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, 2022

001-12934
(Commission file number)

ImmuCell Corporation

(Exact name of registrant as specified in its charter)

Delaware	01-0382980
(State of Incorporation)	(I.R.S. Employer Identification No.)
56 Evergreen Drive, Portland, ME	04103
(Address of principal executive office)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.10 par value per share	ICCC	Nasdaq

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 as of November 3, 2022 was 7,746,864.

ImmuCell Corporation

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PART 1. FINANCIAL INFORMATION
ITEM 1. UNAUDITED FINANCIAL STATEMENTS
BALANCE SHEETS
(Unaudited)

	As of September 30, 2022	As of December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$8,827,772	$10,185,468
Trade accounts receivable, net	1,701,830	2,694,229
Inventory	5,317,783	3,089,974
Other current assets	585,717	295,197
Total current assets	16,433,102	16,264,868
Property, plant and equipment, net	27,570,011	26,893,599
Operating lease right-of-use asset	2,216,236	1,109,133
Goodwill	95,557	95,557
Intangible assets, net	62,088	76,416
Other assets	24,567	26,115
TOTAL ASSETS	$46,401,561	$44,465,688
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of debt obligations	$998,160	$812,207
Current portion of operating lease liability	22,920	108,012
Accounts payable and accrued expenses	1,693,917	1,614,250
Total current liabilities	2,714,997	2,534,469
LONG-TERM LIABILITIES:		
Debt obligations, net of current portion	9,478,683	8,327,122
Operating lease liability, net of current portion	2,225,359	1,027,157
Total long-term liabilities	11,704,042	9,354,279
TOTAL LIABILITIES	14,419,039	11,888,748
CONTINGENT LIABILITIES AND COMMITMENTS (See Note 11)		
STOCKHOLDERS' EQUITY:		
Common stock, $0.10 par value per share, 15,000,000 and 15,000,000 shares authorized, 7,814,165 and 7,814,165 shares issued and 7,746,864 and 7,741,864 shares outstanding, as of September 30, 2022 and December 31, 2021, respectively.	781,417	781,417
Additional paid-in capital	35,912,970	35,692,388
Accumulated deficit	(4,564,633)	(3,738,694)
Treasury stock, at cost, 67,301 and 72,301 shares as of September 30, 2022 and December 31, 2021, respectively	(147,232)	(158,171)
Total stockholders' equity	31,982,522	32,576,940
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$46,401,561	$44,465,688

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

ImmuCell Corporation
STATEMENTS OF OPERATIONS
(Unaudited)

	During the Three-Month Periods Ended September 30,		During the Nine-Month Periods Ended September 30,	
	2022	**2021**	**2022**	**2021**
Product sales	$4,796,025	$5,150,173	$14,657,082	$13,799,129
Costs of goods sold	2,949,974	2,731,469	8,000,479	7,703,915
Gross margin	1,846,051	2,418,704	6,656,603	6,095,214
Product development expenses	1,269,761	1,047,498	3,444,464	3,078,670
Sales and marketing expenses	726,738	656,418	2,197,477	1,613,997
Administrative expenses	466,342	443,698	1,679,851	1,290,574
Operating expenses	2,462,841	2,147,614	7,321,792	5,983,241
NET OPERATING (LOSS) INCOME	(616,790)	271,090	(665,189)	111,973
Other expenses, net	34,421	115,283	154,588	256,356
(LOSS) INCOME BEFORE INCOME TAXES	(651,211)	155,807	(819,777)	(144,383)
Income tax expense	3,867	8,043	6,162	8,043
NET (LOSS) INCOME	($655,078)	$147,764	($825,939)	($152,426)
Basic weighted average common shares outstanding	7,746,864	7,741,864	7,744,534	7,541,884
Basic net (loss) income per share	($0.08)	$0.02	($0.11)	($0.02)
Diluted weighted average common shares outstanding	7,746,864	7,820,294	7,744,534	7,541,884
Diluted net (loss) income per share	($0.08)	$0.02	($0.11)	($0.02)

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

ImmuCell Corporation
STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Common Stock				Treasury Stock		
	Shares	Amount	Additional paid-in capital	Accumulated Deficit	Shares	Amount	Total Stockholders' Equity
During the Three-Month Period Ended September 30, 2022:							
BALANCE,							
June 30, 2022	7,814,165	$781,417	$35,827,848	($3,909,555)	67,301	($147,232)	$32,552,478
Net loss	—	—	—	(655,078)	—	—	(655,078)
Stock-based compensation	—	—	85,122	—	—	—	85,122
BALANCE,							
September 30, 2022	7,814,165	$781,417	$35,912,970	($4,564,633)	67,301	($147,232)	$31,982,522
During the Three-Month Period Ended September 30, 2021:							
BALANCE,							
June 30, 2021	7,814,165	$781,417	$35,605,969	($3,960,592)	72,301	($158,171)	$32,268,623
Net income	—	—	—	147,764	—	—	147,764
Stock-based compensation	—	—	45,488	—	—	—	45,488
BALANCE,							
September 30, 2021	7,814,165	$781,417	$35,651,457	($3,812,828)	72,301	($158,171)	$32,461,875
During the Nine-Month Period Ended September 30, 2022:							
BALANCE,							
December 31, 2021	7,814,165	$781,417	$35,692,388	($3,738,694)	72,301	($158,171)	$32,576,940
Net loss	—	—	—	(825,939)	—	—	(825,939)
Exercise of stock options	—	—	19,733	—	(5,000)	10,939	30,672
Stock-based compensation	—	—	200,849	—	—	—	200,849
BALANCE,							
September 30, 2022	7,814,165	$781,417	$35,912,970	($4,564,633)	67,301	($147,232)	$31,982,522
During the Nine-Month Period Ended September 30, 2021:							
BALANCE,							
December 31, 2020	7,299,009	$729,901	$31,372,093	($3,660,402)	80,173	($175,392)	$28,266,200
Net loss	—	—	—	(152,426)	—	—	(152,426)
Public offering of common stock, net of $17,011 of offering costs	515,156	51,516	4,181,510	—	—	—	4,233,026
Exercise of stock options	—	—	(5,528)	—	(7,872)	17,221	11,693
Stock-based compensation	—	—	103,382	—	—	—	103,382
BALANCE,							
September 30, 2021	7,814,165	$781,417	$35,651,457	($3,812,828)	72,301	($158,171)	$32,461,875

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

ImmuCell Corporation
STATEMENTS OF CASH FLOWS
(Unaudited)

	During the Nine-Month Periods Ended September 30,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	($825,939)	($152,426)
Adjustments to reconcile net loss to net cash (used for) provided by operating activities:		
Depreciation	1,869,000	1,845,612
Amortization of intangible assets	14,328	14,328
Amortization and write-off of debt issuance costs	5,739	5,880
Stock-based compensation	200,849	103,382
(Gain) loss on disposal of property, plant and equipment	(11,000)	32,278
Non-cash rent expense	6,007	8,037
Changes in:		
Trade accounts receivable	992,399	(625,454)
Accrued interest income	—	495
Inventory	(2,227,809)	(574,456)
Prepaid expenses and other current assets	(290,520)	(169,234)
Other assets	1,548	(423)
Accounts payable and accrued expenses	19,349	(121,742)
Net cash (used for) provided by operating activities	(246,049)	366,277
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(2,485,095)	(1,904,055)
Maturities of investments	—	996,000
Proceeds from sale of property, plant and equipment	11,000	13,975
Net cash used for investing activities	(2,474,095)	(894,080)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from public offering, net	—	4,233,026
Proceeds from debt issuance	2,000,000	400,000
Debt principal repayments	(648,918)	(573,366)
(Payments)/net adjustments of debt issuance costs	(19,306)	2,272
Proceeds from exercise of stock options	30,672	11,693
Net cash provided by financing activities	1,362,448	4,073,625
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,357,696)	3,545,822
BEGINNING CASH AND CASH EQUIVALENTS	10,185,468	6,949,937
ENDING CASH AND CASH EQUIVALENTS	$8,827,772	$10,495,759

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

ImmuCell Corporation

STATEMENTS OF CASH FLOWS

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

(Unaudited)

	During the Nine-Month Periods Ended September 30,	
	2022	**2021**
CASH PAID FOR:		
Income taxes	$4,575	$5,135
Interest expense	$247,303	$234,324
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable and accrued expenses	($60,316)	($48,533)
Surrender of shares to exercise stock options	$—	$165,337
Operating lease right-of-use asset and operating lease liability	$1,184,727	$—

The accompanying notes are an integral part of these 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. As disclosed in Note 17, "Segment Information", one of our business segments is dedicated to Scours and the other is focused on Mastitis. We manufacture and market the **First Defense®** product line, providing **Immediate Immunity™** to prevent scours in newborn dairy and beef calves. We have expanded this line into four different products with formulations targeting *E. coli*, coronavirus and rotavirus pathogens. We are also in the late stages of developing **Re-Tain®**, a treatment for lactating dairy cows with subclinical mastitis. Mastitis is 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 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 of new viable products with appropriate regulatory approvals, where applicable.

The global COVID-19 pandemic has created, and continues to create, uncertainty for us. While conditions relating to the pandemic may be improving somewhat, the full impact of this viral outbreak on the global economy, and the duration of such impact, is still uncertain at this time. A combination of the conditions, trends and concerns related to or arising from the pandemic, as well as inflation, rising interest rates and potential recessionary conditions in the United States and/or internationally, could have a corresponding negative effect on our business and operations, including the supply of the colostrum we purchase to produce our **First Defense®** product line, the demand for our products in the U.S. market and our ability to penetrate or maintain a profitable presence in international markets. We are experiencing price increases and shortages in key components, supportive services, transportation and other supplies that may cause production slowdowns that affect our ability to consistently deliver our products to market on time in accordance with customer demand. Despite some recent favorable trends, we maintain our diligence because this is a risk to our business.

1A. RESTATMENT OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS

The Company concluded it should restate its previously issued financial statements by amending its Quarterly Report on Form 10-Q for the quarterly periods ended March 31, 2022 (filed with the Securities and Exchange Commission (the "SEC") on May 12, 2022) and June 30, 2022 (filed with the SEC on August 11, 2022) to reflect the accrual of approximately $222,000 of deferred compensation expense (consisting of earned and unused paid time off) during the first quarter of 2022. This change increases the Company's administrative expenses and accrued expenses by approximately $222,000 with no impact on its cash position. There has been no change to previously disclosed product sales.

In accordance with SEC Staff Accounting Bulletin No. 99, "Materiality," and SEC Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements," the Company evaluated the correction and has determined that the related impact was material to the previously issued financial statements that contained the error reported in the Company's Form 10-Q for the quarterly periods ended March 31, 2022 and June 30, 2022 (the "Affected Quarterly Periods"). Therefore, the Company concluded that the Affected Quarterly Periods should be restated to present the reclassification.

The $222,379 decrease in net income (loss) during the three-month period ended March 31, 2022 and six-month period ended June 30, 2022 lead to a corresponding reduction in the Company's reported accumulated deficit at March 31, 2022 and June 30, 2022. The restatement had no impact on the net operating loss, net loss, or related per-share amounts during the three-month period ended June 30, 2022. The tables below show the impact of these changes on the Statement of Operations:

	As Reported	Adjustment	As Restated
Unaudited Statement of Operations During the Three-Month Period Ended March 31, 2022			
Net operating income	$792,988	($222,379)	$570,609
Net Income	$735,666	($222,379)	$513,287
Basic net income per share	$0.10	($0.03)	$0.07
Diluted net income per share	$0.09	($0.02)	$0.07

	As Reported	Adjustment	As Restated
Unaudited Statement of Operations During the Six-Month Period Ended June 30, 2022			
Net operating income (loss)	$173,980	($222,379)	($48,399)
Net Income (loss)	$51,518	($222,379)	($170,861)
Basic net income (loss) per share	$0.01	($0.03)	($0.02)
Diluted weighted average common shares outstanding	7,781,403	(38,053)	7,743,350
Diluted net income (loss) per share	$0.01	($0.03)	($0.02)

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 accurately 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). We believe that the disclosures are adequate to ensure that the information presented is not misleading.

(b) Cash and Cash Equivalents

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. There are no cash equivalents in excess of Federal Deposit Insurance Corporation (FDIC) limits of $250,000 per financial institution per depositor. 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, 2022 and December 31, 2021, we determined that no allowance for doubtful account 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 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 at 33 Caddie Lane 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 87% of these assets are being depreciated over 10 years. We began depreciating the leasehold improvements to our new **First Defense®** production facility at 175 Industrial Way over the remainder of the 10-year lease term beginning when a certificate of

occupancy was issued during the second quarter of 2020. During August of 2022, this lease term was extended to January of 2043 in connection with a new lease covering space at 165 Industrial Way. Therefore, the net book value (as of August 31, 2022) of these leasehold improvements will be depreciated over the remainder of the extended lease term going forward. Significant repairs to property, plant and equipment 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 the amounts paid in excess of fair value of the net assets (including tax attributes) as goodwill, which is accounted for under the acquisition method of accounting. We assess the impairment of intangible assets and goodwill that have indefinite lives (when applicable) 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, 2022 or the year ended December 31, 2021. See Notes 2(g) and 8 for additional disclosures.

(g) Valuation of Long-Lived Assets

We periodically evaluate our long-lived assets, consisting principally of property, plant and equipment, 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. No impairment was recognized during the nine-month period ended September 30, 2022 or the year ended December 31, 2021.

(h) 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, 2022 and December 31, 2021, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, other assets, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The amount outstanding under our bank debt facilities is measured at carrying value in our accompanying balance sheets. Our bank debt facilities are valued using Level 2 inputs. The 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

and considers factors specific to the investment. We also hold money market accounts in our bank account, which are classified as cash equivalents and measured at fair value. The fair value of these investments is based on their closing published net asset value.

We assess the levels of the investments at each measurement date, and transfers between levels are recognized on the actual date of the event or change in circumstances that caused the transfer in accordance with our accounting policy regarding the recognition of transfers between levels of the fair value hierarchy. During the nine-month period ended September 30, 2022 and during the year ended December 31, 2021, there were no transfers between levels. As of September 30, 2022 and December 31, 2021, our Level 1 assets measured at fair value by quoted prices in active markets consisted of bank savings accounts and money market accounts. There were no assets or liabilities measured at fair value on a nonrecurring basis as of September 30, 2022 or December 31, 2021.

	As of September 30, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and money market accounts	$8,827,772	$—	$—	$8,827,772
Liabilities:				
Bank debt	$—	($10,476,843)	$—	($10,476,843)

	As of December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and money market accounts	$10,185,468	$—	$—	$10,185,468
Liabilities:				
Bank debt	$—	($9,139,329)	$—	($9,139,329)

(i) Concentration of Risk

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

	During the Three-Month Periods Ended September 30,		During the Nine-Month Periods Ended September 30,	
	2022	**2021**	**2022**	**2021**
Company A	41%	47%	39%	46%
Company B	31%	26%	34%	28%

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, 2022	As of December 31, 2021
Company A	39%	38%
Company B	34%	34%
Company C	12%	*

* Amount is less than 10%.

(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 sales 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 are accounted for as a fulfillment cost in costs of goods sold. 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 for additional disclosures.

(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. 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.

