**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 10-Q

**☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended March 31, 2022**

**001-12934**
**(Commission file number)**

# ImmuCell Corporation

**(Exact name of registrant as specified in its charter)**

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of the registrant's common stock outstanding as of May 6, 2022 was 7,742,864.

**ImmuCell Corporation**

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**PART 1. FINANCIAL INFORMATION**
**ITEM 1. UNAUDITED FINANCIAL STATEMENTS**
**BALANCE SHEETS**

| | (Unaudited) As of March 31, 2022 | As of December 31, 2021 |
|---|---|---|
| **ASSETS** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $11,817,136 | $10,185,468 |
| Trade accounts receivable, net | 2,652,591 | 2,694,229 |
| Inventory | 3,435,834 | 3,089,974 |
| Prepaid expenses and other current assets | 393,540 | 295,197 |
| Total current assets | 18,299,101 | 16,264,868 |
| **PROPERTY, PLANT AND EQUIPMENT, net** | 27,132,148 | 26,893,599 |
| **OPERATING LEASE RIGHT-OF-USE ASSET** | 1,078,051 | 1,109,133 |
| **GOODWILL** | 95,557 | 95,557 |
| **INTANGIBLE ASSETS, net** | 71,640 | 76,416 |
| **OTHER ASSETS** | 22,999 | 26,115 |
| **TOTAL ASSETS** | $46,699,496 | $44,465,688 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **CURRENT LIABILITIES:** | | |
| Current portion of debt obligations | $947,279 | $812,207 |
| Current portion of operating lease liability | 110,052 | 108,012 |
| Accounts payable and accrued expenses | 1,293,769 | 1,614,250 |
| Total current liabilities | 2,351,100 | 2,534,469 |
| **LONG-TERM LIABILITIES:** | | |
| Debt obligations, net of current portion | 9,977,743 | 8,327,122 |
| Operating lease liability, net of current portion | 998,114 | 1,027,157 |
| Total long-term liabilities | 10,975,857 | 9,354,279 |
| **TOTAL LIABILITIES** | 13,326,957 | 11,888,748 |
| **CONTINGENT LIABILITIES AND COMMITMENTS (See Note 11)** | | |
| **STOCKHOLDERS' EQUITY:** | | |
| Common stock, $0.10 par value per share, 15,000,000 and 15,000,000 shares authorized, 7,814,165 and 7,814,165 shares issued and 7,742,864 and 7,741,864 shares outstanding, as of March 31, 2022 and December 31, 2021, respectively. | 781,417 | 781,417 |
| Additional paid-in capital | 35,750,133 | 35,395,388 |
| Accumulated deficit | (3,003,028) | (3,738,694) |
| Treasury stock, at cost, 71,301 and 72,301 shares as of March 31, 2022 and December 31, 2021, respectively | (155,983) | (158,171) |
| Total stockholders' equity | 33,372,539 | 32,576,940 |
| **TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY** | $46,699,496 | $44,465,688 |

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

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

| | During the Three-Month Periods Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Product sales | $5,999,684 | $4,107,146 |
| Costs of goods sold | 2,896,461 | 2,504,958 |
| Gross margin | 3,103,223 | 1,602,188 |
| Product development expenses | 1,035,935 | 1,031,064 |
| Sales and marketing expenses | 811,500 | 520,597 |
| Administrative expenses | 462,800 | 425,152 |
| Operating expenses | 2,310,235 | 1,976,813 |
| **NET OPERATING INCOME (LOSS)** | 792,988 | (374,625) |
| Other expenses, net | 56,174 | 66,678 |
| **INCOME (LOSS) BEFORE INCOME TAXES** | 736,814 | (441,303) |
| Income tax expense | 1,148 | — |
| **NET INCOME (LOSS)** | $735,666 | ($441,303) |
| Basic weighted average common shares outstanding | 7,742,120 | 7,219,436 |
| Basic net income (loss) per share | $0.10 | ($0.06) |
| Diluted weighted average common shares outstanding | 7,789,474 | 7,219,436 |
| Diluted net income (loss) per share | $0.09 | ($0.06) |

*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 March 31, 2022: | | | | | | | |
| **BALANCE,** | | | | | | | |
| December 31, 2021 | 7,814,165 | $781,417 | $35,692,388 | ($3,738,694) | 72,301 | ($158,171) | $32,576,940 |
| Net income | — | — | — | 735,666 | — | — | 735,666 |
| Exercise of stock options | — | — | 3,652 | — | (1,000) | 2,188 | 5,840 |
| Stock-based compensation | — | — | 54,093 | — | — | — | 54,093 |
| **BALANCE,** | | | | | | | |
| March 31, 2022 | 7,814,165 | $781,417 | $35,750,133 | ($3,003,028) | 71,301 | ($155,983) | $33,372,539 |
| | | | | | | | |
| During the Three-Month Period Ended March 31, 2021: | | | | | | | |
| **BALANCE,** | | | | | | | |
| December 31, 2020 | 7,299,009 | $729,901 | $31,372,093 | ($3,660,402) | 80,173 | ($175,392) | $28,266,200 |
| Net loss | — | — | — | (441,303) | — | — | (441,303) |
| Exercise of stock options | — | — | 7,305 | — | (2,000) | 4,375 | 11,680 |
| Stock-based compensation | — | — | 34,629 | — | — | — | 34,629 |
| **BALANCE,** | | | | | | | |
| March 31, 2021 | 7,299,009 | $729,901 | $31,414,027 | ($4,101,705) | 78,173 | ($171,017) | $27,871,206 |

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

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

| | During the Three-Month Periods Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net income (loss) | $735,666 | ($441,303) |
| Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities: | | |
| Depreciation | 616,847 | 614,695 |
| Amortization of intangible assets | 4,776 | 4,776 |
| Amortization and write-off of debt issuance costs | 1,905 | 1,960 |
| Stock-based compensation | 54,093 | 34,629 |
| Gain on disposal of fixed assets | (11,000) | (10,000) |
| Non-cash rent expense | 4,079 | 2,679 |
| Changes in: | | |
| Trade accounts receivable | 41,638 | (593,404) |
| Accrued interest income | — | 495 |
| Inventory | (345,860) | (29,936) |
| Prepaid expenses and other current assets | (98,343) | (169,271) |
| Other assets | 3,116 | 2,787 |
| Accounts payable and accrued expenses | (368,382) | (41,653) |
| Net cash provided by (used for) operating activities | 638,535 | (623,546) |
| | | |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchase of property, plant and equipment | (807,496) | (349,316) |
| Maturities of investments | — | 996,000 |
| Proceeds from sale of fixed assets | 11,000 | 10,000 |
| Net cash (used for) provided by investing activities | (796,496) | 656,684 |
| | | |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from debt issuance | 2,000,000 | — |
| Debt principal repayments | (197,385) | (190,377) |
| Payments of debt issuance costs | (18,826) | 2,272 |
| Proceeds from exercise of stock options | 5,840 | 11,680 |
| Net cash provided by (used for) financing activities | 1,789,629 | (176,425) |
| | | |
| **NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | 1,631,668 | (143,287) |
| | | |
| **BEGINNING CASH AND CASH EQUIVALENTS** | 10,185,468 | 6,949,937 |
| | | |
| **ENDING CASH AND CASH EQUIVALENTS** | $11,817,136 | $6,806,650 |

*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 Three-Month Periods Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| **CASH PAID FOR:** | | |
| Income taxes | $5,535 | $— |
| Interest expense | $71,877 | $78,766 |
| **NON-CASH ACTIVITIES:** | | |
| Change in capital expenditures included in accounts payable and accrued expenses | ($47,900) | ($80,213) |

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

## 1. BUSINESS OPERATIONS

ImmuCell Corporation (the "Company", "we", "us", "our") was originally incorporated in Maine in 1982 and reincorporated in Delaware in 1987, in conjunction with our initial public offering of common stock. We are an animal health company whose purpose is to create scientifically-proven and practical products that improve the health and productivity of dairy and beef cattle. As disclosed in Note 17, "Segment Information", one of our business segments is dedicated to growing sales of **First Defense®** and the other is focused on developing sales of **Re-Tain®**. We manufacture and market the **First Defense®** product line for the prevention of 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. This product line provides **Immediate Immunity™** to newborn calves. We are also in the late stages of developing **Re-Tain®**, a treatment for lactating dairy cows with subclinical mastitis, mastitis being the most significant cause of economic loss to the dairy industry. These products help reduce the need to use traditional antibiotics in food producing animals. We are subject to certain risks including dependence on key individuals and third-party providers of critical goods and services, competition from other larger companies, the successful sale of existing products and the development of new viable products with appropriate regulatory approvals, where applicable.

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

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### (a) Basis of Presentation

We have prepared the accompanying unaudited financial statements reflecting all adjustments (which are of a normal recurring nature) that are, in our opinion, necessary in order to ensure that the financial statements are not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets Generally Accepted Accounting Principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP in these footnotes are to the FASB *Accounting Standards Codification™* (Codification). We believe that the disclosures are adequate to ensure that the information presented is not misleading.

### (b) Cash and Cash Equivalents

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits of $250,000 per financial institution per depositor are maintained in money market accounts at financial institutions that are secured, in part, by the Securities Investor Protection Corporation. Amounts in excess of these FDIC limits per bank that are not invested in securities backed by the U.S. government aggregated $0 as of both March 31, 2022 and December 31, 2021. We account for investments in marketable securities in accordance with Codification Topic 320, *Investments — Debt and Equity Securities*. See Note 3.

### (c) Trade Accounts Receivable, net

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful collection when applicable. Management determines the allowance for doubtful accounts on a monthly basis by identifying troubled accounts and by using historical experience applied to an aging of accounts. Accounts receivable are considered to be past due if a portion of the receivable balance is outstanding for more than 30 days. Past due accounts receivable are subject to an interest charge. Accounts receivable are written off when deemed uncollectible. The amount of accounts receivable written off during all periods reported was immaterial. Recoveries of accounts receivable previously written off are recorded as income when received. As of March 31, 2022 and December 31, 2021, we determined that no allowance for doubtful accounts was necessary. See Note 4.

**(d) Inventory**

Inventory includes raw materials, work-in-process and finished goods and is recorded at the lower of cost, on the first-in, first-out method, or net realizable value (determined as the estimated selling price in the normal course of business, less reasonably predictable costs of completion, disposal and transportation). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. At each balance sheet date, we evaluate our ending inventories for excess quantities and obsolescence. Inventories that we consider excess or obsolete are written down to estimated net realizable value. Once inventory is written down and a new cost basis is established, it is not written back up if demand increases. We believe that supplies and raw materials for the production of our products are available from more than one vendor or farm. Our policy is to maintain more than one source of supply for the components used in our products when feasible. See Note 5.

**(e) Property, Plant and Equipment, net**

We depreciate property, plant and equipment on the straight-line method by charges to operations and costs of goods sold in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The facility we have constructed at 33 Caddie Lane to produce the Nisin Drug Substance for **Re-Tain®** is being depreciated over 39 years from when a certificate of occupancy was issued during the fourth quarter of 2017. We began depreciating the equipment for our Nisin Drug Substance facility when it was placed in service during the third quarter of 2018. Approximately 87% of these assets are being depreciated over 10 years. We began depreciating the leasehold improvements to our new **First Defense®** production facility at 175 Industrial Way over the remainder of the 10-year lease term beginning when a certificate of occupancy was issued during the second quarter of 2020. Significant repairs to fixed assets that benefit more than a current period are capitalized and depreciated over their useful lives. Insignificant repairs are expensed when incurred. See Note 7.

**(f) Intangible Assets and Goodwill**

We amortize intangible assets on the straight-line method by charges to costs of goods sold in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. We have recorded intangible assets related to customer relationships, non-compete agreements and developed technology, each with defined useful lives. We have classified as goodwill the amounts paid in excess of fair value of the net assets (including tax attributes) acquired in purchase transactions. We assess the impairment of intangible assets and goodwill that have indefinite lives at the reporting unit level on an annual basis (as of December 31st) and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We would record an impairment charge if such an assessment were to indicate that the fair value of such assets was less than the carrying value. Judgment is required in determining whether an event has occurred that may impair the value of goodwill or identifiable intangible assets. Factors that could indicate that an impairment may exist include significant under-performance relative to plan or long-term projections, significant changes in business strategy and significant negative industry or economic trends. Although we believe intangible assets and goodwill are properly stated in the accompanying financial statements, changes in strategy or market conditions could significantly impact these judgments and require an adjustment to the recorded balance. No goodwill impairments were recorded during the three-month period ended March 31, 2022 or the year ended December 31, 2021. See Notes 2(g) and 8 for additional disclosures.

**(g) Valuation of Long-Lived Assets**

We periodically evaluate our long-lived assets, consisting principally of fixed assets, operating lease right-of-use asset and amortizable intangible assets, for potential impairment. In accordance with the applicable accounting guidance for the treatment of long-lived assets, we review the carrying value of our long-lived assets or asset group that is held and used, including intangible assets subject to amortization, for impairment whenever events and circumstances indicate that the carrying value of the assets may not be recoverable. Under the held for use approach, the asset or asset group to be tested for impairment should represent the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities. We evaluate our long-lived assets whenever events or circumstances suggest that the carrying amount of an asset or group of assets may not be recoverable. No impairment was recognized during the three-month period ended March 31, 2022 or the year ended December 31, 2021.

**(h) Fair Value Measurements**

In determining fair value measurements, we follow the provisions of Codification Topic 820, *Fair Value Measurements and Disclosures*. Codification Topic 820 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. The topic provides a consistent definition of fair value which focuses on an exit price,

which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The topic also prioritizes, within the measurement of fair value, the use of market-based information over entity-specific information and establishes a three-level hierarchy for fair value measurements based on the nature of inputs used in the valuation of an asset or liability as of the measurement date. As of March 31, 2022 and December 31, 2021, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, other assets, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The amount outstanding under our bank debt facilities is measured at carrying value in our accompanying balance sheets. Our bank debt facilities are valued using Level 2 inputs. The estimated fair value of our bank debt facilities approximates their carrying value based on similar instruments with similar maturities. The three-level hierarchy is as follows:

Level 1 — Pricing inputs are quoted prices available in active markets for identical assets or liabilities as of the measurement date.

Level 2 — Pricing inputs are quoted prices for similar assets or liabilities, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data.

Level 3 — Pricing inputs are unobservable for the assets or liabilities, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the asset or liability.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level of an asset or liability within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the investment. From time to time, we also hold money market mutual funds in a brokerage account, which are classified as cash equivalents and measured at fair value. The fair value of these investments is based on their closing published net asset value.

