. This ASU and its amendments became effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption was permitted. We elected to adopt this ASU effective January 1, 2019. In July 2018, the FASB issued ASU 2018-10, *Codification improvements to Topic 842, Leases*. The amendments in ASU 2018-10 provide more clarification in regard to the application and requirements of Topic 842. In July 2018, the FASB issued ASU 2018-11, *Topic 842, Leases - Targeted improvements*. The amendments in ASU 2018-11 provide for the option to adopt the standard prospectively and recognize a cumulative-effect adjustment to the opening balance of retained earnings as well as offer a new practical expedient that allows us to elect, by class of underlying asset, to not separate non-lease and lease components in certain circumstances and instead to account for those components as a single item. Based on our current lease agreements and a review of all of our material vendor relationships for potential embedded lease obligations, we concluded that we were not subject to material lease obligations as of December 31, 2019, and the adoption of Topic 842 beginning did not have a material impact on our financial statements as of January 1, 2019. The lease we entered into on September 12, 2019 to expand our production capacity for

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Notes to Unaudited Financial Statements (continued)

the **First Defense**[®] product line with a Possession Date of November 15, 2019 and a Commencement Date of February 13, 2020 has been accounted for in accordance with Topic 842 beginning during the first quarter of 2020. The only material lease pursuant to which we are the lessee is comprised of real estate property. All leases are classified as operating leases, and therefore, were previously not recognized on our balance sheets. With the adoption of Topic 842, operating lease agreements are required to be recognized on our balance sheets as a right-of-use (ROU) asset with a corresponding lease liability. If at a lease inception date or at some later date during the term of a lease, we consider the exercising of a renewal option to be reasonably certain, we would include the extended term in the calculation of the ROU asset and lease liability. Regarding the discount rate, Topic 842 requires the use of the rate implicit in the lease whenever this rate is readily determinable. As this rate is rarely determinable, we utilize our incremental borrowing rate at lease inception, on a collateralized basis, over a similar term. See Note 12. We elected the following practical expedients in conjunction with implementation of Topic 842:

- Inclusion of both the lease and non-lease components for all classes of underlying assets as a single component.
- Election to exclude short-term lease (i.e., lease with initial terms of twelve months or less) from capitalization on our balance sheets.

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. Topic 815 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, Topic 815 must be applied through a cumulative-effect adjustment. The amended presentation and disclosure guidance is required only prospectively. The adoption of Topic 815 did not have a material impact on our financial statements as of January 1, 2019.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements of fair value measurements. Topic 820 is effective for fiscal years beginning after December 15, 2019, and early adoption is permitted. The adoption of Topic 820 did not have a material impact on our financial statements as of January 1, 2020.

(q) New Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The new guidance is intended to simplify the accounting for income taxes by removing certain exceptions and by updating accounting requirements around goodwill recognized for tax purposes and the allocation of current and deferred tax expense among legal entities, among other minor changes. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Early adoption is permitted. We do not expect the adoption of ASU 2019-12 to have a material impact on our financial statements.

In March 2020, the FASB issued ASU 2020-04, *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. ASU 2020-04 is intended to provide optional expedients and exceptions to the U.S. GAAP guidance on contract modifications and hedge accounting to ease the financial reporting burdens related to the discontinuation of the London Interbank Offered Rate (LIBOR) or by another reference rate expected to be discontinued. The relief offered by this guidance, if adopted, is available to companies for the period March 12, 2020 through December 31, 2022. We do not expect the discontinuation of LIBOR to have a material impact on our financial statements.

3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

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

	As of September 30, 2020	As of December 31, 2019
Cash and cash equivalents	\$3,918,157	\$6,293,293
Short-term investments	1,992,538	2,480,753
Total	<u>\$5,910,695</u>	<u>\$8,774,046</u>

Held to maturity securities (certificates of deposit) are carried at amortized cost. In compliance with a bank debt covenant, we held at least \$1,400,000 of otherwise unrestricted cash, cash equivalents and short-term investments in an escrow account (a non-current asset) in favor of the bank as of September 30, 2020. As of December 31, 2019, we were required to maintain at least \$2,000,000 of otherwise unrestricted cash, cash equivalents and short-term investments in compliance with a bank debt covenant.

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Notes to Unaudited Financial Statements (continued)

4. TRADE ACCOUNTS RECEIVABLE, net

Trade accounts receivable amounted to \$1,542,545 and \$1,637,165 as of September 30, 2020 and December 31, 2019, respectively. No allowance for bad debt and product returns was recorded as of September 30, 2020 or December 31, 2019.

5. INVENTORY

Inventory consisted of the following:

	As of <u>September 30, 2020</u>	As of <u>December 31, 2019</u>
Raw materials	\$575,629	\$791,558
Work-in-process	1,291,260	1,207,457
Finished goods	223,928	519,241
Total	<u>\$2,090,817</u>	<u>\$2,518,256</u>

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of <u>September 30, 2020</u>	As of <u>December 31, 2019</u>
Prepaid expenses	\$321,307	\$218,232
Other receivables	71,053	40,534
Security deposits	800	800
Total	<u>\$393,160</u>	<u>\$259,566</u>

7. PROPERTY, PLANT AND EQUIPMENT, net

Property, plant and equipment consisted of the following:

	Estimated Useful Lives (in years)	As of <u>September 30, 2020</u>	As of <u>December 31, 2019</u>
Laboratory and manufacturing equipment	3-10	\$15,693,928	\$15,437,724
Building and improvements	10-39	18,993,371	17,078,829
Office furniture and equipment	3-10	775,095	719,323
Construction in progress	n/a	2,434,842	1,124,189
Land	n/a	516,867	516,867
Property, plant and equipment, gross		38,414,103	34,876,932
Accumulated depreciation		<u>(11,234,063)</u>	<u>(9,611,194)</u>
Property, plant and equipment, net		<u>\$27,180,040</u>	<u>\$25,265,738</u>

As of September 30, 2020 and December 31, 2019, construction in progress consisted principally of payments toward the **First Defense**[®] production capacity expansion project and equipment needed to bring the formulation and aseptic filling for **Re-Tain**[™] in-house. Property, plant and equipment disposals were approximately \$78,779 and \$4,770 during the three-month periods ended September 30, 2020 and 2019, respectively, and \$100,390 and \$11,164 during the nine-month periods ended September 30, 2020 and 2019, respectively. Depreciation expense was \$596,010 and \$562,722 during the three-month periods ended September 30, 2020 and 2019, respectively, and \$1,719,393 and \$1,691,049 during the nine-month periods ended September 30, 2020 and 2019, respectively.

8. INTANGIBLE ASSETS

The developed technology intangible assets of approximately \$191,000 (which include an immaterial amount of value associated with customer relationships and a non-compete agreement and was valued using the relief from royalty method) are being amortized to costs of goods sold over their useful lives, which are estimated to be 10 years. Intangible amortization expense was \$4,776 during both of the three-month periods ended September 30, 2020 and 2019 and \$14,328 during both of the nine-month periods ended September 30, 2020 and 2019. The net value of these intangibles was \$100,296 and \$114,624 as of September 30, 2020 and December 31, 2019, respectively. Intangible asset amortization expense is estimated to be \$19,104 per year through December 31, 2025. Intangible assets as of September 30, 2020 consisted of the following:

ImmuCell Corporation
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	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	\$184,100	(\$87,447)	\$96,653
Customer relationships	1,300	(618)	682
Non-compete agreements	5,640	(2,679)	2,961
Total	<u>\$191,040</u>	<u>(\$90,744)</u>	<u>\$100,296</u>

Intangible assets as of December 31, 2019 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	\$184,100	(\$73,640)	\$110,460
Customer relationships	1,300	(520)	780
Non-compete agreements	5,640	(2,256)	3,384
Total	<u>\$191,040</u>	<u>(\$76,416)</u>	<u>\$114,624</u>

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of September 30, 2020	As of December 31, 2019
Accounts payable – trade	\$444,252	\$401,958
Accounts payable – capital	19,925	170,220
Accrued payroll	219,252	399,501
Accrued professional fees	78,950	73,781
Accrued other	230,105	175,106
Total	<u>\$992,484</u>	<u>\$1,220,566</u>

10. BANK DEBT

Prior to a refinancing with Gorham Savings Bank during the first quarter of 2020, we had in place five different credit facilities and a line of credit with TD Bank N.A. (Loans #1 to #5). During the first quarter of 2020, we closed on a debt financing with Gorham Savings Bank aggregating \$8,600,000 and a \$1,000,000 line of credit. The debt is comprised of a \$5,100,000 mortgage note (Loan #6) that bears interest at a fixed rate of 3.50% per annum (with a 10-year term and 25-year amortization schedule) and a \$3,500,000 note (Loan #7) that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). The line of credit is available as needed through March 10, 2022. There was no outstanding balance under this line of credit as of September 30, 2020. Interest on borrowings against the line of credit is variable at the rate of the one-month LIBOR plus 2.15% per annum. In connection with these three credit facilities, we incurred debt issuance costs of \$39,789. The amortization of debt issuance costs is being recorded as a component of interest expense, included with other expenses, net, and is being amortized over the underlying terms of the two notes and the line of credit. The proceeds from the debt refinancing were used to repay all bank debt outstanding at the time of closing (Loans #1 to #5) and to provide some additional working capital. These three new credit facilities are secured by liens on substantially all of our assets and are subject to certain restrictions and financial covenants. Under the new debt, we are required to hold \$1,400,000 in escrow (a non-current asset), which reduces the effective availability of our liquid assets for operational needs by that amount.

During the second quarter of 2020, we received \$937,700 in support from the federal government under the Paycheck Protection Program (PPP) (Loan #8). Provided that we use the proceeds only for eligible payroll costs, utility expenses, rent payments and interest expense on certain mortgage debt, in each case incurred and paid during the 24-week period beginning April 13, 2020, our obligation to repay the principal should be forgiven. At least 60% of such forgiven amounts must be used for eligible payroll costs. During the third quarter of 2020, we applied for forgiveness of this funding using 100% eligible payroll expenses. Given current guidance that is available, we believe that we should be eligible to achieve forgiveness of the full loan amount, but this income will not be recognized until our eligible expenses are certified by the federal government. Any such forgiveness of indebtedness, in accordance with the CARES Act, does not give rise to federal taxable income, but these forgiven expenses might not also be deducted for federal tax return purposes. If not forgiven, this funding accrues interest at a rate of 1% per annum beginning on April 10, 2020, and monthly principal and interest payments on the amount outstanding as of March 10, 2021 would be due until April 2025.

During June 2020, we received a \$500,000 loan from the Maine Technology Institute (Loan #9) that is subordinated to all other bank debt. The first 27 months of this loan are interest-free with no interest accrual or required principal payments. Principal and

ImmuCell Corporation
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interest payments at 5% per annum are due quarterly over the final five years of the loan, beginning during the fourth quarter of 2022 and continuing through the third quarter of 2027. The loan may be prepaid without penalty at any time.

Debt proceeds received and principal repayments made during the three-month and nine-month periods ended September 30, 2020 and 2019 are reflected in the following tables by year and by loan:

	During the Three-Month Period Ended September 30, 2020		During the Three-Month Period Ended September 30, 2019	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	\$—	\$—	\$—	(\$17,227)
Loan #2	—	—	—	(22,260)
Loan #3	—	—	—	(140,714)
Loan #4	—	—	—	(32,000)
Loan #5	—	—	—	(2,967)
Loan #6	—	(31,782)	—	—
Loan #7	—	(111,392)	—	—
Loan #8	—	—	—	—
Loan #9	—	—	—	—
Total	\$—	(\$143,174)	\$—	(\$215,168)

	During the Nine-Month Period Ended September 30, 2020		During the Nine-Month Period Ended September 30, 2019	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	\$—	(\$493,696)	\$—	(\$50,989)
Loan #2	—	(2,143,771)	—	(66,780)
Loan #3	—	(3,236,429)	—	(422,143)
Loan #4	—	(2,336,000)	—	(96,000)
Loan #5	—	(309,182)	—	(8,217)
Loan #6	5,100,000	(63,279)	—	—
Loan #7	3,500,000	(221,790)	—	—
Loan #8	937,700	—	—	—
Loan #9	500,000	—	—	—
Total	\$10,037,700	(\$8,804,147)	\$—	(\$644,129)

Principal payments (net of debt issue costs) due under bank loans outstanding as of September 30, 2020 (excluding our \$1,000,000 line of credit) are reflected in the following table by the year that payments are due:

	During the Three- Month Period Ending December 31, 2020	During the Years Ending December 31,					Total
		2021	2022	2023	2024	2025 and After	
Loan #6	\$32,758	\$133,369	\$138,112	\$143,025	\$148,112	\$4,441,345	\$5,036,721
Loan #7	112,836	461,035	477,432	494,413	511,998	1,220,496	3,278,210
Loan #8 ⁽¹⁾	—	184,429	223,352	225,596	227,862	76,461	937,700
Loan #9	—	—	22,160	91,446	96,104	290,290	500,000
Subtotal	\$145,594	\$778,833	\$861,056	\$954,480	\$984,076	\$6,028,592	\$9,752,631
Debt Issuance Costs							(36,323)
Total							\$9,716,308

⁽¹⁾ These principal payments would not be due if the loan amount is forgiven by the federal government.

