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 June 30, 2024

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	The Nasdaq Capital Market

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 August 2, 2024 was 7,833,080.

ImmuCell Corporation

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

	As of June 30, 2024	As of December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$1,324,285	$978,741
Trade accounts receivable	1,950,450	2,185,383
Inventory	7,299,606	7,811,841
Prepaid expenses and other current assets	219,571	493,885
Total current assets	10,793,912	11,469,850
Property, plant and equipment, net	26,397,059	27,575,683
Operating lease right-of-use asset	4,502,595	4,571,149
Goodwill	95,557	95,557
Intangible assets, net	28,656	38,208
Other assets	37,679	57,655
TOTAL ASSETS	$41,855,458	$43,808,102
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of debt obligations	$1,461,216	$1,428,807
Current portion of operating lease liability	533,315	644,276
Accounts payable and accrued expenses	2,562,571	2,124,337
Total current liabilities	4,557,102	4,197,420
LONG-TERM LIABILITIES:		
Debt obligations, net of current portion	9,798,247	10,540,496
Operating lease liability, net of current portion	4,044,646	4,077,109
Total long-term liabilities	13,842,893	14,617,605
TOTAL LIABILITIES	18,399,995	18,815,025
CONTINGENT LIABILITIES AND COMMITMENTS (See Note 11)		
STOCKHOLDER' EQUITY:		
Common stock, $0.10 par value per share, 15,000,000 and 15,000,000 shares authorized, 7,896,381 and 7,814,165 shares issued and 7,833,080 and 7,750,864 shares outstanding, as of June 30, 2024 and December 31, 2023, respectively.	789,639	781,417
Additional paid-in capital	36,780,897	36,357,239
Accumulated deficit	(13,976,591)	(12,007,097)
Treasury stock, at cost, 63,301 shares as of both June 30, 2024 and December 31, 2023	(138,482)	(138,482)
TOTAL STOCKHOLDERS' EQUITY	23,455,463	24,993,077
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$41,855,458	$43,808,102

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

ImmuCell Corporation
STATEMENTS OF OPERATIONS
(Unaudited)

	During the Three-Month Periods Ended June 30,		During the Six-Month Periods Ended June 30,	
	2024	**2023**	**2024**	**2023**
Product sales	$5,472,890	$3,532,681	$12,730,467	$6,979,207
Costs of goods sold	4,242,404	2,488,793	9,204,622	5,634,544
Gross margin	1,230,486	1,043,888	3,525,845	1,344,663
Product development expenses	1,030,502	1,099,538	2,293,053	2,209,907
Sales and marketing expenses	984,957	719,789	1,785,880	1,599,216
Administrative expenses	601,634	529,056	1,133,572	1,096,074
Operating expenses	2,617,093	2,348,383	5,212,505	4,905,197
NET OPERATING LOSS	(1,386,607)	(1,304,495)	(1,686,660)	(3,560,534)
Other expenses, net	143,679	73,694	280,154	131,183
LOSS BEFORE INCOME TAXES	(1,530,286)	(1,378,189)	(1,966,814)	(3,691,717)
Income tax expense	1,340	1,525	2,680	3,050
NET LOSS	($1,531,626)	($1,379,714)	($1,969,494)	($3,694,767)
Basic weighted average common shares outstanding	7,810,037	7,746,864	7,780,450	7,746,864
Basic net loss per share	($0.20)	($0.18)	($0.25)	($0.48)
Diluted weighted average common shares outstanding	7,810,037	7,746,864	7,780,450	7,746,864
Diluted net loss per share	($0.20)	($0.18)	($0.25)	($0.48)

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 June 30, 2024:							
BALANCE,							
March 31, 2024	7,814,165	$781,417	$36,438,349	($12,444,965)	63,301	($138,482)	$24,636,319
Net loss	—	—	—	(1,531,626)	—	—	(1,531,626)
At-The-Market Offering of common stock, net of $164,802 of offering costs	82,216	8,222	244,527	—	—	—	252,749
Stock-based compensation	—	—	98,021	—	—	—	98,021
BALANCE,							
June 30, 2024	7,896,381	$789,639	$36,780,897	($13,976,591)	63,301	($138,482)	$23,455,463
During the Three-Month Period Ended June 30, 2023:							
BALANCE,							
March 31, 2023	7,814,165	$781,417	$36,074,480	($8,547,552)	67,301	($147,233)	$28,161,112
Net loss	—	—	—	(1,379,714)	—	—	(1,379,714)
Stock-based compensation	—	—	75,657	—	—	—	75,657
BALANCE,							
June 30, 2023	7,814,165	$781,417	$36,150,137	($9,927,266)	67,301	($147,233)	$26,857,055
During the Six-Month Period Ended June 30, 2024:							
BALANCE,							
December 31, 2023	7,814,165	$781,417	$36,357,239	($12,007,097)	63,301	($138,482)	$24,993,077
Net loss	—	—	—	(1,969,494)	—	—	(1,969,494)
At-The-Market Offering of common stock, net of $164,802 of offering costs	82,216	8,222	244,527	—	—	—	252,749
Stock-based compensation	—	—	179,131	—	—	—	179,131
BALANCE,							
June 30, 2024	7,896,381	$789,639	$36,780,897	($13,976,591)	63,301	($138,482)	$23,455,463
During the Six-Month Period Ended June 30, 2023:							
BALANCE,							
December 31, 2022	7,814,165	$781,417	$35,978,364	($6,232,499)	67,301	($147,233)	$30,380,049
Net loss	—	—	—	(3,694,767)	—		(3,694,767)
Stock-based compensation	—	—	171,773	—	—	—	171,773
BALANCE,							
June 30, 2023	7,814,165	$781,417	$36,150,137	($9,927,266)	67,301	($147,233)	$26,857,055

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

ImmuCell Corporation
STATEMENTS OF CASH FLOWS
(Unaudited)

	During the Six-Month Periods Ended June 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	($1,969,494)	($3,694,767)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation	1,328,659	1,332,153
Amortization of intangible assets	9,552	9,552
Amortization of debt issuance costs	10,608	3,838
Amortization of debt discounts	10,446	—
Stock-based compensation	179,131	171,773
Loss on disposal of property, plant and equipment	14,557	8,167
Non-cash rent (benefit) expense	(74,871)	28,901
Changes in:		
Trade accounts receivable	234,933	259,752
Inventory	512,235	(1,497,442)
Prepaid expenses and other current assets	274,314	(50,325)
Other assets	19,976	(5,831)
Accounts payable and accrued expenses	450,239	(9,182)
Net cash provided by (used for) operating activities	1,000,285	(3,443,411)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(181,097)	(1,390,654)
Proceeds from sale of property, plant and equipment	4,500	91
Net cash used for investing activities	(176,597)	(1,390,563)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from At-The-Market Offering, net	252,749	—
Proceeds from line of credit	—	1,000,000
Debt principal repayments	(725,856)	(503,277)
Payments of debt issuance costs	(5,037)	—
Net cash (used for) provided by financing activities	(478,144)	496,723
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	345,544	(4,337,251)
BEGINNING CASH AND CASH EQUIVALENTS	978,741	5,791,562
ENDING CASH AND CASH EQUIVALENTS	$1,324,285	$1,454,311

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 Six-Month Periods Ended June 30,	
	2024	**2023**
CASH PAID FOR:		
Income taxes	$5,905	$7,205
Interest expense	$270,068	$176,451
NON-CASH ACTIVITIES:		
Decrease (increase) in capital expenditures included in accounts payable and accrued expenses	$12,005	($58,835)
(Decrease) increase in operating lease right-of-use asset and operating lease liability	($17,012)	$2,090,298

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 an initial public offering of common stock. We are an animal health company whose purpose is to create scientifically proven and practical products that improve the health and productivity of dairy and beef cattle. We focus on the two most critical stages of dairy productivity, those being the first 30 days of life and the first 30 days of lactation. Our concentrated colostrum and purified Nisin technologies offer unique animal health solutions during these periods when immunity is at its most vulnerable. 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. A combination of the conditions, trends and concerns related to or arising from 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. We are experiencing price increases in key components, supportive services, transportation and other supplies that are causing our costs of goods sold to increase. We have historically experienced some contamination events in our production process, as disclosed previously. We implemented a production slowdown during 2023 to remediate this problem, which led to the recognition of lower sales and gross margin.

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. We hold no cash or 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

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 and other relevant factors. 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. It was not necessary to charge interest on past due accounts during the six-month periods ended June 30, 2024 or 2023 because the time past due was not significant, and there was no accrual for such interest charges as of June 30, 2024 or December 31, 2023. Accounts receivable are written off when deemed uncollectible. No accounts receivable were written off during the six-month periods ended June 30, 2024 or 2023. Recoveries of accounts receivable previously written off are recorded as income when received. No such recoveries were recorded during the six-month periods ended June 30, 2024 or 2023. As of June 30, 2024 and December 31, 2023, we determined that no allowance for doubtful accounts was necessary. See Note 4.

(d) Inventory

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

Inventories that we consider excess or obsolete are written down to estimated net realizable value. Once inventory is written down and a new cost basis is established, it is not written back up. 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 (DS) for **Re-Tain®** (**Building 33**) 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 DS facility when it was placed in service during the third quarter of 2018. Approximately 86% 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 (**Building 175A**) 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 additional space at 175 Industrial Way (**Building 175B**). As a result, the net book value of these leasehold improvements as of August 31, 2022 is now being depreciated over the remainder of the extended lease term. 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 Notes 2(h) and 7 for additional information.

(f) Operating Leases

We account for our real estate leases using a right-of-use model, which recognizes that at the date of commencement, a lessee has a financial obligation to make lease payments to the lessor for the right to use the underlying asset during the lease term and recognizes a corresponding right-of-use (ROU) asset related to this right. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of the future lease payments over the expected lease term. The ROU asset is also adjusted for any lease prepayments made, lease incentives received and initial direct costs incurred. For operating leases with lease payments that fluctuate over the lease term, the total lease costs are recognized on a straight-line basis over the lease term. Our leases, at times, may include options to extend the term of the lease. When it is reasonably certain that we will exercise the option, we include the impact of the option in the lease term for purposes of determining future lease payments. For all underlying classes of assets, we made an accounting policy election to not recognize assets or liabilities for leases with a term of twelve months or less and to account for all components in a lease arrangement as a single combined lease component. Short-term lease payments are recognized on a straight-line basis. Certain of our lease agreements include variable rent payments, consisting primarily of amounts paid to the lessor based on cost or consumption, such as maintenance and real estate taxes. These costs are recognized in the period in which the obligation is incurred. Because our leases do not specify an implicit rate, we use an incremental borrowing rate based on information available at the lease commencement date to determine the present value of the lease payments. We evaluate our ROU asset for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. See Notes 2(h) and 12 for additional information.

(g) 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. Amounts paid in excess of the fair value of the net assets (including tax attributes) are recorded as goodwill under the acquisition method of accounting. We assess the impairment of intangible assets that have indefinite lives (when applicable) and goodwill (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 in the future. No goodwill impairments were recorded during the six-month periods ended June 30, 2024 or 2023. See Notes 2(h) and 8 for additional information.

(h) 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 six-month periods ended June 30, 2024 or 2023.

(i) 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 June 30, 2024 and December 31, 2023, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, prepaid expenses and other current assets, other assets, accounts payable and accrued expenses 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 six-month periods ended June 30, 2024 and 2023, there were no transfers between levels. As of June 30, 2024 and December 31, 2023, our Level 1 assets measured at fair value by quoted prices in active markets consisted of cash and money market accounts. There were no assets or liabilities measured at fair value on a nonrecurring basis as of June 30, 2024 or December 31, 2023. The carrying values of our cash and money market accounts as of June 30, 2024 or December 31, 2023 approximated their fair market values. Due to inflation and the changing interest rate environment, the carrying values of our fixed rate bank debt as of June 30, 2024 and December 31, 2023 differed from their fair market values. These values are reflected in the following tables:

	As of June 30, 2024			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and money market accounts	$1,324,285	$—	$—	$1,324,285
Liabilities:				
Bank debt	$—	$9,854,011	$—	$9,854,011

	As of December 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and money market accounts	$978,741	$—	$—	$978,741
Liabilities:				
Bank debt	$—	$10,431,817	$—	$10,431,817

(j) 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 June 30,		During the Six-Month Periods Ended June 30,	
	2024	**2023**	**2024**	**2023**
Company A	44%	47%	45%	47%
Company B	33%	33%	34%	32%

Trade accounts receivable due from significant customers that amounted to 10% or more of our total trade accounts receivable are detailed in the following table:

	As of June 30, 2024	As of December 31, 2023
Company A	39%	43%
Company B	38%	36%

(k) Revenue Recognition

We recognize revenue in accordance with Codification Topic 606, *Revenue from Contracts with Customers (ASC 606)*. 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 ships to a customer. 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 information.

(l) 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 or is deemed to be in excess or obsolete.

(m) Income Taxes

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. We 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 it is more likely than not that we will 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 it is more likely than not that we will not 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 2021. We have evaluated the positions taken on our filed tax returns and have concluded that no uncertain tax positions existed as of June 30, 2024 or December 31, 2023. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 16.

(n) Stock-Based Compensation

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model. Accordingly, we recorded compensation expense pertaining to stock-based compensation of $98,021 and $75,657 during the three-month periods ended June 30, 2024 and 2023, respectively, and $179,131 and $171,773 during the six-month periods ended June 30, 2024 and 2023, respectively. See Note 13.

(o) Net Loss Per Common Share

Net loss per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*. The net loss per share has been computed by dividing the net loss by the weighted average number of common shares outstanding during the period. All stock options have been excluded from the denominator in the calculation of dilutive earnings per share when we are in a loss position 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 618,000 and 624,000 during the three-month periods ended June 30, 2024 and 2023, respectively, and 618,000 and 624,000 during the six-month periods ended June 30, 2024 and 2023, respectively.

	During the Three-Month Periods Ended June 30,		During the Six-Month Periods Ended June 30,	
	2024	**2023**	**2024**	**2023**
Net loss attributable to stockholders	($1,531,626)	($1,379,714)	($1,969,494)	($3,694,767)
Weighted average common shares outstanding - Basic	7,810,037	7,746,864	7,780,450	7,746,864
Dilutive impact of share-based compensation awards	—	—	—	—
Weighted average common shares outstanding - Diluted	7,810,037	7,746,864	7,780,450	7,746,864
Net loss per share:				
Basic	($0.20)	($0.18)	($0.25)	($0.48)
Diluted	($0.20)	($0.18)	($0.25)	($0.48)

(p) Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Although we regularly assess these estimates, actual amounts could differ from those estimates 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 valuation of inventory, deferred tax assets and costs of goods sold.

(q) New Accounting Pronouncements Not Yet Adopted

In November of 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant expenses. The amendments will require disclosure of significant segment expenses that are regularly provided to our chief operating decision-maker and included within segment profit and loss. The amendments are effective for annual periods beginning after December 15, 2023, and interim periods beginning after December 15, 2024, with early adoption permitted, and will be applied retrospectively to all prior periods presented in the financial statements. We are currently evaluating ASU 2023-07 to determine its impact on our financial statements.

In December of 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of income tax rate reconciliation categories and income taxes paid by jurisdiction. The amendments are effective for annual periods beginning after December 15, 2024, with early adoption permitted, and may be applied either prospectively or retrospectively. We are currently evaluating ASU 2023-09 to determine its impact on our financial statements.