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

| | As of March 31, 2022 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Total** |
| Assets: | | | | |
| Cash and money market accounts | $11,817,136 | $— | $— | $11,817,136 |
| | | | | |
| Liabilities: | | | | |
| Bank debt | $— | ($10,925,022) | $— | ($10,925,022) |

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

**(i) Concentration of Risk**

Concentration of credit risk with respect to accounts receivable is principally limited to certain customers to whom we make substantial sales. To reduce risk, we routinely assess the financial strength of our customers and, as a consequence, believe that our accounts receivable credit risk exposure is limited. We maintain an allowance for potential credit losses when deemed necessary, but

historically we have not experienced significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

| | During the Three-Month Periods Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Company A | 39% | 45% |
| Company B | 35% | 33% |

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

| | As of March 31, 2022 | As of December 31, 2021 |
|---|---|---|
| Company A | 39% | 38% |
| Company B | 33% | 34% |

**(j) Revenue Recognition**

We recognize revenue in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*. ASC 606 is a single comprehensive model for companies to use in accounting for revenue arising from contracts with customers. The core principle is that we recognize the amount of revenue to which we expect to be entitled for the transfer of promised goods or services to customers when a customer obtains control of promised goods or services in an amount that reflects the consideration we expect to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. We conduct our business with customers through valid purchase orders or sales orders which are considered contracts and are not interdependent on one another. A performance obligation is a promise in a contract to transfer a distinct product to the customer. The transaction price is the amount of consideration we expect to receive under the arrangement. Revenue is measured based on consideration specified in a contract with a customer. The transaction price of a contract is allocated to each distinct performance obligation and recognized when or as the customer receives the benefit of the performance obligation. Product transaction prices on a purchase or sales order are discrete and stand-alone. We recognize revenue when we satisfy a performance obligation in a contract by transferring control over a product to a customer when product delivery occurs. Amounts due are typically paid approximately 30 days from the time control is transferred. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer 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. We have enhanced disclosures related to disaggregation of revenue sources and accounting policies prospectively as a result of adopting this standard. See Note 14.

**(k) Expense Recognition**

We do not incur costs in connection with product sales to customers that are eligible for capitalization. Advertising costs are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to $16,815 and $15,650 during the three-month periods ended March 31, 2022 and 2021, respectively. All product development expenses are expensed as incurred, as are all related patent costs. We capitalize costs to produce inventory during the production cycle, and these costs are charged to costs of goods sold when the inventory is sold to a customer.

**(l) Income Taxes**

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. During the second quarter of 2018, we assessed our historical and near-term future profitability and decided to record $563,252 in non-cash income tax expense to create a full valuation allowance against our net deferred tax assets (which consist largely of net operating loss carryforwards and federal and state tax credits). At that time, we had incurred a net loss for six consecutive quarters, had not been profitable on a year-to-date basis since the nine-month period ended September 30, 2017 and projected additional net losses for some period going forward before returning to profitability. We consider future taxable income and feasible tax planning strategies in assessing the need for a valuation allowance at each quarter end. If we determine that we would be able to realize our deferred tax assets in the future in excess of the net recorded amount over a reasonably short period of time, a reduction of the valuation allowance would increase income in the period such determination was made. Likewise, if we determine that we would not be able to realize all or part of our net deferred tax asset in the

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 2019. We have evaluated the positions taken on our filed tax returns and have concluded that no uncertain tax positions existed as of March 31, 2022 or December 31, 2021. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 16.

**(m) Stock-Based Compensation**

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model. Accordingly, we recorded compensation expense pertaining to stock-based compensation of $54,093 and $34,629 during the three-month periods ended March 31, 2022 and 2021, respectively.

**(n) Net Income (Loss) Per Common Share**

Net income (loss) per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*. The basic net income per share has been computed by dividing net income by the weighted average number of common shares outstanding during the period. The diluted net income per share has been computed by dividing net income by the weighted average number of shares outstanding during the period, plus all outstanding stock options with an exercise price that is less than the average market price of the common stock during the period, less the number of shares that could have been repurchased at this average market price, with the proceeds from the hypothetical stock option exercises and proceeds from unrecognized compensation. The net (loss) per share has been computed by dividing the net (loss) by the weighted average number of common shares outstanding during the period. All stock options have been excluded from the denominator in the calculation of dilutive earnings per share when we are in a loss position because their inclusion would be anti-dilutive. Outstanding stock options that were not included in this calculation because the effect would be anti-dilutive amounted to 71,000 and 409,000 during the three-month periods ended March 31, 2022 and 2021, respectively.

| | During the Three-Month Periods Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Net income (loss) attributable to stockholders | $735,666 | ($441,303) |
| | | |
| Weighted average common shares outstanding - Basic | 7,742,120 | 7,219,436 |
| Dilutive impact of share-based compensation awards | 47,354 | — |
| Weighted average common shares outstanding - Diluted | 7,789,474 | 7,219,436 |
| | | |
| Income (loss) per share: | | |
| Basic | $0.10 | ($0.06) |
| Diluted | $0.09 | ($0.06) |

**(o) Use of Estimates**

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

**(p) Accounting Pronouncements Recently Adopted**

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The new guidance is intended to simplify the accounting for income taxes by removing certain exceptions and by updating accounting

requirements around goodwill recognized for tax purposes and the allocation of current and deferred tax expense among legal entities, among other minor changes. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Early adoption was permitted. The adoption of ASU 2019-12 did not have a material impact on our financial statements as of January 1, 2021.

In March 2020, the FASB issued ASU 2020-04, *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. ASU 2020-04 is intended to provide optional expedients and exceptions to the U.S. GAAP guidance on contract modifications and hedge accounting to ease the financial reporting burdens related to the discontinuation of the London Interbank Offered Rate (LIBOR) or by another reference rate expected to be discontinued. The relief offered by this guidance, if adopted, is available to companies for the period March 12, 2020 through December 31, 2022. The discontinuation of LIBOR did not have a material impact on our financial statements as of January 1, 2021.

## 3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

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

| | As of March 31, 2022 | As of December 31, 2021 |
|---|---|---|
| Cash and cash equivalents | $11,817,136 | $10,185,468 |
| Short-term investments | — | — |
| Total | $11,817,136 | $10,185,468 |

## 4. TRADE ACCOUNTS RECEIVABLE, net

Trade accounts receivable amounted to $2,652,591 and $2,694,229 as of March 31, 2022 and December 31, 2021, respectively. No allowance for bad debt and product returns was recorded as of March 31, 2022 or December 31, 2021.

## 5. INVENTORY

Inventory consisted of the following:

| | As of March 31, 2022 | As of December 31, 2021 |
|---|---|---|
| Raw materials | $1,732,628 | $971,606 |
| Work-in-process | 1,597,888 | 1,902,299 |
| Finished goods | 105,318 | 216,069 |
| Total | $3,435,834 | $3,089,974 |

## 6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

| | As of March 31, 2022 | As of December 31, 2021 |
|---|---|---|
| Prepaid expenses | $387,393 | $268,713 |
| Other receivables | 6,147 | 26,484 |
| Total | $393,540 | $295,197 |

## 7. PROPERTY, PLANT AND EQUIPMENT, net

Property, plant and equipment consisted of the following:

| | Estimated Useful Lives (in years) | As of March 31, 2022 | As of December 31, 2021 |
|---|---|---|---|
| Laboratory and manufacturing equipment | 3-10 | $17,790,623 | $17,388,757 |
| Buildings and improvements | 10-39 | 19,315,965 | 19,119,698 |
| Office furniture and equipment | 3-10 | 891,453 | 869,191 |
| Construction in progress | n/a | 3,187,950 | 2,992,359 |
| Land | n/a | 516,867 | 516,867 |
| Property, plant and equipment, gross | | 41,702,858 | 40,886,872 |
| Accumulated depreciation | | (14,570,710) | (13,993,273) |
| Property, plant and equipment, net | | $27,132,148 | $26,893,599 |

As of March 31, 2022 and December 31, 2021, construction in progress consisted principally of payments toward the **First Defense®** production capacity expansion project and equipment needed to bring the formulation and aseptic filling for **Re-Tain®** in-house. Property, plant and equipment disposals were $39,410 and $92,121 during the three-month periods ended March 31, 2022 and 2021, respectively. Depreciation expense was $616,847 and $614,695 during the three-month periods ended March 31, 2022 and 2021, respectively.

## 8. INTANGIBLE ASSETS

Intangible assets of $191,040 were valued using the relief from royalty method and are being amortized to costs of goods sold over their useful lives, which are estimated to be 10 years. Intangible amortization expense was $4,776 during both of the three-month periods ended March 31, 2022 and 2021. The net value of these intangibles was $71,640 and $76,416 as of March 31, 2022 and December 31, 2021, respectively. Intangible asset amortization expense is estimated to be $19,104 per year through December 31, 2025.

Intangible assets as of March 31, 2022 consisted of the following:

| | Gross Carrying Value | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Developed technology | $184,100 | ($115,063) | $69,037 |
| Customer relationships | 1,300 | (812) | 488 |
| Non-compete agreements | 5,640 | (3,525) | 2,115 |
| Total | $191,040 | ($119,400) | $71,640 |

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

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

## 9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

| | As of March 31, 2022 | As of December 31, 2021 |
|---|---|---|
| Accounts payable – trade | $595,904 | $726,781 |
| Accounts payable – capital | 66,163 | 18,263 |
| Accrued payroll | 322,033 | 585,939 |
| Accrued professional fees | 59,325 | 82,050 |
| Accrued other | 250,344 | 199,076 |
| Income tax payable | — | 2,141 |
| Total | $1,293,769 | $1,614,250 |

**10. BANK DEBT**

Prior to a refinancing with Gorham Savings Bank (GSB) during the first quarter of 2020, we had in place five different credit facilities and a line of credit with TD Bank N.A. (Loans #1 to #5). During the first quarter of 2020, we closed on a debt financing with GSB aggregating $8,600,000 and a $1,000,000 line of credit. The debt was comprised of a $5,100,000 mortgage note (Loan #6) that bears interest at a fixed rate of 3.50% per annum (with a 10-year term and 25-year amortization schedule and a balloon principal payment of $3,145,888 due during the first quarter of 2030) and a $3,500,000 note (Loan #7) that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). The line of credit is available as needed through March 11, 2024. Interest on borrowings against the line of credit is variable at the National Prime Rate plus 0.00% per annum. There was no outstanding balance under this line of credit as of March 31, 2022 or December 31, 2021. In connection with these three credit facilities, we incurred debt issuance costs of $39,789. The amortization of debt issuance costs is being recorded as a component of interest expense, included with other expenses (income), net, and is being amortized over the underlying terms of the two notes and the line of credit. The proceeds from the debt refinancing were used to repay all bank debt outstanding at the time of closing (Loans #1 to #5) and to provide some additional working capital. We were required by bank debt covenant to maintain $1,400,000 in escrow (a non-current asset). During the fourth quarter of 2020, we closed on a $1,500,000 note with GSB (Loan #10) that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). In connection with this note, we incurred debt issuance costs of $11,075. The amortization of these debt issuance costs is also being recorded as a component of interest expense, included with other expenses (income), net, and is being amortized over the underlying term of the note. Proceeds of $624,167 were used to prepay a portion of the outstanding principal on our mortgage note (Loan #6), which reduced the outstanding balance to 80% of the most recent appraised value of the property securing the debt, which allowed GSB to release the $1,400,000 that had been held in escrow. This resulted in no change in the balloon principal payment of $3,145,888 due during the first quarter of 2030. The remaining proceeds were available for general working capital purposes. During the first quarter of 2022, we closed on an additional $2,000,000 in mortgage debt, which bears interest at the fixed rate of 3.58% per annum. This was accomplished through an amendment of the original mortgage note (Loan #6) 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, with a balloon payment of $3,683,544 due during the first quarter of 2032. These three credit facilities are secured by liens on substantially all of our assets and are subject to certain restrictions and financial covenants. Given the funds we raised through an equity issuance in April 2021, GSB waived the minimum debt service coverage (DSC) ratio requirement of 1.35 for the year ended December 31, 2021. By negotiation with the bank in connection with a mortgage debt financing during the first quarter of 2022, the required minimum DSC ratio was reduced to 1.0 for the year ending December 31, 2022.

During the second quarter of 2020, we received $937,700 in support from the federal government under the Paycheck Protection Program (PPP) (Loan #8). We used the proceeds only for eligible payroll costs incurred and paid during the 24-week period beginning April 13, 2020. Our obligation to repay the principal was forgiven, and we recognized this amount as part of other expenses (income), net, during the fourth quarter of 2020. This forgiveness of indebtedness, in accordance with the CARES Act and Maine law, does not give rise to federal or State of Maine taxable income, and the expenses incurred using PPP proceeds are fully deductible for federal and Maine income tax purposes.

During the second quarter of 2020, we received a loan from the Maine Technology Institute (MTI) (Loan #9) in the aggregate principal amount of $500,000. The first 27 months of this loan are interest-free with no interest accrual or required principal payments. Principal and interest payments at a fixed rate of 5% per annum are due quarterly over the final five years of the loan, beginning during the fourth quarter of 2022 and continuing through the third quarter of 2027. On June 30, 2021, we executed definitive agreements covering a second loan from the MTI (Loan #11) in the aggregate principal amount of $400,000, which proceeds were received in July 2021. The first 24 months of this loan are interest-free with no interest accrual or required principal payments. Beginning in July 2023, principal and interest payments are due quarterly at a fixed rate of 5% per annum based on a 5.5-year amortization schedule until December 2028. These credit facilities are unsecured and subordinated to our indebtedness to Gorham Savings Bank, which senior indebtedness is secured by mortgages and security interests with respect to substantially all of our assets. Failure to make timely payments of principal and interest, or otherwise to comply with the terms of the agreements with the MTI, would entitle the MTI to accelerate the maturity of such debt and demand repayment in full. These loans may be prepaid without penalty at any time.