11. 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

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Notes to Unaudited Financial Statements (continued)

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, 2020. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

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

We enter into agreements with third parties in the ordinary course of business under which we are obligated to indemnify such third parties from and against various risks and losses. The precise terms of such indemnities vary with the nature of the agreement. In many cases, we limit the maximum amount of our indemnification obligations, but in some cases those obligations may be theoretically unlimited. We have not incurred material expenses in discharging any of these indemnification obligations, and based on our analysis of the nature of the risks involved, we believe that the fair value of the liabilities potentially arising under these agreements is minimal. Accordingly, we have recorded no liabilities for such obligations as of September 30, 2020.

We are committed to purchasing certain key parts (syringes) and services (formulation, aseptic filling and final packaging of Drug Product) pertaining to **Re-Tain™**, our Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows, exclusively from contractors. We are investing in the necessary equipment to perform the Drug Product formulation and aseptic filling services in-house.

During the second quarter of 2009, we entered into an exclusive and perpetual (unless terminated for cause) license with the Baylor College of Medicine covering the underlying rotavirus vaccine technology used to generate the specific antibodies for our product line extension, **Tri-Shield First Defense®**. The license is subject to a royalty equal to 4% of the sales of the **First Defense®** product line 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 \$76,876 were paid for the year ended December 31, 2019. Royalties of \$50,075 were accrued as of September 30, 2020.

During the first quarter of 2020, we entered into a Severance Agreement with our President and CEO. Under the terms of this agreement, we agree to pay this executive (or his estate) nine months of his then current salary plus any accrued and unused paid time off in the event of the involuntary termination of his employment by the Company (except for cause) or in the event of termination by him for good reason.

In addition to the commitments discussed above, we had committed \$263,000 to increase our production capacity for the **First Defense®** product line, \$763,000 to construct and equip our own Drug Product formulation and aseptic filling facility for **Re-Tain™**, \$612,000 to the purchase of inventory, \$176,000 to capital expenditures and \$326,000 to other obligations as of September 30, 2020.

12. OPERATING LEASE

On September 12, 2019, we entered into a lease covering approximately 14,300 square feet of office and warehouse space with a Possession Date of November 15, 2019 and a Commencement Date of February 13, 2020. The property is located at 175 Industrial Way in Portland, which is a short distance from our headquarters and manufacturing facility at 56 Evergreen Drive. We renovated this space to meet our needs in expanding our production capacity for the **First Defense®** product line. The lease term is ten years with a right to renew for a second ten-year term and a right of first offer to purchase. At this time, we are not reasonably assured that we would exercise this renewal option in place of other real estate options. A 10-year period is reflected in the right-of-use (ROU) asset and lease liability on our balance sheet. The total lease liability over the initial 10-year term (including inflationary adjustments) aggregates approximately \$1,313,698 and includes real estate and personal property taxes, utilities, insurance, maintenance and related building and operating expenses. Our lease includes variable lease and non-lease components that are included in the ROU asset and lease liability. Such payments primarily include common area maintenance charges and increases in rent payments that are driven by factors such as future changes in an index, such as the Consumer Price Index. As of September 30, 2020, the balance of the operating lease ROU asset was \$1,246,866 and the operating lease liability was \$1,257,755. The calculated amount of the ROU asset and lease liability is impacted by the length of the lease term and the discount rate used for the present value of the minimum lease payments. The following table represents lease costs and other lease information. As we elected not to separate lease and non-lease components for all classes of underlying assets, and instead to account for them as a single lease component, the variable lease cost

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primarily represents variable payments such as real estate taxes and common area maintenance.

	During the Three-Month Periods Ended September 30,		During the Nine-Month Periods Ended September 30,	
	2020	2019	2020	2019
Lease Cost				
Operating lease cost	\$29,499	—	\$74,595	—
Variable lease cost	10,350	—	26,172	—
Total lease cost	\$39,849	—	\$100,767	—
Operating Lease				
Weighted average remaining lease term (in years)	9.3	—	9.3	—
Weighted average discount rate	4.77%	—	4.77%	—

Future lease payments required under non-cancelable operating leases in effect as of September 30, 2020 were as follows:

During the three-month period ending December 31, 2020	\$39,849
During the year ending December 31, 2021	159,396
During the year ending December 31, 2022	162,102
During the year ending December 31, 2023	165,120
During the year ending December 31, 2024	168,210
During the years ending December 31, 2025 and after	905,687
Total lease payments (undiscounted cash flows)	1,600,364
Less: imputed interest (discount effect of cash flows)	(342,609)
Total operating lease liabilities	<u>\$1,257,755</u>

13. STOCKHOLDERS' EQUITY

Common Stock Issuances

From February 2016 to March 2019, we issued the aggregate of 4,037,861 shares of common stock in five different transactions raising gross proceeds of approximately \$22,464,000. These funds are essential to funding our business growth plans. The details of each transaction are discussed below.

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. Having raised \$10,000,000 in gross proceeds under the February 2016, July 2017 and December 2017 equity transactions described below, no additional equity securities can be issued under this registration statement.

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 in a public, registered sale 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

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Notes to Unaudited Financial Statements (continued)

expenses incurred in connection with the equity financing).

On November 20, 2018, we filed a registration statement on Form S-3 (File No. 333-228479) with the Securities and Exchange Commission (SEC) for the potential issuance of up to \$20,000,000 in equity securities (subject to certain limitations). This registration statement became effective on November 29, 2018. Under this form of registration statement, we are limited within a twelve-month period to raising gross proceeds of no more than one-third of the market capitalization of our common stock (as determined by the high price 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 March 29, 2019, we sold 1,636,364 shares of common stock at a price to the public of \$5.50 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately \$9,000,000 and resulting in net proceeds to the Company of approximately \$8,303,000 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

Stock Option Plans

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. As of December 31, 2019, no options were outstanding under the 2000 Plan.

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 expired in June 2020, after which date no further options can be granted under the 2010 Plan. However, options outstanding under the 2010 Plan at that time can be exercised in accordance with their terms. As of September 30, 2020, 250,000 options were outstanding under the 2010 Plan.

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 and subsequently no additional shares have been reserved for 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 can be granted under the 2017 Plan. However, options outstanding under the 2017 Plan at that time can be exercised in accordance with their terms. As of September 30, 2020, 170,500 options were outstanding under the 2017 Plan.

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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 as of December 31, 2018	12,500	270,000	111,500	\$6.37	\$266,020
Grants	—	26,000	25,000	\$5.90	
Terminations	—	(26,000)	(3,000)	\$6.05	
Exercises	(12,500)	(15,000)	—	\$4.37	
Outstanding as of December 31, 2019	—	255,000	133,500	\$6.48	(\$516,475)
Grants	—	7,000	83,000	\$4.88	
Terminations	—	(12,000)	(46,000)	\$5.40	
Exercises	—	—	—	\$—	
Outstanding as of September 30, 2020	—	250,000	170,500	\$6.29	(\$360,558)
Vested as of September 30, 2020	—	165,500	10,000	\$6.04	(\$106,700)
Vested and expected to vest as of September 30, 2020	—	250,000	170,500	\$6.29	(\$360,558)
Reserved for future grants	—	—	129,500		

⁽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 (which is equal to the option exercise price).

The following table displays additional information about the stock option plans described above:

	Number of Shares	Weighted Average Fair Value at Grant Date	Weighted Average Exercise Price
Non-vested stock options as of January 1, 2020	321,000	\$3.49	\$6.55
Non-vested stock options as of September 30, 2020	245,000	\$3.28	\$6.47
Stock options granted during the nine-month period ended September 30, 2020	90,000	\$2.39	\$4.88
Stock options that vested during the nine-month period ended September 30, 2020	110,000	\$3.44	\$5.99
Stock options that were forfeited during the nine-month period ended September 30, 2020	58,000	\$2.80	\$5.40

No stock options were exercised during the nine-month period ended September 30, 2020. During the nine-month period ended September 30, 2019, one director exercised stock options covering 15,000 shares by the surrender of 10,731 shares of common stock with a fair market value of \$71,998 at the time of exercise and \$2 in cash.

The weighted average remaining life of the options outstanding under the 2010 Plan and the 2017 Plan as of September 30, 2020 was approximately 5 years and 7 months. The weighted average remaining life of the options exercisable under these plans as of September 30, 2020 was approximately 5 years and 4 months. The exercise prices of the options outstanding as of September 30, 2020 ranged from \$3.15 to \$8.90 per share. The 90,000 stock options granted during the nine-month period ended September 30, 2020 had exercise prices between \$4.00 and \$5.92 per share. The 20,000 stock options granted during the nine-month period ended September 30, 2019 had exercise prices between \$6.50 and \$7.50 per share. The aggregate intrinsic value of options exercised during the nine-month periods ended September 30, 2020 and September 30, 2019 approximated \$0 and \$28,641, respectively. The weighted-average grant date fair values of options granted during the nine-month periods ended September 30, 2020 and 2019 were \$2.39 and \$3.31, respectively. As of September 30, 2020, total unrecognized stock-based compensation related to non-vested stock options aggregated \$250,412, which will be recognized over a weighted average period of 1 year and 2 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(m), with the following weighted-average assumptions during the three-month and nine-month periods ended September 30, 2020 and 2019:

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Notes to Unaudited Financial Statements (continued)

	During the Three- Month Period Ended September 30, 2020	During the Three- Month Period Ended September 30, 2019	During the Nine- Month Period Ended September 30, 2020	During the Nine- Month Period Ended September 30, 2019
Risk-free interest rate	0.30%	n/a	0.41%	2.20%
Dividend yield	0%	0%	0%	0%
Expected volatility	54%	n/a	53%	52%
Expected life	6.5 years	n/a	6.1 years	5.3 years

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

Common Stock Rights Plan

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

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

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

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

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.

Authorized Common Stock

At the June 14, 2018 Annual Meeting of Stockholders, our stockholders voted to approve an amendment to our Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 8,000,000 to 11,000,000. At the June 10, 2020 Annual Meeting of Stockholders, our stockholders voted to approve an amendment to our Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 11,000,000 to 15,000,000.

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14. 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 as well as 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. There were no material changes between the allocation and timing of revenue recognition during the nine-month period ended September 30, 2020 or the year ended December 31, 2019. We do not have any contract assets 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 sheets are from contracts with customers. We incur no material costs to obtain contracts.

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

	<u>During the Three-Month Periods Ended September 30,</u>		<u>During the Nine-Month Periods Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
United States	\$3,361,820	\$2,728,368	\$10,319,232	\$9,033,592
Other ⁽¹⁾	360,679	242,128	1,279,626	1,057,385
Total product sales	<u>\$3,722,517</u>	<u>\$2,970,496</u>	<u>\$11,598,858</u>	<u>\$10,090,977</u>

⁽¹⁾ Sales outside of the United States included \$133,601 of non-animal health sales during the first quarter of 2019, which product has since been divested.