3. CASH AND CASH EQUIVALENTS

Cash and cash equivalents amounted to $1,324,285 and $978,741 as of June 30, 2024 and December 31, 2023, respectively.

4. TRADE ACCOUNTS RECEIVABLE

Trade accounts receivable amounted to $1,950,450 and $2,185,383 as of June 30, 2024 and December 31, 2023, respectively. No allowance for bad debt or product returns was recorded as of June 30, 2024 or December 31, 2023. We anticipate no future events or conditions that would impact our ability to collect our accounts receivable. Because of the generally short duration from the balance sheet date to the date of collection, our collection rate is not expected to be significantly impacted by events occurring after the balance sheet date. The trade accounts receivable balances included $34,576 and $42,507 due from a related party as of June 30, 2024 and December 31, 2023, respectively. See Note 18.

5. INVENTORY

Inventory consisted of the following:

	As of June 30, 2024	As of December 31, 2023
Raw materials	$1,249,703	$1,594,028
Work-in-process	5,609,045	5,815,194
Finished goods	440,858	402,619
Total	$7,299,606	$7,811,841

These inventory figures are net of write-offs of scrapped inventory in the amounts of $433,122 and $527,133 during the six-month period ended June 30, 2024 and the year ended December 31, 2023, respectively, that resulted principally from contamination events and other production process losses.

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of June 30, 2024	As of December 31, 2023
Prepaid expenses	$196,181	$454,152
Other receivables	23,390	39,733
Total	$219,571	$493,885

7. PROPERTY, PLANT AND EQUIPMENT, net

Property, plant and equipment consisted of the following:

	Estimated Useful Lives (in years)	As of June 30, 2024	As of December 31, 2023
Laboratory and manufacturing equipment	3-10	$21,128,526	$20,953,601
Buildings and improvements	10-39	20,861,288	20,784,565
Office furniture and equipment	3-10	1,038,641	1,036,374
Construction in progress	n/a	2,612,239	2,768,224
Land	n/a	516,867	516,867
Property, plant and equipment, gross		46,157,561	46,059,631
Accumulated depreciation		(19,760,502)	(18,483,948)
Property, plant and equipment, net		$26,397,059	$27,575,683

As of June 30, 2024 and December 31, 2023, 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 $71,162 and $14,380 during the three-month periods ended June 30, 2024 and 2023, respectively, and $71,162 and $56,639 during the six-month periods ended June 30, 2024 and 2023, respectively. Depreciation expense was $666,182 and $680,019 during the three-month periods ended June 30, 2024 and 2023, respectively, and $1,328,659 and $1,332,153 during the six-month periods ended June 30, 2024 and 2023, 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 June 30, 2024 and 2023 and $9,552 during both of the six-month periods ended June 30, 2024 and 2023. The net value of these intangibles was $28,656 and $38,208 as of June 30, 2024 and December 31, 2023, respectively. Intangible asset amortization expense is estimated to be $19,104 per year through December 31, 2025.

Intangible assets as of June 30, 2024 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	$184,100	($156,485)	$27,615
Customer relationships	1,300	(1,105)	195
Non-compete agreements	5,640	(4,794)	846
Total	$191,040	($162,384)	$28,656

Intangible assets as of December 31, 2023 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	$184,100	($147,280)	$36,820
Customer relationships	1,300	(1,040)	260
Non-compete agreements	5,640	(4,512)	1,128
Total	$191,040	($152,832)	$38,208

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of June 30, 2024	As of December 31, 2023
Accounts payable – trade	$436,977	$874,558
Accounts payable – capital	1,170	13,175
Accrued payroll	1,272,813	942,999
Accrued professional fees	78,550	97,800
Accrued other	773,061	192,754
Income tax payable	—	3,051
Total	$2,562,571	$2,124,337

10. BANK DEBT

Loans #1 and #2: During the first quarter of 2020, we closed on a debt financing with Gorham Savings Bank (GSB) aggregating $8,600,000, which 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 proceeds from the 2020 debt refinancing were used to repay all bank debt outstanding at the time of closing and to provide some additional working capital. 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 $3,687,544 and extended the due date of the balloon payment from the first quarter of 2030 to the first quarter of 2032.

Line of Credit (LOC): Also during the first quarter of 2020, GSB extended a $1,000,000 LOC to us that is available, as needed, through September 11, 2025. Interest on borrowings against the LOC is variable at the National Prime Rate per annum. There was no outstanding balance under this LOC as of June 30, 2024 or December 31, 2023.

Loan #3: During the second quarter of 2020, we received a loan from the Maine Technology Institute (MTI) in the aggregate principal amount of $500,000. The first 2.25 years of this loan were interest-free with no interest accrual or required principal payments. Beginning during the fourth quarter of 2022, Loan #3 became subject to quarterly principal and interest payments at a fixed rate of 5% per annum over the final five years of the loan, through the third quarter of 2027 if not repaid before then.

Loan #4: During the fourth quarter of 2020, we closed on a $1,500,000 note with GSB 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. The remaining proceeds were available for general working capital purposes.

Loan #5: On June 30, 2021, we executed definitive agreements covering a second loan from the MTI in the aggregate principal amount of $400,000, proceeds from which were received in July of 2021. The first two 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 5.5 years of the loan, beginning during the third quarter of 2023 and continuing through the fourth quarter of 2028 if not repaid before then.

Loan #6: During the third quarter of 2023, we closed on a $2,000,000 term loan bearing interest at a fixed rate of 7% per annum from GSB. The Finance Authority of Maine (FAME) provided $1,000,000 of loan insurance to GSB. This loan is repayable under a 7-year amortization schedule with a balloon payment of $1,285,060 due during the third quarter of 2026.

Loan #7: Also during the third quarter of 2023, we closed on a $1,000,000 term loan bearing interest at a fixed rate of 8% per annum from FAME. The loan is repayable under a 7-year amortization schedule with a balloon payment of $649,439 due during the third quarter of 2026.

Loans #1, #2, #4, #6 and #7 are secured by liens on substantially all of our assets and are subject to certain restrictions and financial covenants. Loan #7 is subordinated to Loans #1, #2, #4 and #6. Reflecting our poor financial performance during 2023, the debt service covenant (DSC) requirements for the twelve-month periods ended December 31, 2023, June 30, 2024 and September 30, 2024 were waived pre-emptively by our lenders. We are required to meet a minimum DSC ratio of 1.35 for the year ending December 31, 2024 and annually thereafter. In connection with these credit facilities, we incurred aggregate debt issuance and debt discount costs of $173,305 ($5,037 and $0 of which was incurred during the six-month periods ended June 30, 2024 and 2023, respectively). The amortization of these debt issuance and debt discount costs is being recorded as a component of interest expense, included in other expenses, net, and is being amortized on a straight-line basis over the underlying terms of the notes. Loans #3 and #5 are unsecured and subordinated to our indebtedness to GSB and FAME. Failure to make timely payments of principal and interest, or otherwise to comply with the terms of the agreements of Loans #3 and #5, 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 (excluding our $1,000,000 line of credit) are reflected by loan during the periods as described in the tables below:

	During the Three-Month Period Ended June 30, 2024		During the Three-Month Period Ended June 30, 2023	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	$—	$57,148	$—	$55,114
Loan #2	—	127,382	—	122,905
Loan #3	—	23,875	—	22,717
Loan #4	—	53,026	—	51,165
Loan #5	—	16,513	—	—
Loan #6	—	58,143	—	—
Loan #7	—	28,264	—	—
Total	$—	$364,351	$—	$251,901

	During the Six-Month Period Ended June 30, 2024		During the Six-Month Period Ended June 30, 2023	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	$—	$114,346	$—	$110,907
Loan #2	—	253,791	—	245,134
Loan #3	—	47,455	—	45,155
Loan #4	—	105,666	—	102,081
Loan #5	—	32,822	—	—
Loan #6	—	115,613	—	—
Loan #7	—	56,163	—	—
Total	$—	$725,856	$—	$503,277

	During the Year Ended December 31, 2023		During the Year Ended December 31 2022	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	$—	$223,222	$2,000,000	$199,013
Loan #2	—	494,455	—	477,237
Loan #3	—	91,446	—	22,160
Loan #4	—	205,884	—	198,715
Loan #5	—	32,017	—	—
Loan #6	2,000,000	93,054	—	—
Loan #7	1,000,000	45,696	—	—
Total	$3,000,000	$1,185,774	$2,000,000	$897,125

Principal payments (net of debt issuance and debt discount costs) due under bank loans outstanding as of June 30, 2024 (excluding our $1,000,000 line of credit) are reflected in the following table by the year that payments are due:

	During the Six-Month Period Ending December 31,	During the Years Ending December 31,					
	2024	2025	2026	2027	2028	Thereafter	Total
Loan #1	$116,468	$239,876	$248,604	$257,649	$266,537	$4,598,425	$5,727,559
Loan #2	258,326	530,738	549,881	140,445	—	—	1,479,390
Loan #3	48,649	101,001	106,146	83,143	—	—	338,939
Loan #4	107,557	220,994	228,965	240,446	—	—	797,962
Loan #5	33,648	69,856	73,415	77,156	81,086	—	335,161
Loan #6	119,768	253,003	1,418,562	—	—	—	1,791,333
Loan #7	58,265	124,364	715,512	—	—	—	898,141
Subtotal	742,681	1,539,832	3,341,085	798,839	347,623	4,598,425	11,368,485
Debt issuance cost	(11,167)	(21,314)	(13,580)	(5,420)	(3,513)	(11,347)	(66,341)
Debt discount cost	(10,446)	(20,891)	(11,344)	—	—	—	(42,681)
Total	$721,068	$1,497,627	$3,316,161	$793,419	$344,110	$4,587,078	$11,259,463

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 June 30, 2024 or December 31, 2023. 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 recorded no liabilities for such obligations as of June 30, 2024 or December 31, 2023.

We plan to purchase certain key parts (syringes) and services (formulation, aseptic filling and final packaging) pertaining to **Re-Tain®** Drug Product (DP), our Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows, exclusively from contractors. The contract for formulation, aseptic filling and final packaging of DP is scheduled to terminate after the supply of product for our initial controlled market launch. We initiated an investment in the necessary equipment to perform the DP formulation and aseptic filling services in-house, but this investment has been paused at the present time.

Effective March 28, 2022, we entered into an Amended and Restated Separation and Deferred Compensation Agreement (the "Deferred Compensation Agreement") with Mr. Brigham (our President and CEO) that superseded and replaced in its entirety a March 2020 severance agreement between the Company and Mr. Brigham. Upon separation from the Company for any reason, Mr. Brigham's Deferred Compensation Agreement allows Mr. Brigham to be paid, among other amounts, all earned and unused paid time off (which expense totaling $222,379 was accrued during the first quarter of 2022 and $230,162 was included in accounts payable and accrued expenses on the accompanying balance sheets as of both June 30, 2024 and December 31, 2023) and to receive up to an additional $300,000 in deferred compensation (which amount is being accrued over the three-year period ending in January 2025). This deferred compensation payment vested as to $100,000 on January 1, 2023 and an additional $100,000 on January 1, 2024. An

additional $100,000 will vest on January 1, 2025, provided that Mr. Brigham is employed by the Company as of such date. The vested amounts would be paid upon the earlier of January 31, 2025 or within thirty (30) days following his separation from the Company. As of June 30, 2024 and December 31, 2023, $250,000 and $200,000, respectively, was included in accounts payable and accrued expenses on the accompanying balance sheets. 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, in each case as described and defined in the Deferred Compensation Agreement, the Company agrees to pay Mr. Brigham 100% of his then current annual base salary and a lump sum payment equal to the employer portion of the costs of continued health benefits for Mr. Brigham and his covered dependents for a twelve-month period following termination, and certain equity incentive awards granted to Mr. Brigham would continue to vest following such termination in accordance with the terms of the Deferred Compensation Agreement.

Incentive compensation agreements may be entered into with Mr. Brigham, Ms. Brockmann (our Vice President of Sales and Marketing) and Ms. Williams (our Vice President of Manufacturing Operations) which, at times, allow these executives to earn incentive compensation if certain regulatory and financial objectives are met during the year to which the agreement relates, as specified in their agreements. Amounts related to these incentive compensation agreements are accrued over the period they are earned (when it is probable that the amounts will be earned) based on our best estimate of the amounts expected to be earned.

In addition to the commitments discussed above, we had committed $123,000 to increase our production capacity for the **First Defense®** product line, $1,769,000 to the purchase of inventory and $457,000 to other obligations as of June 30, 2024.

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 (**Building 175A**), 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 175 Industrial Way (**Building 175B**), which is connected to the original space, over a 20-year term. The ROU asset and lease liability for the committed space at **Building 175B** was recorded as of April 1, 2023 after construction of the building shell was completed in accordance with the lease agreement. Monthly lease payments commenced as of August 1, 2023. In connection with the lease commitment for space at **Building 175B,** the term of the original lease for **Building 175A** was extended by approximately 13 years. On November 14, 2023 and on June 11, 2024, we amended this lease further to provide for certain tenant improvements on the leased premises to be paid for by our landlord. These improvements will provide heat to an unfinished space, provide additional warehouse space, and create a new primary shipping and receiving facility. In consideration for the landlord agreeing to pay for the cost of those certain tenant improvements, we are obligated to make additional rent payments of $20,000 per month from November of 2023 through December of 2024 and a one-time additional rent payment of $368,743 in January of 2025. Because of these modifications to the lease payments, the ROU asset and lease liability associated with the space at **Building 175B** were remeasured as of the modification dates. Our leases include variable non-lease components. Such payments primarily include common area maintenance charges. As of June 30, 2024, the balance of the operating lease ROU asset was $4,502,595 and the operating lease liability was $4,577,961. As of December 31, 2023, the balance of the operating lease ROU asset was $4,571,149 and the operating lease liability was $4,721,385. 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 June 30,		During the Six-Month Periods Ended June 30,	
	2024	**2023**	**2024**	**2023**
Lease Cost				
Operating lease cost	$106,880	$98,714	$213,759	$146,240
Variable lease cost	19,431	9,720	29,151	17,334
Total lease cost	$126,311	$108,434	$242,910	$163,574
Operating Lease				
Cash paid for operating lease liabilities	$144,315	$30,993	$288,630	$61,734
Weighted average remaining lease term (in years)	18.6	19.6	18.6	19.6
Weighted average discount rate	7.1%	6.3%	7.1%	6.3%

Future lease payments required under non-cancelable operating leases in effect as of June 30, 2024 were as follows:

	Amount
During the six-month period ending December 31, 2024	$288,630
During the years ending December 31,	
2025	711,623
2026	349,744
2027	356,732
2028	363,870
Thereafter	5,949,488
Total lease payments (undiscounted cash flows)	8,020,087
Less: imputed interest (discount effect of cash flows)	(3,442,126)
Total operating liabilities	$4,577,961

13. STOCKHOLDERS' EQUITY

Common Stock Issuances

From February of 2016 to April of 2021, we sold the aggregate of 4,553,017 shares of common stock in six different transactions raising gross proceeds of $26,714,403 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) During February of 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 $5,900,003 and resulting in net proceeds to the Company of $5,313,224 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

2) During October of 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 $3,464,370 and resulting in net proceeds to the Company of $3,160,923 (after deducting placement agent fees and other expenses incurred in connection with the equity financing).

3) During July of 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 $1,034,164 (after deducting expenses incurred in connection with the equity financing).