Debt proceeds received and principal repayments made during the three-month periods ended March 31, 2022 and 2021 are reflected in the following table by period and by loan:

| | During the Three-Month Period Ended March 31, 2022 | | During the Three-Month Period Ended March 31, 2021 | |
|---|---|---|---|---|
| | Proceeds from Debt Issuance | Debt Principal Repayments | Proceeds from Debt Issuance | Debt Principal Repayments |
| Loan #6 | $2,000,000 | ($30,183) | $— | ($28,922) |
| Loan #7 | — | (118,033) | — | (113,991) |
| Loan #10 | — | (49,169) | — | (47,464) |
| Total | $2,000,000 | ($197,385) | $— | ($190,377) |

Debt proceeds received and principal repayments made during the years ended December 31, 2021 and 2020 are reflected in the following table by period and by loan:

| | During the Year Ended December 31, 2021 | | During the Year Ended December 31, 2020 | |
|---|---|---|---|---|
| | Proceeds from Debt Issuance | Debt Principal Repayments | Proceeds from Debt Issuance | Debt Principal Repayments |
| Loan #1 | $— | $— | $— | ($493,696) |
| Loan #2 | — | — | — | (2,143,771) |
| Loan #3 | — | — | — | (3,236,429) |
| Loan #4 | — | — | — | (2,336,000) |
| Loan #5 | — | — | — | (309,182) |
| Loan #6 | — | (115,860) | 5,100,000 | (720,001) |
| Loan #7 | — | (460,637) | 3,500,000 | (334,489) |
| Loan #8[(1)] | — | — | 937,700 | (937,700) |
| Loan #9 | — | — | 500,000 | — |
| Loan #10 | — | (191,774) | 1,500,000 | — |
| Loan #11 | 400,000 | — | — | — |
| Total | $400,000 | ($768,271) | $11,537,700 | ($10,511,268) |

[(1)] Loan #8 was forgiven by the federal government during the fourth quarter of 2020.

Principal payments (net of debt issue costs) due under bank loans outstanding as of March 31, 2022 (excluding our $1,000,000 line of credit) are reflected in the following table by the year that payments are due:

| | During the Nine-Month Period Ending December 31, 2022 | During the Years Ending December 31, | | | | | |
|---|---|---|---|---|---|---|---|
| | | 2023 | 2024 | 2025 | 2026 | Thereafter | Total |
| Loan #6 | $172,626 | $223,349 | $230,891 | $239,876 | $248,604 | $5,118,611 | $6,233,957 |
| Loan #7 | 359,188 | 494,433 | 512,102 | 530,738 | 549,881 | 140,498 | 2,586,840 |
| Loan #9 | 22,160 | 91,446 | 96,104 | 101,001 | 106,146 | 83,143 | 500,000 |
| Loan #10 | 149,540 | 205,878 | 213,217 | 220,994 | 228,965 | 240,463 | 1,259,057 |
| Loan #11 | — | 32,017 | 66,470 | 69,856 | 73,415 | 158,242 | 400,000 |
| Subtotal | 703,514 | 1,047,123 | 1,118,784 | 1,162,465 | 1,207,011 | 5,740,957 | 10,979,854 |
| Debt issuance costs | (5,721) | (7,628) | (7,219) | (7,120) | (7,120) | (20,024) | (54,832) |
| Total | $697,793 | $1,039,495 | $1,111,565 | $1,155,345 | $1,199,891 | $5,720,933 | $10,925,022 |

## 11. CONTINGENT LIABILITIES AND COMMITMENTS

Our bylaws, as amended, in effect provide that the Company will indemnify its officers and directors to the maximum extent permitted by Delaware law. In addition, we make similar indemnity undertakings to each director through a separate indemnification agreement with that director. The maximum payment that we may be required to make under such provisions is theoretically unlimited and is impossible to determine. We maintain directors' and officers' liability insurance, which may provide reimbursement to the Company for payments made to, or on behalf of, officers and directors pursuant to the indemnification provisions. Our indemnification obligations were grandfathered under the provisions of Codification Topic 460*, Guarantees*. Accordingly, we have recorded no liability for such obligations as of March 31, 2022. Since our incorporation, we have had no occasion to make any

indemnification payment to any of our officers or directors for any reason.

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

We enter into agreements with third parties in the ordinary course of business under which we are obligated to indemnify such third parties from and against various risks and losses. The precise terms of such indemnities vary with the nature of the agreement. In many cases, we limit the maximum amount of our indemnification obligations, but in some cases those obligations may be theoretically unlimited. We have not incurred material expenses in discharging any of these indemnification obligations and based on our analysis of the nature of the risks involved, we believe that the fair value of the liabilities potentially arising under these agreements is minimal. Accordingly, we have recorded no liabilities for such obligations as of March 31, 2022.

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

Effective March 25, 2020, the Company entered into a Severance Agreement with Mr. Brigham, under which the Company agreed to pay this executive (or his estate) 75% of his then current salary plus any accrued and unused paid time off in the event of the involuntary termination of his employment by the Company (except for cause) or in the event of termination by him for good reason. Effective March 28, 2022, the Company entered into an amended and restated Separation and Deferred Compensation Agreement (the "Deferred Compensation Agreement") with Mr. Brigham that superseded and replaced in its entirely the March 2020 contract discussed above, and the Company entered into an Incentive Compensation Agreement (the "Incentive Agreement") with Mr. Brigham. Mr. Brigham's Deferred Compensation Agreement allows Mr. Brigham to receive up to an additional $300,000 in deferred compensation and to be paid all earned and unused paid time off upon separation from the Company for any reason. This deferred compensation payment vests as to $100,000 on January 1, 2023, as to an additional $100,000 on January 1, 2024 and as to the final $100,000 on January 1, 2025, provided that Mr. Brigham is employed by the Company on the applicable vesting date. In addition, upon termination of Mr. Brigham's employment (a) by the Company other than for cause, (b) due to death or disability or (c) by Mr. Brigham for good reason, the Company agrees to pay Mr. Brigham 100% of his then current base salary. Mr. Brigham's Incentive Agreement provides for the potential to earn up to an additional $150,000 if certain regulatory and financial objectives are achieved during 2022. Under these contract amendments, Mr. Brigham continues to serve the Company as President and CEO.

In addition to the commitments discussed above, we had committed $940,000 to increase our production capacity for the **First Defense®** product line, $406,000 to construct and equip our own Drug Product formulation and aseptic filling facility for **Re-Tain®**, $2,461,000 to the purchase of inventory, $207,000 to other capital expenditures and $376,000 to other obligations as of March 31, 2022.

**12. OPERATING LEASE**

On September 12, 2019, we entered into a lease covering approximately 14,300 square feet of office and warehouse space with a possession date of November 15, 2019 and a commencement date of February 13, 2020. The property is located at 175 Industrial Way in Portland, which is a short distance from our headquarters and manufacturing facility at 56 Evergreen Drive. We renovated this space to meet our needs in expanding our production capacity for the **First Defense®** product line. The lease term is 10 years with a right to renew for a second 10-year term and a right of first offer to purchase. At this time, we are not reasonably assured that we would exercise this renewal option in place of other real estate options. A 10-year period is reflected in the right-of-use (ROU) asset and lease liability on our balance sheet. The total lease liability over the initial 10-year term (including inflationary adjustments) aggregates approximately $1,313,698 and includes real estate and personal property taxes, utilities, insurance, maintenance and related building and operating expenses. Our lease includes variable lease and non-lease components that are included in the ROU asset and lease liability. Such payments primarily include common area maintenance charges and increases in rent payments that are driven by factors such as future changes in an index, such as the Consumer Price Index. As of March 31, 2022, the balance of the operating lease ROU asset was $1,078,051 and the operating lease liability was $1,108,166. 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. As we elected not to separate lease and non-lease components for all classes of underlying assets, and instead to account for them as a single lease component, the variable lease cost 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 March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Lease Cost | | |
| Operating lease cost | $29,991 | $29,499 |
| Variable lease cost | 10,350 | 10,350 |
| Total lease cost | $40,341 | $39,849 |
| | | |
| Operating Lease | | |
| Weighted average remaining lease term (in years) | 7.8 | 8.8 |
| Weighted average discount rate | 4.77% | 4.77% |

| | During the Years Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Lease Cost | | |
| Operating lease cost | $117,996 | $104,094 |
| Variable lease cost | 41,400 | 36,523 |
| Total lease cost | $159,396 | $140,617 |
| | | |
| Operating Lease | | |
| Weighted average remaining lease term (in years) | 8.1 | 9.1 |
| Weighted average discount rate | 4.77% | 4.77% |

Future lease payments required under non-cancelable operating leases in effect as of March 31, 2022 were as follows:

| | Amount |
|---|---|
| During the nine-month period ending December 31, 2022 | $121,577 |
| **During the Years Ending December 31,** | |
| 2023 | 165,120 |
| 2024 | 168,210 |
| 2025 | 171,383 |
| 2026 | 174,640 |
| Thereafter | 559,664 |
| Total lease payments (undiscounted cash flows) | 1,360,594 |
| Less: imputed interest (discount effect of cash flows) | (252,428) |
| Total operating liabilities | $1,108,166 |

## 13. STOCKHOLDERS' EQUITY

Common Stock Issuances

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

On October 28, 2015, we filed a registration statement on Form S-3 (File No. 333-207635) with the Securities and Exchange Commission (SEC) for the potential issuance of up to $10,000,000 in equity securities (subject to certain limitations). This registration statement became effective on November 10, 2015. Under this form of registration statement, we were limited within a twelve-month period to raising gross proceeds of no more than one-third of the market capitalization of our common stock (as determined by the high price of our common stock within the preceding 60 days leading up to a sale of securities) held by non-

affiliates (non-insiders) of the Company. Having raised $10,000,000 in gross proceeds under the February 2016, July 2017 and December 2017 equity transactions described below, no additional equity securities can be issued under this registration statement.

On February 3, 2016, we sold 1,123,810 shares of common stock at a price to the public of $5.25 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately $5,900,000 and resulting in net proceeds to the Company of approximately $5,313,000 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

On October 21, 2016, we closed on a private placement of 659,880 shares of common stock to nineteen institutional and accredited investors at $5.25 per share, raising gross proceeds of approximately $3,464,000 and resulting in net proceeds to the Company of approximately $3,161,000 (after deducting placement agent fees and other expenses incurred in connection with the equity financing).

On July 27, 2017, we issued 200,000 shares of our common stock at a price of $5.25 per share in a public, registered sale to two related investors pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of $1,050,000 and resulting in net proceeds of approximately $1,034,000 (after deducting expenses incurred in connection with the equity financing).

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

On November 20, 2018, we filed a registration statement on Form S-3 (File No. 333-228479) with the Securities and Exchange Commission (SEC) for the potential issuance of up to $20,000,000 in equity securities (subject to certain limitations). This registration statement became effective on November 29, 2018. Under this form of registration statement, we were limited within a twelve-month period to raising gross proceeds of no more than one-third of the market capitalization of our common stock (as determined by the high price of our common stock within the preceding 60 days leading up to a sale of securities) held by non-affiliates (non-insiders) of the Company. Under SEC rules governing this form of registration statement, this registration statement expired upon the third anniversary of its effectiveness.

On March 29, 2019, we sold 1,636,364 shares of common stock at a price to the public of $5.50 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately $9,000,000 and resulting in net proceeds to the Company of approximately $8,303,000 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

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

Stock Option Plans

In June 2010, our stockholders approved the 2010 Stock Option and Incentive Plan (the “2010 Plan”) pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company’s common stock at no less than fair market value on the date of grant. At that time, 300,000 shares of common stock were reserved for issuance under the 2010 Plan and subsequently no additional shares have been reserved for the 2010 Plan. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case-by-case basis. All options granted under the 2010 Plan expire no later than 10 years from the date of grant. The 2010 Plan expired in June 2020, after which date no further options can be granted under the 2010 Plan. However, options outstanding under the 2010 Plan at that time can be exercised in accordance with their terms. As of March 31, 2022, there were 217,500 options outstanding under the 2010 Plan.

In June 2017, our stockholders approved the 2017 Stock Option and Incentive Plan (the “2017 Plan”) pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company’s common stock at no less than fair market value on the date of grant. At that time, 300,000 shares of common stock were reserved for issuance under the 2017 Plan and subsequently no additional shares have been reserved for the 2017 Plan. A proposal to increase the number of shares reserved for issuance under the 2017 Plan by 350,000 shares from 300,000 shares to 650,000 shares is subject to approval by a vote of stockholders at the 2022 annual meeting of stockholders to be held in June 2022. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case-by-case

basis. All options granted under the 2017 Plan expire no later than 10 years from the date of grant. The 2017 Plan expires in March 2027, after which date no further options can be granted under the 2017 Plan. However, options outstanding under the 2017 Plan at that time can be exercised in accordance with their terms. As of March 31, 2022, there were 279,500 options outstanding under the 2017 Plan. Additionally, contingent grants aggregating 53,500 shares have been made to 47 full-time employees and 5 part-time employees, subject to approval by stockholders of the proposal to increase shares reserved for issuance under the 2017 Plan, described above. If this amendment is not approved, these contingent grants will become null and void.

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, 2019 | 255,000 | 133,500 | $6.48 | ($516,475) |
| Grants | 7,000 | 93,000 | $5.03 | |
| Terminations/forfeitures | (12,000) | (50,000) | $5.45 | |
| Exercises | (12,500) | — | $3.15 | |
| Outstanding as of December 31, 2020 | 237,500 | 176,500 | $6.38 | ($180,038) |
| Grants | — | 86,000 | $9.78 | |
| Terminations/forfeitures | (12,000) | (20,000) | $7.26 | |
| Exercises | (7,000) | (18,000) | $7.08 | |
| Outstanding as of December 31, 2021 | 218,500 | 224,500 | $6.94 | $468,425 |
| Grants | — | 57,000 | $8.17 | |
| Terminations/forfeitures | — | (2,000) | $4.25 | |
| Exercises | (1,000) | — | $5.84 | |
| Outstanding as of March 31, 2022 | 217,500 | 279,500 | $7.10 | $1,269,335 |
| Vested as of March 31, 2022 | 183,500 | 98,500 | $6.78 | $808,490 |
| Vested and expected to vest as of March 31, 2022 | 217,500 | 279,500 | $7.10 | $1,269,335 |
| Reserved for future grants | — | 2,500 | | |

(1) Intrinsic value is the difference between the fair market value of the underlying common stock as of the date indicated and as of the date of the option grant (which is equal to the option exercise price).

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

| | Number of Shares | Weighted Average Fair Value at Grant Date | Weighted Average Exercise Price |
|---|---|---|---|
| Non-vested stock options as of January 1, 2022 | 160,000 | $3.36 | $7.23 |
| Non-vested stock options as of March 31, 2022 | 215,000 | $3.61 | $7.51 |
| Stock options granted during the three-month period ended March 31, 2022 | 57,000 | $4.26 | $8.17 |
| Stock options that vested during the three-month period ended March 31, 2022 | — | $— | $— |
| Stock options that were forfeited during the three-month period ended March 31, 2022 | 2,000 | $2.16 | $4.25 |

During the three-month period ended March 31, 2022, one former employee exercised stock options covering 1,000 shares with $5,840 in cash. During the year ended December 31, 2021, one director and three employees exercised stock options covering 25,000 shares by the surrender of 17,128 shares of common stock with a fair market value of $165,337 at the time of exercise and the payment of $11,693 in cash.