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

	<u>During the Three-Month Periods Ended September 30,</u>		<u>During the Nine-Month Periods Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
First Defense [®] product line	\$3,656,709	\$2,873,732	\$11,406,481	\$9,687,181
Other animal health	65,808	96,764	192,377	270,195
Other	—	—	—	133,601
Total product sales	<u>\$3,722,517</u>	<u>\$2,970,496</u>	<u>\$11,598,858</u>	<u>\$10,090,977</u>

15. OTHER EXPENSES, NET

Other expenses, net, consisted of the following:

	<u>During the Three-Month Periods Ended September 30,</u>		<u>During the Nine-Month Periods Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Interest expense ⁽¹⁾	\$75,941	\$106,999	\$499,940	\$333,030
Interest income	(4,651)	(41,719)	(20,350)	(91,133)
Other expenses, net	<u>\$71,290</u>	<u>\$65,280</u>	<u>\$479,590</u>	<u>\$241,897</u>

⁽¹⁾ During the three-month period ended March 31, 2020 interest expense included the write-off of \$95,000 of debt issuance costs and the payment of \$165,000 to terminate our interest rate swap agreements associated with debt that we repaid.

16. INCOME TAXES

Our income tax expense aggregated \$0 and \$7,439 (amounting to 0% and 2%, respectively, of our loss before income taxes) during the three-month periods ended September 30, 2020 and 2019, respectively. Our income tax (benefit) expense aggregated (\$14,632) and \$31,796 (amounting to (1%) and 3% of our loss before income taxes, respectively) during the nine-month periods ended September 30, 2020 and 2019, respectively. As of December 31, 2019, we had federal net operating loss carryforwards of \$11,949,860 of which \$10,237,953 do not expire and \$1,711,907 which expire in 2034 through 2037 (if not utilized before then) and state net operating loss carryforwards of \$3,299,929 that expire in 2037 through 2038 (if not utilized before then). Additionally, we had federal general business tax credit carryforwards of \$434,838 that expire in 2027 through 2039 (if not utilized before then) and state tax credit carryforwards of \$966,266 that expire in 2023 through 2039 (if not utilized before then).

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

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and liabilities and carryforwards to the extent they are realizable. During the second quarter of 2018, we assessed our historical and near-term future profitability and recorded \$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 credits) based on applicable accounting standards and practices. At that time, we had incurred a net loss for six consecutive quarters, had not been profitable on a year-to-date basis since the nine-month period ended September 30, 2017 and projected additional net losses for some period going forward before returning to profitability. Should future profitability be realized at an adequate level, we would be able to release this valuation allowance (resulting in a non-cash income tax benefit) and realize these deferred tax assets before they expire. 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. Adjustments related to the termination of our interest rate swap agreements were recorded during the first quarter of 2020. 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. We file income tax returns in the U.S. federal jurisdiction and several state jurisdictions. 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.

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% and 97% of our total product sales during the three-month periods ended September 30, 2020 and 2019, respectively. Sales of the **First Defense**[®] product line aggregated 98% and 96% of our total product sales during the nine-month periods ended September 30, 2020 and 2019, respectively. Our primary customers for the majority of our product sales (90% and 92% during the three-month periods ended September 30, 2020 and 2019, respectively, and 89% and 90% during the nine-month periods ended September 30, 2020 and 2019, respectively) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 10% and 8% of our total product sales during the three-month periods ended September 30, 2020 and 2019, respectively, and 11% and 9% of our total sales during the nine-month periods ended September 30, 2020 and 2019, respectively.

18. RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone 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 \$535,457 and \$393,881 of products from us during the nine-month periods ended September 30, 2020 and 2019, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of \$975 to these affiliated companies during the nine-month periods ended September 30, 2020 and 2019, which represent amounts similar to those offered to other distributors of similar status. These payments are expensed as incurred. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated \$37,850 and \$0 as of September 30, 2020 and December 31, 2019, 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 \$30,823 and \$29,081 into the Plan for the three-month periods ended September 30, 2020 and 2019, respectively, and \$95,896 and \$93,752 into the Plan for the nine-month periods ended September 30, 2020 and 2019, respectively.

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20. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of filing on November 12, 2020, the date we have issued this Quarterly Report on Form 10-Q. The COVID-19 pandemic continues to create a great deal of uncertainty for us. We could experience product shortages, backlogs and production slowdowns due to difficulties accessing needed supplies and labor and other restrictions affecting our ability to consistently deliver our products to market. The milk price outlook for 2021 remains uncertain. The weakness in the general economy could result in a reduction in food demand, including dairy products. During the second quarter of 2020, we received \$937,700 in support from the federal government under the Paycheck Protection Program (PPP), which amount was recorded as bank debt as of September 30, 2020. See Note 10. During the third quarter of 2020, we applied to our bank for forgiveness of this funding using 100% eligible payroll expenses. During the fourth quarter of 2020, our bank submitted our application for forgiveness to the federal government. Subsequent to that, we received notice from our bank that this loan has been fully forgiven by the federal government. The \$937,700 is expected to be recognized as other income during the fourth quarter of 2020. As of the time of filing on November 12, 2020, there were no other material, reportable subsequent events.

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

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

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

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: our plans and strategies for our business; projections of future financial or operational performance; the timing and outcome of pending or anticipated applications for regulatory approvals; factors that may affect the dairy and beef industries and future demand for our products; the extent, nature and duration of the COVID-19 pandemic and its consequences, and their direct and indirect impacts on the Company’s production activities, operating results and financial condition and on the customers and markets the Company serves; 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 and producers’ level of interest in treating subclinical mastitis given the current economic and market conditions; 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 anticipated costs of (or time to complete) planned expansions of our manufacturing facilities and the adequacy of our funds available for these projects; 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, efficiency and yield, which are highly subject to biological variability and the product format mix of our sales; the future adequacy of our working capital and the availability and cost of third-party financing; our ability to gain access to all or a substantial portion of the cash escrow funds presently held by our bank lender; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; 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 Nisin Drug Substance; implementation of international trade tariffs that could reduce the export of dairy products, which could in turn 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; the value of our net deferred tax assets; projections about depreciation expense and its impact on income for book and tax return purposes; anticipated market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as “expects”, “may”, “anticipates”, “aims”, “intends”, “would”, “could”, “should”, “will”, “plans”, “believes”, “estimates”, “targets”, “projects”, “forecasts”, “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 (including the **First Defense**[®] product line and **Re-Tain**[™]), competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand, our reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making and delays by regulatory authorities, currency values and fluctuations and other risks detailed from time to time in filings we make with the SEC, 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: OTHER INFORMATION, ITEM 1A – RISK FACTORS** and uncertainties otherwise referred to in this Quarterly Report on Form 10-Q.

Liquidity and Capital Resources

Based on our best estimates and projections, we believe that our cash, cash equivalents and short-term investments, together with gross margin anticipated to be earned from ongoing product sales, will be sufficient to meet our working capital and capital

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expenditure requirements, and to finance our ongoing business operations and planned expenditures, for at least twelve months from the date of this filing, which is the period of time required to be addressed for such purposes by accounting disclosure standards. We have funded most of our business operations principally from the gross margin on our product sales and equity and debt financings. The table below summarizes the changes in selected, key accounts (in thousands, except for percentages):

	As of September 30, 2020	As of December 31, 2019	(Decrease) Increase	
			Amount	%
Cash, cash equivalents, short-term investments and restricted cash	\$7,313	\$8,774	(\$1,461)	(17%)
Net working capital	\$8,135	\$10,694	(\$2,558)	(24%)
Total assets	\$39,987	\$38,692	\$1,295	3%
Stockholders' equity	\$28,021	\$28,991	(\$971)	(3%)
Market capitalization	\$39,166	\$37,147	\$2,020	5%
Common shares outstanding ⁽¹⁾	7,213	7,213	—	—%

⁽¹⁾ There were approximately 421,000 and 389,000 shares of common stock reserved for issuance under stock options that were outstanding as of September 30, 2020 and December 31, 2019, respectively.

From the first quarter of 2016 through the first quarter of 2019, we raised gross proceeds of approximately \$22.5 million (net proceeds were approximately \$20.5 million) from five different common equity transactions priced between \$5.25 and \$7.30 per share. No warrants were issued in connection with any of these transactions, and no convertible or preferred securities were issued.

From 2010 to 2017, we secured five different debt financings with TDBank N.A., each with different maturity dates and balloon principal repayment obligations. On March 11, 2020, we closed on a debt refinancing aggregating \$8.6 million plus a line of credit in the amount of \$1.0 million with Gorham Savings Bank. The new debt is comprised of a \$5.1 million mortgage loan that bears interest at a fixed rate of 3.50% per annum (with a 10-year term and 25-year amortization schedule) and a \$3.5 million note that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). The refinancing proceeds were used to provide some additional working capital but mostly to refinance \$8.3 million of then outstanding bank debt and pay off an interest rate swap termination liability of \$165,000. 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 and at \$3 million in connection with the 2020 refinancing) and our facility at 33 Caddie Lane in Portland (which was independently appraised at \$3.2 million in connection with the 2017 financing and at \$2.5 million in connection with the 2020 refinancing). This new debt improves our liquidity by lowering our interest expense, spreading our principal payments out over a longer time period and eliminating pending balloon principal payments that existed under some of the repaid debt. Under the new debt, we are required to hold \$1.4 million in escrow (a non-current asset), which reduces the effective availability of our liquid assets for operational needs by that amount. If we meet or exceed a minimum debt service coverage ratio set by the bank of 1.35 based on our financial performance during the year ending December 31, 2020, the escrow will be released to the extent that we achieve a loan (the amount of principal then outstanding on the \$5.1 million mortgage) to value (based on new real estate appraisals at that time) ratio equal to less than 80%. This debt service coverage ratio was equal to 1.88 and 1.57 during the twelve-month periods ended September 30, 2020 and December 31, 2019, respectively. We anticipate increasing our cash spend on marketing expenses and inventory build in support of a potential commercial launch of **Re-Tain™** during the third quarter of 2021. If we do not gain access to these escrowed funds, we may need to be cautious with our cash and reduce this planned level of investment somewhat.

During June 2020, we received a \$500,000 loan from the Maine Technology Institute that is subordinated to all other bank debt. The first 27 months of this loan are interest-free with no interest accrual or required principal payments. Principal and interest payments at 5% per annum are due quarterly over the final five years of the loan, beginning during the fourth quarter of 2022 and continuing through the third quarter of 2027. The loan may be prepaid without penalty at any time.

Net cash provided by operating activities improved to \$1.2 million during the nine-month period ended September 30, 2020 in comparison to \$280,000 during the nine-month period ended September 30, 2019. Cash paid for capital expenditures was \$3.8 million and \$700,000 during the nine-month periods ended September 30, 2020 and 2019, respectively. Our total depreciation expense was approximately \$1.7 million during both of the nine-month periods ended September 30, 2020 and 2019. We anticipate that depreciation expense, while not affecting our cash flows from operations, will result in net operating losses until and unless product sales increase sufficiently to offset these non-cash expenses. Going forward, repayments of the indebtedness incurred to acquire these assets will reduce our cash flows. Debt principal payments (exclusive of the \$8.3 million used to repay our refinanced bank debt) were \$488,000 and \$644,000 during the nine-month periods ended September 30, 2020 and 2019, respectively.

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Our capital expenditures during the six-year period from January 1, 2014 to December 31, 2019 are described in the following table (in thousands, except for footnotes):

	Cash Paid During the Years Ended					Total
	A	B	C	D	E	
December 31, 2014	\$1,041	\$—	\$—	\$—	\$471	\$1,512
December 31, 2015	1,991	265	—	—	463	2,719
December 31, 2016	1,173	2,093	—	—	320	3,586
December 31, 2017	—	17,686	—	—	74	17,760
December 31, 2018	—	1,596	—	—	434	2,030
December 31, 2019	—	—	279	538	574	1,391
Total	\$4,205	\$21,640	\$279	\$538	\$2,336	\$28,998

PROJECT A included a 7,100 square foot facility addition at 56 Evergreen Drive and related equipment and cold storage capacity to increase the production capacity for the **First Defense**[®] product line. During the first quarter of 2016, we completed this investment, increasing our freeze drying capacity by 100% and making other improvements to our liquid processing capacity, which, in turn, increased our annual production capacity (in terms of annual sales dollars) to approximately \$16 to \$17 million. The actual value of this production output will vary based on production yields, selling price, product format mix and other factors. This investment also included the construction and equipping of a pilot plant for small-scale Drug Substance production facility for **Re-Tain**[™] within our **First Defense**[®] production facility that is now used to produce the gel tube formats of the **First Defense**[®] product line. Upon the completion of Project C, the gel tube operations will be moved to 175 Industrial Way, and this space will be used to expand our liquid processing capacity at 56 Evergreen Drive.