4) During December of 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 $3,049,991 and resulting in net proceeds to the Company of $2,734,173 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

5) During March of 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 $9,000,002

and resulting in net proceeds to the Company of $8,303,436 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

6) During April of 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 $4,250,038 and resulting in net proceeds of $4,233,026 (after deducting expenses incurred in connection with the equity financing).

7) On April 9, 2024, our shelf registration on Form S-3 (File No. 333-278438) relating to the offer, issuance and sale by the Company of up to $20,000,000 of securities was declared effective by the SEC. Also on April 9, 2024, we entered into an At-The-Market Offering Agreement (ATM Agreement) with Craig-Hallum Capital Group LLC, pursuant to which we may offer and sell up to $11,000,000 of shares of our common stock. As of August 2, 2024, we had sold 82,216 shares pursuant to the ATM Agreement. Legal, accounting and other fees of $152,272 associated with the completion of the shelf registration and the ATM Agreement were initially capitalized and then were offset against the initial proceeds received during the second quarter of 2024. Net proceeds from the at the market offering conducted pursuant to the ATM Agreement (net of the upfront legal, accounting and other fees), less sales commissions of $12,530 were $252,749 through August 2, 2024.

Stock Option Plans

In June of 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 of 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. There were 186,500 and 188,500 options outstanding under the 2010 Plan as of June 30, 2024 and December 31, 2023, respectively.

In June of 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 from 300,000 shares to 650,000 shares was approved by a vote of stockholders at the Annual Meeting of Stockholders in June of 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 of 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 June 30, 2024 and December 31, 2023, there were 431,500 and 430,000 options outstanding under the 2017 Plan, respectively.

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, 2022	202,500	402,500	$7.19	($661,310)
Grants	—	122,000	$5.16	
Terminations/forfeitures[2]	(10,000)	(94,500)	$7.12	
Exercises	(4,000)	—	$4.69	
Outstanding as of December 31, 2023	188,500	430,000	$6.82	($1,071,121)
Grants	—	21,000	$4.30	
Terminations/forfeitures[2]	(2,000)	(19,500)	$7.29	
Exercises	—	—	$—	
Outstanding as of June 30, 2024	186,500	431,500	$6.72	($1,155,451)
Vested as of June 30, 2024	186,500	128,500	$6.87	($637,770)
Vested and expected to vest as of June 30, 2024	186,500	431,500	$6.72	($1,155,451)
Reserved for future grants	—	200,500		

[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).
(2) Terminations and forfeitures are recognized when they occur.

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, 2024	337,500	$3.66	$7.14
Non-vested stock options as of June 30, 2024	303,000	$3.46	$6.56
Stock options granted during the six-month period ended June 30, 2024	21,000	$2.02	$4.30
Stock options that vested during the six-month period ended June 30, 2024	46,000	$4.16	$9.69
Stock options that were terminated or forfeited during the six-month period ended June 30, 2024	21,500	$3.53	$7.29

No stock options were exercised during the three-month or six-month periods ended June 30, 2024 and 2023. The weighted average remaining life of the options outstanding under the 2010 Plan and the 2017 Plan as of June 30, 2024 was approximately 5 years and 3 months. The weighted average remaining life of the options exercisable under these plans as of June 30, 2024 was approximately 3 years. The exercise price of the options outstanding under these plans as of June 30, 2024, ranged from $4.00 to $10.04 per share. The 21,000 stock options granted during the six-month period ended June 30, 2024 had an average exercise price of $4.30 per share. The 108,000 stock options granted during the six-month period ended June 30, 2023 had an average exercise price of $5.19 per share. The weighted-average grant date fair values of options granted during the six-month periods ended June 30, 2024 and 2023 were $2.02 and $2.80 per share, respectively. As of June 30, 2024, total unrecognized stock-based compensation related to non-vested stock options aggregated $446,494 which will be recognized over a weighted average remaining period of approximately 1 year and 8 months. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, for the purpose discussed in Note 2(n), with the following weighted-average assumptions:

	During the Three-Month Periods Ended June 30,		During the Six-Month Periods Ended June 30,	
	2024	2023	2024	2023
Risk-free interest rate(1)	4.24%	3.25%	4.24%	3.48%
Dividend yield(2)	0%	0%	0%	0%
Expected volatility(2)	50%	50%	50%	54%
Expected life(3)	4.7 years	4.9 years	4.8 years	6.2 years

(1) The risk-free interest rate is based on U.S. Treasury yields for a maturity approximating the expected option term.
(2) The dividend yield and expected volatility are derived from averages of our historical data.

(3) The expected life is calculated utilizing the simplified method, which uses the mid-point between the vesting period and the contractual term as the expected life.

Common Stock Rights Plan

In September of 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 Equiniti Trust Company, LLC, 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.

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.

At various times over the years, our Board of Directors, which has the authority to amend the Rights Plan, has voted to authorize amendments to the Rights Plan to extend the expiration date of the Rights Plan. Our Board of Directors decided to seek an advisory vote by stockholders at the Annual Meeting of Stockholders held in June of 2022, as to whether to extend the Rights Plan by one year to September 19, 2023. 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. Our Board of Directors decided to seek another advisory vote by stockholders at the Annual Meeting of Stockholders held in June of 2023, as to whether to extend the Rights Plan by another year to September 19, 2024. Of the votes actually cast on this proposal, 65.10% voted in favor, 34.60% voted against and 0.30% abstained. On the basis of this vote, our Board of Directors voted to extend the Rights Plan by one year to September 19, 2024. Recognizing that there might be a substantial number of broker non-votes, our Board of Directors disclosed that it would be guided by the votes actually cast on these proposals in deciding whether to extend the expiration date of such plan by one year.

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 three-month or six-month periods ended June 30, 2024 or 2023. 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 sheet are from contracts with customers. We incur no material costs to obtain contracts.

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

	During the Three-Month Periods Ended June 30,				During the Six-Month Periods Ended June 30,			
	2024	%	**2023**	%	**2024**	**%**	**2023**	**%**
United States	$4,892,136	89%	$3,254,266	92%	$11,232,777	88%	$6,250,420	90%
Other	580,754	11%	278,415	8%	1,497,690	12%	728,787	10%
Total Product Sales	$5,472,890	100%	$3,532,681	100%	$12,730,467	100%	$6,979,207	100%

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

	During the Three-Month Periods Ended June 30,				During the Six-Month Periods Ended June 30,			
	2024	**%**	**2023**	**%**	**2024**	**%**	**2023**	**%**
First Defense® product line	$5,430,069	99%	$3,482,259	99%	$12,650,710	99%	$6,893,491	99%
Other animal health	42,821	1%	50,422	1%	79,757	1%	85,716	1%
Total Product Sales	$5,472,890	100%	$3,532,681	100%	$12,730,467	100%	$6,979,207	100%

15. OTHER EXPENSES, NET

Other expenses net, consisted of the following:

	During the Three-Month Periods Ended June 30,		During the Six-Month Periods Ended June 30,	
	2024	**2023**	**2024**	**2023**
Interest expense[(1)]	$142,386	$88,577	$288,388	$178,561
Loss (gain) on disposal of property, plant and equipment	14,557	(77)	14,557	8,167
Interest income	(13,264)	(14,806)	(22,791)	(55,438)
Income-other	—	—	—	(107)
Other expenses, net	$143,679	$73,694	$280,154	$131,183

[(1)] Interest expense includes amortization of debt issuance and debt discount costs of $10,806 and $1,919 during the three-month periods ended June 30, 2024 or 2023, respectively, and $21,054 and $3,838 during the six-month periods ended June 30, 2024 and 2023, respectively.

16. INCOME TAXES

Our income tax expense aggregated $1,340 and $1,525 (amounting to less than 1% of our loss before income taxes) during the three-month periods ended June 30, 2024 and 2023, respectively, and $2,680 and $3,050 (amounting to less than 1% of our loss before income taxes) during the six-month periods ended June 30, 2024 and 2023, respectively. As of December 31, 2023, we had federal net operating loss carryforwards of $17,759,519 of which $16,047,612 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 $4,681,644 that expire in 2037 through 2038 (if not utilized before then). Additionally, we had federal general business tax credit carryforwards of $726,474 that expire in 2027 through 2042 (if not utilized before then) and state tax credit carryforwards of $775,473 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 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. Currently, we adjust the valuation allowance at the end of each quarter to reduce the value of our deferred tax assets to zero.

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 a bacteriocin called Nisin. 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 June 30, 2024			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$5,430,069	$42,821	$—	$5,472,890
Costs of goods sold	4,198,849	43,555	—	4,242,404
Gross margin	1,231,220	(734)	—	1,230,486
Product development expense	65,598	928,531	36,373	1,030,502
Sales and marketing expenses	855,513	129,444	—	984,957
Administrative expenses	—	—	601,634	601,634
Operating expenses	921,111	1,057,975	638,007	2,617,093
NET OPERATING INCOME (LOSS)	$310,109	($1,058,709)	($638,007)	($1,386,607)

	During the Three-Month Period Ended June 30, 2023			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$3,482,259	$50,422	$—	$3,532,681
Costs of goods sold	2,453,169	35,624	—	2,488,793
Gross margin	1,029,090	14,798	—	1,043,888
Product development expenses	2,252	1,061,383	35,903	1,099,538
Sales and marketing expenses	558,179	161,610	—	719,789
Administrative expenses	—	—	529,056	529,056
Operating expenses	560,431	1,222,993	564,959	2,348,383
NET OPERATING INCOME (LOSS)	$468,659	($1,208,195)	($564,959)	($1,304,495)

	Scours	**Mastitis**	**Other**	**Total**
Total Assets as of June 30, 2024	$23,240,545	$17,107,377	$1,507,536	$41,855,458
Total Assets as of June 30, 2023	$23,910,633	$18,374,662	$1,721,773	$44,007,068
Depreciation and amortization expense during the three-month period ended June 30, 2024	$342,362	$319,727	$19,676	$681,765
Depreciation and amortization expense during the three-month period ended June 30, 2023	$341,979	$323,661	$21,074	$686,714
Capital Expenditures during the three-month period ended June 30, 2024	$93,338	$17,403	$—	$110,741
Capital Expenditures during the three-month period ended June 30, 2023	$124,911	$583,577	$—	$708,488

	During the Six-Month Period Ended June 30, 2024			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$12,650,710	$79,757	$—	$12,730,467
Costs of goods sold	9,122,397	82,225	—	9,204,622
Gross margin	3,528,313	(2,468)	—	3,525,845
Product development expense	95,093	2,131,473	66,487	2,293,053
Sales and marketing expenses	1,525,252	260,628	—	1,785,880
Administrative expenses	—	—	1,133,572	1,133,572
Operating expenses	1,620,345	2,392,101	1,200,059	5,212,505
NET OPERATING INCOME (LOSS)	$1,907,968	($2,394,569)	($1,200,059)	($1,686,660)

	During the Six-Month Period Ended June 30, 2023			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$6,893,491	$85,716	$—	$6,979,207
Costs of goods sold	5,557,127	77,417	—	5,634,544
Gross margin	1,336,364	8,299	—	1,344,663
Product development expenses	2,543	2,137,728	69,636	2,209,907
Sales and marketing expenses	1,248,723	350,493	—	1,599,216
Administrative expenses	—	—	1,096,074	1,096,074
Operating expenses	1,251,266	2,488,221	1,165,710	4,905,197
NET OPERATING INCOME (LOSS)	$85,098	($2,479,922)	($1,165,710)	($3,560,534)

	Scours	**Mastitis**	**Other**	**Total**
Total Assets as of June 30, 2024	$23,240,545	$17,107,377	$1,507,536	$41,855,458
Total Assets as of June 30, 2023	$23,910,633	$18,374,662	$1,721,773	$44,007,068
Depreciation and amortization expense during the six-month period ended June 30, 2024	$681,281	$638,445	$39,539	$1,359,265
Depreciation and amortization expense during the six-month period ended June 30, 2023	$665,236	$641,285	$39,022	$1,345,543
Capital Expenditures during the six-month period ended June 30, 2024	$132,812	$48,285	$—	$181,097
Capital Expenditures during the six-month period ended June 30, 2023	$696,647	$694,007	$—	$1,390,654

	During the Year Ended December 31, 2023			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$17,293,933	$177,736	$—	$17,471,669
Costs of goods sold	13,453,514	148,871	—	13,602,385
Gross margin	3,840,419	28,865	—	3,869,284
Product development expense	11,103	4,242,329	141,420	4,394,852
Sales and marketing expenses	2,447,137	641,078	—	3,088,215
Administrative expenses	—	—	2,134,295	2,134,295
Operating expenses	2,458,240	4,883,407	2,275,715	9,617,362
NET OPERATING INCOME (LOSS)	$1,382,179	($4,854,542)	($2,275,715)	($5,748,078)

	During the Year Ended December 31, 2022			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$18,411,949	$154,558	$1,455	$18,567,962
Costs of goods sold	10,754,189	136,347	28,647	10,919,183
Gross margin	7,657,760	18,211	(27,192)	7,648,779
Product development expenses	66,346	4,317,921	109,605	4,493,872
Sales and marketing expenses	1,871,926	1,318,107	—	3,190,033
Administrative expenses	—	—	2,263,817	2,263,817
Operating expenses	1,938,272	5,636,028	2,373,422	9,947,722
NET OPERATING INCOME (LOSS)	$5,719,488	($5,617,817)	($2,400,614)	($2,298,943)

	Scours	**Mastitis**	**Other**	**Total**
Total Assets as of December 31, 2023	$24,735,413	$17,827,839	$1,244,850	$43,808,102
Total Assets as of December 31, 2022	$20,539,523	$18,315,492	$6,005,634	$44,860,649
Depreciation and amortization expense during the year ended December 31, 2023	$1,365,988	$1,287,600	$86,032	$2,739,620
Depreciation and amortization expense during the year ended December 31, 2022	$1,169,011	$1,263,318	$62,912	$2,495,241
Capital Expenditures during the year ended December 31, 2023	$1,096,819	$795,694	$—	$1,892,513
Capital Expenditures during the year ended December 31, 2022	$3,513,336	$414,486	$47,452	$3,975,274

18. RELATED PARTY TRANSACTIONS

David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone Inc., a domestic distributor of our products (the **First Defense®** product line and **CMT**). His affiliated company purchased $270,867 and $56,556 of products from us during the six-month periods ended June 30, 2024 and 2023, 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 this affiliated company aggregated $34,576 and $42,507 as of June 30, 2024 and December 31, 2023, 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 $48,579 and $40,630 into the Plan for the three-month periods ended June 30, 2024 and 2023, respectively, and $103,514 and $85,572 for the six-month periods ended June 30, 2024 and 2023, 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

We focus on the two most critical stages of dairy productivity, those being the first 30 days of life and the first 30 days of lactation. Our concentrated colostrum and purified Nisin technologies offer unique animal health solutions during these periods when immunity is at its most vulnerable. Both of our product lines present immediate growth opportunities and, in the future, may potentially be applied in the human health sector, alongside the animal health sector that we currently serve. 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 (Quarterly Report). 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.