The weighted average remaining life of the options outstanding under the 2010 Plan and the 2017 Plan as of March 31, 2022 was approximately 5 years and 4 months. The weighted average remaining life of the options exercisable under these plans as of March 31, 2022 was approximately 4 years. The exercise prices of the options outstanding as of March 31, 2022 ranged from $4.00 to $10.04 per share. The 86,000 stock options granted during the year ended December 31, 2021 had exercise prices between $6.10 and $10.04 per share. The aggregate intrinsic value of options exercised during the three-month period ended March 31, 2022 and the year ended December 31, 2021 approximated $2,480 and $64,977, respectively. The weighted-average grant date fair values of options

granted during the three-month period ended March 31, 2022 and the year ended December 31, 2021 were $4.26 and $4.51 per share, respectively. As of March 31, 2022, total unrecognized stock-based compensation related to non-vested stock options aggregated $533,895, which will be recognized over a weighted average remaining period of 1 year and 11 months. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, for the purpose discussed in Note 2(m), with the following weighted-average assumptions:

| | During the Three-Month Periods Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Risk-free interest rate | 1.63% | 0.43% |
| Dividend yield | 0% | 0% |
| Expected volatility | 52% | 53% |
| Expected life | 6.5 years | 6.5 years |

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

Common Stock Rights Plan

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

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

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

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

At various times over the years, our Board of Directors has voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date, which is currently September 19, 2022. Our Board of Directors has decided to seek an advisory vote by stockholders at the 2022 annual meeting of stockholders to be held in June 2022, as to whether to extend the Rights Plan by one year to September 19, 2023. Our Board of Directors intends to be guided by the votes actually cast on this proposal in deciding whether to extend the expiration date by one year. During the third quarter of 2011, our Board of Directors voted to authorize an amendment to increase the ownership threshold for determining "Acquiring Person" status to 20%. During the second quarter of 2015, our Board of Directors also voted to authorize an amendment to remove a provision that prevented a new group of directors elected following the emergence of an Acquiring Person (an owner of more than 20% of our stock) from controlling the Rights Plan by maintaining exclusive authority over the Rights Plan with pre-existing directors. We did this because such provisions have come to be viewed with disfavor by Delaware courts. Each time that we made such amendments we entered into amendments to the Rights Agreement with the Rights Agent reflecting such extensions, threshold increases or provision changes. No other changes have been made to the terms of the Rights or the

Rights Agreement.

Authorized Common Stock

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

## 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 period ended March 31, 2022 or the year ended December 31, 2021. We do not have any contract assets for which we have satisfied the performance obligations, but do not yet have the right to bill for, or contract liabilities such as customer advances. All trade receivables on our balance sheets are from contracts with customers. We incur no material costs to obtain contracts.

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

| | During the Three-Month Periods Ended March 31, | | | | During the Years Ended December 31, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2022 | % | 2021 | % | 2021 | % | 2020 | % |
| United States | $5,515,749 | 92% | $3,580,516 | 87% | $16,620,363 | 86% | $13,644,768 | 89% |
| Other | 483,935 | 8% | 526,630 | 13% | 2,622,606 | 14% | 1,697,436 | 11% |
| Total Product Sales | $5,999,684 | 100% | $4,107,146 | 100% | $19,242,969 | 100% | $15,342,204 | 100% |

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

| | During the Three-Month Periods Ended March 31, | | | | During the Years Ended December 31, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2022 | % | 2021 | % | 2021 | % | 2020 | % |
| **First Defense®** product line | $5,962,875 | 99% | $4,023,471 | 98% | $18,933,092 | 98% | $15,072,446 | 98% |
| Other animal health | 36,809 | 1% | 83,675 | 2% | 309,877 | 2% | 269,758 | 2% |
| Total Product Sales | $5,999,684 | 100% | $4,107,146 | 100% | $19,242,969 | 100% | $15,342,204 | 100% |

## 15. OTHER EXPENSES, NET

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

| | During the Three-Month Periods Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Interest expense[(1)] | $75,214 | $79,635 |
| Gain on disposal of fixed assets | (11,000) | (10,000) |
| Interest income | (7,188) | (2,957) |
| Income - other | (852) | — |
| Other expenses (income), net | $56,174 | $66,678 |

[(1)] Interest expense included amortization of debt issuance costs of $1,905 and $1,960 during the three-month periods ended March 31, 2022 and 2021, respectively.

## 16. INCOME TAXES

Our income tax expense aggregated $1,148 and $0 (amounting to 0.2% and 0% of our income (loss) before income taxes) during the three-month periods ended March 31, 2022 and 2021, respectively. As of December 31, 2021, we had federal net operating loss carryforwards of $14,734,684 of which $13,022,777 do not expire and of which $1,711,907 expire in 2034 through 2037 (if not utilized before then) and state net operating loss carryforwards of $1,440,707 that expire in 2037 through 2038 (if not utilized before then). Additionally, we had federal general business tax credit carryforwards of $557,795 that expire in 2027 through 2042 (if not utilized before then) and state tax credit carryforwards of $775,473 that expire in 2022 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. Adjustments related to the termination of our interest rate swap agreements were recorded during the first quarter of 2020. No subsequent adjustments were recorded.

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) **First Defense®** and ii) **Re-Tain®**. The category we define as "Other" includes unallocated administrative and overhead expenses and other products excluding **First Defense®** and **Re-Tain®**. 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 or FDA) 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 March 31, 2022 | | | |
|---|---|---|---|---|
| | **First Defense®** | **Re-Tain®** | **Other** | **Total** |
| Product sales | $5,962,875 | $— | $36,809 | $5,999,684 |
| Costs of goods sold | 2,852,329 | — | 44,132 | 2,896,461 |
| Gross margin | 3,110,546 | — | (7,323) | 3,103,223 |
| **OPERATING EXPENSES:** | | | | |
| Product development expenses | 8,416 | 982,129 | 45,390 | 1,035,935 |
| Sales and marketing expenses | 418,667 | 392,833 | — | 811,500 |
| Administrative expenses | — | — | 462,800 | 462,800 |
| Operating activities | 427,083 | 1,374,962 | 508,190 | 2,310,235 |
| **NET OPERATING INCOME (LOSS)** | $2,683,463 | ($1,374,962) | ($515,513) | $792,988 |

| | During the Three-Month Period Ended March 31, 2021 | | | |
|---|---|---|---|---|
| | **First Defense®** | **Re-Tain®** | **Other** | **Total** |
| Product sales | $4,023,471 | $— | $83,675 | $4,107,146 |
| Costs of goods sold | 2,452,159 | — | 52,799 | 2,504,958 |
| Gross margin | 1,571,312 | — | 30,876 | 1,602,188 |
| **OPERATING EXPENSES:** | | | | |
| Product development expenses | 7,518 | 968,254 | 55,292 | 1,031,064 |
| Sales and marketing expenses | 431,153 | 89,214 | 230 | 520,597 |
| Administrative expenses | — | — | 425,152 | 425,152 |
| Operating activities | 438,671 | 1,057,468 | 480,674 | 1,976,813 |
| **NET OPERATING INCOME (LOSS)** | $1,132,641 | ($1,057,468) | ($449,798) | ($374,625) |

| | **First Defense®** | **Re-Tain®** | **Total** |
|---|---|---|---|
| Total Assets as of March 31, 2022 | $24,674,596 | $22,024,900 | $46,699,496 |
| Total Assets as of March 31, 2021 | $17,688,025 | $21,933,437 | $39,621,462 |
| Depreciation and amortization expense during the three-month period ended March 31, 2022 | $308,710 | $314,818 | $623,528 |
| Depreciation and amortization expense during the three-month period ended March 31, 2021 | $264,428 | $357,003 | $621,431 |
| Capital Expenditures during the three-month period ended March 31, 2022 | $740,467 | $67,029 | $807,496 |
| Capital Expenditures during the three-month period ended March 31, 2021 | $349,316 | $— | $349,316 |

| | During the Year Ended December 31, 2021 | | | |
|---|---|---|---|---|
| | **First Defense®** | **Re-Tain®** | **Other** | **Total** |
| Product sales | $18,933,092 | $— | $309,877 | $19,242,969 |
| Costs of goods sold | 10,411,936 | — | 175,104 | 10,587,040 |
| Gross margin | 8,521,156 | — | 134,773 | 8,655,929 |
| **OPERATING EXPENSES:** | | | | |
| Product development expenses | 25,374 | 3,887,781 | 255,363 | 4,168,518 |
| Sales and marketing expenses | 1,942,391 | 561,288 | 247 | 2,503,926 |
| Administrative expenses | — | — | 1,726,100 | 1,726,100 |
| Operating expenses | 1,967,765 | 4,449,069 | 1,981,710 | 8,398,544 |
| **NET OPERATING INCOME (LOSS)** | $6,553,391 | ($4,449,069) | ($1,846,937) | $257,385 |

| | During the Year Ended December 31, 2020 | | | |
|---|---|---|---|---|
| | **First Defense®** | **Re-Tain®** | **Other** | **Total** |
| Product sales | $15,072,446 | $— | $269,758 | $15,342,204 |
| Costs of goods sold | 8,285,073 | — | 194,305 | 8,479,378 |
| Gross margin | 6,787,373 | — | 75,453 | 6,862,826 |
| **OPERATING EXPENSES:** | | | | |
| Product development expenses | 106,393 | 4,022,712 | 225,522 | 4,354,627 |
| Sales and marketing expenses | 2,119,289 | 48,600 | 10 | 2,167,899 |
| Administrative expenses | — | — | 1,720,653 | 1,720,653 |
| Operating expenses | 2,225,682 | 4,071,312 | 1,946,185 | 8,243,179 |
| **NET OPERATING INCOME (LOSS)** | $4,561,691 | ($4,071,312) | ($1,870,732) | ($1,380,353) |

| | First Defense® | Re-Tain® | Total |
|---|---|---|---|
| Total Assets as of December 31, 2021 | $22,476,870 | $21,988,818 | $44,465,688 |
| Total Assets as of December 31, 2020 | $18,416,157 | $21,933,437 | $40,349,594 |
| Depreciation and amortization expense during the year ended December 31, 2021 | $1,095,620 | $1,373,361 | $2,468,981 |
| Depreciation and amortization expense during the year ended December 31, 2020 | $1,003,577 | $1,446,430 | $2,450,007 |
| Capital Expenditures during the year ended December 31, 2021 | $1,655,866 | $952,783 | $2,608,649 |
| Capital Expenditures during the year ended December 31, 2020 | $3,454,076 | $618,463 | $4,072,539 |

## 18. RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone Inc., a domestic distributor of ImmuCell products (the **First Defense®** product line and **CMT**), and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased $226,833 and $112,301 of products from us during the three-month periods ended March 31, 2022 and 2021, respectively, on terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated $53,150 and $55,490 as of March 31, 2022 and December 31, 2021, respectively.

## 19. EMPLOYEE BENEFITS

We have a 401(k) savings plan (the Plan) in which all employees completing one month of service with the Company are eligible to participate. Participants may contribute up to the maximum amount allowed by the Internal Revenue Service. We currently match 100% of the first 3% of each employee's salary that is contributed to the Plan and 50% of the next 2% of each employee's salary that is contributed to the Plan. Under this matching plan, we paid $41,864 and $32,672 into the Plan for the three-month periods ended March 31, 2022 and 2021, respectively.

## 20. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of filing on May 12, 2022, the date we have issued this Quarterly Report on Form 10-Q. As of the time of filing on May 12, 2022, there were no material, reportable subsequent events.

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

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

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

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: our plans and strategies for our business; projections of future financial or operational performance; the timing and outcome of pending or anticipated applications for regulatory approvals; factors that may affect the dairy and beef industries and future demand for our products; the extent, nature and duration of the COVID-19 pandemic and its consequences, and their direct and indirect impacts on our production activities, operating results and financial condition and on the customers and markets that we serve; the impact of Russia's unprovoked military invasion of Ukraine and attack on its people on the world economy including inflation and the price and availability of grain 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 challenges in attracting and retaining needed personnel in this current employment environment; the impact of inflation and rising interest rates on our operating expenses and financial results; the scope and timing of ongoing and future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis and producers' level of interest in treating subclinical mastitis given the current economic and market conditions; the expected efficacy of new products; estimates about the market size for our products; future market share of and revenue generated by current products and products still in development; our ability to increase production output and reduce costs of goods sold per unit; the future adequacy of our own manufacturing facilities or those of third parties with which we have contractual relationships to meet demand for our products on a timely basis; the impacts of backlogs on customer relationships; the anticipated costs of (or time to complete) planned expansions of our manufacturing facilities and the adequacy of our funds available for these projects; the continuing availability to us on reasonable terms of third-party providers of critical products or services; the robustness of our manufacturing processes and related technical issues; estimates about our production capacity, efficiency and yield, which are highly subject to biological variability and the product format mix of our sales; the future adequacy of our working capital and the availability and cost of third-party financing; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; costs associated with sustaining compliance with current Good Manufacturing Practice (cGMP) regulations in our current operations and attaining such compliance for our facilities to produce the Nisin Drug Substance and Drug Product; our effectiveness in competing against competitors within both our existing and our anticipated product markets; the cost-effectiveness of additional sales and marketing expenditures and resources; anticipated changes in our manufacturing capabilities and efficiencies; the value of our net deferred tax assets; projections about depreciation expense and its impact on income for book and tax return purposes; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as "expects", "may", "anticipates", "aims", "intends", "would", "could", "should", "will", "plans", "believes", "estimates", "targets", "projects", "forecasts", "seeks" and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to: difficulties or delays in development, testing, regulatory approval, production and marketing of our products (including the **First Defense**® product line and **Re-Tain**®), competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand (including the consequences of backlogs or excess inventory buildup), uncertainty associated with the timing and volume of customer orders as we come out of a prolonged backlog, adverse impacts of supply chain disruptions on our operations and customer relationships, our reliance upon third parties for financial support, products and services, our small size and dependence on key personnel, changes in laws and regulations, decision making and delays by regulatory authorities, a recurrence of inflation and its impact on our customers' order patterns, currency values and fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission (SEC), including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements involve risks and uncertainties and are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized under **PART II: ITEM 1A – RISK FACTORS** and uncertainties otherwise referred to in this Quarterly Report on Form 10-Q.