(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. We consider future taxable income and feasible tax planning strategies in assessing the need for a valuation allowance against our deferred tax assets at the end of each quarter. 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 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 2018. We have evaluated the positions taken on our filed tax returns and have concluded that no uncertain tax positions existed as of September 30, 2022 or December 31, 2021. 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 $85,122 and $45,488 during the three-month periods ended September 30, 2022 and 2021, respectively, and $200,849 and $103,382 during the nine-month periods ended September 30, 2022 and 2021, respectively. See Note 13.

(n) Net Income (Loss) Per Common Share

Net income (loss) per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*. The basic net income per share has been computed by dividing net income by the weighted average number of common shares outstanding during 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 proceeds from 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 563,000 and 0 during the three-month periods ended September 30, 2022 and 2021, respectively, and 563,000 and 452,000 during the nine-month periods ended September 30, 2022 and 2021, respectively.

	During the Three-Month Periods Ended September 30,		During the Nine-Month Periods Ended September 30,	
	2022	2021	2022	2021
Net (loss) income attributable to stockholders	($655,078)	$147,764	($825,939)	($152,426)
Weighted average common shares outstanding - Basic	7,746,864	7,741,864	7,744,534	7,541,884
Dilutive impact of share-based compensation awards	—	78,430	—	—
Weighted average common shares outstanding - Diluted	7,746,864	7,820,294	7,744,534	7,541,884
Net (loss) income per share:				
Basic	($0.08)	$0.02	($0.11)	($0.02)
Diluted	($0.08)	$0.02	($0.11)	($0.02)

(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) Accounting Pronouncements Recently 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 was permitted. The adoption of ASU 2019-12 did not 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. The discontinuation of LIBOR did not have a material impact on our financial statements.

3. CASH AND CASH EQUIVALENTS

Cash and cash equivalents amounted to $8,827,772 and $10,185,468 as of September 30, 2022 and December 31, 2021, respectively.

4. TRADE ACCOUNTS RECEIVABLE, net

Trade accounts receivable amounted to $1,701,830 and $2,694,229 as of September 30, 2022 and December 31, 2021, respectively. No allowance for bad debt or product returns was recorded as of September 30, 2022 or December 31, 2021.

5. INVENTORY

Inventory consisted of the following:

	As of September 30, 2022	As of December 31, 2021
Raw materials	$2,535,904	$971,606
Work-in-process	2,244,885	1,902,299
Finished goods	536,994	216,069
Total	$5,317,783	$3,089,974

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of September 30, 2022	As of December 31, 2021
Prepaid expenses	$552,431	$268,713
Other receivables	33,286	26,484
Total	$585,717	$295,197

7. PROPERTY, PLANT AND EQUIPMENT, net

Property, plant and equipment consisted of the following:

	Estimated Useful Lives (in years)	As of September 30, 2022	As of December 31, 2021
Laboratory and manufacturing equipment	3-10	$18,072,201	$17,388,757
Buildings and improvements	10-39	19,339,380	19,119,698
Office furniture and equipment	3-10	887,559	869,191
Construction in progress	n/a	4,572,972	2,992,359
Land	n/a	516,867	516,867
Property, plant and equipment, gross		43,388,979	40,886,872
Accumulated depreciation		(15,818,968)	(13,993,273)
Property, plant and equipment, net		$27,570,011	$26,893,599

As of September 30, 2022 and December 31, 2021, 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 $0 and $61,740 during the three-month periods ended September 30, 2022 and 2021, respectively, and $43,305 and $156,788 during the nine-month periods ended September 30, 2022 and 2021, respectively. Depreciation expense was $627,544 and $613,389 during the three-month periods ended September 30, 2022 and 2021, respectively, and $1,869,000 and $1,845,612 during the nine-month periods ended September 30, 2022 and 2021, respectively.

8. INTANGIBLE ASSETS

Intangible assets of $191,040 were valued using the relief from royalty method and 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, 2022 and 2021, and $14,328 during both of the nine-month periods ended September 30, 2022 and 2021. The net value of these intangibles was $62,088 and $76,416 as of September 30, 2022 and December 31, 2021, respectively. Intangible asset amortization expense is estimated to be $19,104 per year through December 31, 2025.

Intangible assets as of September 30, 2022 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	$184,100	($124,268)	$59,832
Customer relationships	1,300	(877)	423
Non-compete agreements	5,640	(3,807)	1,833
Total	$191,040	($128,952)	$62,088

Intangible assets as of December 31, 2021 consisted of the following:

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

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of September 30, 2022	As of December 31, 2021
Accounts payable – trade	$680,756	$726,781
Accounts payable – capital	78,579	18,263
Accrued payroll	576,039	585,939
Accrued professional fees	92,625	82,050
Accrued other	262,190	199,076
Income tax payable	3,728	2,141
Total	$1,693,917	$1,614,250

10. BANK DEBT

During the first quarter of 2020, we closed on a debt financing with Gorham Savings Bank (GSB) aggregating $8,600,000 and a $1,000,000 line of credit. The debt was comprised of a $5,100,000 mortgage note (Loan #1) that bears interest at a fixed rate of 3.50% per annum (with a 10-year term and 25-year amortization schedule and a balloon principal payment of $3,145,888 due during the first quarter of 2030) and a $3,500,000 note (Loan #2) 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 11, 2024. Interest on borrowings against the line of credit is variable at the National Prime Rate plus 0.00% per annum. There was no outstanding balance under this line of credit as of September 30, 2022 or December 31, 2021. The proceeds from the debt refinancing were used to repay all bank debt outstanding at the time of closing and to provide some additional working capital. During the fourth quarter of 2020, we closed on a $1,500,000 note with GSB (Loan #4) that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). Proceeds of $624,167 were used to prepay a portion of the outstanding principal on our mortgage note (Loan #1), which reduced the outstanding balance to 80% of the most recent appraised value of the property securing the debt, which allowed GSB to release the $1,400,000 that had been held in escrow. This resulted in no change in the balloon principal payment of $3,145,888 due during the first quarter of 2030. The remaining proceeds were available for general working capital purposes. During the first quarter of 2022, we closed on an additional $2,000,000 in mortgage debt, which bears interest at the fixed rate of 3.58% per annum. This was accomplished through an amendment of the original mortgage note (Loan #1) that increased the then outstanding principal balance from $4,233,957 to $6,233,957 bearing interest at the blended fixed rate of 3.53% per annum. This increased the balloon payment from $3,145,888 to $3,687,331 and extended the due date of the balloon payment from the first quarter of 2030 to the first quarter of 2032. In connection with these credit facilities, we incurred aggregate debt issuance costs of $70,170. The amortization of these debt issuance costs is being recorded as a component of interest expense, included in other expenses, net, and is being amortized over the underlying terms of the notes. These three credit facilities are secured by liens on substantially all of our assets and are subject to certain restrictions and financial covenants. Given the funds we raised through an equity issuance in April 2021, GSB waived the minimum debt service coverage (DSC) ratio requirement of 1.35 for the year ended December 31, 2021. By negotiation with the bank in connection with the mortgage debt financing during the first quarter of 2022, the required minimum DSC ratio was reduced to 1.0 for the year ending December 31, 2022.

During the second quarter of 2020, we received a loan from the Maine Technology Institute (MTI) (Loan #3) in the aggregate principal amount of $500,000. The first 2.25 years of this loan are interest-free with no interest accrual or required principal payments. Principal and interest payments at a fixed rate of 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 if not repaid before then. On June 30, 2021, we executed definitive agreements covering a second loan from the MTI (Loan #5) in the aggregate principal amount of $400,000, proceeds from which were received in July 2021. The first two years of this loan are interest-free with no interest accrual or required principal payments. Principal and interest payments at a fixed rate of 5% per annum are due quarterly over the final 5.5 years of the loan, beginning during the third quarter of 2023 and continuing through the fourth quarter of 2028 if not repaid before then. These credit facilities are unsecured and subordinated to our indebtedness to GSB. Failure to make timely payments of principal and

interest, or otherwise to comply with the terms of the agreements with the MTI, would entitle the MTI to accelerate the maturity of such debt and demand repayment in full. These loans may be prepaid without penalty at any time.

Debt proceeds received and principal repayments made during the three-month periods ended September 30, 2022 and 2021 are reflected in the following table by period and by loan:

	During the Three-Month Period Ended September 30, 2022		During the Three-Month Period Ended September 30, 2021	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	$—	($53,634)	$—	($28,840)
Loan #2	—	(119,658)	—	(115,456)
Loan #3	—	—	—	—
Loan #4	—	(49,810)	—	(48,061)
Loan #5	—	—	400,000	—
Total	$—	($223,102)	$400,000	($192,357)

Debt proceeds received and principal repayments made during the nine-month periods ended September 30, 2022 and 2021 are reflected in the following table by period and by loan:

	During the Nine-Month Period Ended September 30, 2022		During the Nine-Month Period Ended September 30, 2021	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	$2,000,000	($144,293)	$—	($86,342)
Loan #2	—	(356,278)	—	(343,868)
Loan #3	—	—	—	—
Loan #4	—	(148,347)	—	(143,156)
Loan #5	—	—	400,000	—
Total	$2,000,000	($648,918)	$400,000	($573,366)

Principal payments (net of debt issuance costs) due under bank loans outstanding as of September 30, 2022 (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, 2022	During the Years Ending December 31,					
		2023	2024	2025	2026	Thereafter	Total
Loan #1	$54,740	$223,349	$230,891	$239,876	$248,604	$5,122,386	$6,119,846
Loan #2	120,956	494,433	512,102	530,738	549,881	140,486	2,348,596
Loan #3	22,160	91,446	96,104	101,001	106,146	83,143	500,000
Loan #4	50,366	205,878	213,217	220,994	228,965	240,460	1,159,880
Loan #5	—	32,017	66,470	69,856	73,415	158,242	400,000
Subtotal	248,222	1,047,123	1,118,784	1,162,465	1,207,011	5,744,717	10,528,322
Debt issuance costs	(1,919)	(7,676)	(7,267)	(7,168)	(7,168)	(20,281)	(51,479)
Total	$246,303	$1,039,447	$1,111,517	$1,155,297	$1,199,843	$5,724,436	$10,476,843

11. CONTINGENT LIABILITIES AND COMMITMENTS

Our bylaws, as amended, in effect provide that the Company will indemnify its officers and directors against any liability arising from their responsibilities as officers and directors to the maximum extent permitted by Delaware law. In addition, we make similar indemnity undertakings with each director through a separate indemnification agreement with that director. The maximum payment that we may be required to make under such provisions is theoretically unlimited and is impossible to determine. We maintain directors' and officers' liability insurance, which may provide reimbursement to the Company for payments made to, or on behalf of, officers and directors pursuant to the indemnification provisions. Our indemnification obligations were grandfathered under the provisions of Codification Topic 460, *Guarantees*. Accordingly, we have recorded no liability for such obligations as of September 30, 2022. 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 believe 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, 2022.

We plan to purchase 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.

Effective March 28, 2022, the Company entered into an amended and restated Separation and Deferred Compensation Agreement (the "Deferred Compensation Agreement") with Mr. Brigham that superseded and replaced in its entirely a March 2020 contract, and the Company entered into an Incentive Compensation Agreement (the "Incentive Agreement") with Mr. Brigham. Mr. Brigham's Deferred Compensation Agreement allows Mr. Brigham to be paid all earned and unused paid time off upon separation from the Company for any reason and to receive up to an additional $300,000 in deferred compensation. This deferred compensation payment vests as to $100,000 on January 1, 2023, as to an additional $100,000 on January 1, 2024 and as to the final $100,000 on January 1, 2025, provided that Mr. Brigham is employed by the Company on the applicable vesting dates. The vested amounts would be paid upon the earlier of January 31, 2025 or within thirty (30) days following his separation from the Company. In addition, upon termination of Mr. Brigham's employment (a) by the Company other than for cause, (b) due to death or disability or (c) by Mr. Brigham for good reason, the Company agrees to pay Mr. Brigham 100% of his then current annual base salary. Mr. Brigham's Incentive Agreement provides for the potential to earn up to an additional $150,000 if certain regulatory and financial objectives that may increase stockholder value are achieved during 2022. Under these two contracts, Mr. Brigham continues to serve the Company as President and CEO.

In addition to the commitments discussed above, we had committed $405,000 to increase our production capacity for the **First Defense®** product line, $129,000 to construct and equip our own Drug Product formulation and aseptic filling facility for **Re-Tain®**, $2,054,000 to the purchase of inventory, $587,000 to other capital expenditures and $378,000 to other obligations as of September 30, 2022.

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 original lease term was ten years with a right to renew for a second 10-year term and a right of first offer to purchase. At the time we entered into this lease, we were not reasonably assured that we would exercise this renewal option in place of other real estate options. For that reason, a 10-year period was reflected in the right-of-use (ROU) asset and lease liability on our balance sheet. During the third quarter of 2022, we committed to lease an additional 15,400 square feet of space at 165 Industrial Way, which is connected to the original space at 175 Industrial Way, over a 20-year term. The ROU asset and lease liability for the committed space to be leased at 165 Industrial Way will be recorded upon the commencement date of the new lease, which is anticipated around the end of the first quarter of 2023 after construction of the building shell is completed. In connection with the lease commitment for space at 165 Industrial Way, the term of the original lease for 175 Industrial Way was extended by approximately 13 years. The total lease liability over the amended term (including inflationary adjustments) aggregates $2,247,978. Our lease includes variable non-lease components. Such payments primarily include common area maintenance charges. The balance of the operating lease ROU asset was $2,216,236 and the operating lease liability was $2,248,279 as of September 30, 2022. 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. 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. Variable lease cost primarily represents variable payments such as real estate taxes and common area maintenance.

The following tables describe our lease costs and other lease information.

	During the Three-Month Periods Ended September 30,		During the Nine-Month Periods Ended September 30,	
	2022	2021	2022	2021
Lease Cost				
Operating lease cost	$30,237	$29,499	$90,465	$88,497
Variable lease cost	10,350	10,350	31,050	31,050
Total lease cost	$40,587	$39,849	$121,515	$119,547
Operating Lease				
Weighted average remaining lease term (in years)	20.4	8.3	20.4	8.3
Weighted average discount rate	5.54%	4.77%	5.54%	4.77%

Future lease payments required under non-cancelable operating leases in effect as of September 30, 2022 were as follows:

	Amount
During the three-month period ending December 31, 2022	$30,237
During the years ending December 31,	
2023	155,730
2024	162,384
2025	165,090
2026	168,395
2027	171,760
Thereafter	3,049,071
Total lease payments (undiscounted cash flows)	3,902,667
Less: imputed interest (discount effect of cash flows)	(1,654,388)
Total operating liabilities	$2,248,279

13. STOCKHOLDERS' EQUITY

Common Stock Issuances

From February 2016 to April 2021, we sold the aggregate of 4,553,017 shares of common stock in six different transactions raising gross proceeds of approximately $26,714,000 at the weighted average price of $5.87 per share. These funds have been essential to funding our business growth plans. The details of each transaction are discussed below.

1) 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).

2) On October 21, 2016, we sold, in a private placement, 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).

3) On July 27, 2017, we sold 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).

4) On December 21, 2017, we sold 417,807 shares of common stock at a price to the public of $7.30 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately $3,050,000 and resulting in net proceeds to the Company of approximately $2,734,000 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

5) 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).