OUTLINE TO ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

- **Cautionary Note Regarding Forward-Looking Statements**
- **Liquidity and Capital Resources**
- **Capital Expenditure Investments**
- **Production Contamination Events**
- **Results of Operations (Subsections a through i)**
- **Critical Accounting Policies and Estimates**

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

This Quarterly Report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts, and will often include words such as "expects", "may", "anticipates", "aims", "intends", "would", "could", "should", "will", "plans", "believes", "estimates", "targets", "projects", "forecasts", "seeks" and similar words and expressions. Such statements include, but are not limited to, any forward-looking 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; future demand for our products; the consequences of the COVID-19 pandemic, 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) and the war in the Middle East on the world economy including inflation and the price and availability of grain and oil; 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 impact of inflation and rising interest rates on our operating expenses and financial results; 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 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 efficacy, success and timeline to complete our contamination remediation efforts; the likelihood, severity or impact of future contamination events; 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 robustness of our manufacturing processes and related technical issues; estimates about our production capacity, efficiency and yield; the salability of products currently held in inventory pending regulatory approval; future regulatory requirements relating to our products; future expense ratios and margins; the efficacy of our investments in our business; future compliance with bank debt covenants; anticipated changes in our manufacturing capabilities and efficiencies; our effectiveness in competing against competitors within both our existing and our anticipated product markets; projections about depreciation expense and its impact on income for book and tax return purposes; and any other statements that are not historical facts. These statements are intended to provide management's current expectation of future events as of the date of this earnings release, are based

on management's estimates, projections, beliefs and assumptions as of the date hereof; and are not guarantees of future performance. Such statements involve known and unknown risks and uncertainties that may cause the Company's actual results, financial or operational performance or achievements to be materially different from those expressed or implied by these forward-looking statements, 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), 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, commercial and operational risks relating to our current and planned expansion of production capacity, and other risks and uncertainties 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: OTHER INFORMATION, ITEM 1A-RISK FACTORS** and uncertainties otherwise referred to in this Quarterly Report. In addition, there can be no assurance that future risks, uncertainties or developments affecting us will be those that we anticipate. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Liquidity and Capital Resources

Net cash provided by operating activities was $1 million during the six-month period ended June 30, 2024 in contrast to net cash (used for) operating activities of ($3.4) million during the six-month period ended June 30, 2023. The $4.4 million improvement in net cash provided by operating activities during the six-month period ended June 30, 2024 in contrast to net cash (used for) operating activities during the six-month period ended June 30, 2023 was largely caused by the $1.7 million decrease in the net loss, a $2 million swing from cash (used for) inventory build to an inventory reduction and a $459,000 swing from a reduction in accounts payable to an increase in accounts payable and accrued expenses. Our inventory balance decreased by $512,000 to $7.3 million as of June 30, 2024 from $7.8 million as of December 31, 2023. Interest expense (including amortization of debt issuance and debt discount costs) was $288,000 and $179,000 during the six-month periods ended June 30, 2024 and 2023, respectively. Our debt bears interest at fixed rates. The blended interest rate on the debt outstanding as of June 30, 2024 and December 31, 2023 was 4.51% per annum. We anticipate that interest expense (including amortization of debt issuance and debt discount costs) will be $566,000 and $494,000 during the years ending December 31, 2024 and 2025, respectively. Our total non-cash depreciation, amortization and stock-based compensation expense was approximately $1.5 million during both of the six-month periods ended June 30, 2024 and 2023. 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.

Net cash used for investing activities was $177,000 during the six-month period ended June 30, 2024 in comparison to net cash used for investing activities of $1.4 million during the six-month period ended June 30, 2023 consisting primarily of cash spent to fund the purchase of property, plant and equipment. To conserve cash at this time, we have reduced and deferred all non-essential capital expenditures.

Net cash (used for) financing activities was ($478,000) during the six-month period ended June 30, 2024 in contrast to net cash provided by financing activities of $497,000 during the six-month period ended June 30, 2023. We had aggregate debt outstanding (net of debt issuance and debt discount costs) of approximately $11.3 million and $12 million as of June 30, 2024 and December 31, 2023, respectively. Debt principal repayments (excluding the line of credit) aggregated $726,000 and $503,000 during the six-month periods ended June 30, 2024 and 2023, respectively. We anticipate that debt principal repayments will aggregate approximately $1.5 million during both of the years ending December 31, 2024 and 2025. During the first quarter of 2024, the availability of our $1 million line of credit, which bears interest at the National Prime Rate per annum, was extended until September 11, 2025. No draw on our line of credit was outstanding as of June 30, 2024 or December 31, 2023. Financing activities included a $1 million draw on our line of credit during the six-month period ended June 30, 2023. No such draw was made during the six-month period ended June 30, 2024. See Note 10 to the accompanying unaudited financial statements for more information about our bank debt. During the second quarter of 2024, we entered into an At-The-Market Offering Agreement (ATM Agreement) with Craig-Hallum Capital Group LLC, pursuant to which we may offer and sell up to $11 million of shares of our common stock. As of August 2, 2024, we had sold 82,216 shares under the at the market offering conducted pursuant to the ATM Agreement. Net proceeds (net of approximately $152,000 in upfront legal, accounting and other fees and approximately $13,000 in sales commissions) were approximately $253,000. No shares have been sold pursuant to this offering since May 20, 2024. The ATM Agreement gives our board the flexibility to evaluate the potential uses of proceeds while considering the cost of dilution in real time going forward.

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 June 30, 2024	As of December 31, 2023	Increase (Decrease) Amount	Increase (Decrease) %
Cash and cash equivalents	$1,324	$979	$346	35%
Net working capital	$6,237	$7,272	($1,036)	(14%)
Total assets	$41,855	$43,808	($1,953)	(4%)
Stockholders' equity	$23,455	$24,993	($1,538)	(6%)
Common shares outstanding[(1)]	7,833	7,751	82	1%

[(1)] There were 618,000 and 618,500 shares of common stock reserved for issuance for stock options that were outstanding as of June 30, 2024 and December 31, 2023, respectively.

Capital Expenditure Investments

We have invested and continue to invest in several different capital expenditure projects to increase our estimated annual full production capacity for the **First Defense®** product line from approximately $16.5 million to approximately $30 million currently (with an option to increase further to approximately $40 million in the future) and to complete the development of **Re-Tain®**. When we describe the production capacity for the **First Defense®** product line in this Quarterly 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.

Over the past 10 years or so, we have invested approximately $14 million to increase our production capacity for the **First Defense®** product line to meet the still-growing demand. This investment in equipment and facilities represents approximately 59% of our stockholders' equity as of June 30, 2024. During 2018, it became clear that demand for **Tri-Shield First Defense®** was outpacing production. In response to this increasing demand, we began a series of investments during 2019 to increase our production capacity for the **First Defense®** product line to an estimate of approximately $30 million per year. Our production process is a very complicated one, which makes it difficult to scale-up quickly. We remain deeply committed to continuing to supply **First Defense®** to the market over the long term, despite the current short supply that we are experiencing. We were able to produce approximately 74% and 96% of our current full capacity estimate during the quarters ended June 30, 2024 and March 31, 2024, respectively.

During the three-year period ended December 31, 2016, we invested the aggregate of $4.2 million to construct a 7,100 square foot facility addition at 56 Evergreen Drive (**Building 56**) and related equipment (primarily Freeze-Dryer #2) and cold storage capacity 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. During the first quarter of 2016, we completed this investment, which also included the construction and equipping of a pilot plant for small-scale Drug Substance (DS) production for **Re-Tain®** within **Building 56**. After construction of the DS production facility for **Re-Tain®** at 33 Caddie Lane (**Building 33)** was completed, this space was converted for use in the production of the gel tube formats of the **First Defense®** product line. After renovations of our leased facility at 175 Industrial Way (**Building 175A)** were completed during the second quarter of 2020, this space was converted to double our liquid processing capacity.

During the four-year period ended December 31, 2018, we invested the aggregate of $21.6 million to construct a DS production facility for **Re-Tain®** at **Building 33**. During the fourth quarter of 2017, we completed construction of the DS 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 DS 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 at 14 Wedge Way (**Building 14)**, which will be used for packing, shipping and cold storage of **Re-Tain®** and other warehousing needs.

During 2019, we initiated several additional capital expenditure investments in **First Defense®** and **Re-Tain®**. The primary purpose of the additional investment in **First Defense®** is to fulfill the current backlog and materially reduce the risk of another order backlog. Operating at very close to 100% of available capacity is not efficient or sustainable. Our objective is to be in position to operate without significant contaminations at the capacity level we choose to cover sales with adequate buffer stock, which would allow more time for necessary preventative maintenance. We also need to meet or exceed our production yield assumptions to succeed. The primary purpose of the additional investments in **Re-Tain®** is to bring the formulation and aseptic filling capabilities for **Re-Tain®** Drug Product (DP) into available space in our DS facility in order to lessen or eliminate our reliance on third-party DP manufacturing services as well as to build out warehouse space at **Building 14** for packing and shipping facilities for **Re-Tain®**. We

began initial installation of the filling equipment during the first quarter of 2022 and then paused this installation work pending concurrence with the FDA pertaining to our third submission of the Chemistry, Manufacturing and Controls (CMC) Technical Section, which is discussed in greater detail below. Due to the loss in **First Defense®** gross margin during 2023 caused by the slowdown in production output necessary to remediate the product contamination events discussed below, we have decided to defer the spending of approximately $2 million of these funds for **Re-Tain®**, for the time being. If we decide to resume the in-house strategy, we would anticipate FDA approval of this facility (which is a requirement for commercial manufacturing) at least two years after we resume spending on this project. The amount and timing of these investments are detailed in the following table (in thousands):

Paid During the	First Defense®	Re-Tain®	Other	Total
Year Ended December 31, 2019	$279	$538	$574	$1,391
Year Ended December 31, 2020	2,938	581	554	4,073
Year Ended December 31, 2021	1,633	976	-	2,609
Year Ended December 31, 2022	3,513	415	47	3,975
Year Ended December 31, 2023	1,097	796	-	1,893
Six-Month Period Ended June 30, 2024	133	48	-	181
Total Paid through June 30, 2024	9,593	3,354	1,175	14,122
Estimate to Complete[(1)]	3,500	2,000	600	6,100
Total Project Cost	$13,093	$5,354	$1,775	$20,222

[(1)] The investments of approximately $3.5 million of these funds to increase **First Defense®** production capacity from approximately $30 million to $40 million per year and approximately $2 million to build an in-house aseptic filling facility for **Re-Tain®** have been deferred for the time being. These figures are estimates for the work to be completed based on current information and knowledge and are not based on firm cost quotations or contracts at this time.

The first phase of the additional investments in **First Defense®** beginning in 2019 included significant renovations to a 14,300 square foot leased facility at **Building 175A**, some facility modifications at **Building 56** and the necessary production equipment (including Freeze-Dryer #3) to increase our freeze-drying capacity by 50% and our liquid processing capacity by 100%. This resulted in increasing 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. Renovations of **Building 175A** to enable this expansion were completed during the second quarter of 2020. By moving our powder and gel filling and assembly operations from **Building 56** into this new space, we created space at **Building 56** for the installation of the expanded freeze-drying capacity. The new facilities are built to contemporary current Good Manufacturing Practices (cGMP) standards with efficient material and people flows. A site license approval for this new facility 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 **Building 56** to **Building 175A**, which created the space necessary to double our liquid processing capacity at **Building 56**. We obtained site license approval of the expanded freeze-drying capacity (Freeze-Dryer #3) at **Building 56** from the USDA during the third quarter of 2021, and we obtained site license approval of the expanded liquid processing capacity at **Building 56** from the USDA during the third quarter of 2022. This investment also included equipment and vehicle purchases necessary to expand and improve our colostrum collection capabilities and logistics.

The second phase of the additional investments in **First Defense®** included the installation of Freeze-Dryer #4 to further increase the estimated annual production capacity of the **First Defense®** product line (in terms of annual sales dollars) by an additional 33% from approximately $23 million to approximately $30 million. As of July of 2022, we had completed almost all of the facility expansion work and new equipment installations needed to increase our production capacity to almost $30 million per year. However, the most critical piece of new equipment (being Freeze-Dryer #4) was delivered six months late by the fabricator. Regardless, by the end of 2022, we had Freeze-Dryer #4 installed and approved for use by the USDA. At the same time, Freeze-Dryer #2 stopped operating requiring a six-month repair and netting us back to three operating freeze dryers during the first half of 2023. As of July of 2023, we were back to four operating freeze dryers. This investment also included equipment and facility modifications to scale-up and upgrade our vaccine manufacturing capacity and improve our quality laboratories at **Building 56** as well as the installation of new equipment to increase the throughput of our gel filling operations at **Building 175A**.

The third phase of the additional investments in **First Defense®** involved the construction of an additional 15,400 square feet of space adjacent to and connected to **Building 175A** at 175 Industrial Way (**Building 175B**) and new equipment to further increase our estimated annual **First Defense®** production capacity from approximately $30 million to approximately $40 million with options for further expansion. Given the long lead time required for investments like this, we initiated this project by entering into a lease amendment during the third quarter of 2022 covering a to-be-constructed building shell for approximately $250,000 per year.

Construction of the building shell by our landlord was substantially complete as of April 1, 2023, and rent payments commenced as of August 1, 2023. We made this lease commitment because of the unique proximity of the land adjacent to our currently leased space 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 the potential to install Freeze-Dryers #5, #6, #7 and #8 if justified by market demand in the future, ii) improved space and quality for our powder milling operations by separating our upstream processes (liquid processing) at **Building 56** from our clean downstream processes (milling, formulation, filling and packaging) and iii) much needed additional warehouse space. Freeze-Dryer #5 is the key piece of equipment required to allow us to increase our estimated annual production capacity to above $30 million. Based on past experience, we are planning for approximately 18 months of lead time for fabrication, installation, qualification and implementation of Freeze-Dryer #5. We have been running our equipment and staff close to 100% of capacity in order to fill the backlog of orders. One of our objectives is to create a more sustainable production schedule. However, due to the loss in gross margin during 2023 caused by the slowdown in production output necessary to remediate the product contamination events discussed below, we have decided to defer most of this investment, for the time being. Instead, we initiated the initial steps of this project with a reduced budget of approximately $700,000 at **Building 175B** during the third quarter of 2023. This work was completed during the first quarter of 2024, which provides additional warehousing space and allowed us to move all shipping and receiving functions out of **Building 56** to create more space for liquid processing at **Building 56**. In consideration for our landlord agreeing to pay for the cost of those certain tenant improvements, we were obligated to make additional rent payments of $20,000 per month from November of 2023 through June of 2024 and a one-time additional rent payment of $488,743 in July of 2024. During the second quarter of 2024, this payment obligation was re-negotiated so that we are now obligated to make additional rent payments of $20,000 per month from July of 2024 to December of 2024 and a final additional rent payment of $368,743 in January of 2025.

Production Contamination Events

The past two years or so has been considerably challenging for us. As our increased production capacity was coming online, a first product contamination event likely related to our incoming raw material (that is sourced from many different cows at many different farms) was detected by standard in-process quality control testing around the end of the third quarter of 2022. We took immediate steps to address the contamination, and production ran without issue during the balance of the fourth quarter of 2022. Subsequently, as we began to operate at a higher level of capacity at the beginning of 2023, we were forced to slow down production again to remediate a second contamination event also likely related to our incoming raw material. We then ran for approximately six months without contamination and then experienced a smaller third contamination event in September of 2023 impacting two lots of Work-in-Progress inventory likely related to our increased level of liquid processing. Although all of the incoming material utilized in this production phase had passed quality control testing, the product failed the quality control tests later in the production process. We have experienced a fourth contamination event impacting four lots of Work-in-Process inventory during the first half of 2024. New remediation steps implemented in response to this fourth event during late April of 2024 appear to be very successful so far because we have run without contamination since then and through the date of the filing of this Quarterly Report. Throughout these contamination events, all product that was sold to market had passed final release testing to meet our quality standards.