PROJECT B was related to the Drug Substance production facility for **Re-Tain**[™]. During the fourth quarter of 2017, we completed construction of the Drug Substance production facility. We began equipment installation during the third quarter of 2017, and we completed this installation during the third quarter of 2018. The total cost of this investment for the Drug Substance production facility and related processing equipment was \$20.8 million plus \$331,000 for the land and \$472,000 for the acquisition of an adjacent 4,100 square foot warehouse facility, which is now being used for **First Defense**[®] operations.

PROJECT C consists of significant renovations to a 14,300 square foot leased facility at 175 Industrial Way, some facility modifications at 56 Evergreen Drive and the necessary production equipment to increase the annual production capacity of the **First Defense**[®] product line (in terms of annual sales dollars) from approximately \$16 to \$17 million to approximately \$23 million. These production capacity projections differ moderately from prior estimates largely because of biological yield differences and changes in the product format mix. The actual value of our production output will vary based on biological yields, selling price, product format mix and other factors. This expansion involves a 50% increase in our freeze drying capacity and a 100% increase in our liquid processing capacity. Renovations to our leased facility at 175 Industrial Way to enable this expansion were completed during the second quarter of 2020. A site license approval for this new facility was issued by the USDA during the third quarter of 2020. By moving our powder filling and assembly services from 56 Evergreen Drive into this new space at 175 Industrial Way, we created space at 56 Evergreen Drive for the installation of the expanded freeze drying capacity. We completed that installation early in the fourth quarter of 2020. Next, we intend to move our gel formulation equipment from 56 Evergreen Drive to 175 Industrial Way, creating space for the expanded liquid processing at 56 Evergreen Drive. We have deferred the implementation of this final phase of the expansion project to the second quarter of 2021 to avoid any interruption of finished product releases during our peak selling season. Equipment modifications and relocations of this nature require a shut down of operations for several weeks to validate the modified equipment and achieve USDA approval for its use in its new location. We have been increasing the number of contract farms and cows from which we purchase colostrum throughout 2020 and will continue to do so into 2021 to support our increased production objectives. We are processing all the milk we currently purchase through our existing liquid processing operations. Since this investment was initiated during 2019 and through September 30, 2020, we paid approximately \$3.1 million towards Project C, leaving approximately \$400,000 needed to complete the investment. As part of this \$3.5 million investment, we have made the facility modifications necessary for a future expansion of our freeze drying capacity by an additional 33%, which would increase our annual production capacity to approximately \$30 million. The equipment required to achieve this further production capacity increase would cost approximately an additional \$700,000. We anticipate bringing this new production capacity on-line during the second half of 2022 to meet projected growth in sales demand.

PROJECT D is a \$4 million budgeted investment to bring the formulation and aseptic filling services for **Re-Tain**[™] Drug Product in-house to end our reliance on third-party Drug Product manufacturing services. We expect this facility to be operational during 2022. Since this investment was initiated during 2019 and through September 30, 2020, we paid approximately \$1.1 million

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towards Project D, leaving approximately \$2.9 million needed to complete the investment during 2021 and 2022.

PROJECT E represents other miscellaneous, routine and necessary capital investments during the years. The original budget for the year ending December 31, 2020 of \$300,000 was increased to \$450,000. During the nine-month period ended September 30, 2020, we paid \$311,000 towards Project E.

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 Drug Substance production facility for **Re-Tain™** 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 value of the tax savings will increase (decrease) in proportion to any increase (decrease) in the assessment of the building for city real estate tax purposes. The following table discloses the split of the new rates we have generated between the City of Portland and the Company:

Assessed Value	Twelve-Month Period Ended	Total New Taxes Generated by the Project	Less: TIF Credit	Net Amount Paid by ImmuCell
\$1.7M @ April 1, 2017	June 30, 2018	\$36,000	\$22,000	\$13,000
\$4.0M @ April 1, 2018	June 30, 2019	\$90,000	\$58,000	\$32,000
\$4.0M @ April 1, 2019	June 30, 2020	\$94,000	\$60,000	\$34,000
\$4.0M @ April 1, 2020	June 30, 2021	\$94,000	\$60,000	\$34,000

Results of Operations

2020 Compared to 2019

Product Sales

Total product sales during the three-month period ended September 30, 2020 increased by 25%, or \$752,000, to \$3.7 million from \$3 million during the third quarter of 2019, with domestic sales increasing by 23% and international sales increasing by 49% in comparison to the same period in 2019. Total product sales during the nine-month period ended September 30, 2020 increased by 15%, or \$1.5 million, to \$11.6 million from \$10.1 million during the same period in 2019, with domestic sales increasing by 14% and international sales increasing by 21% in comparison to the same period in 2019. Total product sales during the trailing twelve-month period ended September 30, 2020 increased by 17%, or \$2.2 million, to \$15.2 million from \$13 million during the trailing twelve-month period ended September 30, 2019, with domestic sales increasing by 17% and international sales increasing by 19% in comparison to the trailing twelve-month period ended September 30, 2019. As of September 30, 2020, we had a backlog of orders worth approximately \$130,000, compared to a backlog of approximately \$945,000 as of June 30, 2020. International sales aggregated 10% and 8% of total sales during the three-month periods ended September 30, 2020 and 2019, respectively. International sales aggregated 11% and 10% of total sales during the nine-month periods ended September 30, 2020 and 2019, respectively. International sales aggregated 12% and 11% of total sales during the trailing twelve-month periods ended September 30, 2020 and 2019, respectively. The trailing twelve-month figures are a non-GAAP disclosure and are derived from taking sales during the nine-month period ended September 30th plus sales during the fourth quarter of the prior year. The compound annual growth rate of our total product sales during the nine years ended December 31, 2019 was approximately 13%. The compound annual growth rate of our total product sales during the three years ended December 31, 2019 was approximately 15%.

Investments in the **First Defense®** product line have created positive results. Sales of the **First Defense®** product line increased by 27% during the three-month period ended September 30, 2020 in comparison to the same period during 2019, aggregating 98% and 97% of our total product sales during the three-month periods ended September 30, 2020 and 2019, respectively. Sales of the **First Defense®** product line increased by 18% during the nine-month period ended September 30, 2020 in comparison to the same period during 2019, aggregating 98% and 96% of our total product sales during the nine-month periods ended September 30, 2020 and 2019, respectively. Most of our growth is being realized through increased demand and a deliberate strategy to bias production capacity towards **Tri-Shield First Defense®** (the trivalent format of our product delivered via a gel tube) providing broader protection to calves. Sales of **Dual-Force First Defense®** (the bivalent formats of our product delivered via either a bolus, gel tube or bulk powder) were generally flat during 2019 in comparison to 2018 and decreased somewhat during the first nine months of 2020 in comparison to the first nine months of 2019. 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. Our **Beyond Vaccination®** marketing campaign focuses on providing antibodies without vaccination. A 100% vaccine response rate is biologically impossible. The **First Defense®** product line removes the variability associated with a scour vaccine response and instead provides a measured level of pre-formed

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antibodies, protecting each calf with an equal level of scours protection. There is a strong link between how we sell our product and the challenges we face in producing it. We know better than most how variable a cow's response is to any vaccine. We see this in every batch of **First Defense**[®] that we produce. The value in **First Defense**[®] is that we adjust for this variability in antibody content, as needed, so the newborn is given a steady, equal level of protection with each dose. This technology removes a producer's reliance on variable vaccine responses to generate passive antibody protection and instead protects every calf equally with a measured dose of **Immediate Immunity**[™] against the most common scour pathogens. Plus, an effectively treated calf is much less likely to require expensive antibiotic treatments or build antibiotic resistance. We are the only manufacturer within the scour prevention space offering polyclonal multi-pathogen antibodies.

We are gaining market share in the United States year after year with our **Beyond Vaccination**[®] strategy. Our share of the market (on a unit volume basis) of scour preventative products administered at the calf-level increased to approximately 36% during 2019 (from 34% during 2018 and 32% during 2017). Our share of the market of these scour preventative products administered at the calf-level increased to approximately 41% during the first nine months of 2020 from approximately 35% during the first nine months of 2019. Our share of the market of calves treated with products administered to calves and those administered to the dam prior to calving (adjusting for two doses of dam-level scour vaccines required for primary vaccination of first-calf-heifers) increased to approximately 11% during 2019 (from 10.3% during 2018 and 9.7% during 2017). Our share of these calves treated with products administered to calves and those administered to the dam prior to calving increased to approximately 14% during the first nine months of 2020 from approximately 12% during the first nine months of 2019. We see the potential for future market share growth in the dairy market, and we have increased our focus on the beef market.

Since the third quarter of 2016 and through most of 2017, we had sufficient available inventory and were shipping in accordance with the demand of our distributors. However, we quickly sold out of our initial launch quantities of **Tri-Shield First Defense**[®] soon after regulatory approval was obtained during the fourth quarter of 2017. During most of 2018 and into the first half of 2019, we could only accept purchase orders from customers for **Tri-Shield**[®] to match available inventory, which required a careful allocation of product supply directly to certain end-users and veterinary clinics. Production of this new product format had not kept pace with demand primarily because of our inability to produce enough of the new, complex rotavirus vaccine that is used to immunize our source cows. We worked on production improvements in our vaccine laboratory throughout 2018. Significant improvements in vaccine yield and process repeatability resolved this shortfall going into 2019. Allowing for the five to six month production cycle from the manufacture of our proprietary vaccine to the production of a finished dose, we were able to return to a mass market selling approach through distribution for **Tri-Shield**[®] during the second half of 2019. Given our projections for future demand, we are completing a \$3.5 million investment to further increase our production capacity (Project C, discussed above). We expect to fully realize the benefits of this expanded production capacity beginning in the second quarter of 2021. By maximizing existing production capacity, we achieved sales of \$11.6 million during the first nine months of 2020, which suggests an annualized production rate of approximately \$15.5 million (assuming straight-line production without reflecting changes in inventory balances). Our sales during the second quarter of 2020 (when annualized using the same assumptions) suggest an annual production output rate of approximately \$11.9 million. Our sales during the third quarter of 2020 (when annualized using the same assumptions) suggest an annual production output rate of approximately \$14.9 million. This is an indication of the beginning of our production capacity expansion to approximately \$23 million following the completion of Project C. This production output was not enough to meet demand, and we ended the third quarter with a backlog of orders worth approximately \$130,000 as of September 30, 2020, which was down from approximately \$945,000 and \$1.4 million as of June 30, 2020 and March 31, 2020, respectively. Given our forecasts of future sales demand and our estimates regarding the scaling up of our production output, we may experience some intermittent, short-term backlog into the second quarter of 2021 until increasing production output exceeds growing sales demand.

The extent of the negative impact of the COVID-19 pandemic on the economics of our customers and on the demand for our products going forward is very difficult to assess. During the first nine months of 2020, the Class III milk price (measured in dollars per 100 pounds) averaged \$17.48. This price has been extremely volatile during the pandemic, increasing by 102% from a low of \$12.14 for May 2020 to a high of \$24.54 for July, which is very close to an all-time record high. Initially stay at home orders disrupted the food service supply system as schools closed and restaurants were shut down. In response, producers were forced to reduce the supply of milk to the market by drying off cows early, culling cows from the herd and dumping milk, among other tactics. Market conditions are better now, but this volatility remains a concern, and there is no way to be confident that these recent high milk prices will be sustained. The \$938,000 in funding that we received from the federal government through the Paycheck Protection Program (PPP) under the CARES Act helped us maintain full employment without furloughs or layoffs and continue executing our growth plans, even though we may see a future decline in sales and gross margin as a result of the pandemic. The PPP funding created some needed financial liquidity allowing us to move forward with our investments even though we are not achieving the level of sales anticipated in our 2020 budget. We plan to complete the \$3.5 million investment to increase our production capacity for **First Defense**[®] (Project C, discussed above), complete the \$4 million investment in our own aseptic filling facility for **Re-Tain**[™] (Project D, discussed above), fill the backlog of orders, meet ongoing demand and use any excess production to build inventory stocks by the

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end of 2021. This will require that we invest available cash in inventory. Our inventory balances were \$2.1 million and \$2.5 million as of September 30, 2020 and December 31, 2019, respectively. Our inventory balances consisted of approximately 11% and 21% finished goods as of September 30, 2020 and December 31, 2019, respectively. See Note 5 to the accompanying unaudited financial statements for more details about our inventory.