6) On April 14, 2021, we sold 515,156 shares of our common stock at a price of $8.25 per share in a public, registered sale to seven investors pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately $4,250,000 and resulting in net proceeds of approximately $4,233,000 (after deducting expenses incurred in connection with the equity financing).

Stock Option Plans

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 10 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, 2022, there were 204,500 options 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. An amendment to the 2017 Plan increasing the number of shares reserved for issuance under the 2017 Plan by 350,000 shares from 300,000 shares to 650,000 shares was approved by a vote of stockholders at the Annual Meeting of Stockholders in June 2022. 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 10 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, 2022, there were 358,500 options outstanding under the 2017 Plan.

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

	2010 Plan	2017 Plan	Weighted Average Exercise Price	Aggregate Intrinsic Value[(1)]
Outstanding as of December 31, 2020	237,500	176,500	$6.38	($180,038)
Grants	—	86,000	$9.78	
Terminations/forfeitures	(12,000)	(20,000)	$7.26	
Exercises	(7,000)	(18,000)	$7.08	
Outstanding as of December 31, 2021	218,500	224,500	$6.94	$468,425
Grants	—	156,500	$8.14	
Terminations/forfeitures	(9,000)	(22,500)	$7.47	
Exercises	(5,000)	—	$6.13	
Outstanding as of September 30, 2022	204,500	358,500	$7.25	$127,538
Vested as of September 30, 2022	174,500	98,500	$6.79	$188,040
Vested and expected to vest as of September 30, 2022	204,500	358,500	$7.25	$127,538
Reserved for future grants	—	273,500		

[(1)] Intrinsic value is the difference between the fair market value of the underlying common stock 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, 2022	160,000	$3.36	$7.23
Non-vested stock options as of September 30, 2022	290,000	$3.83	$7.69
Stock options granted during the nine-month period ended September 30, 2022	156,500	$4.36	$8.14
Stock options that vested during the nine-month period ended September 30, 2022	4,000	$3.44	$6.54
Stock options that were forfeited during the nine-month period ended September 30, 2022	31,500	$4.10	$7.47

During the nine-month period ended September 30, 2022, one former employee and two employees exercised stock options covering 5,000 shares with $30,672 in cash. During the year ended December 31, 2021, one director and three employees exercised stock options covering 25,000 shares by the surrender of 17,128 shares of common stock with a fair market value of $165,337 at the time of exercise and the payment of $11,693 in cash.

The weighted average remaining life of the options outstanding under the 2010 Plan and the 2017 Plan as of September 30, 2022 was approximately 5 years and 7 months. The weighted average remaining life of the options exercisable under these plans as of September 30, 2022 was approximately 3 years and 8 months. The exercise prices of the options outstanding as of September 30, 2022 ranged from $4.00 to $10.04 per share. The 156,500 stock options granted during the nine-month period ended September 30, 2022 had exercise prices between $7.60 and $9.39 per share. The 86,000 stock options granted during the year ended December 31, 2021 had exercise prices between $6.10 and $10.04 per share. The aggregate intrinsic value of options exercised during the nine-month period ended September 30, 2022 and the year ended December 31, 2021 approximated $10,525 and $64,977, respectively. The weighted-average grant date fair values of options granted during the nine-month period ended September 30, 2022 and the year ended December 31, 2021 were $4.36 and $4.51 per share, respectively. As of September 30, 2022, total unrecognized stock-based compensation related to non-vested stock options aggregated $775,517, which will be recognized over a weighted average remaining period of 1 year and 10 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 Periods Ended September 30,		During the Nine-Month Periods Ended September 30,	
	2022	2021	2022	2021
Risk-free interest rate	3.98%	0.79%	2.84%	0.85%
Dividend yield	0%	0%	0%	0%
Expected volatility	52%	54%	53%	54%
Expected life	6.6 years	6.5 years	6.5 years	5.0 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 Plan to extend the Final Expiration Date. Our Board of Directors decided to seek an advisory vote by stockholders at the Annual Meeting of Stockholders held in June 2022, as to whether to extend the Rights Plan by one year to September 19, 2023. Recognizing that there might be a substantial number of broker non-votes, our Board of Directors, which has the authority to amend the Rights Plan, disclosed that it would be guided by the votes actually cast on this proposal in deciding whether to extend the expiration date of such plan by one year. Of the votes actually cast on this proposal, 65% voted in favor, 32% voted against and 3% abstained. On the basis of this vote, our Board of Directors voted to extend the Rights Plan by one year to September 19, 2023.

During the third quarter of 2011, our Board of Directors voted to authorize an amendment to the Rights Plan 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 Plan.

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.

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, 2022 or the year ended December 31, 2021. 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 tables present our product sales disaggregated by geographic area:

	During the Three-Month Periods Ended September 30,				During the Nine-Month Periods Ended September 30,			
	2022	%	2021	%	2022	%	2021	%
United States	$4,252,768	89%	$4,550,343	88%	$13,329,834	91%	$12,161,097	88%
Other	543,257	11%	599,830	12%	1,327,248	9%	1,638,032	12%
Total Product Sales	$4,796,025	100%	$5,150,173	100%	$14,657,082	100%	$13,799,129	100%

The following tables present our product sales disaggregated by major product category:

	During the Three-Month Periods Ended September 30,				During the Nine-Month Periods Ended September 30,			
	2022	%	2021	%	2022	%	2021	%
First Defense® product line	$4,751,049	99%	$5,033,428	98%	$14,537,390	99%	$13,529,847	98%
Other animal health	44,976	1%	116,745	2%	119,692	1%	269,282	2%
Total Product Sales	$4,796,025	100%	$5,150,173	100%	$14,657,082	100%	$13,799,129	100%

The following tables present our product sales disaggregated by geographic area:

	During the Years Ended December 31,			
	2021	%	2020	%
United States	$16,620,363	86%	$13,644,768	89%
Other	2,622,606	14%	1,697,436	11%
Total Product Sales	$19,242,969	100%	$15,342,204	100%

The following tables present our product sales disaggregated by major product category:

	During the Years Ended December 31,			
	2021	%	2020	%
First Defense® product line	$18,933,092	98%	$15,072,446	98%
Other animal health	309,877	2%	269,758	2%
Total Product Sales	$19,242,969	100%	$15,342,204	100%

15. OTHER EXPENSES, NET

Other expenses (income), net, consisted of the following:

	During the Three-Month Periods Ended September 30,		During the Nine-Month Periods Ended September 30,	
	2022	2021	2022	2021
Interest expense[(1)]	$89,430	$78,526	$254,884	$237,578
(Gain) loss on disposal of property, plant and equipment	—	42,278	(11,000)	32,278
Interest income	(55,009)	(5,521)	(88,384)	(13,500)
Income - other	—	—	(912)	—
Other expenses, net	$34,421	$115,283	$154,588	$256,356

[(1)] Interest expense includes amortization of debt issuance costs of $1,919 and $1,960 during the three-month periods ended September 30, 2022 and 2021, respectively, and $5,739 and $5,880 during the nine-month periods ended September 30, 2022 and 2021, respectively.

16. INCOME TAXES

Our income tax expense aggregated $3,867 and $8,043 (amounting to less than 1% and 5% of our (loss) income before income taxes) during the three-month periods ended September 30, 2022 and 2021, respectively, and $6,162 and $8,043 (amounting to less than 1% and 6% of our (loss) before income taxes during the nine-month periods ended September 30, 2022 and 2021, respectively). As of December 31, 2021, we had federal net operating loss carryforwards of $14,734,684, of which $13,022,777 do not expire and of which $1,711,907 expire in 2034 through 2037 (if not utilized before then), and state net operating loss carryforwards of $1,440,707 that expire in 2037 through 2038 (if not utilized before then). Additionally, we had federal general business tax credit carryforwards of $557,795 that expire in 2027 through 2042 (if not utilized before then) and state tax credit carryforwards of $981,604 that expire in 2024 through 2042 (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 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 the end of 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.

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 unaudited financial statements.

17. SEGMENT INFORMATION

Our business operations (being the development, acquisition, manufacture and sale of products that improve the health and productivity of dairy and beef cattle) are described in Note 1. Pursuant to Codification Topic 280, *Segment Reporting*, we operate in the following two reportable business segments: i) Scours and ii) Mastitis. The Scours segment consists of the **First Defense®** product line. The core technology underlying the Scours segment is derived around polyclonal antibodies. The Mastitis segment includes our products, **CMT** and **Re-Tain®**. **Re-Tain®** is projected to be the driver of this segment when approved for sale. The core technology underlying the Mastitis segment is derived around polypeptide antimicrobials. The category we define as "Other" includes unallocated administrative and overhead expenses and other products. The significant accounting policies of these segments are described in Note 2. Product sales are the primary factor we use in determining our reportable segments. The governing regulatory authority (USDA for **First Defense®** or FDA for **Re-Tain®**) is also a factor in determining our reportable segments. Management monitors and evaluates segment performance from sales to net operating income (loss) closely. We are not organized by geographic region. No segments have been aggregated. The revenues and expenses allocated to each segment are in some cases direct and in other cases involve reasonable and consistent estimations by management. Each 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.

	During the Three-Month Period Ended September 30, 2022			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$4,751,049	$44,976	$—	$4,796,025
Costs of goods sold	2,898,897	45,441	5,636	2,949,974
Gross margin	1,852,152	(465)	(5,636)	1,846,051
OPERATING EXPENSES:				
Product development expenses	6,421	1,246,243	17,097	1,269,761
Sales and marketing expenses	369,439	357,299	—	726,738
Administrative expenses	—	—	466,342	466,342
Operating expenses	375,860	1,603,542	483,439	2,462,841
NET OPERATING INCOME (LOSS)	$1,476,292	($1,604,007)	($489,075)	($616,790)

	During the Three-Month Period Ended September 30, 2021			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$5,033,428	$35,736	$81,009	$5,150,173
Costs of goods sold	2,671,310	25,814	34,345	2,731,469
Gross margin	2,362,118	9,922	46,664	2,418,704
OPERATING EXPENSES:				
Product development expenses	17,326	1,001,354	28,818	1,047,498
Sales and marketing expenses	496,010	160,408	—	656,418
Administrative expenses	—	—	443,698	443,698
Operating expenses	513,336	1,161,762	472,516	2,147,614
NET OPERATING INCOME (LOSS)	$1,848,782	($1,151,840)	($425,852)	$271,090

	Scours	**Mastitis**	**Other**	**Total**
Total Assets as of September 30, 2022	$18,678,408	$18,634,760	$9,088,393	$46,401,561
Total Assets as of September 30, 2021	$14,070,880	$19,310,110	$10,850,473	$44,231,463
Depreciation and amortization expense during the three-month period ended September 30, 2022	$302,235	$316,317	$15,688	$634,240
Depreciation and amortization expense during the three-month period ended September 30, 2021	$259,993	$344,554	$15,579	$620,126
Capital Expenditures during the three-month period ended September 30, 2022	$665,825	$21,032	$47,452	$734,309
Capital Expenditures during the three-month period ended September 30, 2021	$477,844	$193,561	$3,995	$675,400

	During the Nine-Month Period Ended September 30, 2022			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$14,537,390	$118,237	$1,455	$14,657,082
Costs of goods sold	7,870,420	104,092	25,967	8,000,479
Gross margin	6,666,970	14,145	(24,512)	6,656,603
OPERATING EXPENSES:				
Product development expenses	23,025	3,331,311	90,128	3,444,464
Sales and marketing expenses	1,127,676	1,069,801	—	2,197,477
Administrative expenses	—	—	1,679,851	1,679,851
Operating expenses	1,150,701	4,401,112	1,769,979	7,321,792
NET OPERATING INCOME (LOSS)	$5,516,269	($4,386,967)	($1,794,491)	($665,189)

	During the Nine-Month Period Ended September 30, 2021			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$13,529,846	$102,977	$166,306	$13,799,129
Costs of goods sold	7,559,174	73,864	70,877	7,703,915
Gross margin	5,970,672	29,113	95,429	6,095,214
OPERATING EXPENSES:				
Product development expenses	24,892	2,837,830	215,948	3,078,670
Sales and marketing expenses	1,279,673	334,324	—	1,613,997
Administrative expenses	—	—	1,290,574	1,290,574
Operating expenses	1,304,565	3,172,154	1,506,522	5,983,241
NET OPERATING INCOME (LOSS)	$4,666,107	($3,143,041)	($1,411,093)	$111,973

	Scours	Mastitis	Other	Total
Total Assets as of September 30, 2022	$18,678,408	$18,634,760	$9,088,393	$46,401,561
Total Assets as of September 30, 2021	$14,070,880	$19,310,110	$10,850,473	$44,231,463
Depreciation and amortization expense during the nine-month period ended September 30, 2022	$895,045	$946,878	$47,144	$1,889,067
Depreciation and amortization expense during the nine-month period ended September 30, 2021	$756,714	$1,062,703	$46,403	$1,865,820
Capital Expenditures during the nine-month period ended September 30, 2022	$2,050,107	$387,536	$47,452	$2,485,095
Capital Expenditures during the nine-month period ended September 30, 2021	$1,055,412	$840,675	$7,968	$1,904,055

	During the Year Ended December 31, 2021			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$18,933,092	$143,280	$166,597	$19,242,969
Costs of goods sold	10,411,936	99,957	75,147	10,587,040
Gross margin	8,521,156	43,323	91,450	8,655,929
OPERATING EXPENSES:				
Product development expenses	25,374	3,887,781	255,363	4,168,518
Sales and marketing expenses	1,942,391	561,535	—	2,503,926
Administrative expenses	—	—	1,726,100	1,726,100
Operating expenses	1,967,765	4,449,316	1,981,463	8,398,544
NET OPERATING INCOME (LOSS)	$6,553,391	($4,405,993)	($1,890,013)	$257,385

	During the Year Ended December 31, 2020			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$15,072,446	$136,210	$133,548	$15,342,204
Costs of goods sold	8,285,073	119,329	74,976	8,479,378
Gross margin	6,787,373	16,881	58,572	6,862,826
OPERATING EXPENSES:				
Product development expenses	106,393	4,022,712	225,522	4,354,627
Sales and marketing expenses	2,119,289	48,610	—	2,167,899
Administrative expenses	—	—	1,720,653	1,720,653
Operating expenses	2,225,682	4,071,322	1,946,175	8,243,179
NET OPERATING INCOME (LOSS)	$4,561,691	($4,054,441)	($1,887,603)	($1,380,353)

	Scours	Mastitis	Total
Total Assets as of December 31, 2021	$22,442,944	$22,022,744	$44,465,688
Total Assets as of December 31, 2020	$18,416,157	$21,933,437	$40,349,594
Depreciation and amortization expense during the year ended December 31, 2021	$1,094,810	$1,374,171	$2,468,981
Depreciation and amortization expense during the year ended December 31, 2020	$1,002,360	$1,447,647	$2,450,007
Capital Expenditures during the year ended December 31, 2021	$1,655,866	$952,783	$2,608,649
Capital Expenditures during the year ended December 31, 2020	$3,456,307	$616,232	$4,072,539

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 $500,015 and $419,754 of products from us during the nine-month periods ended September 30, 2022 and 2021, respectively, all on terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated $11,672 and $55,490 as of September 30, 2022 and December 31, 2021, 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 $44,043 and $37,767 into the Plan for the three-month periods ended September 30, 2022 and 2021, respectively, and $123,887 and $108,886 into the Plan for the nine-month periods ended September 30, 2022 and 2021, respectively.

20. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of filing on the date we have issued this Quarterly Report on Form 10-Q. As of the time of filing, there were no 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, objectives or expectations 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 our production activities, operating results and financial condition and on the customers and markets that we serve; the impact of Russia's unprovoked military invasion of Ukraine and attack on its people on the world economy including inflation and the price and availability of grain, oil, and natural gas; the impact of the global supply-chain disruptions on our ability to obtain, in a timely and cost-effective fashion, all the supplies and components we need to produce our products; the challenges in attracting and retaining needed personnel in this current employment environment; the impact of inflation and rising interest rates on our operating expenses and financial results and on our suppliers and customers; the effects of a potential United States or global recession on us and our direct and indirect customers, the duration and severity of which are difficult to predict or anticipate; 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 per unit; 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 impacts of backlogs on customer relationships; 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; 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 our facilities to produce the Nisin Drug Substance and Drug Product; our effectiveness in competing against competitors within both our existing and our anticipated product markets; the cost-effectiveness of additional sales and marketing expenditures and resources; anticipated changes in our manufacturing capabilities and efficiencies; the value of our net deferred tax assets; projections about depreciation expense and its impact on income for book and tax return purposes; 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 (including the consequences of backlogs or excess inventory buildup), uncertainty associated with the timing and volume of customer orders as we come out of a prolonged backlog, adverse impacts of supply chain disruptions on our operations and customer and supplier relationships, our reliance upon third parties for financial support, products and services, our small size and dependence on key personnel, changes in laws and regulations, decision making and delays by regulatory authorities, a continuation or worsening of recent inflationary conditions and their impact on our customers' order patterns, uncertainty and possible adverse effects on us and our customers arising from an economic recession, currency values and fluctuations (that could make our products more expensive for international customers) and other risks detailed from time to time in filings we make with the Securities and Exchange Commission (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: ITEM 1A – RISK FACTORS** and uncertainties otherwise referred to in this Quarterly Report on Form 10-Q.

Liquidity and Capital Resources

Net cash (used for) operating activities was ($246,000) during nine-month period ended September 30, 2022 in contrast to net cash provided by operating activities of $366,000 during the nine-month period ended September 30, 2021. The $612,000 decrease in cash provided by operating activities from period to period was largely the net result of a $674,000 increase in the net loss with a significant increase in cash generated from the collection of accounts receivable being offset by the use of cash to build inventory. As we increased our production capacity to eliminate the backlog of orders, our inventory balance increased from $3.1 million as of December 31, 2021 to $5.3 million as of September 30, 2022. Our total depreciation expense was approximately $1.9 million during both of the nine-month periods ended September 30, 2022 and 2021. We anticipate that depreciation expense, while not affecting our cash flows from operations, will be a significant factor in creating annual net operating losses until and unless product sales increase sufficiently to offset these non-cash expenses. Cash (used for) investing activities was ($2.5 million) during the nine-month period ended September 30, 2022 in comparison to cash (used for) investing activities of ($900,000) during the nine-month period ended September 30, 2021. Cash paid to acquire property, plant and equipment was $2.5 million and $1.9 million during the nine-month periods ended September 30, 2022 and 2021, respectively, which payments were largely related to our ongoing investments to expand our manufacturing facilities. However, during 2021, we realized proceeds of $996,000 from the maturity of investments, which helped to offset part of the capital expenditures. Cash provided by financing activities decreased to $1.4 million during the nine-month period ended September 30, 2022 in comparison to cash provided by financing activities of $4.1 million during the nine-month period ended September 30, 2021. Going forward, repayments of the indebtedness incurred to fund these capital expenditures and acquire these assets will reduce our cash flows.

We entered into several bank debt refinancings and amendments with Gorham Savings Bank (GSB) from the first quarter of 2020 to the first quarter of 2022 that have improved our liquidity by lowering our interest expense, spreading our principal payments out over a longer period of time and pushing out balloon principal payment obligations that existed under some of the repaid debt. Also, because all of this debt bears interest at fixed rates, we are avoiding the adverse effects of rising interest rates on our debt service costs. The blended interest rate on this debt, including the State of Maine debt from the Maine Technology Institute (MTI) aggregating $900,000 described below, is 3.65% per annum (3.52% per annum excluding the MTI debt). As of September 30, 2022, we had total bank debt outstanding (including the MTI debt) of $10.5 million as compared to $9.1 million as of December 31, 2021. Debt principal repayments aggregated $844,000 and $719,000 (excluding a one-time principal repayment in the amount of $624,000 made in connection with a mortgage debt refinancing during the fourth quarter of 2020) during the trailing twelve-month periods ended September 30, 2022 and 2021, respectively. We anticipate that debt principal repayments will aggregate approximately $1 million during the twelve-month period ending September 30, 2023. Interest expense was $322,000 and $308,000 during the trailing twelve-month periods ended September 30, 2022 and 2021, respectively. We anticipate that interest expense will be $357,000 during the trailing twelve-month period ending September 30, 2023. During the first quarter of 2022, the availability of our $1.0 million line of credit, which bears interest at the National Prime Rate plus 0.00% per annum, was extended until March 11, 2024. These credit facilities are secured by substantially all of our assets, including our facility at 56 Evergreen Drive in Portland (which was independently appraised at $6.3 million in connection with a 2022 financing) and our facility at 33 Caddie Lane in Portland (which was independently appraised at $3.2 million in connection with a 2017 financing and at $2.5 million in connection with a 2020 refinancing). These credit facilities are subject to certain restrictions and financial covenants. We are required to meet a minimum debt service coverage (DSC) ratio set by GSB of 1.35. Our actual DSC ratio was equal to 2.68, 2.03 and 1.57 during the years ended December 31, 2021, 2020 and 2019, respectively. However, based on current projections of our future financial performance, which includes a high level of ongoing product development expenses to support **Re-Tain®**, we may not satisfy this annual requirement for the year ending December 31, 2022. By negotiation with GSB in connection with a 2022 financing, the required minimum DSC ratio was reduced to 1.0 for the year ending December 31, 2022.

During June 2020, we received a $500,000 loan from the Maine Technology Institute (MTI). The first 2.25 years of this loan were interest-free with no interest accrual or required principal payments. Principal and interest payments at a fixed rate of 5% per annum are due quarterly over the final 5 years of the loan, beginning during the fourth quarter of 2022 and continuing through the third quarter of 2027. During July 2021, we received an additional $400,000 loan from the MTI. The first 2 years of this second loan are interest-free with no interest accrual or required principal payments. Principal and interest payments at a fixed rate of 5% per annum are due quarterly over the final 5.5 years of the loan, beginning during the third quarter of 2023 and continuing through the fourth quarter of 2028. Both loans are unsecured and subordinated to all other bank debt from GSB and may be prepaid without penalty at any time. This support from the State of Maine through the MTI helps us move forward aggressively with our investments while increasing our total employee count.

From the first quarter of 2016 through the second quarter of 2021, we raised gross proceeds of approximately $26.7 million (net proceeds were approximately $24.8 million) from six different common equity transactions priced between $5.25 and $8.25 per share with a weighted average price of approximately $5.87 per share. No warrants were issued in connection with any of these transactions, and no convertible or preferred securities were issued. This capital, together with our bank debt and gross margin from product sales, has allowed us to transform the Company. We are (and have been) investing significantly to increase our capacity to produce the **First Defense**® product line from $16.5 million to over $40 million in annual sales volume per year. The actual value of our production capacity varies based on biological and process yields, product format mix, selling price and other factors. Based on our best estimates and projections, we believe that our cash and cash equivalents, together with gross margin anticipated to be earned from ongoing product sales, will be sufficient to meet our currently planned working capital and capital expenditure requirements and to finance our ongoing business operations for at least 12 months (which is the period of time required to be addressed for such purposes by accounting disclosure standards) from the date of this filing. The table below summarizes the changes in selected, key accounts (in thousands, except for percentages):

	As of September 30, 2022	As of December 31, 2021	(Decrease) Increase	
			Amount	%
Cash and cash equivalents	$8,828	$10,185	($1,358)	(13%)
Net working capital	$13,718	$13,730	($12)	(<1%)
Total assets	$46,402	$44,466	$1,936	4%
Stockholders' equity	$31,983	$32,577	($594)	(2%)
Common shares outstanding[(1)]	7,747	7,742	5	<1%

[(1)] There were approximately 563,000 and 443,000 shares of common stock reserved for issuance for stock options that were outstanding as of September 30, 2022 and December 31, 2021, respectively.

We have invested and continue to invest in eight different capital expenditure projects to increase our production capacity for the **First Defense**® product line and complete the development of **Re-Tain**®. When we describe the production capacity for the **First Defense**® product line in this report, it should be noted that the actual value of this capacity varies based on biological and process yields, product format mix, selling price and other factors. From 2014 to 2019, we initiated four capital expenditure investments, as described in the following table (in thousands):

	Cash Paid on Projects Initiated Before 2021 During the				
	A	B	C	D	Total
Year Ended December 31, 2014	$1,041	$—	$—	$—	$1,041
Year Ended December 31, 2015	1,991	265	—	—	2,256
Year Ended December 31, 2016	1,173	2,093	—	—	3,266
Year Ended December 31, 2017	—	17,686	—	—	17,686
Year Ended December 31, 2018	—	1,596	—	—	1,596
Year Ended December 31, 2019	—	—	279	538	817
Year Ended December 31, 2020	—	—	2,938	581	3,519
Year Ended December 31, 2021	—	—	432	886	1,318
Nine-Month Period Ended September 30, 2022	—	—	4	308	312
Total Paid through September 30, 2022	4,205	21,640	3,653	2,313	31,811
Estimate to Complete	—	—	—	1,687	1,687
Total Project Cost	$4,205	$21,640	$3,653	$4,000	$33,498

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 increased our annual production capacity (in terms of annual sales dollars) to approximately $16.5 million. This investment also included the construction and equipping of a pilot plant for small-scale Drug Substance production for **Re-Tain**® within our **First Defense**® production facility at 56 Evergreen Drive. After **PROJECT B** was completed, this space was converted for use in the production of the gel tube formats of the **First Defense**® product line at 56 Evergreen Drive. After **PROJECT C** was completed, this space was converted to double our liquid processing capacity at 56 Evergreen Drive.

PROJECT B was related to the Drug Substance production facility for **Re-Tain**® at 33 Caddie Lane. 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 4,080 square foot warehouse facility, which will be used for packing, shipping and cold storage of **Re-Tain®** and other warehousing needs.

PROJECT C consisted 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 $16.5 million to approximately $23 million. This expansion involved a 50% increase in our freeze-drying equipment 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. By moving our powder and gel 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. The new facilities are built to contemporary cGMP standards with good material and people flows. A site license approval for this new facility at 175 Industrial Way was issued by the USDA during the third quarter of 2020. During the second quarter of 2021, we completed the relocation of our gel formulation equipment from 56 Evergreen Drive to 175 Industrial Way, which created the space necessary to double our liquid processing capacity at 56 Evergreen Drive. We obtained site license approval of the expanded freeze-drying capacity at 56 Evergreen Drive from the USDA during the third quarter of 2021, and we obtained site license approval of the expanded liquid processing capacity at 56 Evergreen Drive from the USDA during the third quarter of 2022. As part of this investment, we also made the facility modifications at 56 Evergreen Drive to create the space necessary to expand our freeze-drying equipment by an additional 33%, which would increase our annual production capacity from approximately $23 million to approximately $30 million or more (together with the work involved in **PROJECT F** discussed below).

PROJECT D is a $4 million budgeted investment to bring the formulation and aseptic filling capabilities for **Re-Tain®** Drug Product into available space in our Drug Substance facility to end our reliance on third-party Drug Product manufacturing services. We began initial equipment installation during the first quarter of 2022. We have presently paused this installation work pending concurrence with the FDA pertaining to our third submission of the CMC Technical Section, which is discussed in greater detail below. We anticipate FDA approval of this facility (which is a requirement for commercial manufacturing) by the third quarter of 2024.

During 2021, we initiated three more capital expenditure investments, and during the second quarter of 2022, we initiated one additional capital expenditure investment, as described in the following table (in thousands):

	Cash Paid on Projects Initiated During 2021 or After During the				
	E	**F**	**G**	**H**	**Total**
Year Ended December 31, 2021	$452	$296	$282	$—	$1,030
Nine-Month Period Ended September 30, 2022	185	616	928	4	1,733
Total Paid through September 30, 2022	637	912	1,210	4	2,763
Estimate to Complete	113	48	1,790	1,696	3,647
Total Project Cost	$750	$960	$3,000	$1,700	$6,410

PROJECT E represents a $750,000 budget for equipment and vehicle investments necessary to expand and improve our colostrum collection capabilities and logistics. We anticipate completing this investment by the end of the first quarter of 2023.

PROJECT F represents a budget estimate of $960,000 to increase our freeze-drying equipment by an additional 33% to expand on **PROJECT C** to further increase the annual production capacity of the **First Defense®** product line (in terms of annual sales dollars) from approximately $23 million to approximately $30 million or more. We initiated **PROJECT F** during the third quarter of 2021. Due to supply disruptions affecting key components and equipment, the anticipated completion of this investment has been delayed into the fourth quarter of 2022.

PROJECT G represents an increased budget estimate of $3,000,000 (from the previous budget estimate of $2,840,000) for equipment and facility modifications to scale-up and upgrade our vaccine manufacturing capacity, construct pack & ship facilities for **Re-Tain®**, improve our quality laboratories and install new equipment for our gel filling operations. We estimate that the investment in our gel filling equipment will increase our annual production capacity for the **First Defense®** product line (in terms of annual sales dollars) further from approximately $30 million to approximately $35 million by the end of 2022.

PROJECT H represents a new investment in building modifications and equipment to further increase our annual **First Defense®** production capacity (at 100%) from the $35 million level that we expect to reach by the end of 2022 to approximately $47 million during the second half of 2024 with options for further expansion. These levels of production output require running

equipment and staff at nearly 100% of capacity. We have been running hard near to that level over the last couple of years in order to fill the backlog of orders. This opens us up to product contaminations and forces us to defer preventative maintenance of equipment, while subjecting us to more disruptive emergency maintenance. One of the objectives of **PROJECT H** is to create a more sustainable production schedule. For example, by running at 80% of maximum capacity, **PROJECT H** could increase our annual production output from approximately $27.7 million to approximately $37.3 million. During the third quarter of 2022, we entered into a lease covering a to-be-constructed 15,400 square foot building shell at 165 Industrial Way for approximately $250,000 per year, which operating cost is not included in the capital expenditure table above. We anticipate a lease commencement date (after the landlord completes construction of the building shell) during the second quarter of 2023. We made this lease commitment during the third quarter of 2022 because of the unique proximity of the land adjacent to our currently leased space at 175 Industrial Way and the high level of demand for properties of this type in the Portland market. We did not want to risk losing this opportunity to others. The anticipated benefits to us from this new lease include: i) space for significantly more freeze-drying capacity, ii) improved space and quality for our powder milling operations and iii) much needed additional warehouse space. The freeze-drying equipment that would be critical to achieving the next level of production capacity expansion requires approximately 18 to 24 months of lead time for fabrication, installation, qualification and implementation. In order to have the first of potentially up to four new pieces of freeze-drying equipment (which would increase our freeze-drying equipment by an additional 25%) operational by the second half of 2024, we recently committed $1.7 million to its purchase. The $1.7 million listed in the capital expenditure table above represents the amount of funds committed to **PROJECT H** to date. We intend to consider the investments in three additional similar pieces of freeze-drying equipment if justified by market demand after 2024. We plan to develop the full cost estimates in the coming months for the work required to modify the building shell to meet our needs optimally. We expect to define the scope and budget for **PROJECT H** more definitively by year end.