Our proprietary production process allows us to create an effective product out of a non-aseptic starting raw material. This requires a careful monitoring of the tradeoff between the benefit of adding more heat for longer periods of time to reduce bacterial load against the alternative benefit of less heat for shorter periods of time to preserve more antibody content. Although using more heat could potentially reduce bacterial load, our yield is higher when we use less heat. For example, we know that putting our Work-in-Process inventory through freeze/thaw cycles is not beneficial to yield and increases the risk of contamination. One effective improvement we have implemented, where appropriate, is to lengthen the time of a heat treatment step instead of running two shorter heat treatment steps separated by a freeze/thaw. As we continue to optimize this critical process parameter, we believe we can significantly reduce the risk of further contaminations and improve our gross margin.

Although these types of losses are expected to happen from time to time in the production of a biological product such as ours, we believe we have mitigated the risk of reoccurrence of such losses through the implementation of certain new quality control steps and manufacturing process and facility improvements. To meet our goals, we must run without significant equipment failures or contamination losses, and we must improve our production yields.

The production contamination events and other production process losses experienced resulted in scrapped inventory valued as shown in the following table (in thousands):

	Approximate Cost of Work-in-Process Scrap	Approximate Retail Value of Finished Goods[1]
Year Ended December 31, 2022	$589	$2,193
Year Ended December 31, 2023	$527	$2,487
Three-Month Period Ended March 31, 2023	$236	$1,087
Three-Month Period Ended June 30, 2023	$69	$297
Six-Month Period Ended June 30, 2023	$305	$1,384
Three-Month Period Ended March 31, 2024	$117	$474
Three-Month Period Ended June 30, 2024	$316	$1,444
Six-Month Period Ended June 30, 2024	$433	$1,918

[1] This estimate approximates the retail value of this work-in-process inventory in the event that additional costs had been incurred to complete the production process to prepare it for sale utilizing the approximate product format mix during that period.

We believe that we are on the right track to move past the contamination events that have materially affected our output since late 2022, but we still have more work to do to catch up to product demand. As we look back at these production contamination events, we believe that the root cause of the initial contaminations was associated with rapid growth at the farms where we acquire our raw material. Having largely remediated that problem, we experienced additional contaminations that we believe were largely caused by our rapidly increased production capacity. As we continue to optimize our investments to increase production capacity and to implement the corrective actions being taken in response to these contamination events, we aspire to reach an annual full production capacity of approximately $30 million per year going forward. While we produced far less than we needed during 2023, we believe that our remediation efforts are allowing us to steadily ramp back up to full production capacity. As we resume full production, our goal is to be able to produce at least $6 million or more worth of product per quarter, which would annualize to about 80% or more of our estimated $30 million annual production capacity to balance production output with regularly scheduled preventative maintenance. Finished goods produced increased steadily from approximately $3.3 million to $4 million and further to $5.3 million during the first, second and third quarters of 2023, respectively, before dropping modestly to $5.1 million during the fourth quarter of 2023. We were able to increase finished goods production to $7.2 million during the first quarter of 2024, which annualizes to approximately $28.7 million (or approximately 96% of $30 million). This level of production will remain our aspirational goal, but we do not expect that it can be repeated or exceeded on a regular basis. During the second quarter of 2024, finished goods production decreased to $5.5 million, which annualizes to approximately $22 million (or approximately 74% of $30 million). During the six-month period ended June 30, 2024, finished goods production was approximately $12.7 million, which annualizes to approximately $25.4 million (or approximately 85% of $30 million).

Since February of 2023, we have been pursuing an insurance claim under our business interruption policy to offset a small portion of the losses that we have incurred related to the contamination events discussed above. While our financial losses are far larger, we are seeking an insurance benefit of approximately $700,000. To date, we have received $250,000. The balance of this claim remains under review by our underwriter. We cannot estimate the likelihood of our success with this claim.

The increase in sales demand for **First Defense®** is both exciting and challenging for us. The learnings from the remediation of the contamination events have improved our production processes going forward. We have implemented several important improvements at the source farm level including more product and environmental testing, more training of farm staff and better enforcement of our protocols. While we never release product to the market that does not pass our final quality control release tests, we had allowed product to advance in the production process at risk, while the in-process quality control tests were being performed. We no longer advance product to the next stage at risk before the complete in-process quality control test results are available. While this does add time to the overall production cycle, we believe that it has helped us reduce the cost of further contaminations. Notwithstanding the challenges that contamination events have posed for us, we are excited to be approaching both our estimated full capacity of approximately $30 million per year for **First Defense®** (with an option to increase our estimated full capacity to approximately $40 million per year in the future with the additional capital investments discussed above) while, at the same time, advancing to the final stages of a very significant FDA product development initiative with **Re-Tain®**.

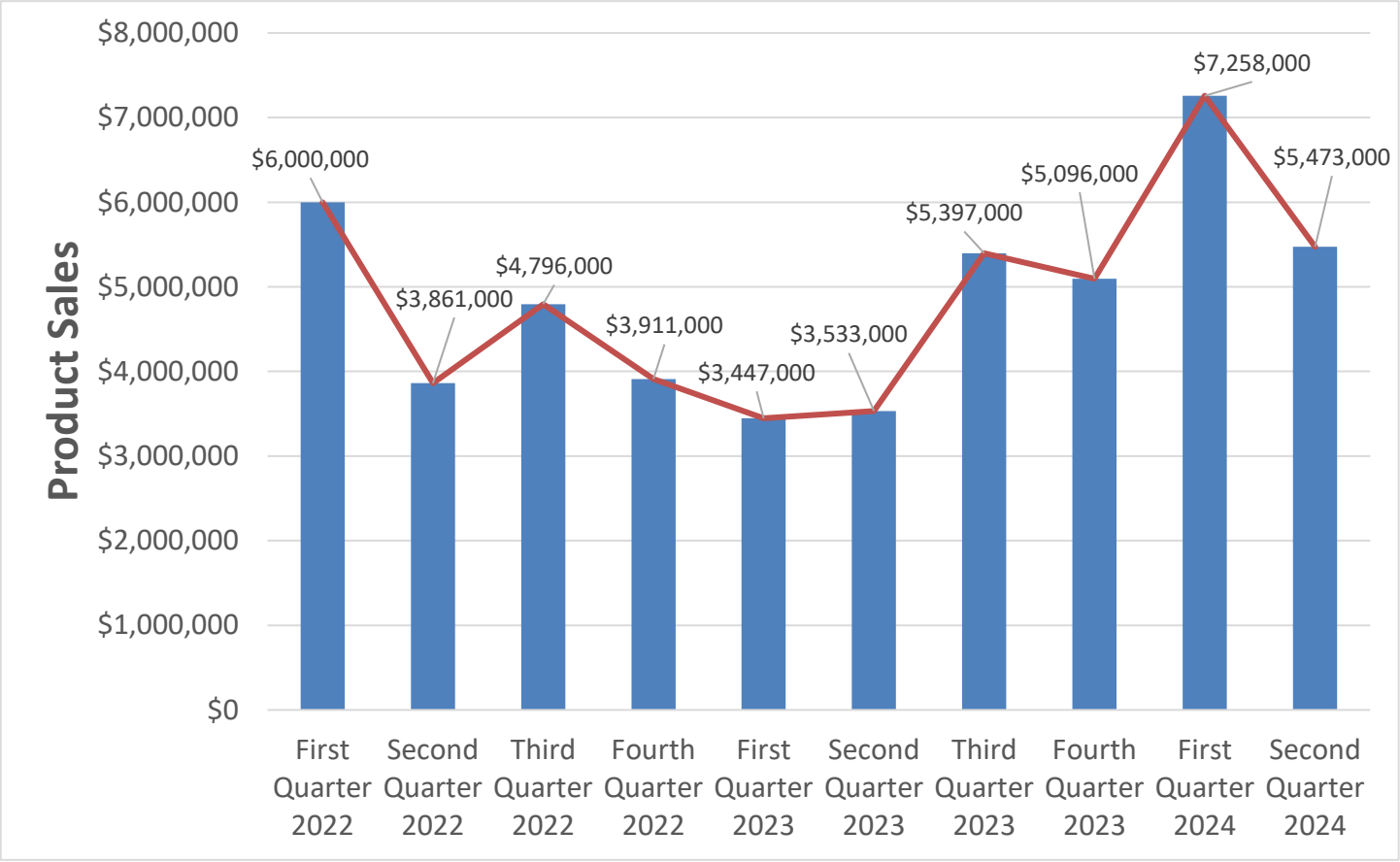
Results of Operations

a) Product Sales

Our near-term goal is to increase and stabilize supply, regain lost business and re-establish our growth curve. If we are able to avoid further significant contamination events and achieve our goal of balancing supplies to meet projected demand by the end of 2024, we anticipate being able to achieve approximately $24 million in sales during 2024. This projection not only aims to meet end-user demand but also to replenish the distribution chain with the necessary buffer stock. This target would surpass our total product

sales of approximately $17.5 million and $18.6 million achieved during the years ended December 31, 2023 and 2022, respectively. Our longer-term goal is to exceed $35 million of annual total product sales as soon as possible during the four-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 during the three-month period ended March 31, 2023 were $3.4 million, representing a 12%, or $464,000, decrease from sales of $3.9 million during the fourth quarter of 2022. Sales during the three-month period ended June 30, 2023 were $3.5 million, representing a 2%, or $86,000, increase over sales during the first quarter of 2023. Sales during the three-month period ended September 30, 2023 were $5.4 million, representing a 53%, or $1.9 million, increase over sales during the second quarter of 2023. Sales during the three-month period ended December 31, 2023 were $5.1 million, representing a 6%, or $301,000, decrease from sales during the third quarter of 2023. Sales during the second half of 2023 were stronger as we were able to increase production. Sales during the six-month period ended December 31, 2023 were $10.5 million, representing a 50%, or $3.5 million, increase over sales of $7 million during the six-month period ended June 30, 2023. Sales during the three-month period ended March 31, 2024 were $7.3 million, representing a 42%, or $2.2 million, increase over sales during the fourth quarter of 2023. Sales during the three-month period ended June 30, 2024 were $5.5 million, representing a 25%, or $1.8 million, decrease from sales during first quarter of 2024. Quarter to quarter sales over the past two years are displayed in the following table:



An increase in selling price and product supply allowed us to capture a 55% increase in sales during the second quarter of 2024 compared to the second quarter of 2023. Domestic sales during the three-month period ended June 30, 2024 increased by 50%, and international sales increased by 109%, in comparison to the three-month period ended June 30, 2023. International sales aggregated 11% and 8% of total sales during the three-month periods ended June 30, 2024 and 2023, respectively. The quarterly sales results are summarized in the following table (in thousands, except for percentages):

	During the Three-Month Periods Ended June 30,		Increase	
	2024	2023	Amount	%
Total product sales	$5,473	$3,533	$1,940	55%

An increase in selling price and product supply allowed us to capture an 82% increase in sales during the six-month period ended June 30, 2024 compared to the six-month period ended June 30, 2023. Domestic sales during the six-month period ended June 30, 2024 increased by 80%, and international sales increased by 106%, in comparison to the six-month period ended June 30, 2023. International sales aggregated 12% and 10% of total sales during the six-month periods ended June 30, 2024 and 2023, respectively. The sales results for the six-month periods are summarized in the following table (in thousands, except for percentages):

	During the Six-Month Periods Ended June 30,		Increase	
	2024	2023	Amount	%
Total product sales	$12,730	$6,979	$5,751	82%

An increase in selling price and product supply allowed us to capture a 48% increase in sales during the trailing twelve-month period ended June 30, 2024 compared to the trailing twelve-month period ended June 30, 2023. Domestic sales during the trailing twelve-month period ended June 30, 2024 increased by 47%, and international sales increased by 54%, in comparison to the trailing twelve-month period ended June 30, 2023. International sales aggregated 10% of total sales during both of the trailing twelve-month periods ended June 30, 2024 and 2023. The sales results for the trailing twelve-month periods are summarized in the following table (in thousands, except for percentages):

	During the Trailing Twelve-Month Periods Ended June 30,		Increase	
	2024	2023	Amount	%
Total product sales	$23,223	$15,686	$7,537	48%

Sales of the **First Defense®** product line aggregated 99% of our total sales during both of the three-month periods ended June 30, 2024 and 2023 and during both of the six-month periods ended June 30, 2024 and 2023 and during both of the trailing twelve-month periods ended June 30, 2024 and 2023. Our sales are generally seasonal with highest demand expected during the first quarter of each year. The compound annual growth rate (CAGR) of our total product sales was 10.8%, 9.7% and 6.2% during the twelve-year, five-year, and four-year periods ended December 31, 2023, respectively.

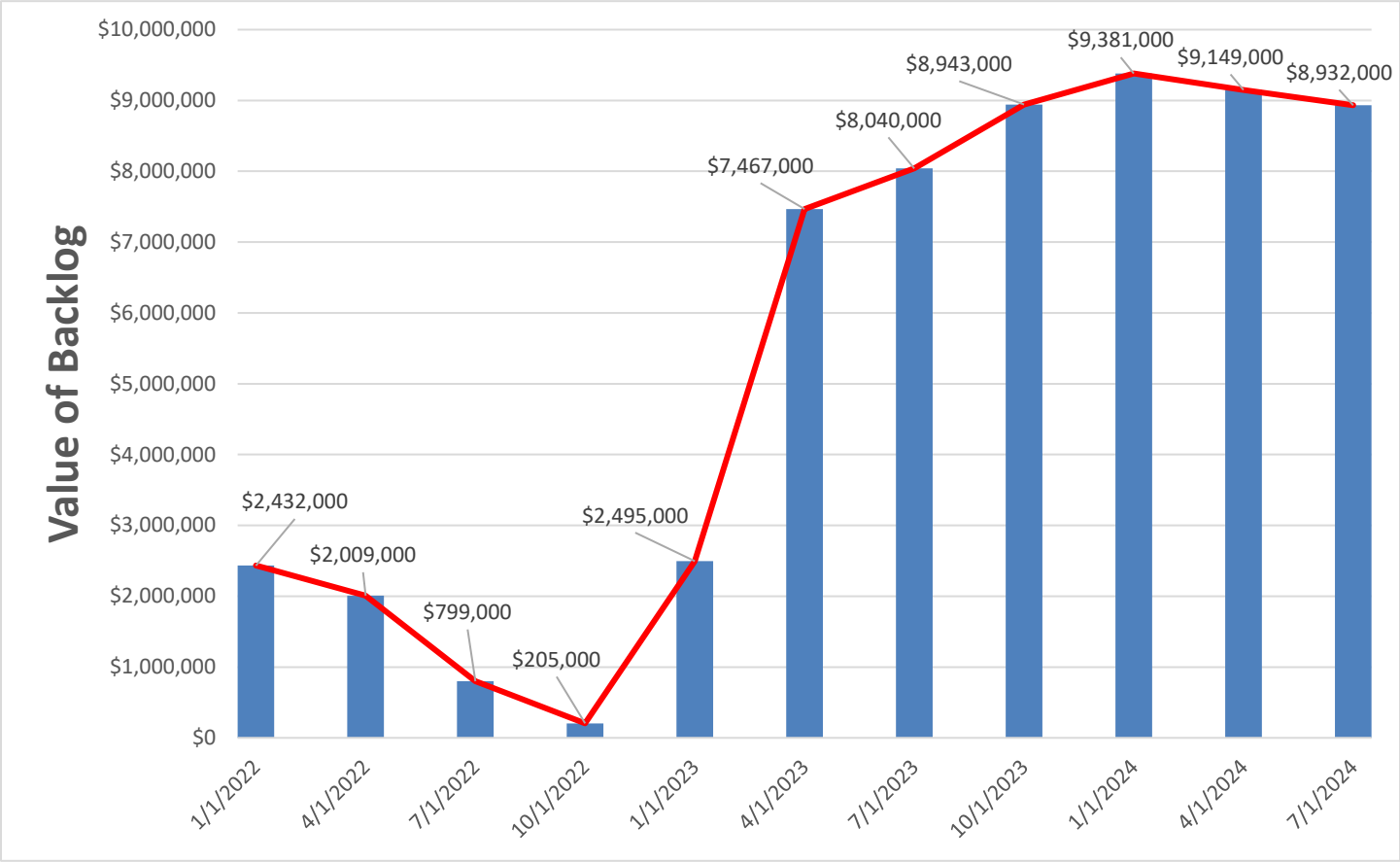
We obtained USDA approval of **Tri-Shield First Defense®** (the trivalent format of our product delivered via a gel tube, which provides broader protection to calves) near the end of 2017. Around the time of this new product format launch, total product sales during the years ended December 31, 2017 and 2018 were $10.4 million and $11 million, respectively. While this product is very well received by the market for its effectiveness, it does require two separate liquid production processes for each dose of **Tri-Shield®** sold to the market, in contrast to the bivalent product formats that require just one, which makes it more expensive to produce. This new product format has become the most significant component of our total sales, as demonstrated in the table below (in thousands, except for percentages):