After making several inquiries into different laboratories, we were able to have our antibodies tested for effectiveness against COVID-19 during the second quarter of 2020. While we understood that COVID-19 and bovine coronavirus are in different taxonomic groups, we wanted to investigate whether our antibodies could offer some cross-neutralization of COVID-19 in the laboratory testing. Unfortunately, the test results indicated, as expected, that our antibodies offered no viral neutralization activity, meaning they would be ineffective against COVID-19.

Effective in December of 2018, we implemented an 11% price increase for **Tri-Shield First Defense**[®]. Effective January 1, 2019, we implemented a 2% price increase for **Dual-Force**[®]. Effective February 1, 2020, we implemented a price increase of approximately 2% on the **First Defense**[®] product line (except for **Tri-Shield**[®] and the 90-dose bulk powder) and **CMT**.

Sales of products other than the **First Defense**[®] product line decreased by 32%, or \$31,000, to \$66,000 during the three-month period ended September 30, 2020 in comparison to the same period during 2019. Sales of these other products aggregated approximately 2% and 3% of our total product sales during the three-month periods ended September 30, 2020 and 2019, respectively. Sales of products other than the **First Defense**[®] product line decreased by 52%, or \$211,000, to \$192,000 during the nine-month period ended September 30, 2020 in comparison to the same period during 2019. Sales of these other products aggregated approximately 2% and 4% of our total product sales during the nine-month periods ended September 30, 2020 and 2019, respectively. We acquired several private label products (our second leading source of product sales during 2019 and 2018 and our third leading source during the nine-month period ended September 30, 2020) in connection with our January 2016 acquisition of certain gel formulation technology. We sell our own **CMT** (our third leading source of product sales during 2019 and 2018 and our second leading source during the nine-month period ended September 30, 2020), which is used to detect somatic cell counts in milk. We have made and sold bulk reagents for **Isolate**[™] (our fourth leading source of product sales during 2019 and 2018), which is a drinking water test that is sold by our former distributor in the United Kingdom. Sales of this product amounted to just \$24,000 during the year ended December 31, 2018. We made one final sale of this product to this distributor worth \$134,000 during the first quarter of 2019. Because this product was non-core to our strategic focus, we sold the underlying cell line assets and intellectual property to our former distributor during the third quarter of 2018 for \$700,000. We have retained the rights to all animal health, diagnostic, feed and nutritional applications of this technology.

Gross Margin

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

	During the Three-Month Periods Ended September 30,		Increase (Decrease)	
	2020	2019	Amount	%
	Gross margin	\$1,722	\$1,451	\$271
Percent of product sales	46%	49%	(3%)	(5%)

	During the Nine-Month Periods Ended September 30,		Increase (Decrease)	
	2020	2019	Amount	%
	Gross margin	\$5,242	\$4,902	\$340
Percent of product sales	45%	49%	(3%)	(7%)

	During the Trailing Twelve-Month Periods Ended September 30,		Increase (Decrease)	
	2020	2019	Amount	%
	Gross margin	\$7,080	\$6,298	\$782
Percent of product sales	46%	48%	(2%)	(4%)

The gross margin (product sales less costs of goods sold) as a percentage of product sales was 49%, 47% and 50% during the years ended December 31, 2019, 2018 and 2017, respectively. The gross margin as a percentage of sales was lower than what we normally expect, but we did increase the gross margin dollars in each period being reported. A number of factors account for the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter. Like most U.S.

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manufacturers, we have also been experiencing increases in the cost of labor and raw materials. We also invest to sustain compliance with current Good Manufacturing Practices (cGMP) in our production processes. Increasing production can be more expensive in the initial stages. To achieve our inventory production growth objectives, we are acquiring more raw material (colostrum) from many more cows at many new farms. As is the case with any vaccine program, animals respond less effectively to their first exposure to a new vaccine and then the effectiveness of their immune response improves in response to subsequent immunizations. As a result, during this expansion phase, similar quantities of colostrum are yielding fewer doses of finished product, which results in higher costs of goods sold. Additionally, the biological yields from our raw material are always variable, which impacts our costs of goods sold in a similar way. 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 vaccines. The value of our **First Defense**[®] product line is that we compensate for the variability in a cow's immune response by standardizing each dose of finished product. This ensures that every calf is equally protected, which is something that dam-level commercial scours vaccines cannot offer. The gross margin percentage for the legacy format (capsule) of the **First Defense**[®] product line was in excess of 50%, which was in line with prior years. The new gel formats of our product are more complex (i.e. three antibodies for **Tri-Shield**[®] versus two antibodies for **Dual-Force**[®]) and more expensive to produce and presently contribute a lower gross margin percentage but a higher gross margin dollar per unit. These new formats are creating sales growth for us, and we are focused on increasing total gross margin dollars, even if that is accomplished with a lower gross margin as a percentage of sales. We continue to work on processing and yield improvements and other opportunities to reduce costs, while enhancing process knowledge and robustness. Over time, we have been able to reduce the impact of cost increases by implementing yield improvements. 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 and amortization expenses) as a percentage of total sales of almost 50%.

Product Development Expenses

During the three-month period ended September 30, 2020, product development expenses increased by 14%, or \$138,000, to \$1.1 million in comparison to \$985,000 during the same period in 2019. Product development expenses aggregated 30% and 33% of product sales during the three-month periods ended September 30, 2020 and 2019, respectively. It is important to note that these figures include approximately \$401,000 and \$407,000 of non-cash depreciation and stock-based compensation expenses during the three-month periods ended September 30, 2020 and 2019, respectively. During the nine-month period ended September 30, 2020, product development expenses increased by 17%, or \$469,000, to \$3.2 million in comparison to \$2.7 million during the same period in 2019. Product development expenses aggregated 27% of product sales during both of the nine-month periods ended September 30, 2020 and 2019. It is important to note that these figures include approximately \$1.2 million of non-cash depreciation and stock-based compensation expenses during both of the nine-month periods ended September 30, 2020 and 2019. We do expect our product development expenses to decrease after **Re-Tain**[™] is commercialized and most of the costs incurred to maintain and run our Drug Substance production facility become part of our costs of goods sold.

The majority of our product development spending has been focused on the development of **Re-Tain**[™], our purified Nisin treatment for subclinical mastitis in lactating dairy cows. Approval by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA) of the New Animal Drug Application (NADA) for **Re-Tain**[™] is required before any sales of the product can be initiated. The NADA is comprised of five principal Technical Sections and one administrative submission that are subject to phased review by the 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. 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.
- 4) Human Food Safety: 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

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treatment with our product.

- 5) Chemistry, Manufacturing and Controls (CMC): Having previously achieved the four different Technical Section Complete Letters from the FDA discussed above, approval of the CMC Technical Section is the fifth and final significant step required before **Re-Tain™** product sales can be initiated in the United States. Implementing Nisin Drug Substance (the active pharmaceutical ingredient) production at our commercial facility, which is a required component of the CMC Technical Section, has been the most expensive and lengthy part of this project. We previously entered into an agreement with a multi-national pharmaceutical ingredient manufacturer for our commercial-scale supplies of Nisin. However, we determined during 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, we concluded that a partner would have taken an unduly large share of the gross margin from all future product sales of **Re-Tain™**. The regulatory and marketing feedback about the prospects for this product that we received from prospective partners, following their due diligence, was positive. During the third quarter of 2014, we completed an investment in facility modifications and processing equipment necessary to produce the Nisin Drug Substance at small-scale at our 56 Evergreen Drive facility. 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 risks associated with our investment in the commercial-scale Drug Substance production facility. Having raised equity during 2016 and 2017, we were able to move away from these earlier strategies and assume control over the commercial-scale manufacturing process in our own facility. During the fourth quarter of 2015, we acquired land near our existing Portland facility for the construction of a new commercial-scale Drug Substance production facility. We commenced construction of this facility during the third quarter of 2016 and completed construction during the fourth quarter of 2017. Equipment installation and qualification was initiated during the third quarter of 2017 and completed during the third quarter of 2018. Total construction and equipment costs aggregated approximately \$20.8 million.

We have always believed that the fastest route to FDA approval and market launch is with the services of Norbrook Laboratories Limited of Newry, Northern Ireland (an FDA-approved Drug Product manufacturer), benefiting from their demonstrated expertise in aseptic filling. From 2010 to 2015, we had been a party to an exclusive product development and contract manufacturing agreement with Norbrook covering the Drug Product formulation, aseptic filling and final packaging services. Norbrook provided services to us under this contract throughout the FDA process for use in all of our pivotal studies. During the fourth quarter of 2015, this agreement was amended and restated to create a Product Development and Contract Manufacture Agreement (the 2015 Agreement) to, among other things, extend the term of the agreement to January 1, 2024 provided that FDA approval for commercial sales of **Re-Tain™** in the United States was obtained by December 19, 2019. It had been our expectation that we would have these services available through both the remainder of the development process to FDA approval and for approximately the first four years of commercial sales of **Re-Tain™**. Due to unexpected difficulties and delays encountered by Norbrook and the statutory FDA timeline for processing CMC Technical Sections, this December 2019 product approval target date was not achieved. During the third quarter of 2019, we entered into a Development Services and Commercial Supply Agreement (the 2019 Agreement) with Norbrook. The 2019 Agreement replaces and supersedes the 2015 Agreement in its entirety. Under the 2019 Agreement, Norbrook will continue to provide formulation, aseptic filling and final packaging services as required in order for us to make the needed Drug Product submission to obtain the FDA's approval of the CMC Technical Section. The 2019 Agreement also provides for Norbrook to perform formulation, aseptic filling and final packaging services in accordance with purchase orders that we submit from time to time for inventory build and subsequent product sales worth up to approximately \$7 million for orders placed through December 31, 2021 with deliveries extending into the first half of 2022. We believe that the 2019 Agreement will enable us to commence sales of **Re-Tain™** without delay upon receipt of the anticipated FDA approval. We intend to use the supply provided under the 2019 Agreement to bridge until our own formulation and aseptic filling capacity is available, which we expect to occur during the fourth quarter of 2022 (if one, six-month review cycle by the FDA) or second quarter of 2023 (if two, six-month review cycles by the FDA).

Our potential alternative options for the formulation and aseptic filling services are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). Consequently, we have decided to perform these services internally. Through a public offering of our common stock in March of 2019, we received net proceeds of approximately \$8.3 million, of which approximately \$4 million has been allocated to the equipping and commencement of operations of our own Drug Product formulation and aseptic filling facility. Based on current construction plans and equipment ordering and installation timelines, we expect our facility to be operational during the first half of 2022, and we are working to achieve FDA approval of this facility by the fourth quarter of 2022. This new facility will be subject to FDA inspection and approval and will have enough formulation and aseptic filling capacity to exceed the expected production capacity of our Drug Substance facility, which is at least \$10 million in annual sales. This production capacity estimate is based on our assumptions as to product pricing and does not yet reflect inventory build strategies in advance of product approval or ongoing yield improvement initiatives.