In addition to the specific projects listed above, our budget for routine and miscellaneous capital expenditures for the year ending December 31, 2022 is $825,000. We spent $446,000 of this budget during the first nine months of 2022. These routine and miscellaneous capital expenditures amounted to $260,000, $554,000 and $574,000 during the years ended December 31, 2021, 2020 and 2019, respectively. The spend on this budget category during 2021 was lower than expected, and the spend during 2022 is anticipated to be higher than the historical norm.

We have set aside approximately $5.7 million (including a contingency of approximately $226,000) of the $8.8 million of the cash we had on hand as of September 30, 2022 to: i) complete **PROJECT D, PROJECT E, PROJECT F** and **PROJECT G**, ii) fund the initial $1.7 million towards **PROJECT H** and iii) pay for our other routine and miscellaneous capital expenditures during the last quarter of 2022, leaving the remaining cash balance of approximately $3.1 million available for the completion of **PROJECT H** and for general working capital purposes, including anticipated further inventory builds for both **First Defense®** and **Re-Tain®**.

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 year 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 increases (decreases) in the assessment of the building for city real estate tax purposes or the City's tax rate. The following table discloses how much of the new taxes we have generated is being relieved by the TIF and how much is being paid by ImmuCell:

Assessed Value	Twelve-Month Period Ended	Total New Taxes Generated by the Project	Less: TIF Credit	Net Amount Paid by ImmuCell
$1.7 million @ April 1, 2017	June 30, 2018	$36,000	$22,000	$13,000
$4.0 million @ April 1, 2018	June 30, 2019	$90,000	$58,000	$32,000
$4.0 million @ April 1, 2019	June 30, 2020	$94,000	$60,000	$34,000
$4.0 million @ April 1, 2020	June 30, 2021	$94,000	$60,000	$34,000
$4.3 million @ April 1, 2021	June 30, 2022	$55,000	$36,000	$20,000
$4.3 million @ April 1, 2022	June 30, 2023	$58,000	$37,000	$21,000

Results of Operations

Business Segments

As detailed in Note 17, "Segment Information", to the accompanying unaudited financial statements, we operate in two business segments. The Scours segment is dedicated to manufacturing and selling **First Defense®**, a product used to prevent scours in newborn calves, which is regulated by the USDA. The Mastitis segment is focused on developing and commercializing **Re-Tain®**, a

product to treat subclinical mastitis in lactating dairy cows, which is regulated by the FDA.

Product Sales

Through both continued growth in sales of the **First Defense®** product line and a successful launch of **Re-Tain®** as soon as possible, and with a measured approach to expanding our customer-facing staff, it is our objective to increase our current annual level of total product sales of approximately $19.2 million during the year ended December 31, 2021. As additional resources are dedicated to production, sales, marketing and technical services, our longer-term goal is to exceed $35 million of annual total product sales as soon as possible during the five-year period after the market launch of **Re-Tain®**. We do not solely benchmark our sales expectations off trailing twelve-month sales results. Instead, we look at the sales of competitive products to assess the size of the addressable market and plan for growth when projecting our future production capacity needs.

Sales decreased by 7%, or $354,000, to $4.8 million during the three-month period ended September 30, 2022, in comparison to the three-month period ended September 30, 2021. Domestic sales decreased by 7%, and international sales decreased by 9%, in comparison to the three-month period ended September 30, 2021. International sales aggregated 11% and 12% of total sales during the three-month periods ended September 30, 2022 and 2021, respectively. The three-month sales results are summarized in the following table:

	During the Three-Month Periods Ended September 30,		(Decrease)	
(In thousands, except for percentages)	2022	2021	Amount	%
Total product sales	$4,796	$5,150	($354)	(7%)

Sales increased by 6%, or $858,000, to $14.7 million during the nine-month period ended September 30, 2022, in comparison to the nine-month period ended September 30, 2021. Domestic sales increased by 10%, and international sales decreased by 19%, in comparison to the nine-month period ended September 30, 2021. International sales aggregated 9% and 12% of total sales during the nine-month periods ended September 30, 2022 and 2021, respectively. The nine-month sales results are summarized in the following table:

	During the Nine-Month Periods Ended September 30,		Increase	
(In thousands, except for percentages)	2022	2021	Amount	%
Total product sales	$14,657	$13,799	$858	6%

Sales increased by 15%, or $2.6 million, to $20.1 million during the trailing twelve-month period ended September 30, 2022, in comparison to the trailing twelve-month period ended September 30, 2021. Domestic sales increased by 15%, and international sales increased by 12%, in comparison to the trailing twelve-month period ended September 30, 2021. International sales aggregated 12% of total sales during both of the trailing twelve-month periods ended September 30, 2022 and 2021. The trailing twelve-month sales results are summarized in the following table:

	During the Trailing Twelve-Month Periods Ended September 30,		Increase	
(In thousands, except for percentages)	2022	2021	Amount	%
Total product sales	$20,101	$17,542	$2,558	15%

Sales of the **First Defense®** product line aggregated 99% and 98% of our total sales during the three-month periods ended September 30, 2022 and 2021, respectively, and 99% and 98% of our total sales during the nine-month periods ended September 30, 2022 and 2021, respectively. Our sales are seasonal with highest sales expected during the first quarter of each year. Most of our growth (when not limited by backlog) is being realized through increased demand and a deliberate strategy to prioritize production capacity towards **Tri-Shield First Defense®** (the trivalent format of our product delivered via a gel tube), which provides broader protection to calves. The compound annual growth rate of our total product sales during the ten years ended December 31, 2021 was approximately 15%. The compound annual growth rate of our total product sales during the three years ended December 31, 2021 was approximately 18%.

Valuation of the backlog is a non-GAAP estimate that is based on purchase orders on hand at the time that could not be met because of a lack of available inventory. The backlog was reduced from approximately $2.4 million as of December 31, 2021 to approximately $205,000 as of September 30, 2022. We had adequate finished goods inventory to ship most of this backlog during the third quarter, but the product was held for cold shipping on the first Monday of October. Quantification of the backlog during the current periods has become far less comparable to prior periods. At times, customers have placed orders for more than a month's worth of their demand, perhaps in reaction to our ongoing backlog situation, whereas in the past they ordered more closely in line

with their current demand. While our backlog is a very positive indication about the strong demand for our **First Defense®** product line, we likely lost some business during 2021 as a result of the backlog. Our inability to timely meet the needs of our customers could result in the loss of some customers who seek alternative scours management products during this period of short supply and who may not resume purchasing our product when we have eliminated the backlog. While we worked to allocate product directly to certain large customers during this period of short supply, we likely lost some customers that could not access product. While backlog is a better problem to have than seeing product expiring on our shelves, it is nonetheless a significant challenge when we do not get our customers everything that they want. Our sales team is resuming more normal sales growth initiatives with more inventory becoming available as we move forward. We are working to regain customers that we may have lost while we were short on product and aggressively competing for new business. As we emerge from an extended period of time on backlog, we anticipate higher than normal sales fluctuations quarter to quarter. What is most important to us at this time is that we achieve sales growth over the longer periods of time, even if we experience some quarter-to-quarter fluctuations.

We completed the critical objectives of our investment to increase our **First Defense®** production capacity from approximately $16.5 million to approximately $23 million in terms of annual sales value during the fourth quarter of 2021. During the third quarter of 2021, we initiated an additional investment of approximately $960,000 to increase our annual production capacity for the **First Defense®** product line further from approximately $23 million to approximately $30 million or more per year by the end of fourth quarter of 2022 (see discussion of **PROJECT F** above). Completion of this investment was delayed into the fourth quarter of 2022 due to a delivery failure by one of our equipment fabricators. During the fourth quarter of 2021, we initiated an additional investment to further increase our annual **First Defense®** production capacity to approximately $35 million (at 100%) by the end of the fourth quarter of 2022 (see discussion of **PROJECT G** above). Equipment modifications and relocations of this nature can require a shutdown of operations for several weeks or more to install and validate the modified equipment and achieve USDA approval for its use in its new location. This process must be managed carefully to minimize disruption. Considering the lead time required for facility modifications and equipment fabrication (which is approximately 18 to 24 months), during the second quarter of 2022, we initiated the preliminary steps related to an additional investment to increase this annual capacity further to approximately $47 million (at 100%) by the third quarter of 2024 (see discussion of **PROJECT H** above). These investments have been and are being made to materially reduce the risk of another order backlog. We have been operating at very close to 100% of available capacity recently, which is not efficient or sustainable. Going forward, we will be in a position to operate at the capacity level we choose to cover sales with adequate buffer stock. This allows more time for necessary preventative maintenance and redundancy for when equipment failures occur. The actual value of our production output varies based on biological and process yields, product format mix, selling price and other factors.

A supply disruption pertaining to needed plastic syringes used in our gel product format resulted in the drop in sales during the second quarter. We believe that this supply disruption was addressed during the third quarter of 2022. The significant global supply-chain disruptions that almost all industries are experiencing presently are a challenge to us and contribute to our order backlog. Prices for raw materials and critical supplies are increasing significantly, and it is more and more difficult to obtain timely delivery of the orders that we place. Therefore, we have little choice but to pay the higher prices and try to take on more months of supply than we would have held previously if we could get our orders fulfilled.

Effective January 1, 2022, we increased our selling price of the **First Defense®** product line by approximately 5% and **CMT** by approximately 7%. Effective January 1, 2021, we increased our selling price of the **First Defense®** product line in the domestic market by approximately 1.6% to 3%, depending on product format, and we increased our selling price of **CMT** by almost 4%.

We acquired a private label product (our second leading source of product sales during 2021) in connection with our January 2016 acquisition of certain gel formulation technology. This product was discontinued during the first quarter of 2022 because it was not a significant contributor to our total sales and it competed for valuable time and space in our production schedule. We sell our own **CMT** (our third leading source of product sales during 2021), which is used to detect somatic cell counts in milk. Sales of these products (other than the **First Defense®** product line) decreased by 61%, or $72,000, to $45,000 during the three-month period ended September 30, 2022, in comparison to the three-month period ended September 30, 2021. Sales of these other products aggregated approximately 1% and 2% of our total product sales during the three-month periods ended September 30, 2022 and 2021, respectively. Sales of these products (other than the **First Defense®** product line) decreased by 56%, or $150,000, to $120,000 during the nine-month period ended September 30, 2022, in comparison to the nine-month period ended September 30, 2021. Sales of these other products aggregated approximately 1% and 2% of our total product sales during the nine-month periods ended September 30, 2022 and 2021, respectively.

Gross Margin

Changes in our gross margin (product sales less costs of goods sold) and our gross margin as a percentage of 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,		(Decrease)	
	2022	2021	Amount	%
Gross margin	$1,846	$2,419	($573)	(24%)
Percent of product sales	38%	47%	(8%)	(18%)

The gross margin during the third quarter of 2022 was significantly less than what we have experienced historically and significantly less than what we anticipate going forward. We experienced several product contamination events that resulted in scrap. This resulted in a total charge to costs of goods sold of approximately $412,000 (approximately half of which occurred and was recorded during the third quarter of 2022 and the other half occurred and was recorded during the fourth quarter of 2022). We believe we can prevent such losses from re-occurring by making certain process and facility improvements, but this does happen from time-to-time in the production of a biological product such as ours. Absent this contamination write-off, our gross margin as a percentage of product sales would have been approximately 43% during the third quarter of 2022.

	During the Nine-Month Periods Ended September 30,		Increase	
	2022	2021	Amount	%
Gross margin	$6,657	$6,095	$561	9%
Percent of product sales	45%	44%	1%	3%

	During the Trailing Twelve-Month Periods Ended September 30,		Increase	
	2022	2021	Amount	%
Gross margin	$9,217	$7,716	$1,501	19%
Percent of product sales	46%	44%	2%	4%

The gross margin as a percentage of product sales was 45%, 45%, 49%, 47% and 50% during the years ended December 31, 2021, 2020, 2019, 2018 and 2017, respectively. During the first quarter of 2021, the gross margin of 39% was lower than what we normally expect. This gross margin improved to 46% during the second quarter of 2021 and further to 47% during both the third and fourth quarters of 2021 and then further to 52% during the first quarter of 2022, as we began to spread these fixed costs over increasing production output. However, this gross margin declined to 44% during the second quarter of 2022 and further to 38% during the third quarter of 2022, due to the contamination events described above. While our biological and process yields can be variable, we have seen a favorable improvement to our finished goods yield recently. The costs of our supplies, components, raw materials and services increased significantly during 2021 and that trend has continued. The **Tri-Shield®** product format is more complex (i.e., three antibodies versus two antibodies for **Dual-Force®**) making it more costly to produce, and both the bivalent and trivalent gel product formats are more expensive to produce than the bolus format. 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 are investing significantly in equipment, infrastructure and operating expenses to increase our annual production capacity from approximately $16.5 million to approximately $47 million (at 100%). Increased labor and other upfront costs were necessary to benefit from the scale-up of our production output going forward. A number of other factors contribute to the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter and from year to year. Like most U.S. 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 thereafter the effectiveness of their immune response improves in response to subsequent immunizations. During this expansion phase, colostrum quality can be more variable. 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. 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. We believe that gross margin results should be viewed over longer periods of time than just one quarter. As we fully integrate and utilize our increased capacity and evaluate our product costs and selling price, one of our goals is to achieve a gross margin (before related depreciation and amortization expenses) as a percentage of total sales approaching 50%.

Product Development Expenses

Overview: The majority of our product development expenses pertain to the development of **Re-Tain®**. During the three-month period ended September 30, 2022, product development expenses increased to approximately $1.3 million in comparison to the approximately $1 million during three-month period ended September 30, 2021. Product development expenses aggregated 26% and 20% of product sales during the three-month periods ended September 30, 2022 and 2021, respectively. Product development expenses included approximately $360,000 and $379,000 of non-cash depreciation and stock-based compensation expenses during the three-month periods ended September 30, 2022 and 2021, respectively. During the nine-month period ended September 30, 2022, product development expenses increased to approximately $3.4 million in comparison to approximately $3.1 million during the nine-month period ended September 30, 2021. Product development expenses aggregated 24% and 22% of product sales during the nine-month periods ended September 30, 2022 and 2021, respectively. Product development expenses included approximately $1.1 million and $1.2 million of non-cash depreciation and stock-based compensation expenses during the nine-month periods ended September 30, 2022 and 2021, respectively. We expect our product development expenses to decrease after **Re-Tain®** is commercialized and some of the costs incurred to maintain and run our Drug Substance production facility become part of our costs of goods sold.