	During the Three-Month Periods Ended June 30,				During the Six-Month Periods Ended June 30,			
	2024	% of Total	2023	% of Total	2024	% of Total	2023	% of Total
Tri-Shield®	$3,591	66%	$2,029	57%	$7,645	60%	$3,672	53%
Other	1,882	34%	1,504	43%	5,085	40%	3,307	47%
Total Sales	$5,473	100%	$3,533	100%	$12,730	100%	$6,979	100%

We likely lost some business beginning during 2022 and through the first half of 2024 as a result of the backlog. During the first half of 2023, the impact of tight supplies hit even harder leaving our customers without product during their busiest calving season. The 2023 production shortage caused largely by the contamination events discussed above may prove to be more detrimental to our growth curve than any prior production shortage because it depleted distributor inventories and impacted more customers for a longer period of time. 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 some of these customers 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 preparing to resume more normal sales growth initiatives as we expect product supply to exceed demand. We will work to regain end-user customers that we may have lost while we were short on product and will aggressively compete 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.

The production slowdown during the first ten months of 2023, in part, caused an increase in the amount of our order backlog. We cannot be certain that this backlog will be converted to sales. 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. We are reporting this figure because it reflects the orders on our books presently that we cannot ship. 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. We are concerned that this backlog amount may not be highly relevant at this time as it includes very old orders, redundancy in demand and orders that may be cancelled given the time that has passed since they were originally placed.

The backlog was reduced from approximately $2.4 million as of December 31, 2021 to approximately $205,000 as of September 30, 2022. In part because of a first contamination event experienced around the end of the third quarter of 2022, our backlog increased to approximately $2.5 million as of December 31, 2022. In part because of a second contamination event experienced during the first quarter of 2023, the backlog continued to increase to approximately $7.5 million as of March 31, 2023, to approximately $8 million as of June 30, 2023, to approximately $8.9 million as of September 30, 2023 and to approximately $9.4 million as of December 31, 2023. We were able to reduce this backlog modestly to approximately $9.1 million as of March 31, 2024 and then reduce it further to approximately $8.9 million and $7.9 million as of June 30, 2024 and August 6, 2024, respectively. As sales demand increased while our production output was reduced, the value of our order backlog has fluctuated as demonstrated in the following table:



We also sell our own **CMT**, which is used to detect somatic cell counts in milk. Sales of **CMT** aggregated approximately 1% of our total product sales during the periods reported. Sales of **CMT** decreased by 15%, or $8,000, to $43,000 during the three-month period ended June 30, 2024, in comparison to the three-month period ended June 30, 2023. Sales of **CMT** decreased by 7%, or $6,000 during the six-month period ended June 30, 2024 in comparison to the six-month period ended June 30, 2023. Sales of **CMT** increased by 3%, or $5,000, to $172,000 during the trailing twelve-month period ended June 30, 2024, in comparison to the trailing twelve-month period ended June 30, 2023.

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, 2023, we increased our selling price of the **First Defense®** product line by approximately 4%

(range of 2% to 8%) and **CMT** by approximately 5%. Effective November 15, 2023, we adjusted the pricing of backlogged orders to accommodate our rising costs of goods and eliminate any irrelevant purchase orders. We notified distributors that all pending orders would either be removed from our system or modified (with their authorization) to reflect the new pricing structure representing an increase of approximately 8%. Subsequently, most distributors opted to increase the prices on these older purchase orders to retain them on the list for fulfillment. The backlog of orders was worth approximately $9 million just before this most recent price change. Also effective November 15, 2023, we increased our selling price for **CMT** by approximately 12%.

b) Gross Margin

The change in our gross margin (product sales less costs of goods sold) and our gross margin as a percentage of product sales during the three-month periods, the six-month periods and the trailing twelve-month periods ended June 30, 2024 and 2023 are summarized in the following tables (in thousands, except for percentages):

	During the Three-Month Periods Ended June 30,		Increase (Decrease)	
	2024	**2023**	**Amount**	**%**
Gross margin	$1,230	$1,044	$187	18%
Percent of product sales	22%[1]	30%[2]	(7%)	(24%)

[1] This gross margin would have been 28% if there had been no write-off of scrapped inventory during the three-month period ended June 30, 2024.
[2] This gross margin would have been 31% if there had been no write-off of scrapped inventory during the three-month period ended June 30, 2023.

	During the Six-Month Periods Ended June 30,		Increase	
	2024	**2023**	**Amount**	**%**
Gross margin	$3,526	$1,345	$2,181	162%
Percent of product sales	28%[3]	19%[4]	8%	44%

[3] This gross margin would have been 31% if there had been no write-off of scrapped inventory during the six-month period ended June 30, 2024.
[4] This gross margin would have been 24% if there had been no write-off of scrapped inventory during the six-month period ended June 30, 2023.

	During the Trailing Twelve-Month Periods Ended June 30,		Increase (Decrease)	
	2024	**2023**	**Amount**	**%**
Gross margin	$6,050	$4,183	$1,868	45%
Percent of product sales	26%[5]	27%[6]	(1%)	(2%)

[5] This gross margin would have been 29% if there had been no write-off of scrapped inventory during the twelve-month period ended June 30, 2024.
[6] This gross margin would have been 32% if there had been no write-off of scrapped inventory during the twelve-month period ended June 30, 2023.

The gross margin during recent periods was significantly less than what we have experienced historically and significantly less than what we anticipate going forward. Gross margin has been running at less than our 40% target (including depreciation). The recent reduction in production output was largely the result of our decision to slow down our production rate while remediating the production contamination events discussed above. During this period, we did not benefit from spreading our fixed costs over higher volumes as we normally do. Further, we did not furlough any labor during this production slowdown. As we build back sales, we are increasing the amount of gross margin earned compared to prior periods and working to improve the gross margin as a percentage of sales. The gross margin as a percentage of product sales was 22%, 41%, 45%, 45%, 49%, 47% and 50% during the years ended December 31, 2023, 2022, 2021, 2020, 2019, 2018 and 2017, respectively. The 22% gross margin percentage during the three-month period ended June 30, 2024 and the year ended December 31, 2023 (with the 2023 annual gross margin including even lower gross margin percentages during the first quarter of 2023 and during the six-month period ended June 30, 2023) was our lowest ever. The following table displays the relationship between sales and gross margin during recent periods (in thousands except for percentages):

	Product Sales	Gross Margin Dollars	Gross Margin Percentage
Year Ended December 31, 2022	$18,568	$7,648	41%
Year Ended December 31, 2023	$17,472	$3,869	22%
Decrease during 2023 under 2022	$1,096	$3,779[(1)]	19%
Three-Month Period Ended December 31, 2022	$3,911	$992	25%
Three-Month Period Ended December 31, 2023	$5,096	$1,258	25%
Three-Month Period Ended March 31, 2023	$3,447	$301	9%
Three-Month Period Ended June 30, 2023	$3,532	$1,044	30%
Six-Month Period Ended June 30, 2023	$6,979	$1,345	19%
Three-Month Period Ended March 31, 2024	$7,257	$2,295	32%
Three-Month Period Ended June 30, 2024	$5,473	$1,231	22%
Six-Month Period Ended June 30, 2024	$12,730	$3,526	28%

[(1)] This $3.8 million decrease in gross margin earned required a very sudden, material and unexpected decrease in our available cash.

As of the end of the periods noted in the table below, Work-in-Process inventory as a percentage of total inventory has ranged from 57% to 77%, and the dollar value of Work-in-Process inventory has increased significantly since December 31, 2021. The colostrum we purchase for use in the production of **First Defense®** is the largest component of Work-in-Process inventory. As we began to increase our production capacity, we also increased the number of farms that we work with in order to increase the amount of this critical ingredient. As certain contamination events discussed above slowed the implementation of our increased capacity, we accumulated more colostrum than originally planned. While this is a good safety measure to have in place to ensure that we do not run short of colostrum, we do expect to reduce this use of cash as we move forward with our increased production rate. In a frozen state, this colostrum has a 30-month useable shelf life. Work-in-Process inventory has increased as demonstrated in the following table (in thousands, except for percentages):

As of	Value of Work-in-Process Inventory	% of Total Inventory
December 31, 2021	$1,902	62%
December 31, 2022	$3,469	57%
December 31, 2023	$5,815	74%
March 31, 2024	$5,506	77%
June 30, 2024	$5,609	77%

Achieving process yield improvements (in addition to running without significant contaminations) will be essential to increasing our gross margin. For example, one process heating step that had been increased to address the contaminations is now being carefully reduced within the parameters of our USDA-approved Outline of Production. Based on preliminary data, we currently estimate that this change could result in a yield improvement of approximately 17% per liquid processing batch. Another example is related to new filter equipment that was implemented during mid 2024 to increase our liquid processing output. We believe that optimizing this filtration step could improve yields by approximately 5% per week.

While our biological and process yields can be variable, we have seen a favorable improvement to our finished goods yield recently, but these yields continue to be variable. 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. 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. 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 continue to acquire more raw material (colostrum) from many more cows at several new farms. 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 the time of year and immune competency, our source cows have similar biological variances in response to our proprietary vaccines. 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. While this variability impacts our costs of producing inventory, the commercial 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. In the past, we have been able to reduce the impact of cost increases by implementing yield improvements.

Additionally, the significant global supply-chain disruptions that almost all industries are experiencing presently are a challenge to us. The costs of our supplies, components, raw materials, utilities and services increased significantly during 2021 and that trend continued during 2022, 2023 and into 2024. Prices for raw materials and critical supplies are increasing significantly, and it is becoming increasingly 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 timely. We believe that gross margin results going forward 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 including depreciation equal to 40% of product sales. This goal has been reduced from prior projections given the lower rates experienced during 2023 and to date in 2024.

c) Product Development Expenses and Strategy

Overview: The majority of our product development expenses pertain to the development of **Re-Tain®**. During the three-month period ended June 30, 2024, product development expenses decreased by 6%, or $69,000, to $1.0 million in comparison to $1.1 million during the three-month period ended June 30, 2023. Product development expenses aggregated 19% and 31% of product sales during the three-month periods ended June 30, 2024 and 2023, respectively. Product development expenses included non-cash depreciation and stock-based compensation expenses of $377,000 and $375,000 during the three-month periods ended June 30, 2024 and 2023, respectively. Approximately $299,000 and $315,000 of these non-cash expenses were comprised of depreciation expenses pertaining to our DS facility and equipment for **Re-Tain®** during the three-month periods ended June 30, 2024 and 2023, respectively. During the six-month period ended June 30, 2024, product development expenses increased by 4%, or $83,000, to $2.3 million in comparison to $2.2 million during the six-month period ended June 30, 2023. Product development expenses aggregated 18% and 32% of product sales during the six-month periods ended June 30, 2024 and 2023, respectively. Product development expenses included non-cash depreciation and stock-based compensation expenses of $744,000 and $749,000 during the six-month periods ended June 30, 2024 and 2023, respectively. Approximately $597,000 and $629,000 of these non-cash expenses were comprised of depreciation expenses pertaining to our DS facility and equipment for **Re-Tain®** during the six-month periods ended June 30, 2024 and 2023, respectively. We began depreciating this asset when the Certificate of Occupancy for the new construction was issued during the fourth quarter of 2017, but sales of our new product cannot be realized until we achieve FDA approval. We expect product development expenses to decrease during the second half of 2024 as inventory production of **Re-Tain®** for implementation of our controlled launch strategy described below (pending FDA approval) has now been largely completed.

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 DS 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 we are paying:

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
$4.3 million @ April 1, 2023	June 30, 2024	$61,000	$39,000	$22,000
Total		$488,000	$312,000	$176,000

Development objective: As we work to change the way that mastitis is managed in the dairy industry, we aim to demonstrate that our bacteriocin, 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 an FDA-required milk discard or meat withhold. While milk prices vary, the cost of the milk discard associated with traditional antibiotics ranges from approximately $36.00 (for 3.5 days of milk at 60 pounds per day at the Class III milk price average of $17.02 per hundredweight during 2023) to approximately $150.00 (for 11 days of milk at 80 pounds per day at the Class III milk price average of $17.02 per hundredweight during 2023) 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 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 plus 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.

Subclinical mastitis, and the study required to achieve an effectiveness claim for it, is defined under the FDA/Center for Veterinary Medicine Guidance #49: Target Animal Safety and Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products (Lactating and Non-Lactating Cow Products). Trial eligibility requires both pretreatment samples to be positive for the mastitis pathogen (except for *Staphylococcus aureus* and *Streptococcus agalactiae*, where a single pretreatment sample qualifies a cow for enrollment). For all pathogens, both samples taken between 14 and 28 days post treatment (and at least 5 days apart) must be negative to be judged a cure. These conservative criteria generally result in enrolling cows with chronic subclinical disease, which rarely self-resolves.

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 DS production, which is a required component of the CMC Technical Section, has been the most 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. As a result, 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) determine 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 DS submission (without the DP submission) during the first quarter of 2019 that 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 DS and DP, during the first quarter of 2021. 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 (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. We made a second DS and DP submission of the CMC Technical Section during the first quarter of 2022. During the third quarter of 2022, we received an Incomplete Letter from the FDA with regards to this second DS and DP submission of the CMC Technical Section. The submission required that internal and external laboratories re-develop and qualify several analytical tests and associated controls. We made this third DS and DP submission of the CMC Technical Section during the third quarter of 2023.

In late October of 2023, the FDA notified us that it was refusing to review our third submission because Norbrook was identified as the DP manufacturer in our submission, but the FDA was expecting that we would identify our own in-house services as the DP manufacturer (instead of Norbrook). This miscommunication was due to a statement in our April of 2022 response to an FDA 483 inspectional observation in which we noted that Norbrook was expected to exit the DP manufacturing agreement with us at the end of 2022, which would have required us to procure and install some long lead time equipment (filler and labeler) in our DS suite in late 2022. Instead, we were able to extend the agreement with Norbrook to complete the manufacture of DP inventory for the initial commercial sales under our controlled launch strategy. As a result, we continued to identify Norbrook as our DP manufacturer. As a result of this miscommunication, we were required to re-submit our third submission the CMC Technical Section in November of 2023. During May of 2024, the FDA issued another Incomplete Letter to us. Pursuant to this Incomplete Letter, the FDA has provided some minor questions about our third submission requiring a fourth submission of the CMC Technical Section. The FDA also noted that all inspectional observations at our DS facility must be cleared before this fourth submission could be made. The FDA notified us during the second quarter of 2024 that the inspectional observation at our DS facility had been cleared.