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Establishing our own Drug Product formulation and aseptic filling capability provides us with the longer-term advantage of controlling the manufacturing process for **Re-Tain™** in one facility, thereby potentially reducing our manufacturing costs and eliminating international cold chain shipping logistics and costs. The Drug Product formulation and aseptic filling operation will be located in existing facility space that we had intended to utilize to double our Drug Substance production capacity if warranted by sales volumes following market launch. As a result, we would need to explore alternative strategies (in parallel with ongoing Drug Substance yield improvement initiatives) to expand our Drug Substance production capacity in order to meet anticipated long-term **Re-Tain™** sales demand. This integrated manufacturing capability for **Re-Tain™** will substantially reduce our dependence on third parties. Upon completion of our formulation and aseptic filling facility, the only significant third-party input for **Re-Tain™** will be the Drug Product syringes. It is anticipated that Hubert De Backer of Belgium (HDB) will supply these syringes in accordance with purchase orders that we submit. HDB is a syringe supplier for many of the largest participants in the human and veterinary medical industries, and with whom Norbrook presently works. Based on HDB's performance history and reputation in the industry, we are confident that HDB will be a dependable supplier of syringes in the quantity and of the quality needed for **Re-Tain™**. We have not yet determined if we will perform the final packaging services in-house or contract to have those services performed by a qualified third party in the United States.

The Chemistry, Manufacturing and Controls Technical Section is very complex and comprehensive. Under the FDA's phased submission process, the first-phased submission covers the Nisin Drug Substance (DS), and the second-phased submission covers the DS and the **Re-Tain™** Drug Product (formulated Nisin DS filled in a syringe, or DP). This process allows a sponsor to respond to identified queries and/or deficiencies from the first-phased DS submission at the time of the second-phased DS and DP submission, which will include detailed information about the manufacturing process and controls for the DP. We made our first-phased DS submission during the first quarter of 2019. This submission included data from the DS Registration Batches produced at commercial scale in our new DS manufacturing facility. As part of the phased submission process, the FDA issued a Technical Section Incomplete Letter with regard to this first-phased DS submission during the third quarter of 2019 with various requests and queries in addition to referring to the fact that the second-phased DS and DP submission had yet to be submitted. We expected this response. Having reviewed the comments from the FDA, we see no roadblocks on our path to FDA approval for **Re-Tain™**. We believe we can respond effectively to the FDA's comments without significant additional cost or time delays. In addition to responding to comments raised by the FDA regarding the first-phased DS submission, one of the key components of the second-phased DS and DP submission is demonstrating stability of the product over time using the commercial process and the commercial syringe in its final packaged form. Given a current assessment of the work that has been completed and that needs to be performed, we still are expecting to make the first submission of the second-phased DS and DP submission before the end of 2020. A response from the FDA to our second-phased DS and DP submission is anticipated six months after the submission date, which would be during the second quarter of 2021. This type of complex submission is often subject to two reviews by the FDA. We do not expect three submissions. If the FDA responds with a Technical Section Incomplete Letter, we would need time to prepare our response and then make one or more additional submissions (each subject to its own six-month review period) until the FDA is satisfied that we have adequately responded to their queries before the final 60-day administrative review period (the last step in the regulatory approval process) can be initiated. In this scenario, product approval could not be expected before the first quarter of 2022. Given the risk reduction we achieved by making the first-phased DS submission and by working with an FDA-approved DP manufacturer, it is possible that we could receive a first-time approval of the DS and DP submission during the second quarter of 2021, which could lead to FDA approval of our NADA and market launch during the third quarter of 2021. While being prudent with how much cash we invest into inventory that would have short expiry dating if market launch is not until the first quarter of 2022, we do intend to build some inventory during 2020 and 2021 in preparation for the potential of a market launch during the third quarter of 2021, and we plan to continue to build more inventory during 2021 for the potential of a market launch during the first quarter of 2022.

Successful FDA inspections of the manufacturing facilities must also be achieved before the NADA can be approved. During the third quarter of 2019, the FDA conducted a pre-approval inspection of our DS facility. This resulted in the issuance of certain deficiencies as identified on the FDA's Form 483. We submitted responses and data summaries in a phased manner over the fourth quarter of 2019 and first quarter of 2020. We anticipate a follow-up inspection by the FDA during the first half of 2021 to confirm the corrective actions that we have implemented. This inspection process has been managed without significant cost or impact on the timeline to product approval.

Our second most important product development initiative (in terms of dollars invested and, we believe, potential market impact) has been focused on other improvements, extensions or additions to our **First Defense®** product line. During the second quarter of 2009, we entered into an exclusive license with the Baylor College of Medicine covering the animal health rights to the underlying rotavirus vaccine technology that we use to generate the specific antibodies. 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 (CFIA) to sell **Tri-Shield®** in Canada. We initiated sales in Canada during the fourth quarter of 2019. We

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achieved USDA approval of our bivalent gel tube formulation (formerly marketed as **First Defense Technology**[®]) during the fourth quarter of 2018 and have re-branded this product format as **Dual-Force First Defense**[®]. During the first quarter of 2019, we obtained CFIA approval to sell the gel tube format of **Dual-Force**[®] in Canada and have initiated commercial sales there. We are currently working to establish USDA claims for our bivalent bulk powder formulation of **First Defense Technology**[®]. We are also investing in additional studies to further support the **First Defense**[®] product line in the market.

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 first quarter of 2019, we extended this exclusive option agreement through the first quarter of 2021. This technology focuses on bacteriocins having activity against Gram-negative infections (as opposed the Gram-positive coverage offered by Nisin) 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.

Sales and Marketing Expenses

During the three-month period ended September 30, 2020, sales and marketing expenses decreased by approximately 8%, or \$39,000 to \$459,000 in comparison to \$498,000 during the same period in 2019, amounting to 12% and 17% of product sales during the three-month periods ended September 30, 2020 and 2019, respectively. Sales and marketing expenses included approximately \$22,000 and \$12,000 of non-cash depreciation and stock-based compensation expenses during the three-month periods ended September 30, 2020 and 2019, respectively. During the nine-month period ended September 30, 2020, sales and marketing expenses decreased by approximately 7%, or \$121,000, to \$1.5 million in comparison to \$1.6 million during the same period in 2019, amounting to 13% and 16% of product sales during the nine-month periods ended September 30, 2020 and 2019, respectively. Sales and marketing expenses included approximately \$75,000 and \$79,000 of non-cash depreciation and stock-based compensation expenses during the nine-month period ended September 30, 2020 and 2019, respectively. Our sales team has pivoted effectively to alternative selling strategies and methods during the COVID-19 pandemic to be successful at a time when most trade shows have been cancelled and travel and on-farm visitations have been limited. The reduced travel and trade show expenses and having two open sales positions (that have since been filled) resulted in some cost savings. We continue to leverage the efforts of our small sales force by using animal health distributors. Our current budgetary objective in 2020 is to invest less than 20% of product sales in sales and marketing expenses on an annual basis. This ratio is expected to come down incrementally as sales grow.

Administrative Expenses

During the three-month period ended September 30, 2020, administrative expenses decreased by approximately 2%, or \$7,000, to \$392,000 in comparison to \$399,000 during the same period in 2019. Administrative expenses included approximately \$35,000 and \$56,000 of non-cash depreciation and stock-based compensation expenses during the three-month periods ended September 30, 2020 and 2019, respectively. During the nine-month period ended September 30, 2020, administrative expenses increased by approximately 2%, or \$27,000, to \$1.3 million in comparison to \$1.27 million during the same period in 2019. Expenses during first quarter of 2020 included fees paid to predecessor auditors, a new employee hiring fee and some extra legal work. Administrative expenses included approximately \$115,000 and \$155,000 of non-cash depreciation and stock-based compensation expense during the nine-month periods ended September 30, 2020 and 2019, respectively. 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, which includes meeting investors in face-to-face meetings in different cities approximately four days per quarter. Given travel restrictions related to the COVID-19 pandemic, this initiative has pivoted to a virtual meeting format, which is less expensive. At the same time, we continue to provide full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as in Current Reports on Form 8-K when legally required or deemed appropriate by management. These efforts may have helped us access the capital markets to fund our growth objectives. Additional information about us is available in our annual Proxy Statement. All of these reports are filed with the SEC and are available on-line or upon request to the Company.

Net Operating Loss

During the three-month period ended September 30, 2020, our net operating loss was \$252,000 in comparison to \$430,000 during the same period in 2019. The net operating losses included approximately \$663,000 and \$636,000 of non-cash depreciation, amortization of intangible assets and stock-based compensation expenses during the three-month periods ended September 30, 2020 and 2019, respectively. During the nine-month period ended September 30, 2020, our net operating loss was \$746,000 in comparison

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to \$711,000 during the same period in 2019. The net operating losses included approximately \$1.9 million of non-cash depreciation, amortization of intangible assets and stock-based compensation during both of the nine-month periods ended September 30, 2020 and 2019. Our debt principal payments are a partial offset to these non-cash expenses, as they represent uses of cash that are not recorded as an expense. The COVID-19 pandemic is causing very challenging economic conditions. What comes next is very uncertain as we proceed quarter by quarter. The \$938,000 in Paycheck Protection Program (PPP) funding from the federal government under the CARES Act that we received during the second quarter of 2020 provided increased financial flexibility, strengthening our balance sheet with more liquidity and cash on hand, thereby enabling us to remain focused on our critical growth objectives and investments. The PPP funding has also given us the confidence to advance our \$4 million investment to bring the formulation and aseptic filing services for **Re-Tain™** Drug Product in-house. Nationally, the PPP has provided \$521 billion in forgivable loans to approximately 650,000 businesses, supporting employers and workers by paying salaries and benefits through the economic downturn. This support has helped us avoid layoffs and furloughs thus far. The PPP funding has been recorded as a liability on our balance sheet. While the funds can be used to support certain operating costs as long as at least 60% of the total amount to be forgiven is used for payroll costs, we have requested forgiveness of this full loan amount using 100% payroll costs. Any portion not forgiven can be repaid over five years at 1% per annum (unless this repayment period is extended). Our results for the nine-month period ended September 30, 2020 do not include any income recognized from forgiveness of the PPP loan. Revenue will not be recognized until the eligibility of our expenses is certified by the federal government. Based on our current estimates, we believe that we will be able to achieve forgiveness of the full \$938,000 and recognize this as a reduction in operating expenses during the first quarter of 2021.

Other expenses, net

During the three-month periods ended September 30, 2020 and 2019, other expenses, net, aggregated \$71,000 and \$65,000, respectively. During the nine-month periods September 30, 2020 and 2019, other expenses, net, aggregated \$480,000 and \$242,000, respectively. Interest expense (including non-cash amortization of debt issuance costs of approximately \$2,000 and \$4,000 during the three-month periods ended September 30, 2020 and 2019, respectively) decreased by approximately 29%, or \$31,000, to \$76,000 during the three-month period ended September 30, 2020 in comparison to \$107,000 during the same period in 2019. Interest expense (including non-cash amortization and write-off of debt issuance costs of approximately \$101,000 and \$13,000 during the nine-month periods ended September 30, 2020 and 2019, respectively) increased by approximately 50%, or \$167,000, to \$500,000 during the nine-month period ended September 30, 2020 in comparison to \$333,000 during the same period in 2019. In connection with our March 2020 bank debt refinancing, we wrote off \$95,000 in debt issuance costs and paid \$165,000 to terminate our interest rate swap agreements, both of which were associated with the repaid debt. Given the debt refinancing to fixed rate loans during March 2020, we now anticipate that our interest expense will be approximately \$323,000 (excluding the write-off of debt issuance costs and the payment to terminate interest rate swaps, discussed above) during the year ending December 31, 2020. In comparison, interest expense was \$432,000 during the year ended December 31, 2019. This projected expense reduction is achieved with more principal outstanding under the refinanced debt structure than would have been outstanding had we not refinanced the debt. Interest income decreased by 89%, or \$37,000, to \$5,000 during the three-month period ended September 30, 2020, in comparison to \$42,000 during the same period in 2019. Interest income decreased by 78%, or \$71,000, to \$20,000 during the nine-month period ended September 30, 2020, in comparison to \$91,000 during the same period in 2019. Less interest income was earned during 2020 largely because we had less cash and short-term investments on hand due to more of the cash generated from an equity issuance during the first quarter of 2019 being invested in capital expenditures during 2020.