Development objective: As we work to revolutionize the way that mastitis is managed in the dairy industry, we aim to demonstrate that our polypeptide antimicrobial, Nisin A, which is designed specifically for subclinical mastitis, can provide producers the freedom to change when and how mastitis is treated. **Re-Tain®** is not a broad spectrum antibiotic used in human health. Rather, it consists of a highly targeted active ingredient without a milk discard or meat withhold requirement. While milk prices vary, the cost of the milk discard associated with traditional antibiotics ranges from approximately $37.80 (for 3.5 days of milk at 60 pounds per day) to $158.40 (for 11 days of milk at 80 pounds per day) per treated animal. These high milk discard costs associated with traditional antibiotic treatments lead producers to only treat mastitis after clinical signs develop. We expect that **Re-Tain®** will be a first-of-its-kind product that can be used to economically treat at the earliest stage of infection, giving producers the ability to get ahead of mastitis before clinical signs develop so the best cows stay at their best performance level and in the herd longer. The final and most critical development objective for **Re-Tain®** is to scale-up and achieve regulatory approval of our manufacturing operations.

Development status: 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 a sixty-day administrative review at the end. Each Technical Section can be reviewed and approved separately. By statute, each Technical Section submission is generally subject to one or more six-month review cycles by the FDA. 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. During the second quarter of 2021, we received further clarification through a new Environmental Impact Technical Section Complete Letter covering the current dosage regimen and labeling.

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 anticipated product label (which remains subject to FDA approval) carries claims for the treatment of subclinical mastitis associated with *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, and coagulase-negative staphylococci in lactating dairy cattle.

4) Human Food Safety: During the third quarter of 2018, we received the Human Food Safety Technical Section Complete Letter from the FDA confirming, among other things, a zero milk discard period and a zero meat withhold period during and after treatment with our product. Achieving this critical differentiating feature for our product encouraged us to continue the significant product development investment necessary to bring **Re-Tain®** to market. It would have been hard to justify an ongoing investment of this nature in a product without this significant competitive advantage. During the second quarter of 2021, we updated this Technical Section Complete Letter with FDA approval of the official analytical method to measure Nisin in milk.

5) Chemistry, Manufacturing and Controls (CMC): The CMC Technical Section is very complex and comprehensive. 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, or DS) production, 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 DS. 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. Next, 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®**. However, the regulatory and marketing feedback 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 our DS 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 DS production facility. Having raised equity during 2016 and 2017, we were able to move away from these earlier partnering 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 DS 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. With construction of the facility complete, we continue to work with outside parties to investigate improvements to our DS production yields as well as potential efficacy enhancements.

Under the FDA's phased submission process, we made a first-phased submission covering just the DS during the first quarter of 2019. The first-phased DS submission included data from the DS Registration Batches produced at commercial scale in our new DS manufacturing facility. This first-phased submission was followed by a second-phased submission covering both the DS and the formulated Drug Product (DP), during the first quarter of 2021. This two-phased submission process allowed us to respond to identified queries and/or deficiencies from the first-phased DS submission at the time of the second-phased combined DS and DP submission. The second-phased DS and DP submission responded to comments raised by the FDA regarding the first-phased DS submission and included detailed information about the manufacturing process and controls for DP. One of the key components of the second-phased DS and DP submission was also demonstrating stability of the product through expiry. During the third quarter of 2021, the FDA issued a Technical Section Incomplete Letter with regard to this second-phased DS and DP submission. This response was not unexpected as it is common for the FDA to issue queries and comments, especially related to an aseptic DP submission with associated sterilization validation information. We made a second submission of the DS and DP Technical Section during the first quarter of 2022. During the third quarter of 2022, we received a Technical Section Incomplete Letter from the FDA with regards to this second DS and DP submission of the CMC Technical Section. We are working to make our third submission as soon as possible in the coming months and expect to make the submission by the end of the first quarter of 2023, if not sooner. The principal issue remaining is a successful pre-approval re-inspection of our manufacturing facility. We are completing preparations for such and intend to notify the FDA of our readiness for the pre-approval re-inspection as part of our third submission. Continued focus on these preparations is critical to a successful pre-approval re-inspection outcome. No substantive issues were raised in the other FDA comments (in addition to the comment requiring a successful pre-approval re-inspection), and the comments are not related to the safety or efficacy of the product. These comments principally relate to DP, not DS. This clarifies the required path to product approval. Our third CMC Technical Section submission will be subject to a statutory six-month review period by the FDA. If the FDA issues a Technical Section Complete Letter in response to this third submission, we believe that we could commence commercial sales approximately nine months from the submission date.

While being prudent with how much cash we invest into inventory that would have short expiry dating if market launch is delayed, we are building more DS inventory during 2022 to bridge the transition between DP supply from our contract manufacturer to our own in-house services. Our contract manufacturer has agreed to convert this DS to DP during the middle of 2023 with associated product expirations during the middle of 2025. This inventory must support the market needs and have sufficient dating to bridge the transition from our contract manufacturing agreement to when our in-house DP production is approved by the FDA. We must consider short expiry dating in the event that our NADA approval is delayed as well as manage the number of new customers we obtain at launch in order to minimize potential supply disruptions.

Our DS manufacturing facility and that of our DP contract manufacturer (and our future DP manufacturing facility) are subject to ongoing FDA inspections. 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. During the first quarter of 2022, the FDA conducted another

pre-approval inspection of our DS facility. This also resulted in the issuance of certain deficiencies as identified on the FDA's Form 483. We have since responded to all of the queries and are preparing for a re-inspection. This inspection process has been managed without significant cost.

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 DP manufacturer) (Norbrook), reducing our risk by benefiting from their demonstrated expertise in aseptic filling. From 2010 to the present, we have worked with Norbrook under several amended contract manufacturing agreements covering the DP formulation, aseptic filling and final packaging services. Under our current agreement, Norbrook has agreed to provide the formulation, aseptic filling and final packaging services as required in order for us to submit the CMC Technical Section to the FDA and to provide a supply of product during 2023 that we believe will enable us to commence sales of **Re-Tain®** without delay upon receipt of the anticipated FDA approval and provide us with a supply bridge until our own formulation and aseptic filling capacity is available, which is anticipated by the third quarter of 2024 (see discussion of **PROJECT D** above). DP produced under this agreement during the middle of 2023 is expected to have expiry dating during the middle of 2025.

Our potential alternative third-party options for the formulation and aseptic filling services that are presently being performed by Norbrook 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 (see discussion of **PROJECT D** above). We are investing approximately $4 million in the equipping and commencement of operations of our own DP formulation and aseptic filling facility. We began initial equipment installation during the first quarter of 2022. Subject to the timing of our installation and validation work, we anticipate FDA approval of this facility (which is a requirement for commercial manufacturing) during the fourth quarter of 2023 if the FDA requires only one six-month review cycle or by the second quarter of 2024 if the FDA requires two six-month review cycles. 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 DS 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. Establishing our own DP 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 DP formulation and aseptic filling operation will be located in existing facility space that we had intended to utilize to double our DS production capacity if warranted by sales volumes following market launch. As a result, we would need to explore alternative strategies (in parallel with ongoing DS yield improvement initiatives) to expand our DS production capacity. 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 DP 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®**.

Other product development initiatives: Our second most important product development initiative has been focused on other improvements, extensions or additions to our **First Defense®** product line. We are currently working to establish USDA claims for our bivalent bulk powder formulation of **First Defense Technology®**. 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, subject to the availability of the needed funding.

Sales and Marketing

During the three-month period ended September 30, 2022, sales and marketing expenses increased by approximately 11%, or $70,000, to $727,000 in comparison to $656,000 during the three-month period ended September 30, 2021, amounting to 15% and 13% of product sales during the three-month periods ended September 30, 2022 and 2021, respectively. Sales and marketing expenses included approximately $44,000 and $20,000 of non-cash depreciation and stock-based compensation expenses during the three-month periods ended September 30, 2022 and 2021, respectively. During the nine-month period ended September 30, 2022, sales and marketing expenses increased by approximately 36%, or $583,000, to approximately $2.2 million in comparison to $1.6 million during the nine-month period ended September 30, 2021, amounting to 15% and 12% of product sales during the nine-month periods ended September 30, 2022 and 2021, respectively. Sales and marketing expenses included approximately $123,000 and $50,000 of non-cash depreciation and stock-based compensation expenses during the nine-month periods ended September 30, 2022 and 2021, respectively. We expect these expenses to increase to approximately 18% of total product sales during 2022. Our budgetary guideline

for 2022 and after is to keep these expenses under 20% of total sales. We continue to leverage the efforts of our small sales force by using animal health distributors.

The **First Defense**® product line serves dairy and beef producers by protecting their calf crop from scours, the leading cause of pre-weaning mortality and morbidity. When calves are healthy during this crucial development period, they mature into more productive milking cows and more efficient beef generators. Our primary competition in this category is vaccines that are also regulated for effectiveness and safety by the USDA. However, vaccine results are inherently variable. COVID breakthrough infections in humans have reminded us that a vaccine does not guarantee immunity. That is true for our competitors as well. In the most controlled research settings, only 80% of animals respond to a vaccine. This leaves 20% of the calf crop unprotected when the scour prevention program relies on scour vaccines. Those unprotected calves can be disease carriers. Not only are they more susceptible to death or likely to require life-saving treatment (sometimes with antibiotics), but they also shed pathogens into the environment creating a greater disease pressure for their herd mates. The **First Defense**® product line removes the inconsistency inherent with vaccine protection. We sell the only USDA-licensed products in the scour prevention category that are therapeutic polyclonal antibodies. This technology eliminates a producer's reliance on a variable vaccine response to generate antibodies and, instead, can protect every calf equally with a measured dose of antibody-driven immunity against both bacterial and viral scour pathogens.

In this space, we treat more calves than our competitors where products are primarily vaccines administered directly to the calf at birth, and we are second in sales dollars to the market leader within the dam-level competitor category, which constitutes vaccines given to the cow pre-calving. Despite these successes, there remains significant opportunity to displace more competition within North America. There is also opportunity to grow our sales by expanding into international markets. We are being strategic in how we invest in international market development in order not to divert our limited resources away from achieving domestic growth, which is often more efficient to obtain.

Our expanded sales and marketing team has proven to be a worthy investment, validating that our message resonates well with customers. Now that our increased production capacity is in place, we anticipate being able to escalate our growth curve after we recover from the brand damage that can come with an extended duration of short supply. Unfortunately, just after we largely eliminated the backlog of orders, we experienced several contamination events in our production process around the end of the third quarter. This loss of inventory has put us back into a backlog situation that could increase to approximately $900,000 at year end before we fill the pipeline with new inventory from our expanded production capacity as we enter 2023. The amount of the projected backlog as of December 31, 2022 approximates the sales value of product that was discarded as the result of recent contamination events experienced in our production process.

We see ourselves as the "non-pharma" pharma company. Rather than offering variations of "me-too" technology like vaccines and antibiotics, we have taken the path less traveled by developing first-of-their kind products fueled by novel active ingredients such as polyclonal antibodies (for **First Defense**®) and bacteriocins (for **Re-Tain®**). While we expect that **Re-Tain®** could be a significant market disrupter, we project the **First Defense**® market could be larger, especially during the first years of the commercial launch of **Re-Tain**®. We anticipate that these category developing innovations will drive greater value for the livestock industry and, in turn, for our stockholders.

We believe that **Re-Tain**® could revolutionize the way that mastitis is managed by making earlier treatment of subclinical infections (while these cows are still producing saleable milk) economically feasible by not requiring a milk discard or a meat withhold during, or for a period of time after, treatment. No other FDA-approved mastitis treatment product on the market can offer this value proposition. We believe we can demonstrate a return on investment to the dairy producer and the milk processor that will justify a premium over other mastitis treatments on the market today, which are all sold subject to milk discard and meat withhold requirements. By creating this value for our customers, we believe we can, in turn, create value for our stockholders.

Re-Tain® could increase the lifetime profitability of a cow and reduce disease transfer to herd mates. It is generally current practice to treat mastitis only when the disease has progressed to the clinical stage where the milk from an infected cow cannot be sold, leaving most subclinically infected cows untreated. Without a milk discard cost, we expect producers to be more motivated to identify and treat cows at the subclinical stage. This creates a substantial animal welfare benefit. By treating mastitis early at the subclinical level, producers could preserve optimal milk yields. We also know that animals infected with subclinical mastitis have higher abortion rates and often progress to the clinical disease state requiring antibiotic treatment and milk discard. We believe that societal animal welfare objectives will put more and more pressure on the industry to treat cows with subclinical infections.

It is common practice to move sick cows from their regular herd group to a sick cow group for treatment and the related milk discard. This movement causes stress on the cow and a reduction in milk production. While practices may vary farm-to-farm, there would be no requirement to move cows treated with our product, allowing this costly drop in production to be avoided.

The over-use of antibiotics that are medically important to human healthcare is a growing public health concern of our society and an active issue with the FDA, largely because of the growing evidence that this over-use contributes to antibiotic resistance and the rise of "super-bugs". Sustainability objectives require that less antibiotics be used in food producing animals, yet a new FDA-approved drug to treat mastitis has not been developed in years. Our product improves sustainability by utilizing a polypeptide antimicrobial as an alternative to traditional antibiotics that are used in human medicine. In the big picture, we are introducing an entirely new class of antimicrobial as an animal drug, a bacteriocin, that does not promote resistance against antibiotics used in human medicine making it more socially responsible. As the great NHL hockey player, Wayne Gretzky, is known to have said, "I skate to where the puck is going to be, not where it has been." This is motivational to us. The industry could keep treating this very significant disease with traditional antibiotics, but it takes innovation to bring a polypeptide antimicrobial like Nisin to market. **Re-Tain®** would, when introduced, offer a needed alternative to these traditional antibiotics, while at the same time improving milk quality and the quantity of milk produced by treated cows. We believe our product fits very well with where the industry is going to be in the coming years.

As with all new products, the market determines the value. Our objective is to gain market acceptance of this new product concept as we develop a new product category. Despite our product's exciting benefits, it will take time to change this longstanding treatment paradigm and develop this new market. It will take time for the market to understand, evaluate, implement and adapt to the use and benefits of **Re-Tain®**. As we prepare for market launch after we receive the anticipated and required FDA approval of this product, we continue to carefully consider our best go-to-market strategy in consultation with industry-leading consultants, veterinarians, dairy producers and others. Informed by consultations with these industry experts and key opinion leaders, we have opted to carefully control the launch of this novel product over the first eighteen months or so after FDA approval, as we seek to revolutionize the way that mastitis is treated in the dairy industry over the long term. Under this controlled launch, our sales and technical support team will work directly with early adopters to ensure that the best treatment candidates are selected and that the product is properly administered in accordance with its label, creating exceptional customer experiences and strong customer testimonials. The goal of our direct sales team is to help early adopters develop easy to use protocols, optimize treatment results and realize a positive return on their investment. We intend to limit initial distribution of **Re-Tain®** to a level that enables our sales team to select the optimal dairy farms at which to introduce **Re-Tain®** and to limit the initial numbers of participating farms so that the desired levels of support and guidance relating to effective usage of **Re-Tain®** can be provided. We believe that the operational adjustments and accommodations that dairy farmers will need to make to effectively use **Re-Tain®** and avoid the potential problems described below under **PART II: OTHER INFORMATION ITEM 1A – RISK FACTORS**, "Product Risks", to this Quarterly Report will not be so burdensome as to deter its adoption and usage. Our overarching objective is to minimize the risk of early-stage unsatisfactory outcomes that could harm the longer-term prospects and market acceptance of **Re-Tain®**. This strategic choice means that we have elected not to pursue an alternative strategy that might have maximized short-term, initial sales quickly through a mass market approach where we provide product to distribution and let them sell it to as many farms as possible. While we are dedicated to increasing our sales revenue, we must consider the damage a premature mass market strategy could cause to the long-term value of the product. We have seen products sold by much larger companies that were substantially damaged by such failed market launch strategies. The goal of these prudent steps is to create a smooth and successful launch with the momentum to optimize product sales over the longer period, while safeguarding the longer-term performance of our investment in **Re-Tain®**. Secondarily, this strategy also reduces the amount of inventory that we would need to build at risk before regulatory approvals of the product and our production facilities are achieved, and it reduces the amount of cash we would need to spend to purchase inventory from our contract manufacturer before our in-house aseptic filling services are approved by the FDA.