**Liquidity and Capital Resources**

Net cash provided by operating activities was $639,000 during three-month period ended March 31, 2022 in contrast to net cash (used for) operating activities of ($624,000) during the three-month period ended March 31, 2021. The $1.3 million increase in cash provided by operating activities from period to period was largely the result of a $1.2 million increase in our net income. As we increased our production capacity to fill the backlog of orders, our inventory balance increased by $346,000 from December 31, 2021 to March 31, 2022. Our total depreciation expense was approximately $617,000 and $615,000 during the three-month periods ended March 31, 2022 and 2021, respectively. We anticipate that depreciation expense, while not affecting our cash flows from operations, will result in annual net operating losses until and unless product sales increase sufficiently to offset these non-cash expenses. Cash (used for) investing activities was ($796,000) during the three-month period ended March 31, 2022 in contrast to cash provided by investing activities of $657,000 during the three-month period ended March 31, 2021. Cash paid for capital expenditures was $807,000 and $349,000 during the three-month periods ended March 31, 2022 and 2021, respectively, which payments were largely related to our ongoing investments to expand our manufacturing facilities. Cash provided by financing activities increased to $1.8 million during the three-month period ended March 31, 2022 in contrast to cash (used for) financing activities of ($176,000) during the three-month period ended March 31, 2021. The $2 million loan amendment we completed during the first quarter of 2022 was the largest cause of this change. Going forward, repayments of the indebtedness incurred to fund these capital expenditures and acquire these assets will reduce our cash flows.

From the first quarter of 2016 through the second quarter of 2021, we raised gross proceeds of approximately $26.7 million (net proceeds were approximately $24.8 million) from six different common equity transactions priced between $5.25 and $8.25 per share with a weighted average price of approximately $5.87 per share. No warrants were issued in connection with any of these transactions, and no convertible or preferred securities were issued.

As a result of several bank debt refinancings and amendments with, and scheduled principal repayments to, Gorham Savings Bank (GSB) since the first quarter of 2020, we had $10.9 million in outstanding bank debt as of March 31, 2022, compared to $9.3 million as of March 31, 2021. We have improved our liquidity by lowering our interest expense, spreading our principal payments out over a longer period of time and pushing out pending balloon principal payment obligations that existed under some of the repaid debt. Debt principal repayments aggregated $775,000 and $1.2 million during the twelve-month periods ended March 31, 2022 and 2021, respectively. The higher debt repayments during the twelve-month period ended March 31, 2021 reflect our decision to prepay approximately $624,000 of our then outstanding mortgage debt to remove a restricted cash bank debt covenant at that time. We anticipate that debt principal repayments will aggregate approximately $907,000 during the twelve-month period ending March 31, 2023, exclusive of any consideration given to the two loans from the Maine Technology Institute (MTI) discussed below. Interest expense was $302,000 and $304,000 during the twelve-month periods ended March 31, 2022 and 2021, respectively. We anticipate that interest expense will be $337,000 during the twelve-month period ending March 31, 2023. During the first quarter of 2022, the availability of our $1.0 million line of credit, which bears interest at the National Prime Rate plus 0.00% per annum, was extended until March 11, 2024. We may use some of the loan proceeds to repay two loans from the MTI aggregating $900,000 (described below) when they become subject to quarterly principal and interest payments, bearing interest at the fixed rate of 5% per annum during the fourth quarter of 2022 and the third quarter of 2023. These GSB credit facilities are secured by substantially all of our assets, including our facility at 56 Evergreen Drive in Portland (which was independently appraised at $6.3 million in connection with a 2022 financing, at $3 million in connection with a 2020 refinancing and at $4.2 million in connection with a 2015 financing) and our facility at 33 Caddie Lane in Portland (which was independently appraised at $3.2 million in connection with a 2017 financing and at $2.5 million in connection with a 2020 refinancing). These credit facilities are subject to certain restrictions and financial covenants. We are required to meet a minimum debt service coverage (DSC) ratio set by GSB of 1.35. Our actual DSC ratio was equal to 2.68, 2.03 and 1.57 during the years ended December 31, 2021, 2020 and 2019, respectively. However, based on current projections of our future financial performance, which includes a high level of ongoing product development expenses to support **Re-Tain®**, we may not satisfy this annual requirement for the year ending December 31, 2022. By negotiation with GSB in connection with a 2022 financing, the required minimum DSC ratio was reduced to 1.0 for the year ending December 31, 2022.

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

We have funded most of our business operations principally from the gross margin on our product sales and from the equity and debt financings described above. 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 March 31, 2022 | As of December 31, 2021 | Increase | |
|---|---|---|---|---|
| | | | Amount | % |
| Cash and cash equivalents | $11,817 | $10,185 | $1,632 | 16% |
| Net working capital | $15,948 | $13,730 | $2,218 | 16% |
| Total assets | $46,699 | $44,466 | $2,234 | 5% |
| Stockholders' equity | $33,373 | $32,577 | $796 | 2% |
| Common shares outstanding[(1)] | 7,743 | 7,742 | 1 | 0% |

(1) There were approximately 497,000 and 443,000 shares of common stock reserved for issuance for stock options that were outstanding as of March 31, 2022 and December 31, 2021, respectively.

From 2014 to 2019, we initiated four capital expenditure investments, as described in the following table (in thousands):

| | Cash Paid on Projects Initiated before 2021 During the | | | | |
|---|---|---|---|---|---|
| | A | B | C | D | Total |
| Year Ended December 31, 2014 | $1,041 | $— | $— | $— | $1,041 |
| Year Ended December 31, 2015 | 1,991 | 265 | — | — | 2,256 |
| Year Ended December 31, 2016 | 1,173 | 2,093 | — | — | 3,266 |
| Year Ended December 31, 2017 | — | 17,686 | — | — | 17,686 |
| Year Ended December 31, 2018 | — | 1,596 | — | — | 1,596 |
| Year Ended December 31, 2019 | — | — | 279 | 538 | 817 |
| Year Ended December 31, 2020 | — | — | 2,938 | 581 | 3,519 |
| Year Ended December 31, 2021 | — | — | 432 | 886 | 1,318 |
| Three-Month Period Ended March 31, 2022 | — | — | 4 | 17 | 21 |
| Total Paid through March 31, 2022 | 4,205 | 21,640 | 3,653 | 2,022 | 31,520 |
| Estimate to Complete | — | — | — | 1,978 | 1,978 |
| Total Project Cost | $4,205 | $21,640 | $3,653 | $4,000 | $33,498 |

**PROJECT A** included a 7,100 square foot facility addition at 56 Evergreen Drive and related equipment and cold storage capacity to increase the production capacity for the **First Defense®** product line. During the first quarter of 2016, we completed this investment, increasing our freeze drying capacity by 100% and making other improvements to our liquid processing capacity, which increased our annual production capacity (in terms of annual sales dollars) to approximately $16.5 million. The actual value of our production output varies based on production yields, selling price, product format mix and other factors. This investment also included the construction and equipping of a pilot plant for small-scale Drug Substance production for **Re-Tain®** within our **First Defense®** production facility at 56 Evergreen Drive. After **PROJECT B** was completed, this space was converted for use in the production of the gel tube formats of the **First Defense®** product line. One of the objectives of **PROJECT C** was a relocation of these gel tube operations to 175 Industrial Way, vacating production space at 56 Evergreen Drive for use in doubling our liquid processing capacity.

**PROJECT B** was related to the Drug Substance production facility for **Re-Tain®** at 33 Caddie Lane. During the fourth quarter of 2017, we completed construction of the Drug Substance production facility. We began equipment installation during the third quarter of 2017, and we completed this installation during the third quarter of 2018. The total cost of this investment for the Drug Substance production facility and related processing equipment was $20.8 million plus $331,000 for the land and $472,000 for the acquisition of an adjacent 4,080 square foot warehouse facility, which will be used for cold storage of **Re-Tain®** inventory and other warehousing needs.

**PROJECT C** consisted of significant renovations to a 14,300 square foot leased facility at 175 Industrial Way, some facility modifications at 56 Evergreen Drive and the necessary production equipment to increase the annual production capacity of the **First Defense®** product line (in terms of annual sales dollars) from approximately $16.5 million to approximately $23 million. The actual

value of our production output varies based on production yields, selling price, product format mix and other factors. This project was completed at the end of 2021 at approximately 4%, or $153,000, over its budget of $3.5 million. This expansion involved a 40% increase in our freeze drying capacity and a 100% increase in our liquid processing capacity. Renovations to our leased facility at 175 Industrial Way to enable this expansion were completed during the second quarter of 2020. By moving our powder filling and assembly services from 56 Evergreen Drive into this new space at 175 Industrial Way, we created space at 56 Evergreen Drive for the installation of the expanded freeze drying capacity. The new facilities are built to contemporary cGMP standards with good material and people flows. A site license approval for this new facility at 175 Industrial Way was issued by the USDA during the third quarter of 2020. During the second quarter of 2021, we completed the relocation of our gel formulation equipment from 56 Evergreen Drive to 175 Industrial Way, creating space for the doubling of our liquid processing capacity at 56 Evergreen Drive. We obtained site license approval of the expanded freeze drying capacity at 56 Evergreen Drive from the USDA during the third quarter of 2021, and we obtained temporary (subject to final USDA review and approval) site license approval of the expanded liquid processing capacity at 56 Evergreen Drive from the USDA during the first quarter of 2022. As part of this investment, we also made the facility modifications at 56 Evergreen Drive necessary to expand our freeze drying capacity by an additional 35%, which would increase our annual production capacity from approximately $23 million to approximately $30 million or more (see **PROJECT F** below).

**PROJECT D** is a $4 million budgeted investment to bring the formulation and aseptic filling capabilities for **Re-Tain®** Drug Product in-house to end our reliance on third-party Drug Product manufacturing services. We began initial equipment installation during the first quarter of 2022. We anticipate FDA approval of this facility (which is a requirement for commercial manufacturing) by the second quarter of 2024.

During the second quarter of 2021, we initiated three more capital expenditure investments, as described in the following table (in thousands):

| | Cash Paid on Projects Initiated in 2021 During the | | | |
|---|---|---|---|---|
| | **E** | **F** | **G** | **Total** |
| Year Ended December 31, 2021 | $452 | $296 | $282 | $1,030 |
| Three-Month Period Ended March 31, 2022 | 55 | 190 | 351 | 596 |
| Total Paid through March 31, 2022 | 507 | 486 | 633 | 1,626 |
| Estimate to Complete | 243 | 439 | 2,087 | 2,769 |
| Total Project Cost | $750 | $925 | $2,720 | $4,395 |

**PROJECT E** represents an original budget of $500,000 for equipment and vehicle investments necessary to expand and improve our colostrum collection capabilities and logistics. During the second quarter of 2021, this budget was increased from $500,000 to $550,000. To enable the continuing expansion of our colostrum collection capacity, we now anticipate this project will be completed for approximately $750,000, which would be $200,000 over its revised budget.

**PROJECT F** represents a budget estimate of $925,000 for freeze drying equipment to expand on **PROJECT C** to further increase the annual production capacity of the **First Defense®** product line (in terms of annual sales dollars) from approximately $23 million to approximately $30 million or more by increasing our freeze drying capacity by an additional 33%. The actual value of our production output varies based on production yields, selling price, product format mix and other factors. We initiated **PROJECT F** during the third quarter of 2021, and we anticipate completing this investment during the third quarter of 2022.

**PROJECT G** first represented an initial estimate of $1 million for equipment and facility modifications costs to scale-up and upgrade our vaccine manufacturing capacity. During the third quarter of 2021, the scope of this project was expanded to include less money for vaccine equipment and more money for pack & ship facilities for **Re-Tain®**, improvements to our quality offices and laboratories and new equipment for our gel filling operations. We estimate the additional investments in our gel filling equipment will increase our annual production capacity for the **First Defense®** product line (in terms of annual sales dollars) further from approximately $30 million to approximately $35 million. The actual value of our production output varies based on production yields, selling price, product format mix and other factors. As a result of these significant scope changes, the preliminary project budget was increased to $2.52 million. We now anticipate this project will be completed for approximately $2.72 million, which would be $200,000 over its revised budget.

In addition to the specific projects listed above, our budget for routine and miscellaneous capital expenditures for the year ending December 31, 2022 is $512,000. We spent $191,000 of this budget during the first quarter of 2022, and we anticipate that we may run approximately $313,000 over this budgeted amount during the year ending December 31, 2022 for a revised annual total of approximately $825,000. These routine and miscellaneous capital expenditures amounted to $260,000, $554,000 and $574,000 during the years ended December 31, 2021, 2020 and 2019, respectively. While the spend on this budget category during 2021 was lower than expected and the spend during 2022 is anticipated to be higher than expected, the average of the two years is anticipated to be

approximately $543,000 per year. We have set aside approximately $5.4 million of the $11.8 million of the cash we had on hand as of March 31, 2022 to complete **PROJECT D** to **PROJECT G** as well as to pay for our other routine and miscellaneous capital expenditures during 2022, leaving the remaining cash balance of approximately $6.4 million available for general working capital purposes including anticipated inventory builds for both **First Defense®** and **Re-Tain®**.

During the third quarter of 2016, the City of Portland approved a Tax Increment Financing (TIF) credit enhancement package that reduces the real estate taxes on our Drug Substance production facility for **Re-Tain®** by 65% over the eleven-year period beginning on July 1, 2017 and ending June 30, 2028 and by 30% during the year ending June 30, 2029, at which time the rebate expires. During the second quarter of 2017, the TIF was approved by the Maine Department of Economic and Community Development. The value of the tax savings will increase (decrease) in proportion to any increases (decreases) in the assessment of the building for city real estate tax purposes or the City's tax rate. The following table discloses how much of the new taxes we have generated is being relieved by the TIF and how much is being paid by ImmuCell:

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

**Results of Operations**

**Business Segments**

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

**Product Sales**

Through both continued growth in sales of the **First Defense®** product line and a successful launch of **Re-Tain®** as soon as possible, and with a measured approach to expanding our customer-facing staff, it is our objective to increase our current annual level of total product sales of approximately $19.2 million for the year ended December 31, 2021 to approximately $23 million or more by the year ending December 31, 2023. As additional resources are dedicated to production, sales, marketing and technical services, our longer-term goal is to exceed $35 million of annual total product sales as soon as possible during the five-year period after the market launch of **Re-Tain®**.