Loss Before Income Taxes

During the three-month period ended September 30, 2020, our loss before income taxes of \$323,000 was in comparison to a loss before income taxes of \$495,000 during the three-month period ended September 30, 2019. Our losses before income taxes included approximately \$665,000 and \$640,000 of non-cash depreciation, amortization of intangible assets, amortization of debt issuance costs and stock-based compensation expenses during the three-month periods ended September 30, 2020 and 2019, respectively. During the nine-month period ended September 30, 2020, our loss before income taxes of \$1.2 million was in comparison to a loss before income taxes of \$953,000 during the nine-month period ended September 30, 2019. Our losses before income taxes included \$2 million and \$1.9 million of non-cash depreciation, amortization of intangible assets, amortization and write-off of debt issuance costs and stock-based compensation expenses during the nine-month periods ended September 30, 2020 and 2019, respectively.

Income Taxes and Net Loss

During the three-month period ended September 30, 2020, we recorded no income tax expense (benefit). During the three-month period ended September 30, 2019, we recorded income tax expense at the rate of 2% of our loss before income taxes. Our net loss of \$323,000, or \$0.04 per share, during the three-month period ended September 30, 2020 was in comparison to a net loss of \$503,000, or \$0.07 per share, during the three-month period ended September 30, 2019. During the nine-month period ended

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September 30, 2020, we recorded income tax benefit of the rate of 1% of our loss before income taxes. During the nine-month period ended September 30, 2019, we recorded income tax expense at the rate of 3% of our loss before income taxes. Our net loss of \$1.2 million, or \$0.17 per share, during the nine-month period ended September 30, 2020 was in comparison to a net loss of \$985,000 or \$0.15 per share during the nine-month period ended September 30, 2019.

For tax return purposes only, our depreciation expense for the Nisin Drug Substance production facility and equipment was approximately \$9.2 million and \$1.5 million for the years ended December 31, 2018 and 2017, respectively. This significant increase was largely related to accelerated depreciation allowed for tax purposes. This increased our federal net operating loss carryforward to approximately \$11.8 million as of December 31, 2018 from approximately \$1.7 million as of December 31, 2017. As of December 31, 2019, our federal net operating loss carryforward was approximately \$12 million, which will be available to offset future taxable income. On December 22, 2017, the Tax Cuts and Jobs Act was signed into law. This legislation makes significant changes in the U.S. tax laws, 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 34% to 21%. Our income tax rate differs from this standard tax rate primarily because we are currently providing for a full valuation allowance against our deferred tax assets. While we are recording this full valuation allowance and therefore not recognizing a benefit on our tax losses, our income tax expense is largely comprised of the tax effect of the interest rate swap agreements that we terminated during the first quarter of 2020.

In addition to the above results from our Statements of Operations, we believe it is important to consider our Statements of Cash Flows in the accompanying unaudited financial statements to assess the cash generating ability of our operations.

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, 2020 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 calves. We recognize revenue in accordance with the five step model in ASC 606. These include the following: 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

We do not believe that inflation, interest rates or currency exchange rates have had a significant effect on our revenues and expenses. However, future increases in inflation or interest rates could affect our customers and the demand for our products. We hope to increase the level of our future sales of products outside the United States. The cost of our products to international customers could be affected by currency fluctuations. The decline of the U.S. dollar against other currencies could make our products less expensive to international customers. Conversely, a stronger U.S. dollar could make our products more costly for international customers. The current devaluation of the dollar makes Euro-based purchases more expensive for us. We had outstanding bank debt totaling approximately \$8.3 million as of September 30, 2020 that bears interest at the fixed rate of 3.5% per annum and is not subject to interest rate swaps. Also, as of September 30, 2020, we had a forgivable (if certain conditions are met) loan from the federal

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government outstanding in the amount of \$937,700 and a subordinated loan from the State of Maine outstanding in the amount of \$500,000 that are both discussed in detail in Note 10 to the accompanying unaudited financial statements.

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, 2020. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported, within the time periods specified in the SEC'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 Quarterly 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. Management assesses the effectiveness of the Company's internal control over financial reporting at the end of each quarter. Based on management's assessment, we believe that our internal control over financial reporting was effective as of September 30, 2020. This Quarterly Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's internal control report was not subject to annual or quarterly attestation by the Company's independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report.

Changes in Internal Controls over Financial Reporting. The individual who serves as our principal executive and principal financial officer periodically evaluates any change in internal control over financial reporting which has occurred during the prior fiscal quarter. We have concluded that there was no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1 - LEGAL PROCEEDINGS

In the ordinary course of business, we may become subject to 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

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, during the years ended December 31, 2012, 2013, 2015 and 2016, during the nine-month period ended September 30, 2017 or during the three-month period ended March 31, 2019, without the gross margin that we earned on sales of the **First Defense®** product line.

Gross margin on product sales: One of our goals is to achieve a gross margin (before related depreciation expenses) as a percentage of total sales close to 50% after the initial launch of new products. Depreciation expense will be a larger component of costs of goods sold for **Re-Tain™** than it is for the **First Defense®** product line. Gross margins generally improve over time, but this anticipated improvement may not be realized. Many factors discussed in this report impact our costs of goods sold. There is a risk that

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we are not able to achieve our gross margin goals, which would adversely affect our operating results and could impact our future operating plans.

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. The timing of FDA approval of **Re-Tain**[™] and the initiation of commercial sales of that product will have a material impact on our net (loss) income during 2021 and 2022. Additionally, this complexity and uncertainty is magnified by the risks relating to and arising out of the duration, extent and nature of adverse effects from the COVID-19 pandemic.

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 materially increase our costs of goods sold and reduce our production output, leading to an order backlog that could adversely affect our customer relationships and operating results. There is no assurance that we will continue to achieve market acceptance of the **First Defense**[®] product line 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. Similar concerns exist with **Re-Tain**[™] as we bring that product to market.

Concentration of sales: Sales of the **First Defense**[®] product line aggregated 97% of our total product sales during the years ended December 31, 2019 and 2018 and 98% and 96% during the nine-month periods ended September 30, 2020 and 2019, respectively. Our primary customers for the majority of our product sales (89% and 87% during the years ended December 31, 2019 and 2018, respectively, and 89% and 90% during the nine-month periods ended September 30, 2020 and 2019, respectively) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 10% and 13% of our total product sales during the years ended December 31, 2019 and 2018, respectively, and 11% and 9% of our total sales during the nine-month periods ended September 30, 2020 and 2019, respectively. The concentration of our sales from one product into one market is a risk to our business. 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 (69% and 66% during the years ended December 31, 2019 and 2018, respectively, and 70% and 69% during the nine-month periods ended September 30, 2020 and 2019, respectively) was made to two large distributors. A large portion of our trade accounts receivable (76% and 72% as of December 31, 2019 and 2018, respectively, and 65% and 64% as of September 30, 2020 and 2019, respectively) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us in a manner unfavorable to us.

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 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.

Production capacity constraints: We are completing an investment of approximately \$3.5 million of the additional capital we raised during the first quarter of 2019 to increase the production capacity (in terms of annual sales dollars) for the **First Defense**[®] product line from approximately \$16 to \$17 million to approximately \$23 million. The inability to meet market demand for our products, discussed elsewhere in this report in more detail, 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 and our leased facility at 175 Industrial Way, as well as assessment of functional obsolescence and reliability of equipment. While this capacity expansion investment is currently proceeding on budget for completion during the second quarter of 2021, there is a risk of future cost overruns and a risk that we will not be able to achieve our production capacity growth objectives on a timely basis and that we could experience an interruption to, or a short fall in, product supply during or following the expansion process.

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 **Re-Tain**[™], our new product to treat subclinical mastitis, which has required (and will continue to require) a substantial investment of capital resources and personnel. Our efforts are subject to inspection and approval by the FDA. There is no assurance whether or when we will obtain regulatory approval for this product.

*Regulatory requirements for the **First Defense**[®] product line:* **First Defense**[®] is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991, with subsequent approvals of line extensions in 2017 and 2018. As a result, our operations are subject to periodic inspection by the USDA. The potency of serial lots is

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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, which could interrupt sales and adversely affect our operating results. Territories outside of the United States may require additional regulatory oversight that we may not be able to meet with our current facilities, processes and resources.

*Regulatory requirements for **Re-Tain**TM:* The commercial introduction of this product in the United States requires us to obtain FDA approval. We have disclosed a timeline of events that could lead to potential product approval during the period from the third quarter of 2021 to the first quarter of 2022. Completing the development through to approval of the NADA by the FDA involves risk. While four of the five required Technical Sections have been approved, the development process timeline has been extensive (approximately 20 years) and has involved multiple commercial production strategies. The first-phased Chemistry, Manufacturing and Controls Technical Section was submitted for the Nisin Drug Substance during the first quarter of 2019, and the FDA response was received during the third quarter of 2019. We expect to make the second-phased Drug Substance and Drug Product submission before the end of 2020. Completion of the Drug Product development and scale-up work and subsequent product stability testing defines the remaining timeline to product approval. To reduce the risk associated with this process, we have engaged Norbrook Laboratories for alignment of the required validations and Drug Product manufacture and continue to meet with the FDA to align on filing strategy and requirements. There remains a risk that the required FDA approvals of our product and facilities could be delayed or not obtained. International regulatory approvals would be required for sales outside of the United States.

Reliance on outside party to provide certain services under contract for us: We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Re-Tain**TM, who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. We are investing approximately \$4 million of the additional capital we raised during the first quarter of 2019 to construct and equip our own Drug Product formulation and aseptic filling capability for **Re-Tain**TM inside our existing Drug Substance facility. The objective of this investment is to end our reliance on an outside party to perform these services for us. Actual project costs could exceed our current estimates, and we could fail to access adequate funding to complete this investment if costs were to increase. Completion of this project could be delayed due to a number of factors outside our control, including delays in equipment fabrication, equipment delivery or facility construction. In addition, there is a risk that we fail to achieve regulatory approval of the new facility. We face the risk of potential supply interruption if we do not effectively manage the end of supply provided from Norbrook for orders placed by December 31, 2021 for delivery into the first half of 2022 to align with the new supply from our own formulation and aseptic filling facility expected to be available and producing during the fourth quarter of 2022 or second quarter of 2023.

*Risks associated with our funding strategy for **Re-Tain**TM:* Failure to maintain adequate cash and liquidity to support the commercialization of **Re-Tain**TM is a risk to our business. Achieving FDA approval of our pharmaceutical-grade Nisin produced at commercial-scale is the most critical action in front of us on our path to U.S. regulatory approval of **Re-Tain**TM. Having completed the construction and equipping of the Drug Substance production facility described elsewhere in this report at a cost of approximately \$20.8 million, we will continue to incur product development expenses to operate and maintain this facility. The additional debt we incurred to fund this project has significantly increased our debt service costs. These loans are subject to certain financial covenants. Absent sufficient sales of **Re-Tain**TM at a profitable gross margin, we would be required to fund all debt service costs from sales of the **First Defense**[®] product line, which would reduce, and could eliminate, our expected profitability going forward and significantly reduce our cash flows.

Uncertainty of market size and product sales estimates: Estimating the size of the total addressable market and future sales growth potential for our **First Defense**[®] product line is based on our experience and understanding of market dynamics but is inherently subjective. Estimating the size of the market for any new product, such as **Re-Tain**TM, involves more uncertainties than projections for established products. We do not know whether, or to what extent, our products will achieve, maintain or increase market acceptance and profitability. Some of the uncertainties surrounding **Re-Tain**TM include market acceptance, the effect of a premium selling price on market penetration, cost of manufacture and competition from new and existing products sold by substantially larger competitors with greater market reach and promotional resources. Since **Re-Tain**TM is a novel approach to treating mastitis, there are many uncertainties with regards to how quickly and to what extent we can develop the subclinical mastitis treatment market. Producers' current practice generally is to treat only clinical mastitis, which has the visual indicator of abnormal milk. We will need to change that practice and increase awareness of the importance of treating subclinical disease. This will require the producers' ability and willingness to diagnose without visual indicators. Bacteriocin technology (over traditional antibiotics) is expected to be viewed positively, but acceptance by dairy producers, processors and consumers cannot be assured and may be dependent on type of processes used for cheese production.