It is difficult to accurately estimate the potential size of the market for the treatment of subclinical mastitis because presently this disease is largely left untreated. We believe that approximately 20% to 40% of the U.S. dairy herd is infected with subclinical mastitis at any given time, although not all of these animals would qualify for treatment depending on the nature of their infection. This compares to approximately 2% of the U.S. herd that is thought to be infected with clinical mastitis, where approximately $60 million per year is spent on drug treatments. Finding candidate cows will require farms to obtain monthly individual cow somatic cell count (SCC) data through participation in organizations such as the National Dairy Herd Improvement Association (DHIA) or by installing monitors to indicate high SCC cows or a potential health event. DHIA testing can provide this data monthly, and emerging technology can provide this data real-time. Testing results at an elevated level could indicate a good treatment candidate. Likewise, testing results showing a reduced level after treatment could indicate a treatment success. To reach the portion of the market that does not have access to this data presently, we would need to show new customers that the benefit of using our product is worth the roughly $2.00 per cow per month test cost. Similar market opportunities are likely to exist outside the United States, but a milk discard may be required in some or all of these territories. We believe the use of **Re-Tain®** could be expanded, with additional data and regulatory approval, to support treatment late in lactation and possibly for clinical stage mastitis. We also believe there may be a market for **Re-Tain®** in small ruminants (such as goats and sheep) where the majority of mastitis cases are caused by strep-like organisms aligned with our effectiveness data.

We expect the Drug Substance production facility that we constructed for approximately $20.8 million to have initial annual production capacity sufficient to meet at least $10 million in sales of **Re-Tain**® at current production yields. This production capacity estimate does not yet reflect any inventory build strategies or ongoing yield improvement initiatives. Expansion of the estimated annual capacity of the Drug Substance facility beyond approximately $10 million (without factoring in potential yield improvements) would require relocation of the Drug Product formulation and aseptic filling module to another facility, or the acquisition and equipping of other Drug Substance production facilities or adopting alternative manufacturing strategies.

As disclosed in previously filed reports, we have made preliminary assessments and estimates relating to the market opportunity for **Re-Tain**®, both during and after its initial launch, and have described the principal challenges facing the launch of a new product by a company such as ours with limited sales, marketing and financial resources into a competitive market populated with several global pharmaceutical enterprises. We expect annual sales to be well below the $36 million level that we previously estimated as the potential of the market opportunity for our product five years after product launch. This is because we are taking a more controlled launch approach, respecting the challenges of introducing a paradigm changing technology. We are going to be very transparent with the launch of **Re-Tain**®. To that end, we have expanded Note 17, "Segment Information", to the accompanying unaudited financial statements to now display a break-out of our financial results among the following three components of our business: i) Scours, ii) Mastitis and iii) Other. This will allow investors to see our progress as we develop both product categories. We generally do not provide financial projections, as we know such projections can prove to be materially inaccurate. However, in this case, we are providing a high-level projection for **Re-Tain**® that under this controlled launch plan strategy, we think we can achieve sales of approximately $1 million during the first year on the market and then about double that during the second year on the market. If we are successful with this launch strategy, we would aim to pivot to a mass market sales approach with our distributors and grow this curve after the first 18 to 24 months on the market. Actual sales results will vary from these projections up or down. We believe this strategy lends itself to a more gradual adoption curve but higher and more sustainable sales over the long-term.

Administrative Expenses

During the three-month period ended September 30, 2022, administrative expenses increased by 5%, or approximately $23,000, to $466,000 in comparison to $444,000 during the three-month period ended September 30, 2021. Administrative expenses included approximately $44,000 and $35,000 of non-cash depreciation and stock-based compensation expenses during the three-month periods ended September 30, 2022 and 2021, respectively. During the nine-month period ended September 30, 2022, administrative expenses increased by 30%, or approximately $389,000, to $1.7 million in comparison to $1.3 million during the nine-month period ended September 30, 2021. The increase in administrative expenses during the nine-month period ended September 30, 2022 compared to the nine-month period ended September 30, 2021 was largely the result of the accrual of approximately $222,000 in deferred compensation expense (consisting of earned and unused paid time off) during the first quarter of 2022. Administrative expenses included approximately $110,000 and $90,000 of non-cash depreciation and stock-based compensation expenses during the nine-month periods ended September 30, 2022 and 2021, 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. Given the growth in our business, our administrative staff has increased to four talented individuals reporting to our CEO. 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. Given travel restrictions related to the COVID-19 pandemic, this initiative has pivoted to a virtual meeting format, which is less expensive. Having experienced this efficiency, it is our intent to continue with the same strategy, for the most part, even as travel restrictions continue to be reduced. 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. We believe these efforts have helped us access the capital markets to fund our growth objectives. Considering inflation and all the necessary support services that fit into this category, we believe that approximately $2 million per year is an efficient budget goal to fund the administrative expenses of a publicly-held company.

Net Operating (Loss) Income

During the three-month period ended September 30, 2022, our net operating (loss) of ($617,000) was in contrast to net operating income of $271,000 during the three-month period ended September 30, 2021. The $573,000 decrease in gross margin during the third quarter of 2022, compared to the third quarter of 2021, was the largest contributor to this swing from income to loss. During the nine-month period ended September 30, 2022, our net operating (loss) of ($665,000) was in contrast to net operating income of $112,000 during the nine-month period ended September 30, 2021. The $1.3 million increase in operating expenses was offset, in part, by a $561,000 increase in gross margin.

Other Expenses, net

During the three-month period ended September 30, 2022 other expenses, net, aggregated $34,000 in comparison to other

expenses, net, of $115,000 during the three-month period ended September 30, 2021. Interest expense increased to $89,000 during the three-month period ended September 30, 2022 from $79,000 during the three-month period ended September 30, 2021. Non-cash amortization of debt issuance costs (which is included as a component of interest expense) was $2,000 during both of the three-month periods ended September 30, 2022 and 2021. Interest income was $55,000 and $6,000 during the three-month periods ended September 30, 2022 and 2021, respectively. More interest income was earned during 2022 largely because of the higher interest rate environment.

During the nine-month period ended September 30, 2022 other expenses, net, aggregated $155,000 in comparison to other expenses, net, of $256,000 during the nine-month period ended September 30, 2021. Interest expense increased to $255,000 during the nine-month period ended September 30, 2022 from $238,000 during the nine-month period ended September 30, 2021. Non-cash amortization of debt issuance costs (which is included as a component of interest expense) was $6,000 during both of the nine-month periods ended September 30, 2022 and 2021. We anticipate that our interest expense will be approximately $339,000, $352,000 and $323,000 during the years ending December 31, 2022, 2023 and 2024, respectively. Interest income was $88,000 and $14,000 during the nine-month periods ended September 30, 2022 and 2021, respectively. More interest income was earned during 2022 largely because we had more cash on hand during most of the first nine months of 2022 compared to the first nine months of 2021 during a higher interest rate environment. Proceeds from the sale of property, plant and equipment were $11,000 and $14,000 during the nine-month periods ended September 30, 2022 and 2021, respectively.

(Loss) Income Before Income Taxes

During the three-month period ended September 30, 2022, our (loss) before income taxes was ($651,000) in contrast to income before income taxes of $156,000 during the three-month period ended September 30, 2021. During the nine-month period ended September 30, 2022, our (loss) before income taxes was ($820,000) in comparison to a (loss) before income taxes of ($144,000) during the nine-month period ended September 30, 2021.

Income Taxes and Net (Loss) Income

During the three-month periods ended September 30, 2022 and 2021, we recorded income tax expense of $4,000 and $8,000, respectively, which is comprised of minimum state tax liabilities. During the nine-month periods ended September 30, 2022 and 2021, we recorded income tax expense of $6,000 and $8,000, respectively, which is comprised of minimum state tax liabilities. Our net (loss) of ($655,000), or ($0.08) per basic share, during the three-month period ended September 30, 2022 was in contrast to a net income of $148,000, or $0.02 per diluted share, during the three-month period ended September 30, 2021. Our net (loss) of ($826,000), or ($0.11) per basic share, during the nine-month period ended September 30, 2022 was in comparison to a net (loss) of ($152,000), or ($0.02) per basic share, during the nine-month period ended September 30, 2021.

We have substantial net operating loss carryforwards that largely offset our income tax expense. For tax return purposes only, our depreciation expense for the Nisin Drug Substance production facility and equipment was approximately $492,000, $464,000, $639,000, $9.2 million and $1.5 million for the years ended December 31, 2021, 2020, 2019, 2018 and 2017, respectively. The significant increase during 2018 was largely related to accelerated depreciation allowed for tax purposes. As of December 31, 2021, our federal net operating loss carryforward was approximately $14.7 million, which will be available to offset future taxable income, subject to possible annual limitations based on ownership changes. 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, we are not recognizing the benefit of our tax losses.

In addition to the results discussed above 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, 2022 have been taken into consideration in preparing the financial statements. The preparation of financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, income taxes, contingencies and the useful lives and carrying values of intangible and long-lived assets. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the

basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have chosen to highlight certain policies that we consider critical to the operations of our business and understanding our financial statements.

We sell products that provide **Immediate Immunity™** to newborn dairy and beef cattle. We recognize revenue in accordance with the five step model in ASC 606. These include 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. Inventory is a critical accounting policy because of the estimates and assumptions used by management to determine its cost accounting and because of the variability of the cost per dose due to fluctuations in the biological yield.

ITEM 3 — QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Inflation, interest rates and currency exchange rates are having a more adverse effect on our revenues and expenses than we previously experienced. 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 (which is generally set in U.S. dollars) to international customers is affected by currency fluctuations. The stronger U.S. dollar makes our products more costly for international customers. Conversely, the decline of the U.S. dollar against other currencies could make our products less expensive to international customers. We had outstanding bank debt totaling approximately $10.5 million as of September 30, 2022 (including two State of Maine loans aggregating $900,000) that bears interest at the blended fixed rate of 3.65% per annum. See Note 10 to the accompanying unaudited financial statements for more details about our debt.

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, 2022. 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 not effective as of September 30, 2022. 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.

Material Weaknesses in Internal Controls over Financial Reporting: Management assesses the effectiveness of the Company's internal control over financial reporting at the end of each quarter. Based on this assessment, we have concluded that our internal control over financial reporting was not effective as of September 30, 2022, June 30, 2022 and March 31, 2022, because during our assessment for the third quarter of 2022, we identified one material weakness related to the first and second quarters of 2022 and a second one related to the third quarter of 2022, which have not yet been remediated. First, we did not accrue approximately $222,000 of deferred compensation expense (consisting of earned and unused paid time off), which impacted the amount of our administrative expenses, accrued expenses and the related disclosures. Second, we did not properly account for the extension of our lease agreement at 175 Industrial Way, which would have understated the value of our operating lease right-of-use asset and operating lease liability by approximately $1,200,000 if the error had not been detected before we issued our Quarterly Report on Form 10-Q for the three-month and nine-month periods ended September 30, 2022. These errors had no impact on our product sales or cash position. We do believe that the design of our internal controls is effective, but those internal controls were not effectively operating. We are implementing some changes to our internal controls over financial reporting, including documenting the accounting for all contractual obligations in excess of $50,000 in written memorandums in consultation with our external consultants as considered necessary and then communicated with our independent registered public accounting firm quarterly. We are working to remediate these material weaknesses in internal controls during the fourth quarter of 2022.

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, 2022 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

Financial Risks

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 approaching 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 for **Re-Tain®**. Many factors discussed in this report (including inflation and the COVID-related and other cost increases, supply-chain disruptions and the rising price of oil and other commodities and supplies) impact our costs of goods sold. There is a risk (which was experienced during the third quarter of 2022) that we are not able to achieve our gross margin goals, which would adversely affect our operating results and could impact our future operating plans. There is a risk that our plans to maintain or improve our gross margin may not be realized due to cost increases, inability to raise our selling prices, or both.

Exposure to interest rates and debt service obligations: 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, but materially and adversely, affect our business. We removed the direct aspect of this particular exposure to our business by refinancing our bank debt with fixed rate notes at 3.50% per annum during the first quarter of 2020. The $2 million in additional mortgage debt we secured during the first quarter of 2022 bears interest at the fixed rate of 3.58% per annum. The two State of Maine loans aggregating $900,000 bear interest at the fixed rate of 5% per annum. The additional debt we incurred to fund our growth objectives has significantly increased our total debt service costs. We are obligated to make principal and interest payments aggregating approximately $1.2 million during the year ending December 31, 2022 and approximately $1.4 million during the year ending December 31, 2023. See Note 10 to the accompanying unaudited financial statements for more details about our debt. A decline in sales or gross margin, coupled with this debt service burden, could impair our ability to fund our capital and operating needs and objectives.

Debt covenants: Our bank debt is subject to certain financial covenants. We are required to meet a minimum debt service coverage (DSC) ratio of 1.35, which is measured annually. Our actual DSC ratios were 2.68 and 2.03 for the years ended December

31, 2021 and 2020, respectively. However, based on current projections of our future financial performance, which includes a high level of ongoing product development expenses to support **Re-Tain®**, we may not satisfy this annual requirement for the year ending December 31, 2022, and there can be no assurance that we can exceed that required level in subsequent years. By negotiation with the bank in connection with a mortgage debt financing during the first quarter of 2022, the required minimum DSC ratio was reduced to 1.0 for the year ending December 31, 2022. If we are unable to achieve the required 1.35 DSC ratio, or reach agreement with our bank to another amendment to that requirement, we would be in violation of that covenant, which could result in unfavorable amendments to the terms of our bank debt.

Inflation: Inflation is having a material and adverse impact on almost all supplies we purchase and labor we hire and retain. Continuing or increasing inflationary trends could materially reduce our gross margin on product sales if we are unable or unwilling to impose offsetting price increases on our customers. According to the Consumer Price Index for All Urban Consumers (CPI-U) during the twelve-month period ended September 30, 2022, the all items index increased 8.2% before seasonal adjustment.

Projection of net (loss) income: Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Weaker than expected sales of the **First Defense®** product line could lead to less profits or deeper operating losses. The timing of FDA approval of **Re-Tain®** will have a material impact on our net (loss) income until sufficient commercial sales are generated and sustained.

*Risks associated with our funding strategy for **Re-Tain®**:* The inability to maintain adequate cash and liquidity to support the commercialization of **Re-Tain®** is a risk to our business. Achieving FDA approval of our pharmaceutical-grade Nisin produced at commercial-scale is the most critical action remaining in front of us on our path to U.S. regulatory approval of **Re-Tain®**. 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 until commercialization. Absent sufficient sales of **Re-Tain®** at a profitable gross margin, we would be required to fund all debt service costs from available cash and 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®**, involves more uncertainties than do 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®** include the product's effectiveness against currently prevalent pathogens, market acceptance, the effect of a premium selling price on market penetration, cost of manufacture, competition from new and existing products sold by substantially larger competitors with greater market reach and promotional resources and other risks described under "Product Risks" – "Sales risks pertaining to **Re-Tain®**" below. Since **Re-Tain®** 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. We believe that polypeptide antimicrobial technology may be viewed positively (relative to traditional antibiotics). If realized, this may offset some of these risks and result in better overall market acceptance.