Sales of the **First Defense®** product line aggregated 99% and 98% of our total sales during the three-month periods ended March 31, 2022 and 2021, respectively. We set successive records for high sales during the first quarter of 2022 and the fourth, third and second quarters of 2021 in comparison to the same quarters of the prior years. Sales of the **First Defense®** product line increased from approximately $4,473,000 during the quarter ended June 30, 2021 to $5,033,000 during the quarter ended September 30, 2021 to $5,403,000 during the quarter ended December 31, 2021 to $5,963,000 during the quarter ended March 31, 2022. Most of our growth (when not limited by the backlog) is being realized through increased demand and a deliberate strategy to prioritize production capacity towards **Tri-Shield®** (the trivalent format of our product delivered via a gel tube), which provides broader protection to calves. The compound annual growth rate of our total product sales during the ten years ended December 31, 2021 was approximately 15%. The compound annual growth rate of our total product sales during the three years ended December 31, 2021 was approximately 18%.

| | During the Three-Month Periods Ended March 31, | | Increase | |
|---|---|---|---|---|
| (In thousands, except for percentages) | 2022 | 2021 | Amount | % |
| Total product sales | $6,000 | $4,107 | $1,893 | 46% |

Sales increased by 46%, or $1.9 million, to $6 million during the three-month period ended March 31, 2022, in comparison to the three-month period ended March 31, 2021. Domestic sales increased by 54%, and international sales decreased by 8%, in comparison to the three-month period ended March 31, 2021. International sales aggregated 8% and 13% of total sales during the

three-month periods ended March 31, 2022 and 2021, respectively.

| (In thousands, except for percentages) | During the Twelve-Month Periods Ended March 31, 2022 | 2021 | Increase Amount | % |
|---|---|---|---|---|
| Total product sales | $21,136 | $14,539 | $6,597 | 45% |

Sales increased by 45%, or $6.6 million, during the twelve-month period ended March 31, 2022, in comparison to the twelve-month period ended March 31, 2021. Domestic sales increased by 44%, and international sales increased by 54%, in comparison to the twelve-month period ended March 31, 2021. International sales aggregated 12% and 11% of total sales during the twelve-month periods ended March 31, 2022 and 2021, respectively.

Starting in the third quarter of 2016 and through most of 2017, we had sufficient available inventory and were shipping in accordance with the demand of our distributors. However, we quickly sold out of our initial launch quantities of **Tri-Shield First Defense®** (which added a valuable rotavirus claim to our legacy *E. coli* and coronavirus product) soon after regulatory approval was obtained during the fourth quarter of 2017. **Tri-Shield®** has changed our capacity models significantly because it requires almost twice as much production capacity to produce each finished dose and demand for this product format has increased each year. Initially, production of this new product format did not keep pace with demand primarily because of our inability to produce enough of the new, complex rotavirus vaccine that is used to immunize our source cows. Work on production improvements in our vaccine laboratory throughout 2018 led to significant improvements in vaccine yield and process repeatability. Allowing for the five to six month production cycle from the manufacture of our proprietary vaccine to the production of a finished dose, we were able to return to a mass market selling approach through distribution for **Tri-Shield®** during the second half of 2019, and we ended the year with no backlog as of December 31, 2019. Sales of the **First Defense®** product line during the years ended December 31, 2020 and 2021 continued to increase, creating a backlog of orders at the end of each quarter during this two-year period. Valuation of the backlog is a non-GAAP estimate that is based on purchase orders on hand at the time that could not be met because of a lack of available inventory. The backlog was worth approximately $2.4 million as of December 31, 2021 and approximately $1.6 million as of May 6, 2022. However, 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 more current demand. Additionally, we believe that our distributors are reacting to this global economic challenge by ordering in more product for their inventory, which is a very different cash management strategy from the recent past, when they were much more likely to invest less money in their inventory and order from us more often to meet just current demand ("just-in-time" cash management). The growth in our sales (which are seasonal) and the expansion of our production capacity (which is generally delivered approximately evenly across the four quarters of the year) are described in the following table:

| | Quarterly | Annualized |
|---|---|---|
| Estimated production capacity before current expansion | $4,125,000 | $16,500,000 |
| Targeted production capacity as of December 31, 2021 | $5,750,000 | $23,000,000[(1)] |
| Targeted production capacity by September 30, 2022 | $7,500,000 | $30,000,000 |
| Targeted production capacity by December 31, 2022 | $8,750,000 | $35,000,000 |

(1) When factoring in changes in beginning and ending inventory balances, the fourth quarter of 2021 annualized manufacturing output of $22.9 million compared to our $23 million target. The first quarter of 2022 annualized manufacturing output of $23.8 million exceeded the $23 million target.

We have completed the critical objectives of our investment to increase our **First Defense®** production capacity from approximately $16.5 million to approximately $23 million in terms of annual sales value. These capacity estimates are subject to biological yield variance, product format mix, selling price and other factors. Equipment modifications and relocations of this nature require a shutdown of operations for weeks to months to install and validate the modified equipment and achieve USDA approval for its use in its new location. The qualification and implementation of the final two pieces of equipment required to complete this project were delayed past our June 30, 2021 target but are now complete (see **PROJECT C** above). We worked around this setback to meet our increased production requirements by utilizing our expanded manufacturing staff to extend shifts and temporarily produce more product from the existing equipment. During the third quarter of 2021, we initiated an additional investment of approximately

$925,000 to increase our annual production capacity for the **First Defense®** product line further from approximately $23 million to approximately $30 million or more per year by the third quarter of 2022 (see **PROJECT F** above). Then, during the fourth quarter of 2021, we initiated an additional investment to further increase our annual production capacity to approximately $35 million by the end of 2022 (see **PROJECT G** above). The actual value of our production output varies based on production yields, selling price, product format mix and other factors.

The significant global supply-chain disruptions that almost all industries are experiencing presently are a challenge to us and contribute to our order backlog. Most prices for certain essential raw materials and critical supplies are increasing significantly, and it is more and more difficult to obtain timely delivery of the orders that we place. Therefore, we have little choice but to pay the higher prices and try to take on more months of supply than we would have held previously if we could get our orders fulfilled.

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

Effective January 1, 2022, we increased our selling price of the **First Defense®** product line by approximately 5%. Effective January 1, 2021, we increased our selling price of the **First Defense®** product line in the domestic market by approximately 1.6% to 3%, depending on product format, and we increased our selling price of **CMT** by almost 4%. Effective February 1, 2020, we implemented a price increase of approximately 2% on the **First Defense®** product line (except for **Tri-Shield®** and the 90-dose bulk powder format) and **CMT**. Effective January 1, 2019, we implemented a 2% price increase for **Dual-Force®**.

Sales of products other than the **First Defense®** product line decreased by 56%, or $47,000, to $37,000 during the three-month period ended March 31, 2022 in comparison to the three-month period ended March 31, 2021. Sales of these other products aggregated approximately 1% and 2% of our total product sales during both of the three-month periods ended March 31, 2022 and 2021, respectively. We acquired a private label product (our second leading source of product sales during 2021) in connection with our January 2016 acquisition of certain gel formulation technology. This product was discontinued during the first quarter of 2022 because it was not a significant contributor to our total sales and it competed for valuable time and space in our production schedule. We sell our own **CMT** (our third leading source of product sales during 2021), which is used to detect somatic cell counts in milk.

**Impact of Global COVID-19 Pandemic and Russia's Unprovoked Military Invasion of Ukraine**

We are facing significant production constraints, supply disruptions and inflationary increases caused, in large part, by COVID and Russia's war. The extent of the negative impact of the COVID-19 pandemic on the economics of our customers and on the demand for our products going forward is very difficult to assess. The Class III milk price has been extremely volatile during the pandemic. Initially, stay at home orders disrupted the food service supply system as schools closed and restaurants were shut down. In response, producers were forced to reduce the supply of milk to the market by drying off cows early, culling cows from the herd and dumping milk, among other tactics. Market conditions have improved somewhat, but this volatility remains a concern. Additionally, like most input costs, the cost of feed is rising, which puts a strain on the profitability of our customers. The $938,000 in funding that we received from the federal government through the Paycheck Protection Program (PPP) under the CARES Act (which loan was forgiven by the federal government during 2020) helped us maintain full employment without furloughs or layoffs and continue executing our growth plans. The PPP funding created some needed financial liquidity, allowing us to move forward with our investments even though we did not achieve the level of sales anticipated in our 2020 budget.

**Gross Margin**

Changes in our gross margin (product sales less costs of goods sold) are summarized in the following table for the respective periods (in thousands, except for percentages):

| | During the Three-Month Periods Ended March 31, | | Increase | |
|---|---|---|---|---|
| | 2022 | 2021 | Amount | % |
| Gross margin | $3,103 | $1,602 | $1,501 | 94% |
| Percent of product sales | 52% | 39% | 13% | 33% |

| | During the Twelve-Month Periods Ended March 31, | | Increase | |
|---|---|---|---|---|
| | 2022 | 2021 | Amount | % |
| Gross margin | $10,157 | $6,229 | $3,928 | 63% |
| Percent of product sales | 48% | 43% | 5% | 12% |

The gross margin as a percentage of product sales was 45%, 45%, 49%, 47% and 50% during the years ended December 31, 2021, 2020, 2019, 2018 and 2017, respectively. During the first quarter of 2021, the gross margin of 39% was lower than what we normally expect. This gross margin improved to 46% during the second quarter of 2021 and further to 47% during both the third and fourth quarters of 2021 and then further to 52% during the first quarter of 2022, as we began to spread these fixed costs over increasing production output. This high percentage experienced during the first quarter of 2022 may not be repeatable on a consistent basis. While our biological and process yields can be variable, we have seen a favorable improvement to our finished goods yield recently. We believe that gross margin results should be viewed over longer periods of time than just one quarter. For example, our gross margin was equal to 49.5% of sales during the six-month period ended March 31, 2022. As we fully integrate and utilize our increased capacity, we expect to be able to achieve an annual gross margin in the range of 46% to 50%. The costs of most of our supplies, components, raw materials and services increased significantly during 2021 and that trend continues into 2022. 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 (after we fulfill the backlog) even if that is accomplished with a lower gross margin as a percentage of sales. We are investing significantly in equipment, infrastructure and operating expenses to increase our annual production capacity from approximately $16.5 million to approximately $35 million. Increased labor and other upfront costs were necessary to benefit from the scale-up of our production output going forward. A number of other factors contribute to the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter and from year to year. Like most U.S. manufacturers, we have also been experiencing increases in the cost of labor and raw materials. We also invest to sustain compliance with current Good Manufacturing Practices (cGMP) in our production processes. Increasing production can be more expensive in the initial stages. To achieve our inventory production growth objectives, we are acquiring more raw material (colostrum) from many more cows at many new farms. As is the case with any vaccine program, animals respond less effectively to their first exposure to a new vaccine, and thereafter the effectiveness of their immune response improves in response to subsequent immunizations. During this expansion phase, colostrum quality can be more variable. Additionally, the biological yields from our raw material are always variable, which impacts our costs of goods sold in a similar way. Just as our customers' cows respond differently to commercial dam-level vaccines, depending on time of year and immune competency, our source cows have similar biological variances in response to our proprietary vaccines. The value of our **First Defense®** product line is that we compensate for the variability in a cow's immune response by standardizing each dose of finished product. This ensures that every calf is equally protected, which is something that dam-level commercial scours vaccines cannot offer. We continue to work on processing and yield improvements and other opportunities to reduce costs, while enhancing process knowledge and robustness. Over time, we have been able to reduce the impact of cost increases by implementing yield improvements. As we evaluate our product costs and selling price, one of our goals is to achieve a gross margin (before related depreciation and amortization expenses) as a percentage of total sales approaching 50%.

**Product Development Expenses**

*Overview:* During the three-month period ended March 31, 2022, product development expenses remained the same at just over $1 million in comparison to the three-month period ended March 31, 2021. Product development expenses aggregated 17% and 25% of product sales during the three-month periods ended March 31, 2022 and 2021, respectively. Product development expenses included approximately $348,000 and $386,000 of non-cash depreciation and stock-based compensation expenses during the three-month periods ended March 31, 2022 and 2021, respectively. We do expect our product development expenses to decrease further after **Re-Tain®** is commercialized and some of the costs incurred to maintain and run our Drug Substance production facility become part of our costs of goods sold.

*Development objective:* We aim to demonstrate that our polypeptide antimicrobial, Nisin A, can play a productive role in the

treatment of subclinical mastitis in today's dairy industry by providing a novel alternative to traditional antibiotics. Because label requirements of all intramammary drugs on the market require that milk be discarded and that meat be withheld during treatment and for a period of time thereafter, it is common practice in the dairy industry today to not treat sick cows that are still producing saleable milk. **Re-Tain®** provides an animal welfare benefit by removing this economic disincentive to treating subclinical mastitis and allows sick cows to be treated without the milk discard and meat withhold penalties. In addition to improved animal welfare, **Re-Tain®** enhances food safety and sustainability by utilizing a polypeptide antimicrobial that is not used in human medicine. The overuse of traditional antibiotics is thought to create antibiotic resistance, which is a growing public health concern. By treating mastitis early at the subclinical level, producers could preserve peak milk yields and reduce the number of infections that develop into clinical cases requiring antibiotic treatment and milk discard. **Re-Tain®** could increase the lifetime profitability of a cow and reduce disease transfer to herd mates. 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 those exciting benefits, it will take time to change this longstanding treatment paradigm and develop this new market. It will take time for the market to understand, evaluate, implement and adapt to the use and benefits of **Re-Tain®**. As we prepare for market launch after we receive the anticipated and required FDA approval of this product, we are carefully considering our best go-to-market strategy in consultation with industry-leading consultants, veterinarians, dairy producers and others. We believe that the primary market for **Re-Tain®** (at least initially) may be limited to the approximately half of farms that have access to somatic cell count data at the cow or quarter level, since that is the most common and efficient way to identify subclinical infections and to assess the effectiveness of treatment. We are making plans for a controlled launch where our sales and technical support team can work directly with early adopters to help ensure that the best candidate cows are selected and that the product is properly administered in accordance with its label. We believe that developing a solid foundation of in-the-field successes early on will give **Re-Tain®** the best opportunity for success.