This fourth submission has not been made yet because all inspectional observations must also be cleared at the DP facility of our contract manufacturer before the FDA will issue a Technical Section Complete Letter. Our contract manufacturer submitted responses to its inspectional observations in early July of 2024 . Clearing the outstanding inspectional observations with the FDA defines the critical path timeline. Once the DP facility inspection is cleared by the FDA, we anticipate making a Non-Administrative NADA submission that would include our fourth submission of the CMC Technical Section, together with the minor technical sections covering All Other Information and Product Labeling. We are implementing this filing strategy to attempt to eliminate the need for the 60-day review period allowed for an Administrative NADA submission at the end of the application process. By statute, this submission would be subject to a review period of up to 180 days. However, we believe that a shorter review period may be provided because the responses to the CMC Incomplete Letter are not complex.

Upon FDA approval, we intend to implement our previously disclosed limited distribution, controlled launch strategy with product expiration dating estimated at between the second quarter of 2025 and the first quarter of 2026, subject to confirmation of final product shelf-life disposition by the FDA. While being prudent with how much cash we invested into inventory that would have short expiry dating if market launch is delayed, we built more DS inventory during 2022 and 2023 to support the initial commercial sales of **Re-Tain®**. We presently have no arrangement in place to aseptically fill new DP inventory and are planning to reduce operating costs at our DS production facility until initial market acceptance (and perhaps the interest of a marketing partner) justifies a new arrangement for aseptic filling and the production of additional inventory. We anticipate a pause in the supply of product to market after the initial launch goods are sold and before the product is re-launched with DP produced by our in-house aseptic filling

operations (if that investment is re-funded) or by an alternative contractor that we have not identified to date.

While we do not expect **Re-Tain®** to make a significant contribution to our sales growth in the early years after market launch, we do see value in achieving regulatory approval and testing market acceptance. With all production of DS for our controlled launch now complete, we are reducing operating costs at our DS facility by implementing an aggressive idling of these operations beginning during the second half of 2024.

Our DS manufacturing facility and that of our DP contract manufacturer (and our potential 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 responded to all of the queries. Early during the first quarter of 2024, the FDA conducted another pre-approval inspection of our DS facility. This resulted in the issuance of one deficiency as identified on the FDA's Form 483. Since then, we have fully responded to this inspectional observation. The facility of our DP contract manufacturer is subject to similar inspectional compliance obligations. As discussed above, a pre-approval inspection of that facility was conducted around the end of the first quarter of 2024.

We have always believed that the fastest route to FDA approval and market launch is with the services of Norbrook (an FDA-approved DP manufacturer), 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 is providing DP for our controlled launch with production into 2024.

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). During the first quarter of 2022, we initiated an investment in the installation of equipment to produce DP at our own facility at **Building 33**. Given the loss in gross margin during the first ten months of 2023 caused by the slowdown in production output that was necessary to remediate the production contamination events discussed above, we decided to defer the completion of this investment for the time being. Subject to the timing of our installation and validation work, we anticipate FDA approval of this facility (which is a requirement for commercial manufacturing) at least two years from when this project is restarted allowing for two six-month review cycles. This will be a post-approval submission. If we decide to complete our potential future DP manufacturing facility, such facility will, upon completion, be subject to FDA inspection and approval. We anticipate it would have enough formulation and aseptic filling capacity to exceed the expected production capacity of our DS facility, which is approximately $7 million to $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 would provide 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, if completed, 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, if we decide to complete this DP facility (rather than utilizing a third party for these services), 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®** would 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®** would 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, line extensions or additions to our **First Defense®** product line. The bolus format of **First Defense®** and **Tri-Shield First Defense®** have been listed with the Organic Materials Research Institute (OMRI) since 2013 and 2019, respectively. This means they can be used on organic farms. During the third quarter of 2024, the gel tube format of **First Defense®** also became OMRI listed. We are currently working to establish USDA claims for our bivalent bulk powder formulation of **First Defense Technology®**. During the third quarter of 2024, we entered into a research agreement with the Mayo Clinic, a non-profit, educational, research and healthcare institution, to explore potential applications of Nisin in certain human surgical situations. 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.

d) Sales and Marketing Expenses and Selling Strategy

We see ourselves as the “non-pharma” pharma company. Rather than offering variations of “copy-cat” 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.

During the three-month period ended June 30, 2024, sales and marketing expenses increased by 37%, or $265,000, to $985,000 in comparison to $720,000 during the three-month period ended June 30, 2023, amounting to 18% and 20% of product sales during the three-month periods ended June 30, 2024 and 2023, respectively. Sales and marketing expenses included non-cash depreciation and stock-based compensation expenses of $44,000 and $39,000 during the three-month period ended June 30, 2024 and 2023, respectively. During the six-month period ended June 30, 2024, sales and marketing expenses increased by 12%, or $187,000, to $1.8 million in comparison to $1.6 million during the six-month period ended June 30, 2023, amounting to 14% and 23% of product sales during the six-month periods ended June 30, 2024 and 2023, respectively. Sales and marketing expenses included non-cash depreciation and stock-based compensation expenses of $88,000 and $87,000 during the six-month period ended June 30, 2024 and 2023, respectively. Our current budgetary guideline 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 multi-valent 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.

During the twelve-month period ended December 31, 2023, we treated more calves than our next largest calf-level competitive product, which is a vaccine administered to the newborn at birth. Compared to the dam-level competitive products (which are vaccines given to the cow pre-calving), we are second in sales dollars to the market leader. 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.

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 without an FDA-required 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 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. 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 sub clinically 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.

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 bacteriocin 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. The industry could keep treating this very significant disease with traditional antibiotics, but it takes innovation to bring a bacteriocin 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®**. Based on consultations with industry experts and key opinion leaders, we have opted to carefully control the launch of this novel product over the first 18 to 24 months or so after FDA approval, as we seek to transform the way that mastitis is treated in the dairy industry over the long term. Our goal is to help early adopters select treatment candidates, 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 number of participating farms so that the desired levels of support and guidance relating to effective usage of **Re-Tain®** can be provided with our available resources. We recognize that it will be important to manage expectations from the producer to the milk processor because it is possible that processors may express reservations with regards to the zero milk discard claim. Our controlled launch strategy reduces the amount of inventory that we would need to build at risk before regulatory approval is achieved. 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 considered available product supply and the damage a 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. We continue to develop detailed launch plans, focusing on the readiness of dairy operators to successfully introduce **Re-Tain®** to their herds. We believe that these prudent steps, while potentially leading to lower initial **Re-Tain®** revenues, may create a smooth and successful launch and could safeguard the longer term performance of our investment in **Re-Tain®**. We also 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 under **PART II: OTHER INFORMATION, ITEM 1A – RISK FACTORS**, 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®**.

e) Administrative Expenses

During the three-month period ended June 30, 2024, administrative expenses increased by 14%, or $73,000, to $602,000 in comparison to $529,000 during the three-month period ended June 30, 2023. Administrative expenses amounted to 11% and 15% of product sales during the three-month periods ended June 30, 2024 and 2023, respectively. Administrative expenses included non-cash depreciation and stock-based compensation expenses of $55,000 and $47,000 during the three-month periods ended June 30, 2024 and 2023, respectively. During the six-month period ended June 30, 2024, administrative expenses increased by 3%, or $37,000, to just over $1.1 million in comparison to just under $1.1 million during the six-month period ended June 30, 2023. Administrative expenses amounted to 9% and 16% of product sales during the six-month periods ended June 30, 2024 and 2023, respectively. Administrative expenses included non-cash depreciation and stock-based compensation expenses of $101,000 and $96,000 during the six-month periods ended June 30, 2024 and 2023, respectively. We strive to be efficient with these expenses while funding 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 employees 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 have been eliminated. 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 to $2.5 million per year is an efficient budget goal to fund the administrative expenses of a publicly-held company.

f) Net Operating Loss

During the three-month period ended June 30, 2024, our net operating loss was $1.4 million in comparison to a net operating loss of $1.3 million during the three-month period ended June 30, 2023. During the six-month period ended June 30, 2024, our net operating loss of $1.7 million was significantly less than our net operating loss of $3.6 million during the six-month period ended June 30, 2023. The $1.9 million decrease in our net operating loss during the six-month period ended June 30, 2024 compared to the six-month period ended June 30, 2023 was largely caused by the $2.2 million increase in gross margin.

g) Other Expenses, net

During the three-month period ended June 30, 2024, other expenses, net, aggregated $144,000 in comparison to other expenses, net, of $74,000 during the three-month period ended June 30, 2023. Interest expense increased to $142,000 during the three-month period ended June 30, 2024 from $89,000 during the three-month period ended June 30, 2023. Non-cash amortization of debt issuance and debt discount costs (which is included as a component of interest expense) was $11,000 and $2,000 during the three-month periods ended June 30, 2024 and 2023, respectively. Interest income was $13,000 and $15,000 during the three-month periods ended June 30, 2024 and 2023, respectively. We incurred a $15,000 loss on disposal of property, plant and equipment during the three-month period ended June 30, 2024 compared to no loss during the three-month period ended June 30, 2023.

During the six-month period ended June 30, 2024, other expenses, net, aggregated $280,000 in comparison to other expenses, net, of $131,000 during the six-month period ended June 30, 2023. Interest expense increased to $288,000 during the six-month period ended June 30, 2024 from $179,000 during the six-month period ended June 30, 2023. Non-cash amortization of debt issuance and debt discount costs (which is included as a component of interest expense) was $21,000 and $4,000 during the six-month periods ended June 30, 2024 and 2023, respectively. We anticipate that our interest expense will be approximately $566,000 and $494,000 during the years ending December 31, 2024 and 2025, respectively. Interest income was $23,000 and $55,000 during the six-month periods ended June 30, 2024 and 2023, respectively. We incurred a $15,000 loss on disposal of property, plant and equipment during the six-month period ended June 30, 2024 compared to an $8,000 loss during the six-month period ended June 30, 2023.

h) Loss Before Income Taxes

During the three-month period ended June 30, 2024, our loss before income taxes was $1.5 million in comparison to a loss before income taxes of $1.4 million during the three-month period ended June 30, 2023. During the six-month period ended June 30, 2024, our loss before income taxes was $2 million in comparison to a loss before income taxes of $3.7 million during the six-month period ended June 30, 2023. The $1.7 million decrease in our net loss during the six-month period ended June 30, 2024 compared to the six-month period ended June 30, 2023 was largely the result of the $2.2 million increase in gross margin that was reduced by a $307,000 increase in operating expenses.

i) Income Taxes and Net Loss

During the three-month periods ended June 30, 2024 and 2023, we recorded income tax expense of $1,300 and $1,500, respectively, which is comprised of minimum state tax liabilities. Our net loss of $1.5 million, or $0.20 per basic share, during the three-month period ended June 30, 2024 was in comparison to net loss of $1.4 million, or $0.18 per basic share, during the three-month period ended June 30, 2023. During the six-month periods ended June 30, 2024 and 2023, we recorded income tax expense of $2,700 and $3,000, respectively, which is comprised of minimum state tax liabilities. Our net loss of $2 million, or $0.25 per basic share, during the six-month period ended June 30, 2024 was in comparison to net loss of $3.7 million, or $0.48 per basic share, during the six-month period ended June 30, 2023.

We have substantial net operating loss carryforwards that largely offset future income tax expense. As of December 31, 2023, our federal net operating loss carryforward was $17.8 million. As of December 31, 2023, our state net operating loss carryforward was $4.7 million. On December 22, 2017, the Tax Cuts and Jobs Act was signed into law. This legislation made 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 statutory 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 and the discussion under **Liquidity and Capital Resources**, above, to assess the cash generating ability of our operations.

Critical Accounting Policies and Estimates

The unaudited 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 June 30, 2024 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. Significant estimates include our valuation of inventory, deferred tax assets and costs of goods sold. 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 of our financial statements. These critical accounting estimates have been consistently applied.

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

Not applicable

ITEM 4 - CONTROLS AND PROCEDURES

Disclosure Controls and Procedures: 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. 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. 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 defined in Exchange Act Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of June 30, 2024. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date.

Changes in Internal Controls over Financial Reporting: Our principal executive and principal financial officer and our Director of Finance and Administration periodically evaluate 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 June 30, 2024 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

OUTLINE TO ITEM 1A - RISK FACTORS

- **Financial Risks**
- **Product Risks**
- **Regulatory Risks**
- **Economic Risks Pertaining to the Dairy and Beef Industries**
- **Small Size of the Company**
- **Global Risks**
- **Risks Pertaining to Common Stock**
- **Other Risks**

Financial Risks

Gross margin on product sales: One of our goals is to achieve a gross margin as a percentage of total sales of 40% or more (including depreciation expense) 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 Quarterly Report (including contaminations, process yields, inflation, 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 that we are not able to achieve our gross margin goal, which would adversely affect our operating results and could impact our future operating plans. We missed our gross margin goal during the year ended December 31, 2023 and during the first half of 2024 with realized gross margins of 22% and 28%, respectively. There is a risk that our plans to maintain or improve our gross margin may not be realized due to cost increases, production yield losses, additional manufacturing contamination events, production equipment failures, the inability to raise our selling prices, or any combination of these factors. In addition, such negative events, depending on their severity, could deplete our cash resulting in an inability to fund our business.

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. During the first quarter of 2020, we removed the direct aspect of this particular exposure to our business by refinancing our bank debt (with the exception of our line of credit) with fixed rate notes. Our mortgage debt outstanding as of June 30, 2024 was $5.7 million bearing interest at the fixed rate of 3.53% per annum. Our equipment loans outstanding as of June 30, 2024 were $2.3 million bearing interest at the fixed rate of 3.50% per annum. The outstanding balance on the two State of Maine loans as of June 30, 2024 was approximately $700,000 bearing interest at the fixed rate of 5% per annum. The $3 million in debt that we secured during the third quarter of 2023 bears interest at the blended fixed rate of 7.33% per annum and had an outstanding balance of $2.7 million as of June 30, 2024. Our outstanding debt as of June 30, 2024 aggregating $11.4 million bears interest at the blended fixed rate of 4.51% per annum. Increasing interest rates would negatively impact the cost of any future borrowings. This was experienced on the new debt facilities aggregating $3 million that we closed during the third quarter of 2023. 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. 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 $2 million during both of the years ending December 31, 2024 and 2025. See Note 10 to the accompanying unaudited financial statements for more details about our debt.

Debt covenants: Our debt with Gorham Savings Bank and the Finance Authority of Maine is subject to certain financial covenants. We are required to meet a minimum debt service coverage (DSC) ratio of 1.35. Our actual DSC ratios were (1.10), 0.44, 2.68 and 2.03 for the years ended December 31, 2023, 2022, 2021 and 2020, respectively. Our actual DSC ratio was (0.18) for the trailing twelve-month period ended June 30, 2024. There can be no assurance that we can exceed the required level in subsequent years. During the first quarter of 2023, the DSC ratio covenant for the year ending December 31, 2023 was waived by our lender. Instead, we were required to meet a minimum DSC ratio requirement of 1.35 for the twelve-month periods ending June 30, 2024, September 30, 2024 and December 31, 2024, and then again annually after that. During the first quarter of 2024, the DSC ratio covenant for the twelve-month period ended June 30, 2024 was preemptively waived by our lenders. During the third quarter of 2024, the DSC ratio covenant for the twelve-month period ending September 30, 2024 was preemptively waived by our lenders. If we are unable to achieve the required DSC ratio going forward or reach a favorable agreement with our lenders regarding that requirement (including an amendment to or waiver of such requirement), we would be in violation of that covenant, which could result in unfavorable amendments to the terms of our bank debt or have other adverse impacts on our business and results of operations.