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 actual and projected profitability in the future. We will continue to assess the need for the valuation allowance each quarter.

Product Risks

Product risks generally: We set objectives for our products that we believe we can achieve, but the achievement of such goals is not a certainty. 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 lower margins and/or an order backlog that could adversely affect our customer relationships and operating results. **First Defense®** is sold, and we expect **Re-Tain®** to be sold, at significant price premiums relative to competitive products. There is no assurance that we will continue to achieve market acceptance of the **First Defense®** product line, or achieve and sustain market acceptance of **Re-Tain®**, 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. As we bring **Re-Tain®** to market, these risks could be heightened by the additional uncertainties associated with introducing a new product requiring a shift in customer behavior.

*Sales risks pertaining to **Re-Tain®**:* Actual or prospective **Re-Tain®** customers may decide to discontinue, reduce or avoid usage of **Re-Tain®** due to the following risks:

1) A rejection of a tank of milk by a positive milk inhibitor test because too much of the milk in a bulk tank is comprised of milk from cows being treated with **Re-Tain®**, when tested randomly for inhibitors by a milk hauler.

2) A failed or stalled cheese tank occurs when our recommended on-farm limit of 3% to 5% of milk from cows being treated with **Re-Tain®** is exceeded or not effectively diluted through the milk transportation and collection system, if a cheese starter culture is used that is susceptible to Nisin.

3) Producers' current practice generally is to treat only clinical mastitis, which has the visual indicator of abnormal milk. In order to gain market penetration for **Re-Tain®**, 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. Users of **Re-Tain®** could have unsatisfactory treatment outcomes if they lack the equipment needed to measure and monitor somatic cell counts (SCC) of the herd or individual cows (for which data is needed). This risk limits our access to treatment cows because about 40% of farms do not presently access this kind of testing at the cow level, and thus are not good candidates for the use of **Re-Tain®**.

4) Lower than anticipated treatment cure rates could be experienced because the product is administered to cows that we would not identify as the best treatment candidates based on SCC data.

5) Lower than anticipated treatment cure rates could be experienced because the product is administered to cows that are infected with pathogens outside of our label claims.

6) Off-label use of our product in cows infected with clinical mastitis before we have run the required studies and achieved a label claim extension for this disease state, resulting in negative treatment outcomes.

7) Producers either do not choose to use it or might use it improperly, rather than follow our label instructions to administer one dose after each of three consecutive milkings, or they may limit use within the herd in an abundance of caution to avoid the negative outcomes described above.

*Reliance on sales of the **First Defense®** product line:* We are 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 years ended December 31, 2012, 2013, 2015 and 2016, during the nine-month periods ended September 30, 2017 or during the three-month periods ended March 31, 2019, December 31, 2020, June 30, 2021, September 30, 2021, December 31, 2021 and March 31, 2022 without the gross margin that we earned on sales of the **First Defense®** product line.

Concentration of sales: Sales of the **First Defense®** product line aggregated 99% and 98% of our total product sales during the nine-month periods ended September 30, 2022 and 2021, respectively. Our primary customers for the majority of our product sales (91% and 88% during the nine-month periods ended September 30, 2022 and 2021, 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 9% and 12% of our total product sales during the nine-month periods ended September 30, 2022 and 2021, respectively. Sales of the **First Defense®** product line aggregated 98% of our total product sales during both of the years ended December 31, 2021 and 2020. Our primary customers for the majority of our product sales (86% and 89% during the years ended December 31, 2021 and 2020, 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 14% and 11% of our total product sales during the years ended December 31, 2021 and 2020, respectively. The concentration of our sales from one product into just two markets (the dairy and beef markets) 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 (72% and 74% during the nine-month periods ended September 30, 2022 and 2021, respectively, and 73% and 71% during the years ended December 31, 2021 and 2020, respectively) was made to two large distributors. A large portion of our trade accounts receivable (75% and 72% as of September 30, 2022 and December 31, 2021, 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.

Production capacity constraints: We invested approximately $3.7 million from 2019 to the first quarter of 2022 to increase our production capacity (in terms of annual sales dollars) for the **First Defense®** product line from approximately $16.5 million to approximately $23 million based on current selling prices and estimated production yields. During the fourth quarter of 2021, we reached this new, higher level of production output on an annualized basis. While this capacity expansion investment has proceeded very close to budget, there is a risk of cost overruns in our ongoing projects and any future production expansions that we may

undertake, and a risk that we will not be able to achieve our production capacity growth objectives on a timely basis, resulting in a continuing or increasing shortfall in supply to the market. The inability to meet market demand for our products is a risk to our business. The historically large backlog of orders, as well as any ongoing order backlog, presents a risk that we could lose customers during this period that are not easily regained thereafter, when our production capacity is expected to meet or exceed sales demand. During 2021, we initiated three additional investments aggregating approximately $4.7 million to increase our annual production capacity for the **First Defense®** product line to approximately $35 million, which we intend to complete by the end of 2022. We are making initial plans and investments to further increase our production capacity in 2024 and after. 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. This review and assessment could identify a need to fund unexpected equipment maintenance or replacement costs.

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.

Regulatory Risks

*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, and we are at risk of an unfavorable outcome from such inspections. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the Reference Standard). Due to the unique nature of the label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product, 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®**:* The commercial introduction of this product in the United States requires us to obtain FDA approval. 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 regulatory development process timeline has been extensive (approximately 15 years from when the product rights were returned to us by a former partner in 2007) and has involved multiple commercial production strategies and multiple submissions of the Chemistry, Manufacturing and Controls (CMC) Technical Section. Most recently, we received an Incomplete Letter from the FDA regarding this CMC Technical Section during the third quarter of 2022. The principal issue remaining is a successful pre-approval re-inspection of our manufacturing facility. We are completing preparations for this re-inspection. Substantive issues that could have caused further significant delays did not appear in the FDA comments. The other comments received (in addition to the comment requiring a successful pre-approval re-inspection) appear not to be substantive and are not related to the safety or efficacy of the product. We expect to make our third submission of the CMC Technical Section as soon as possible in the coming months and do expect to make the submission by the end of the first quarter of 2023, if not sooner. This clarifies the required path to product approval. To reduce the risk associated with this process, we are working with a qualified contract manufacturer (Norbrook) for alignment of the required validations and Drug Product manufacture and have met with the FDA to clarify filing strategy and requirements. Our CMC Technical Section submission will be subject to a statutory six-month review period by the FDA. We believe we can successfully complete the pre-approval re-inspection inside of this time frame. Our efforts continue to be subject to inspection and approval by the FDA. 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 of **Re-Tain®** outside of the United States. Sales in these international territories would also be subject to milk discard and meat withhold restrictions, thereby reducing the competitive advantage of **Re-Tain®** in those territories.

Economic Risks Pertaining to the Dairy and Beef Industries

The industry data referred to below is compiled from USDA databases.

Cattle count: 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, reaching 94,800,000 as of January 1, 2019 before declining to 93,800,000 as of both January 1, 2020 and January 1, 2021 and to 91,900,000 as of January 1, 2022. Reflecting seasonal trends, this figure was equal to 102,000,000, 101,000,000 and 98,800,000 as of July 1, 2020, 2021 and 2022, respectively.

Herd size: Prior to 1957, there were over 20,000,000 cows in the U.S. dairy herd. Prior to 1986, there were over 10,000,000 cows in the U.S. dairy herd. From 1998 through 2021, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 in 2004 to the high of 9,448,000 in 2021. This average declined to 9,403,000 during the first nine months of 2022. A significant decline in the herd size could negatively affect the size of our addressable market.

Milk price and feed costs: 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. 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 the year ended December 31, 2020, this average milk price was equal to $18.16, but it was extremely volatile during the year 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 2020 to $21.04 in June 2020 set an all-time record for variability. The average price for 2021 decreased by 6% to $17.08. This price average increased by 30% to $22.20 during the first ten months of 2022. The annual fluctuations in this milk price level are demonstrated in the following table:

Average Class III Milk Price During the Years 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%
2020	$18.16	7%
2021	$17.08	(6%)

The actual level of milk prices may be less important than its level relative to feed costs. One measure of this relationship is known as the milk-to-feed price ratio, which represents the amount of feed that one pound of milk can buy. An increase in feed costs also has a negative impact on the beef industry. This ratio varies farm-to-farm based on individual operating parameters. Since this ratio reached 3.24 in 2005, it has not exceeded 3.00. This ratio averaged 1.76 for 2021, amounting to a significant decline of 24% from the 2020 average of 2.31. This average has not been lower since 2013. During the first nine months of 2022, this ratio improved by 10% to 1.94. The following table demonstrates the annual volatility and the low values of this ratio recently:

Average Milk-To-Feed Price Ratio During the Years 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	2.25	10%
2020	2.31	3%
2021	1.76	(24%)

Milk cow price: 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 $1,205 during 2019 before increasing to $1,300 during 2020 and to $1,363 during 2021. This price for January, April and July of 2022 increased to an average of $1,553.

Market volatility: 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. 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®** and **Re-Tain®**) into the dairy market.

Small Size of Company

Dependence on key personnel: We are a small company with 71 employees (including 7 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 of these key employees could adversely affect our operations until a qualified replacement is hired and trained, which could be even more challenging in the present very difficult labor market. Our competitive position will be highly influenced by our ability to attract, retain and motivate key scientific, manufacturing, managerial and sales and marketing personnel. With increased manufacturing staffing required to operate our expanded **First Defense®** production capacity and to operate our **Re-Tain®** production facility, we anticipate that our employment level could grow to approximately 80 employees during 2022. The cost of attracting and retaining the needed additional personnel in this current job market and inflationary environment could adversely affect our margins and profitability.

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®**, who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. One example of this outside reliance is Norbrook, our Drug Product (DP) contract manufacturer. Because Norbrook has elected to terminate its supply agreement with us effective as of the end of 2022 (with final deliveries anticipated during the middle of 2023), we are investing approximately $4 million of the additional capital we raised during the first quarter of 2019 to construct and equip our own DP formulation and aseptic filling capability for **Re-Tain®** inside our existing Drug Substance facility. We face the risk of potential supply interruption and adverse effects on the market launch of **Re-Tain®** if we do not effectively manage the end of the DP supply provided from our contract manufacturer for orders scheduled for delivery during the middle of 2023 to align with the new supply from our own formulation and aseptic filling facility, which we currently expect to be operational during the third quarter of 2024. 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. 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 or that such approval is delayed or requires significant additional expenditures to obtain.

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®**, 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 **Re-Tain®**, 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 which 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.

Global Risks

Impact of global COVID-19 pandemic and Russia's unprovoked military invasion of Ukraine: We are facing significant production constraints, supply disruptions and inflationary increases which appear to have been caused, in large part directly or indirectly, by the pandemic and Russia's unprovoked military invasion of Ukraine. The extent and duration of the negative impact of the pandemic on the economics of our customers and on the demand for our products going forward are very difficult to assess. 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. The Class III milk price has been extremely volatile during the pandemic. 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 have improved somewhat, but this volatility remains a concern. Additionally, like most input costs, the cost of grain and other feed is rising, which puts a strain on the profitability of our customers. 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. 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. The pandemic has created risk, and continues to create uncertainty and challenges for us. The emergence of the Delta and Omicron variants and the resulting rising number of positive cases during the latter part of 2021 and into 2022 has been a more recent concern. The pandemic has created or contributed to global supply-chain disruptions and has affected international trade, while creating a worldwide health and economic crisis. While presently there are some indications that suggest the situation may be improving, the full impact of this viral outbreak on the global economy, and the duration of such impact, remains very

uncertain at this time. Stock market valuations have declined and recovered somewhat and remain very volatile. Inflation has increased significantly, and tax rates may increase. 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. A combination of the 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 **First Defense®** product line, the demand for our products in the U.S. market and our ability to penetrate or maintain a profitable presence in international markets. We are experiencing shortages in key components and needed products, backlogs and production slowdowns due to difficulties accessing needed supplies and labor and other restrictions which increase our costs and affect our ability to consistently deliver our products to market in a timely manner. 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 qualifying alternate suppliers and components and by our early and continued compliance with recommended hygiene. Despite our best efforts and intentions, there is a risk that an employee could become infected and could infect others. Russia's unprovoked military invasion of Ukraine and attack on its people is having a significant negative impact on the world economy, worsening trends that were already moving in an unfavorable direction. Among other exposures, the increasing price of oil is already impacting our transportation-related expenses materially, and we expect this supply stress to increase the cost of petroleum-based products that we purchase (mostly plastics).

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.

Risks Pertaining to Common Stock

Stock market valuation and liquidity: Our common stock trades on The Nasdaq Stock Market (Nasdaq: ICCC). Our average daily trading volume (which was approximately 8,237 shares per day during the twenty-day period ended November 3, 2022) is lower, our bid/ask stock price spread can be larger and our share price can be more volatile than what other companies experience, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire. Our share price as of November 3, 2022 was $7.875. Most companies in the animal health sector have market capitalization values that greatly exceed our current market capitalization of approximately $61 million as of November 3, 2022. Our product sales during the trailing twelve-month period ended September 30, 2022 were $20 million. This means that our market valuation as of November 3, 2022 was equal to approximately three times our sales during the trailing twelve-month period ended September 30, 2022. 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 product under development and may therefore be negatively affected by the related uncertainties and risks.

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.

No expectation to pay any dividends or repurchase stock for the foreseeable future: We do not anticipate paying any dividends to, or repurchasing stock from, our stockholders for the foreseeable future. Instead, we expect to use cash to fund product development costs and investments in our 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 to access the capital markets again 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.

Other Risks

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, we are experiencing 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 currently dependent on one manufacturer for the supply of the syringes used for our gel tube formats of **Dual-Force First Defense®** and **Tri-Shield®**. We are actively investigating a second supplier. We will be dependent on one other manufacturer for the supply of syringes for **Re-Tain®**. We are dependent on a contract with Norbrook for the Drug Product formulation and aseptic filling of our Nisin Drug Product for orders scheduled for delivery during the middle of 2023. We expect to achieve the required regulatory approval for use by the third quarter of 2024. The facility we are constructing 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 issues or non-compliance) would adversely affect the production of inventory and result in significant added expenses and potential loss of future sales.

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 trade secrets, operational safeguards and contractual agreements. Reliance upon trade secret, rather than patent, protection may cause us to be vulnerable to competitors who successfully replicate (knock off) 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 to us. 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. Russia's unprovoked military invasion of Ukraine may elevate the risk of such cyberattacks. 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. While this exposure is common to all companies, larger companies with greater resources may be better able to mitigate this risk than we can.

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

None

ITEM 3 - DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4 - MINE SAFETY DISCLOSURES

None

ITEM 5 - OTHER INFORMATION

None

ITEM 6 – EXHIBITS

Exhibit 10	Third Amended and Restated Incentive Compensation Agreement between the Company and Elizabeth L. Williams dated as of November 11, 2022.
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-the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File-the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 21, 2022

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