*Development status of **Re-Tain®***: The majority of our product development spending has been focused on the development of **Re-Tain®**, our purified Nisin treatment for subclinical mastitis in lactating dairy cows. Approval by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA) of the New Animal Drug Application (NADA) for **Re-Tain®** is required before any sales of the product can be initiated. The NADA is comprised of five principal Technical Sections that are generally subject to one or more six-month review cycle(s) by the FDA and a sixty-day administrative review at the end. By statute, each Technical Section submission is generally subject to a six-month review cycle by the FDA. Each Technical Section can be reviewed and approved separately. Upon review and assessment by the FDA that all requirements for a Technical Section have been met, the FDA may issue a Technical Section Complete Letter. The current status of our work on these submissions to the FDA is as follows:

1) Environmental Impact: During the third quarter of 2008, we received the Environmental Impact Technical Section Complete Letter from the FDA. During the second quarter of 2021, we received further clarification through a new Environmental Impact Technical Section Complete Letter covering the current dosage regimen and labeling.

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

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

4) Human Food Safety: During the third quarter of 2018, we received the Human Food Safety Technical Section Complete Letter from the FDA confirming, among other things, a zero milk discard period and a zero meat withhold period during and after treatment with our product. During the second quarter of 2021, we updated this Technical Section Complete Letter with FDA approval of the official analytical method to measure Nisin in milk.

5) Chemistry, Manufacturing and Controls (CMC): The CMC Technical Section is very complex and comprehensive. Having previously achieved the four different Technical Section Complete Letters from the FDA discussed above, approval of the CMC Technical Section is the fifth and final significant step required before **Re-Tain®** product sales can be initiated in the United States. Implementing Nisin Drug Substance (the active pharmaceutical ingredient) production, which is a required component of the CMC Technical Section, has been the most expensive and lengthy part of this project. We previously entered into an agreement with a multi-national pharmaceutical ingredient manufacturer for our commercial-scale supplies of Nisin. However, we determined during 2014 that the agreement did not offer us the most advantageous supply arrangement in terms of either cost or long-term dependability. We presented this product development opportunity to a variety of large and small animal health companies. While such a corporate partnership could have provided access to a much larger sales and marketing team and allowed us to avoid the large investment in a commercial-scale production facility, we concluded that a partner would have taken an unduly large share of the gross margin from all future product sales of **Re-Tain®**, but 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 the Nisin Drug Substance at small-scale at our 56 Evergreen Drive facility. This small-scale facility was used to: i) expand our process knowledge and controls, ii) establish operating ranges for critical process parameters, iii) conduct product stability studies, iv) optimize process yields and v) verify the cost of production. We believe these efforts have reduced the risks associated with our investment in the commercial-scale Drug Substance production facility, discussed below. Having raised equity during 2016 and 2017, we were able to move away from these earlier strategies and assume control over the commercial-scale manufacturing process in our own facility. During the fourth quarter of 2015, we acquired land near our existing Portland facility for the construction of a new commercial-scale Drug Substance production facility. We commenced construction of this facility during the third quarter of 2016 and completed construction during the fourth quarter of 2017. Equipment installation and qualification was initiated during the third quarter of 2017 and completed during the third quarter of 2018. Total construction and equipment costs aggregated approximately $20.8 million. With construction of the facility complete, we continue to work with outside parties to investigate improvements to our Nisin Drug Substance (DS) production yields as well as potential efficacy enhancements.

Under the FDA's phased submission process, we made a first-phased submission covering just the Nisin DS during the first quarter of 2019, which was followed by a second-phased submission covering both the DS and the formulated DS filled in a syringe, or **Re-Tain®** Drug Product (DP) during the first quarter of 2021. This process allowed us to respond to identified queries and/or deficiencies from the first-phased DS submission at the time of the second-phased combined DS and DP submission. The first-phased DS submission included data from the DS Registration Batches produced at commercial scale in our new DS manufacturing facility. 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 expiration dating. During the third quarter of 2021, the FDA issued a Technical Section Incomplete Letter with regard to this second-phased DS and DP submission. This response was not unexpected as it is common for the FDA to issue queries and comments, especially related to an aseptic DP submission with associated sterilization validation information. We made a second submission of the DS and DP Technical Section during the first quarter of 2022. Allowing time for the six-month review by the FDA and for the final sixty-day administrative review at the end of the process, we could achieve market launch during the fourth quarter of 2022 if the FDA approves our second DS and DP submission. Because we cannot predict the FDA's responses, we cannot project the probability of success with this DS and DP submission. We intend to be completely transparent about the FDA's response (positive or negative) around August 2022. While being prudent with how much cash we invest into inventory that would have short expiry dating if market launch is not achieved by the third quarter of 2022, we plan to continue to build more inventory during 2022 to bridge the transition between DP supply from our contract manufacturer to our own in-house services, as discussed further below.

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

Our potential alternative third-party options for the formulation and aseptic filling services that are presently being performed by Norbrook are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). Consequently, we have decided to perform these services internally (see **PROJECT D** above). We are

investing approximately $4 million in the equipping and commencement of operations of our own DP formulation and aseptic filling facility. We began initial equipment installation during the first quarter of 2022. Subject to the timing of our installation and validation work, we anticipate FDA approval of this facility (which is a requirement for commercial manufacturing) during the fourth quarter of 2023 if the FDA requires only one six-month review cycle or by the second quarter of 2024 if the FDA requires two six-month review cycles. This new facility will be subject to FDA inspection and approval and will have enough formulation and aseptic filling capacity to exceed the expected production capacity of our DS facility, which is at least $10 million in annual sales. This production capacity estimate is based on our assumptions as to product pricing and does not yet reflect inventory build strategies in advance of product approval or ongoing yield improvement initiatives. Establishing our own DP formulation and aseptic filling capability provides us with the longer-term advantage of controlling the manufacturing process for **Re-Tain®** in one facility, thereby potentially reducing our manufacturing costs and eliminating international cold chain shipping logistics and costs. The DP formulation and aseptic filling operation will be located in existing facility space that we had intended to utilize to double our DS production capacity if warranted by sales volumes following market launch. As a result, we would need to explore alternative strategies (in parallel with ongoing DS yield improvement initiatives) to expand our DS production capacity. This integrated manufacturing capability for **Re-Tain®** will substantially reduce our dependence on third parties. Upon completion of our formulation and aseptic filling facility, the only significant third-party input for **Re-Tain®** will be the DP syringes. It is anticipated that Hubert De Backer of Belgium (HDB) will supply these syringes in accordance with purchase orders that we submit. HDB is a syringe supplier for many of the largest participants in the human and veterinary medical industries, and with whom Norbrook presently works. Based on HDB's performance history and reputation in the industry, we are confident that HDB will be a dependable supplier of syringes in the quantity and of the quality needed for **Re-Tain®**.

Our DS manufacturing facility and that of our DP contract manufacturer are subject to ongoing FDA inspections. During the third quarter of 2019, the FDA conducted a pre-approval inspection of our DS facility. This resulted in the issuance of certain deficiencies as identified on the FDA's Form 483. We submitted responses and data summaries in a phased manner over the fourth quarter of 2019 and first quarter of 2020. During the first quarter of 2022, the FDA conducted another pre-approval inspection of our DS facility. This also resulted in the issuance of certain deficiencies as identified on the FDA's Form 483. We have since responded to some of the queries and are preparing our responses to the remaining findings. We anticipate a reinspection by the FDA prior to approval. This inspection process has been managed without significant cost.

*Other product development initiatives:* Our second most important product development initiative has been focused on other improvements, extensions or additions to our **First Defense®** product line. We are currently working to establish USDA claims for our bivalent bulk powder formulation of **First Defense Technology®**. Subject to the availability of resources, we intend to begin new development projects that are aligned with our core competencies and market focus. We also remain interested in acquiring, on suitable terms, other new products and technologies that fit with our sales focus on the dairy and beef industries, subject to the availability of the needed funding.

**Sales and Marketing**

During the three-month period ended March 31, 2022, sales and marketing expenses increased by approximately 56%, or $291,000, to $812,000 in comparison to $521,000 during the three-month period ended March 31, 2021, amounting to 14% and 13% of product sales during the three-month periods ended March 31, 2022 and 2021, respectively. Sales and marketing expenses included approximately $36,000 and $17,000 of non-cash depreciation and stock-based compensation expenses during the three-month periods ended March 31, 2022 and 2021, respectively. We do expect these expenses to increase to approximately 20% of total product sales during 2022 as we begin to invest in the anticipated market launch of **Re-Tain®** before any new sales are realized and as in-person marketing opportunities, such as industry events, return with the lifting of COVID restrictions. Our budgetary guideline for 2022 and after is to keep these expenses under 20% of total sales. We continue to leverage the efforts of our small sales force by using animal health distributors.

We believe that **Re-Tain®** could revolutionize the way that mastitis is treated by making earlier treatment of subclinically infected cows (while these cows are still producing saleable milk) economically feasible by not requiring a milk discard during, or for a period of time after, treatment, which would be a significant competitive advantage for our product. No other FDA-approved mastitis treatment product on the market can offer this value proposition. 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. Because the milk from cows treated with traditional antibiotics must be discarded, most dairy producers simply do not treat subclinically infected cows. The ability to treat such cases without a milk discard could revolutionize the way mastitis is managed in a herd. 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. Our product likely will be priced at a premium to the traditional

antibiotic products currently on the market, which are all sold subject to a milk discard requirement. Common milk discard periods cover the duration of treatment and extend from 1.5 to 3 days after last treatment, depending on the antibiotic. On average, a cow produces approximately 60 to 80 pounds of milk per day. While milk prices vary significantly, at an average value of $18.00 per 100 pounds, a cow produces approximately $10.80 to $14.40 worth of milk per day. These estimated figures would result in milk discard costs ranging from approximately $37.80 (for 3.5 days of milk at 60 pounds per day) to $158.40 (for 11 days of milk at 80 pounds per day) per treated animal. We estimate that the approximate cost to the U.S. dairy industry of this discarded milk may be around $300 million per year. These high milk discard costs associated with traditional antibiotic treatments lead producers to only treat mastitis after clinical signs develop. The **Re-Tain®** label will be for subclinical mastitis (not clinical). Without a milk discard cost, we expect producers to be more motivated to identify and treat cows at the subclinical stage. We believe that the product's value proposition demonstrates 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.

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

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 eighteen months or so after FDA approval, as we seek to revolutionize the way that mastitis is treated in the dairy industry over the long term. Through our direct sales team, our goal is to create exceptional customer experiences with first adopters. We believe that the resulting positive customer testimonials should help create the momentum necessary to optimize product sales over the longer period. 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 numbers of participating farms so that the desired levels of support and guidance relating to effective usage of **Re-Tain®** can be provided. We believe that the operational adjustments and accommodations that dairy farmers will need to make to effectively use **Re-Tain®** and avoid the potential problems described under **ITEM 1A – RISK FACTORS**, "Product Risks", to this Quarterly Report will not be so burdensome as to deter its adoption and usage. Our overarching objective is to minimize the risk of early stage unsatisfactory outcomes that could harm the longer term prospects and market acceptance of **Re-Tain®**. This strategy also reduces the amount of inventory that we would need to build at risk before regulatory approvals of the product and our production facilities are achieved, and it reduces the amount of cash we would need to spend to purchase inventory from our contract manufacturer before our in-house aseptic filling services are approved by the FDA. This strategic choice means that we have elected not to pursue an alternative strategy that might have maximized short-term, initial sales quickly through a mass market approach where we provide product to distribution and let them sell it to as many farms as possible. While we are dedicated to increasing our sales revenue, we must consider the damage a pre-mature 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 are developing 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®**.

In the big picture, we are introducing an entirely new class of antimicrobial as an animal drug, a bacteriocin, that does not promote resistance against antibiotics used in human medicine making it more socially responsible. As the great NHL hockey player, Wayne Gretzky, is known to have said, "I skate to where the puck is going to be, not where it has been." This is motivational to us. We believe our product fits very well with where the industry is going to be in the coming years. Sustainability objectives of the industry 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. The over-use of antibiotics that are medically important to human healthcare is a growing 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". The industry could keep treating this very significant disease with traditional antibiotics, but it takes

innovation to bring a polypeptide antimicrobial like Nisin to market. **Re-Tain®** will, 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 also know that animals infected with subclinical mastitis have higher abortion rates and often progress to the clinical disease state. We believe that societal animal welfare objectives will put more and more pressure on the industry to treat cows with subclinical infections.

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

As disclosed in previously filed reports, we have made preliminary assessments and estimates relating to the market opportunity for **Re-Tain®**, both during and after its initial launch, and have described the principal challenges facing the launch of a new product by a company such as ours with limited sales, marketing and financial resources into a competitive market populated with several global pharmaceutical enterprises. We expect annual sales to be well below the $36.1 million level that we previously estimated as the potential of the market opportunity for our product five years after product launch. This is because we are taking a more controlled launch approach, respecting the challenges of introducing a paradigm changing technology. We are going to be very transparent with the launch of **Re-Tain®**. To that end, we have expanded Note 17, “Segment Information”, to the accompanying unaudited financial statements to now display a break-out of our financial results among the following two components of our business: i) **First Defense®** and ii) **Re-Tain®**. This will allow investors to see our progress with both products. We generally do not provide financial projections, as we know such projections can prove to be materially inaccurate. However, in this case, we are providing a high-level projection for **Re-Tain®** that under this controlled launch plan strategy, we think we can achieve sales of approximately $1 million in 2023 and then about double that in 2024. This assumes FDA approval is achieved and that product launch is initiated around the beginning of the fourth quarter of 2022. If we are successful with this launch strategy, we would aim to grow this curve in 2024 and after. We believe this strategy lends itself to a more gradual adoption curve but higher and more sustainable sales over the long-term. Actual sales results will vary from these projections up or down.

**Administrative Expenses**

During the three-month period ended March 31, 2022, administrative expenses increased by 9%, or approximately $38,000, to $463,000 in comparison to $425,000 during the three-month period ended March 31, 2021. Administrative expenses included approximately $33,000 and $29,000 of non-cash depreciation and stock-based compensation expenses during the three-month periods ended March 31, 2022 and 2021, respectively. We strive to be efficient with these expenses while funding costs associated with complying with the Sarbanes-Oxley Act of 2002 and all the legal, audit and other costs associated with being a publicly-held company. 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. At the same time, we continue to provide full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as in Current Reports on Form 8-K when legally required or deemed appropriate by management. These efforts may have helped us access the capital markets to fund our growth objectives.