Currency exchange fluctuation: We do not believe that currency exchange rates have had a significant effect on our revenues and expenses. However, future increases in the value of the U.S. dollar could affect our customers and the demand for our products. We hope to increase the level of our future sales of products outside the United States. The cost of our products to international customers could be affected by currency fluctuations. The decline of the U.S. dollar against other currencies could make our products less expensive to international customers. Conversely, a stronger U.S. dollar could make our products more costly for international customers. A weaker U.S. dollar makes international purchases more expensive for us.

Inflation, supply disruptions, tax rates and economic downturns: 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. We are facing significant production constraints, supply disruptions and inflationary increases which were initially triggered, in large part directly or indirectly, by the COVID-19 pandemic. The extent and duration of the negative impact 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 since the onset of the pandemic. 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 who 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 created risk and continues to create uncertainty and challenges for us and has created or contributed to global supply-chain disruptions and has affected international trade, while creating a worldwide health and economic crisis. Stock market valuations have declined and recovered somewhat but 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.

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 deeper operating losses or less profits. 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 DS production facility (as described in more detail in **PART I: ITEM 2** of this Quarterly 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.

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.

Contamination events, equipment failures and gross margin from our production process: During the first half of 2024 as well as during 2023 and 2022, we experienced certain contamination events and equipment failures in our production process that resulted in scrapped inventory and a slowdown of our production process, which had a significant negative impact on our operating results. The realization of this risk following the contamination events discussed above did result in a slowdown of our production output during 2023 to remediate this problem, which led to less sales and gross margin during the year. We are at risk of further such production contaminations or equipment failures resulting in more scrapped inventory. Additional contamination events or equipment failures causing significantly less production output, depending on their severity, could deplete our cash resulting in an inability to fund our business operations.

*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, which could create legal liability.

2) A failed or stalled cheese tank occurs when a Nisin susceptible cheese starter culture is impacted by residues in milk that exceed our on-farm treatment recommendations, which aims to limit concentrations of bulk tanks or tankers to 1% of milk from cows treated with **Re-Tain®** or is not effectively diluted through the milk collection and transportation system. After we study this potential impact during our controlled launch of **Re-Tain®**, we may decide to seek a post-approval label change requiring a short discard of milk, which may be limited to just the treated quarter of the cow.

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 have access to 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 or because the product is administered to cows that are infected with pathogens outside of our label claims.

5) 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 and potential legal liability.

6) 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.

7) No sales after first quarter of 2026 until we secure additional DP supply.

*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. Our anticipated return to profitability is contingent upon the gross margin we earn from **First Defense®** and prudent management of product development expenses.

Concentration of sales: Sales of the **First Defense®** product line aggregated 99% of our total product sales during both of the years ended December 31, 2023 and 2022 and during both of the six-month periods ended June 30, 2024 and 2023. Our primary customers for the majority of our product sales (91% and 92% during the years ended December 31, 2023 and 2022, respectively, and 88% and 90% during the six-month periods ended June 30, 2024 and 2023, 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 8% of our total product sales during the years ended December 31, 2023 and 2022, respectively, and 12% and 10% during the six-month periods ended June 30, 2024 and 2023, 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 (79% and 73% during the years ended December 31, 2023 and 2022, respectively, and 79% and 78% during the six-month periods ended June 30, 2024 and 2023, respectively) was made to two large distributors. A large portion of our trade accounts receivable (77% and 79% as of June 30, 2024 and December 31, 2023, 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 $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. During 2021, we initiated three additional investments aggregating $4.7 million to increase our estimated annual production capacity for the **First Defense®** product line to approximately $30 million, which we completed at the end of 2022. We are making initial plans to further increase our production capacity. While previous capacity expansion investments have 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. Our long-term capital 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 facilities at 175 Industrial Way, as well as assessment of costs, 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. There is a risk that we will become subject to regulatory actions in the future, including actions that result in our inability to ship product. In these cases, the resulting interruption in sales could have a material and adverse effect on our operating results.

*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 17 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. We received an Incomplete Letter from the FDA regarding this CMC Technical Section during the third quarter of 2022 that clarified the required path to product approval. During May of 2024, we received an Incomplete Letter from the FDA in response to our November of 2023 re-submission. To reduce the risk associated with this process, we are working with a qualified contract manufacturer (Norbrook) for alignment of the required validations and DP manufacture and have met with the FDA to clarify filing strategy and requirements. Early during the first quarter of 2024, the FDA conducted another pre-approval inspection of our DS facility. This resulted in the issuance of one deficiency as identified on the FDA's Form 483. Since then, we have cleared the inspectional observation with the FDA. However, our efforts continue to be subject to inspection and approval by the FDA and other factors outside of our control, and there remains a risk that the required FDA approvals of our product and facilities could be delayed or not obtained. The facility of our contract manufacturer is subject to similar inspectional obligations and is currently working to resolve certain inspectional observations at their facility with the FDA. International regulatory approvals would be required for sales of **Re-Tain**® outside of the United States, and there is a risk that these approvals would be or become too costly to pursue or be delayed or not obtained.

Regulatory requirements limiting access to suppliers and customer base: Maine, where our principal executive office and manufacturing facilities are located, has adopted product reporting and phase-out requirements for per- and polyfluoroalkyl substances ("PFAS"). Maine's statute establishes a phased ban for products that contain intentionally added PFAS, with all products (subject to certain exceptions) other than cooling, heating, ventilation, air conditioning or refrigeration equipment being banned by 2032 unless the Maine Department of Environmental Protection ("DEP") has determined that the use of PFAS within the product is a "currently unavoidable use." Beginning January 1, 2032, the sale of products containing intentionally added but "currently unavoidable" PFAS also is banned if the manufacturer of such products has failed to report to the DEP information concerning the presence of PFAS in those products. The phased bans may limit our ability to access supplies and may limit those customers to whom we may sell our products. The U.S. Environmental Protection Agency also has adopted a PFAS reporting law, which requires that importers of articles that contain PFAS report the presence of such substances to the extent such information is known or reasonably ascertainable. This reporting requirement may limit our ability to import supplies.

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. This count continued to decline to 92,100,000 as of January 1, 2022 and to 88,800,000 as of January 1, 2023. This count dropped to 87,200,000 as of January 1, 2024. Reflecting seasonal trends, this figure was equal to 102,000,000, 101,000,000, 98,600,000 and 95,900,000 as of July 1, 2020, 2021, 2022, and 2023, respectively. A significant decline in the cattle count could negatively affect the size of our addressable market.

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 the low of 9,011,000 in 2004 to the high of 9,448,000 in 2021. This average declined to 9,402,000 during the year ended December 31, 2022 and then

declined to 9,386,000 during the year ended December 31, 2023. This average declined slightly to 9,336,000 during the six-month period ended June 30, 2024. A significant decline in the herd size could negatively affect the size of our addressable market.

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 2022 increased significantly to an average of $1,598, which is a 17% increase over 2021. The 2023 average price of $1,763 represents a 10% increase over prior year. This average price increased to $2,005 as of January and April of 2024. A significant decline in the milk cow price could negatively affect the size of our addressable market.

Milk price: The dairy market, similar to many others, has been unstable for several reasons including as a result of the pandemic. The price paid to producers for milk has been very volatile. This market volatility, and the resulting impact on our primary end users, could negatively impact our ability to maintain and grow sales at a profitable level. 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 of 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 of 2020 to $21.04 in June of 2020 set an all-time record for variability. The average price for 2021 decreased by 6% to $17.08. This price average increased by 29% to $21.96 during the year ended December 31, 2022. The average price decreased by 22% to $17.02 during the year ended December 31, 2023. The average price increased to $17.33 during the seven-month period ended July 31, 2024. 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%)
2022	$21.96	29%
2023	$17.02	(22%)

Feed Costs: 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 and therefore could have a resulting negative impact on our business and results of operations. 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 1.74 for 2021, amounting to a significant decline of 25% from the 2020 average of 2.32. This average has not been lower since 2012. During 2022, this ratio improved by 10% to 1.91. This ratio dropped to 1.68 during the year ended December 31, 2023. This ratio increased to 2.17 during the six-month period ended June 30, 2024. 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	2.32	3%
2021	1.74	(25%)
2022	1.91	10%
2023	1.69	(12%)

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 the Company

Dependence on key personnel: We are a small company with approximately 80 employees (including 5 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 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. We will require increased staffing levels to operate our expanded **First Defense®** production capacity and to operate our **Re-Tain®** production facility. 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 DP contract manufacturer. Because Norbrook notified us of its intent to terminate its supply agreement with us, we initiated an investment of approximately $4 million during 2022 to construct and equip our own DP formulation and aseptic filling capability for **Re-Tain®** in our existing DS facility. Due to the loss in gross margin during 2023 caused by the slowdown in production output necessary to remediate product contamination events, we have decided to defer spending of approximately $2 million of these funds for the near term. 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. We are evaluating alternatives for DP supply going forward, which include the resumption of the investment in our own in-house DP services (when prudent based on our cash reserves) or another contract manufacturing agreement or a further extension with Norbrook. We anticipate a supply interruption under our controlled launch of **Re-Tain®** after the DP supply provided from our contract manufacturer is consumed and until new supply from a new contract manufacturing agreement or our own formulation and aseptic filling facility is implemented.

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 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 does not carry an FDA-required milk discard or meat withhold). 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

Russia's unprovoked military invasion of Ukraine and the war in the Middle East: Russia's unprovoked military invasion of Ukraine (and attack on its people) and the war in the Middle East are 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). Both of these military actions could cause more stress on the global economy.

Climate change: Our business, and our activities and the activities of our customers and suppliers, could be disrupted by climate change. Potential physical risks from climate change may include altered distribution and intensity of rainfall, prolonged droughts or flooding, increased frequency of wildfires and other natural disasters, rising sea levels, and a rising heat index, any of which could cause negative impacts to our and our customers' and suppliers' businesses. Increased temperatures and rising water levels may negatively impact our dairy and beef livestock customers by increasing the prevalence of parasites and diseases that affect food

animals. The physical changes caused by climate change may also prompt changes in regulations or consumer preferences which in turn could have negative consequences for our and our customers' businesses. Climate change may negatively impact our customers' operations, through climate-related impacts such as increased air and water temperatures, rising water levels and increased incidence of disease in livestock. In addition, concerns regarding greenhouse gas emissions and other potential environmental impacts of livestock production have led to some consumers opting to limit or avoid consuming animal products. If such events affect our customers' businesses, they may purchase fewer of our products, and our revenues may be negatively impacted. Climate driven changes could have a material adverse impact on the financial performance of our business and on our customers. In addition, increased frequency of natural disasters and adverse weather conditions may disrupt our manufacturing processes or our supply chain. These disruptions may have a material adverse effect on our business, financial condition, results of operations and/or cash flows.

Bovine diseases: The potential for epidemics of bovine diseases such as Highly Pathogenic Avian Influenza (HPAI), 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 concentrated bovine 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 Capital Market (Nasdaq: ICCC). Our average daily trading volume (which was 8,669 shares per day during the 20-day period ended August 2, 2024) 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 August 2, 2024 was $3.82. Most companies in the animal health sector have market capitalization values that greatly exceed our market capitalization of approximately $30 million as of August 2, 2024. Our product sales during the trailing twelve-month period ended June 30, 2024 were $23.2 million. This means that our market capitalization as of August 2, 2024 was equal to approximately 1.29 times our sales during the trailing twelve-month period ended June 30, 2024. 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 are accessing the capital markets and issuing additional common stock under an At-The-Market Offering Agreement in order to fund our growth objectives, as described elsewhere in this Quarterly Report. Such issuances 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 will be dependent on one manufacturer for the supply of syringes for **Re-Tain®**. We are currently dependent on a contract with Norbrook for the DP formulation and aseptic filling for supply of our Nisin DP through 2024. Any facility used to perform these services will be subject to FDA inspection and approval, the outcome and timing of which are not within our control. We anticipate that this FDA approval process would take at least two years. 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 lack of financing, regulatory issues or non-compliance) would adversely affect the production of inventory and result in significant added expenses and potential loss of future sales. We anticipate a supply interruption and adverse effects on our controlled launch of **Re-Tain®** beginning during the first quarter of 2026 (subject to confirmation of final product shelf-life disposition by the FDA). These goods represent the initial DP production from our contract manufacturer. The extent of the interruption will be subject to the supply timeline from a new contract manufacturing agreement or from our own formulation and aseptic filling facility for DP.

Failure to protect intellectual property: The protection and enforcement of our intellectual property rights may require the expenditure of significant financial, managerial and operational resources. We rely on trademark, copyright and patent law, trade secret protection, agreements and other methods with our employees and others to protect our proprietary rights. However, we may be unable to adequately protect our intellectual property rights or prevent third parties from infringing or misappropriating our intellectual property rights. We may not be able to obtain registration for all intellectual property we seek to register, and effective intellectual property protection may not be available in every country in which our products are sold. 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. Further, our confidentiality agreements may not effectively prevent disclosure of our proprietary information, technologies and processes and may not provide an adequate remedy in the event of unauthorized disclosure of such information. Others may independently develop similar trade secrets or technology or obtain access to our unpatented trade secrets or proprietary technology. Others 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. Any of our intellectual property rights may be challenged by others or invalidated through administrative process or litigation. Third parties may claim in the future, that we have infringed their intellectual property rights, which could result in significant costs and potential damages and license requirements. We may initiate claims or litigation against others for infringement, misappropriation or violation of our intellectual property rights or other proprietary rights or to establish the validity of such rights. However, we may be unable to discover or determine the extent of any infringement, misappropriation or other violation of our intellectual property rights and other proprietary rights. In addition, we may be unable to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights and other proprietary rights.

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 since 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 10.1	At The Market Offering Agreement, dated April 9, 2024, by and between ImmuCell Corporation and Craig-Hallum Capital Group LLC (incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K filed April 9, 2024).
Exhibit 10.2	Consent and First Amendment to Economic Recovery Loan Program Loan Agreement, dated April 8, 2024, by and between the Company and the Finance Authority of Maine (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed April 9, 2024).
Exhibit 10.3	Fourth Amendment of Indenture of Lease for Premises Located in Portland, Maine between the Company and TVP, LLC dated as of June 11, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed June 14, 2024).
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.

+Management contract or compensatory plan or arrangement.
*Filed herewith.

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: August 13, 2024

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

Exhibit 31

CERTIFICATION PURSUANT TO REQUIRED BY RULE 13a-14(a)

I, Michael F. Brigham, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ImmuCell Corporation (the Company);

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the Company is made known to me by others within the Company, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's Board of Directors (or persons performing the equivalent function):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: August 13, 2024

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

Exhibit 32
CERTIFICATION PURSUANT TO SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES- OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of ImmuCell Corporation (the "Company") for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael F. Brigham, President, Chief Executive Officer and Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

/s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer and Principal Financial Officer
August 13, 2024

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