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Economics of the dairy and beef industries:

- The January count of all cattle and calves in the United States had steadily declined from 97,000,000 as of January 1, 2007 to 88,500,000 as of January 1, 2014. Then this figure increased each year to reach 94,800,000 as of January 1, 2019 before declining slightly to 94,400,000 as of January 1, 2020. Reflecting seasonal trends, this figure was equal to 103,000,000 and 102,900,000 as of July 1, 2020 and 2019, respectively.
- From 1998 through 2019, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 (2004) to the high of 9,399,000 (2018). This annual average dropped slightly to 9,336,000 during 2019. The herd size average increased slightly to 9,366,000 during the first nine months of 2020. Some analysts project this figure may decrease during the balance of 2020 in response to decreased market demand for dairy products caused by the COVID-19 pandemic, which, in turn, could reduce our sales and have a negative impact on our cash flows.
- 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 its highest point (since these prices were first reported in 1980) during 2014 at \$22.34 (peaking at \$24.60 in September 2014), which price level has never been repeated. During 2019, this milk price average increased by 16% over 2018 to \$16.96. The low price level during 2018 and into the beginning of 2019 was very challenging to the profitability of our customers. During the first nine months of 2020, this average milk price was equal to \$17.48, but it has been extremely volatile due largely to disruption in demand related to the COVID-19 pandemic. The one-month fluctuation of 73% from a low of \$12.14 in May to \$21.04 in June set an all-time record for variability. This milk price increased significantly to \$24.54 for July 2020, which is very close to the all-time record high of \$24.60 set in September 2014. The price of \$16.43 for September increased to \$21.61 for October, showing the continued volatility in this milk price. The annual fluctuations in this milk price level are demonstrated in the following table:

	Average Class III Milk Price During the Year Ended December 31,	(Decrease) Increase
2014	\$22.34	
2015	\$15.80	(29%)
2016	\$14.87	(6%)
2017	\$16.17	9%
2018	\$14.61	(10%)
2019	\$16.96	16%

- 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. This ratio varies farm-to-farm based on individual operating parameters. The highest annual average this ratio has reached since this ratio was first reported in 1985 was 3.64 in 1987. The annual average for this ratio of 1.52 in 2012 was the lowest recorded since it was first reported in 1985. Since this ratio reached 3.24 in 2005, it has not exceeded 3.00. The annual average of 2.54 for 2014 was the highest this ratio has been since it was 2.81 in 2007. This ratio averaged 2.05 during 2018 and increased to 2.24 during 2019. This ratio increased to 2.27 during the first nine months of 2020. 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 During the Year Ended December 31,	(Decrease) Increase
2014	2.54	
2015	2.14	(16%)
2016	2.26	6%
2017	2.42	7%
2018	2.05	(15%)
2019	2.24	9%

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- While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk, the price for milk is also influenced by very volatile international demand for milk products.
- The all-time high value (annual average) for a milk cow was \$1,993 during 2015. Since then, this annual average value steadily declined to \$1,208 during 2019 before increasing to \$1,310 as of July 2020.
- The industry data referred to above is compiled from USDA databases.

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 **Re-Tain**[™]) into the dairy market.

Net deferred tax assets: The realizability of our net 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 net deferred tax assets that significantly increased our net loss in comparison to other periods. This non-cash expense could be reversed, and this valuation allowance could be reduced or eliminated, if warranted by our future profitability and projected profitability in the future. We will continue to assess the need for the valuation allowance at each quarter.

Exposure to debt service obligations and debt covenants: Rising interest rates could negatively affect the operating costs of dairy and beef producers and thus put further financial pressure on an already stressed business sector, which could indirectly affect our business. We removed the direct aspect of this exposure to our business by refinancing our bank debt to fixed rate notes at 3.5% per annum during the first quarter of 2020. Under our refinanced bank debt agreements, we are required by bank debt covenant to maintain at least \$1.4 million in cash escrow in favor of the bank until we achieve certain debt service coverage and collateral value metrics. This requirement effectively reduces the availability of our liquid assets for operational needs. We are obligated to make principal and interest payments aggregating approximately \$874,000 over the twelve-month period ending September 30, 2021.

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 and sales/distribution capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. 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, although it does not have an *E. coli* claim (which ours does). With **Tri-Shield First Defense**[®], we can now compete more effectively against vaccines that are given to the mother cow (dam) to improve the quality of the colostrum that she produces for the newborn calf. Elanco, Merck and Zoetis provide these dam vaccine products to the market. There are many companies competing in the mastitis treatment market, most notably Boehringer Ingelheim, Merck and Zoetis. The subclinical 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 (unlike our product that carries zero milk discard and zero milk withhold claims). There is no assurance that our products will compete successfully in these markets. 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 for the **First Defense**[®] product line. A significant reduction in farm capacity 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 **Re-Tain**[™]. We are and will be dependent on one manufacturer for the supply of the syringes used for our gel tube formats of **Dual-Force First Defense**[®] and **Tri-Shield First Defense**[®] and one other manufacturer for the supply of syringes for **Re-Tain**[™]. We expect to be dependent on a contract with Norbrook for the Drug Product formulation and aseptic filling of our Nisin Drug Substance for orders placed through December 31, 2021 with deliveries extending into the first half of 2022. We expect to complete the investment to perform these services in-house during 2022. The facility we intend to construct to perform these services in-house will be subject to FDA inspection and approval, the outcome and timing of which are not within our control. The potential alternative options for these services are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). Any significant damage to or other disruption in the services at any of these third-party facilities or our own facilities (including due to regulatory non-approval or non-compliance) would adversely affect the production of inventory and result in significant added expenses and potential loss of future sales.

Small size; dependence on key personnel: We are a small company with 57 employees (including 4 part-time employees). As such, we rely on certain key employees to support multiple operational functions, with limited redundancy in capacity. The loss of any

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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, retain and motivate key scientific, manufacturing, managerial and sales and marketing personnel.

Cost burdens of our reporting obligations as a public company: Operating a public company involves substantial costs and administrative burdens to comply with reporting obligations under federal securities laws and the provisions of the Sarbanes-Oxley Act of 2002.

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. If that were to be the case, 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.

Increasing dependence on the continuous and reliable operation of our information technology systems: We rely on information systems throughout our company. Any disruption of these systems or significant security breaches could adversely affect our business. Although we maintain information security policies and employ system backup measures and engage in information system redundancy planning and processes, such policies, measures, planning and processes, as well as our current disaster recovery plan may be ineffective or inadequate to address all eventualities. As information systems and the use of software and related applications by us, our business partners, suppliers, and customers become more cloud-based, we become inherently more susceptible to cyberattacks. There has been an increase in global cybersecurity vulnerabilities and threats, including more sophisticated and targeted cyber-related attacks that pose a risk to the security of our information systems and networks and the confidentiality, availability and integrity of data and information. There are reports of increased activity by hackers and scammers during the COVID-19 pandemic. Any such attack or breach could compromise our networks and the information stored thereon could be accessed, publicly disclosed, lost, or stolen. While we have invested in our data and information technology infrastructure (including working with an information security technology consultant to assess and enhance our security systems and procedures, and periodically training our employees in such systems and procedures), there can be no assurance that these efforts will prevent a system disruption, attack, or security breach and, as such, the risk of system disruptions and security breaches from a cyberattack remains. We have not experienced any material adverse effect on our business or operations as a consequence of any such attack or breach but may incur increasing costs in performing the tasks described above. Given the unpredictability of the timing, nature and scope of such disruptions and the evolving nature of cybersecurity threats, which vary in technique and sources, if we or our business partners or suppliers were to experience a system disruption, attack or security breach that impacts any of our critical functions, or our customers were to experience a system disruption, attack or security breach via any of our connected products and services, we could potentially be subject to production downtimes, operational delays or other detrimental impacts on our operations. Furthermore, any access to, public disclosure of, or other loss of data or information (including any of our - or our customers' or suppliers' - confidential or proprietary information or personal data or information) as a result of an attack or security breach could result in governmental actions or private claims or proceedings, which could damage our reputation, cause a loss of confidence in our products and services, damage our ability to develop (and protect our rights to) our proprietary technologies and have a material adverse effect on our business, financial condition, results of operations or prospects.

Global COVID-19 pandemic (novel coronavirus, technically known as SARS-CoV-2): The positive indications about the improving health of the U.S. economy since 2008 and prior to the COVID-19 pandemic have proven to be temporary. The COVID-19 pandemic (that began in China and has spread throughout the world) has affected international trade and created a worldwide economic crisis. The full impact of this viral outbreak on the global economy is very uncertain at this time. Stock market valuations have declined and recovered somewhat and remain volatile. There is a risk of a period of economic downturn, the severity and duration of which are difficult to know. Prior to the pandemic and the responsive federal economic stimulus programs, many feared the United States had taken on too much national debt. Now the debt load is significantly higher. The dairy market, similar to many others, has been unstable as a result of the pandemic. The price paid to producers for milk has been very volatile. Milk was dumped on farms earlier in the year largely because of the loss of demand for dairy products from closed restaurants and school lunch programs and other negative impacts of the pandemic, but conditions have improved since then. There is also economic uncertainty for beef producers, as the supply chain is interrupted or otherwise adversely affected due to closures of processing plants and reduced throughput caused by, among other things, restaurants closing or curtailing their operations. This is a very unusual situation for farmers that work so hard to improve production quality and efficiency in order to help feed a growing population with high-quality and cost-effective proteins. A combination of the

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conditions, trends and concerns summarized above could have a corresponding negative effect on our business and operations, including the supply of the colostrum we purchase to produce our product, the demand for our products in the U.S. market and our ability to penetrate or maintain a profitable presence in international markets. We could experience product shortages, backlogs and production slowdowns due to difficulties accessing needed supplies and labor and other restrictions affecting our ability to consistently deliver our products to market. Our exposure to this risk is mitigated to some extent by the fact that our supply chain is not heavily dependent on foreign manufacturers, by our on-going cross-training of our employees, by our implementation of remote work practices (where feasible) and by our early and continued compliance with recommended hygiene and social distancing practices. Despite our best efforts and intentions, there is a risk that an employee could become infected and could infect others. This could lead to plant shutdowns and production interruptions and have other negative economic and health and safety impacts.

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, potentially preventing acquisitions that have not been approved by our Board of Directors; and
- Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner.

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

Stock market valuation and liquidity: Our common stock trades on The Nasdaq Stock Market (Nasdaq: ICCC). Our average daily trading volume 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. Most companies in the animal health sector have market capitalization values that greatly exceed our current market capitalization of approximately \$38.3 million as of October 30, 2020. Our product sales during the trailing twelve-month period ended September 30, 2020 were \$15.2 million. This means that our market valuation as of October 30, 2020 was equal to approximately 2.5 times our sales during the trailing twelve-month period ended September 30, 2020. 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 and may therefore be negatively affected by the related uncertainties and risks.

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

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development costs and investments in our facilities and production equipment, and to increase our working capital and to reduce debt. Stockholders must be prepared to rely on market 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.

Possible dilution: We may need again to access the capital markets and issue additional common stock in order to fund our growth objectives, as described elsewhere in this report. Such issuances could have a dilutive effect on our existing stockholders.

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.

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 12, 2020

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

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**EXHIBIT 31
CERTIFICATIONS REQUIRED BY RULE 13a-14(a)**

I, Michael F. Brigham, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ImmuCell Corporation (the Company);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the Company is made known to me by others within the Company, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, 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;
 - c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's Board of Directors (or persons performing the equivalent function):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: November 12, 2020

/s/ Michael F. Brigham

Michael F. Brigham

President, Chief Executive Officer and Principal Financial Officer

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EXHIBIT 32

**CERTIFICATION PURSUANT TO SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-
OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of ImmuCell Corporation (the “Company”) for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Michael F. Brigham, President, Chief Executive Officer and Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the “Exchange Act”); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition, results of operations and cash flows of the Company.

This certification is provided pursuant to 18 U.S.C. Section 1350 and Item 601(b)(32) of Regulation S-K (“Item 601(b)(32)”) promulgated under the Securities Act of 1933, as amended (the “Securities Act”), and the Exchange Act. In accordance with clause (ii) of Item 601(b)(32), this certification (A) shall not be deemed “filed” for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and (B) shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

/s/ Michael F. Brigham

Michael F. Brigham

President, Chief Executive Officer and Principal Financial Officer

November 12, 2020

A signed original of this written statement required by Section 906 has been provided to ImmuCell Corporation and will be retained by ImmuCell Corporation and furnished to the Securities and Exchange Commission or its staff upon request.