**Net Operating Income (Loss)**

During the three-month period ended March 31, 2022, our net operating income of $793,000 was in contrast to a net operating (loss) of ($375,000) during the three-month period ended March 31, 2021. The substantial increase in product sales during the first quarter of 2022, which in turn created the $1.5 million increase in gross margin during the three-month period ended March 31, 2022 compared to the three-month period ended March 31, 2021, was the largest contributor to this swing from (loss) to income.

**Other Expenses, net**

During the three-month period ended March 31, 2022 other expenses, net, aggregated $56,000 in comparison to other expenses, net, of $67,000 during the three-month period ended March 31, 2021. Interest expense decreased to $75,000 during the three-month period ended March 31, 2022 from $80,000 during the three-month period ended March 31, 2021. Non-cash amortization of debt issuance costs (which is included as a component of interest expense) was $2,000 during both of the three-month periods ended March 31, 2022 and 2021. Cash-based interest expense decreased slightly to $73,000 during the three-month period ended March 31, 2022 from $78,000 during the three-month period ended March 31, 2021. We anticipate that our interest expense will be

approximately $332,000, $320,000 and $288,000 during the years ending December 31, 2022, 2023, and 2024, respectively. Interest income was $7,000 and $3,000 during the three-month periods ended March 31, 2022 and 2021, respectively. Less interest income was earned during 2021 largely because we had less cash and short-term investments on hand and a lower interest rate environment. The quarterly results included $11,000 and $10,000 from the sale of fixed assets during the three-month periods ended March 31, 2022 and 2021, respectively.

**Income (Loss) Before Income Taxes**

During the three-month period ended March 31, 2022, our income before income taxes was $737,000 in contrast to a (loss) before income taxes of ($441,000) during the three-month period ended March 31, 2021.

**Income Taxes and Net Income (Loss)**

During the three-month periods ended March 31, 2022, we recorded income tax expense of $1,000 in comparison to no income tax expense during the three-month period ended March 31, 2021. We have substantial net operating loss carryforwards that largely offset our income tax expense. Our tax expense is largely comprised of state tax liabilities. Our net income of $736,000, or $0.09 per diluted share, during the three-month period ended March 31, 2022 was in contrast to a net (loss) of ($441,000), or ($0.06) per basic share, during the three-month period ended March 31, 2021.

For tax return purposes only, our depreciation expense for the Nisin Drug Substance production facility and equipment was approximately $492,000, $464,000, $639,000, $9.2 million and $1.5 million for the years ended December 31, 2021, 2020, 2019, 2018 and 2017, respectively. The significant increase during 2018 was largely related to accelerated depreciation allowed for tax purposes. As of December 31, 2021, our federal net operating loss carryforward was approximately $14.7 million, which will be available to offset future taxable income, subject to possible annual limitations based on ownership changes. On December 22, 2017, the Tax Cuts and Jobs Act was signed into law. This legislation makes significant changes in the U.S. tax laws, including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from 34% to 21%. Our income tax rate differs from this standard tax rate primarily because we are currently providing for a full valuation allowance against our deferred tax assets. While we are recording this full valuation allowance, we are not recognizing the benefit of our tax losses.

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

**Critical Accounting Policies**

The financial statements are presented on the basis of accounting principles that are generally accepted in the United States. All professional accounting standards that were effective and applicable to us as of March 31, 2022 have been taken into consideration in preparing the financial statements. The preparation of financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, income taxes, contingencies and the useful lives and carrying values of intangible and long-lived assets. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have chosen to highlight certain policies that we consider critical to the operations of our business and understanding our financial statements.

We sell products that provide **Immediate Immunity™** to newborn dairy and beef cattle. We recognize revenue in accordance with the five step model in ASC 606. These include the following: i) identification of the contract with the customer, ii) identification of the performance obligations in the contract, iii) determination of the transaction price, iv) allocation of the transaction price to the separate performance obligations in the contract and v) recognition of revenue associated with performance obligations as they are satisfied. We recognize revenue at the time of shipment (including to distributors) for substantially all products, as title and risk of loss pass to the customer on delivery to the common carrier after concluding that collectability is reasonably assured. We do not bill for or collect sales tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We generally have experienced an immaterial amount of product returns.

Inventory includes raw materials, work-in-process and finished goods and is recorded at the lower of cost, on the first-in, first-out method, or net realizable value (determined as the estimated selling price in the normal course of business, less reasonably predictable costs of completion, disposal and transportation). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. Inventory is a critical accounting policy because of the estimates and assumptions used by management to

determine its cost accounting and because of the variability of the cost per dose due to fluctuations in the biological yield.

**ITEM 3 — QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Inflation, interest rates and currency exchange rates are having a more adverse effect on our revenues and expenses than we previously experienced. Future increases in inflation or interest rates could affect our customers and the demand for our products. We hope to increase the level of our future sales of products outside the United States. The cost of our products to international customers could be affected by currency fluctuations. The decline of the U.S. dollar against other currencies could make our products less expensive to international customers. Conversely, a stronger U.S. dollar could make our products more costly for international customers. The current devaluation of the dollar makes Euro-based purchases more expensive for us. We had outstanding bank debt totaling approximately $10 million as of March 31, 2022 that bears interest at the blended fixed rate of 3.52% per annum. Also, as of March 31, 2022, we had two subordinated loans from the State of Maine outstanding aggregating $900,000. The first loan bears no interest until the fourth quarter of 2022, at which time it bears interest at a fixed rate of 5% per annum, unless it is repaid. The second loan bears no interest until the third quarter of 2023, at which time it bears interest at a fixed rate of 5% per annum, unless it is repaid. See Note 10 to the accompanying unaudited financial statements for more details about our debt.

**ITEM 4 — CONTROLS AND PROCEDURES**

*Disclosure Controls and Procedures:* Our management, with the participation of the individual who serves as our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

*Management's Quarterly Report on Internal Control Over Financial Reporting:* The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. We conducted an evaluation of the effectiveness of the internal controls over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. This evaluation included a review of the documentation of controls, evaluation of the design effectiveness of controls, testing the operating effectiveness of the controls and a conclusion on this evaluation. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management assesses the effectiveness of the Company's internal control over financial reporting at the end of each quarter. Based on management's assessment, we believe that our internal control over financial reporting was effective as of March 31, 2022. This Quarterly Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's internal control report was not subject to annual or quarterly attestation by the Company's independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report.

*Changes in Internal Controls over Financial Reporting:* The individual who serves as our principal executive and principal financial officer periodically evaluates any change in internal control over financial reporting which has occurred during the prior fiscal quarter. We have concluded that there was no change in our internal control over financial reporting that occurred during the quarter ended March 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II: OTHER INFORMATION**

**ITEM 1 - LEGAL PROCEEDINGS**

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

operations, or financial condition.

## ITEM 1A — RISK FACTORS

### Financial Risks

*Gross margin on product sales:* One of our goals is to achieve a gross margin (before related depreciation expenses) as a percentage of total sales of approximately 50% after the initial launch of new products. Depreciation expense will be a larger component of costs of goods sold for **Re-Tain®** than it is for the **First Defense®** product line. Gross margins generally improve over time, but this anticipated improvement may not be realized for **Re-Tain®**. Many factors discussed in this report (including the COVID-related 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 goals, which would adversely affect our operating results and could impact our future operating plans. There is a risk that our plans to maintain or improve our gross margin may not be realized due to cost increases, inability to raise our selling prices, or both.

*Exposure to interest rates and debt service obligations:* Rising interest rates could negatively affect the operating costs of dairy and beef producers and thus put further financial pressure on an already stressed business sector, which could indirectly affect our business. We removed the direct aspect of this particular exposure to our business by refinancing our bank debt to fixed rate notes at 3.50% per annum during the first quarter of 2020. The $2 million in additional mortgage debt we secured during the first quarter of 2022 bears interest at the fixed rate of 3.58%. However, the additional debt we incurred to fund our growth objectives has significantly increased our total debt service costs. Reflecting the mortgage debt financing we completed during the first quarter of 2022, we are obligated to make principal and interest payments aggregating approximately $1.2 million during the year ending December 31, 2022 and approximately $1.24 million during the year ending December 31, 2023. See Note 10 to the accompanying unaudited financial statements for more information. A decline in sales or gross margin, coupled with this debt service burden, could impair our ability to fund our capital and operating needs and objectives.

*Debt covenants:* Our bank debt is subject to certain financial covenants. We are required to meet a minimum debt service coverage (DSC) ratio of 1.35, which is measured annually. Our actual DSC ratios were 2.68 and 2.03 for the years ended December 31, 2021 and 2020, respectively. However, based on current projections of our future financial performance, which includes a high level of ongoing product development expenses to support **Re-Tain®**, we may not satisfy this annual requirement for the year ending December 31, 2022, and there can be no assurance that we can exceed that required level in subsequent years. By negotiation with the bank in connection with a mortgage debt financing during the first quarter of 2022, the required minimum DSC ratio was reduced to 1.0 for the year ending December 31, 2022.

*Inflation:* Inflation is having a material and adverse impact on almost all supplies we purchase and labor we hire. Continuing or increasing inflationary trends could materially reduce our gross margin on product sales.

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

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

*Uncertainty of market size and product sales estimates:* Estimating the size of the total addressable market and future sales growth potential for our **First Defense®** product line is based on our experience and understanding of market dynamics but is inherently subjective. Estimating the size of the market for any new product, such as **Re-Tain®**, involves more uncertainties than do projections for established products. We do not know whether, or to what extent, our products will achieve, maintain or increase market acceptance and profitability. Some of the uncertainties surrounding **Re-Tain®** include the product's effectiveness against currently prevalent pathogens, market acceptance, the effect of a premium selling price on market penetration, cost of manufacture, competition from new and existing products sold by substantially larger competitors with greater market reach and promotional resources and other risks described under "Product Risks – The impact of Nisin on milk and cheese" 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. Our belief that polypeptide antimicrobial technology will be viewed positively (relative to traditional antibiotics), if realized, 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:* 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 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 to competitive products. There is no assurance that we will continue to achieve market acceptance of the **First Defense®** product line, or achieve 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.

*The impact of Nisin on milk and cheese:* 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. In recognition of the safety data that we presented to the FDA for our highly purified preparation of Nisin, the FDA granted us the zero milk discard and zero meat withhold claims that we sought. However, there is a risk that dairy producers and processors will not accept this new technology because of the risk that a tank of milk would have to be discarded if it is comprised of more than 1% of milk from cows being treated with **Re-Tain®** when tank contents are tested for inhibitors through random testing by milk haulers. There is also a risk that our product may negatively affect cheese making if present in a high enough concentration in any cheese batch that utilizes a starter culture that is susceptible to Nisin. If treatment rates exceed our usage recommendation, there is a risk that milk from treated cows will not be diluted adequately with milk from non-treated cows to keep the tank average below this sensitivity level.

*Market launch 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 more than 1% of the milk in a bulk tank is comprised of milk from cows being treated with **Re-Tain®**, when tested randomly by a milk hauler. See the Risk Factor above for more detail.

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

3) Users of **Re-Tain®** could have unsatisfactory treatment outcomes if they lack the equipment needed to measure and monitor somatic cell counts (SCC) of the herd or individual cows (for which data is needed). This risk limits our access to treatment cows because about 40% of farms do not presently access this kind of testing at the cow level, and thus are not good candidates for the use of **Re-Tain®**.

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

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

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

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

*Reliance on sales of the **First Defense®** product line:* We are reliant on the market acceptance of the **First Defense®** product line to generate product sales and fund our operations. Our business would not have been profitable during the years ended December 31, 2012, 2013, 2015 and 2016, during the nine-month periods ended September 30, 2017 or during the three-month periods ended March 31, 2019, December 31, 2020, June 30, 2021, September 30, 2021, December 31, 2021 and March 31, 2022 without the gross margin that we earned on sales of the **First Defense®** product line.

*Concentration of sales:* Sales of the **First Defense®** product line aggregated 99% and 98% of our total product sales during the three-month periods ended March 31, 2022 and 2021, respectively. Our primary customers for the majority of our product sales (92% and 87% during the three-month periods ended March 31, 2022, and 2021) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 8% and 13% of our total product sales during the three-month periods ended March 31, 2022, and 2021, respectively. Sales of the **First Defense®** product line aggregated 98% of our total product sales during both of the years ended December 31, 2021 and 2020. Our primary customers for the majority of our product sales (86% and 89% during the years ended December 31, 2021 and 2020, respectively) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 14% and 11% of our total product sales during the years ended December 31, 2021 and 2020, respectively. The concentration of our sales from one product into just two markets (the dairy and beef markets) is a risk to our business. The animal health distribution segment has been aggressively consolidating over the last few years with larger distributors acquiring smaller distributors. A large portion of our product sales (75% and 78% during the three-month periods ended March 31, 2022 and 2021, respectively, and 73% and 71% during the years ended December 31, 2021 and 2020, respectively) was made to two large distributors. A large portion of our trade accounts receivable (71% and 72% as of March 31, 2022 and December 31, 2021, respectively) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us in a manner unfavorable to us.

*Production capacity constraints:* We invested approximately $3.6 million to increase our production capacity (in terms of annual sales dollars) for the **First Defense®** product line from approximately $16.5 million to approximately $23 million based on current selling prices and estimated production yields. During the fourth quarter of 2021, we reached this new, higher level of production output on an annualized basis. While this capacity expansion investment has proceeded very close to budget, there is a risk of cost overruns in our ongoing projects and any future production expansions that we may undertake, and a risk that we will not be able to achieve our production capacity growth objectives on a timely basis, resulting in a continuing or increasing shortfall in supply to the market. The inability to meet market demand for our products is a risk to our business. The large backlog of orders, as well as any ongoing order backlog, presents a risk that we could lose customers during this period that are not easily regained thereafter, when our production capacity is expected to meet or exceed sales demand. During the third quarter of 2021, we initiated additional investments to increase our annual production capacity for the **First Defense®** product line to approximately $35 million which we intend to complete by the end of 2022. Our plan to continue to expand the **First Defense®** product line requires ongoing review of equipment capacity and utilization across the manufacturing value stream at the 56 Evergreen Drive facility and our leased facility at 175 Industrial Way, as well as assessment of functional obsolescence and reliability of equipment. This review and assessment could identify a need to fund unexpected equipment maintenance or replacement costs.

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

**Regulatory Risks**

*Regulatory requirements for the **First Defense®** product line:* **First Defense®** is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991, with subsequent approvals of line extensions in 2017 and 2018. As a result, our operations are subject to periodic inspection by the USDA, and we are at risk of an unfavorable outcome from such inspections. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the Reference Standard). Due to the unique nature of the label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product, which could interrupt sales and adversely affect our operating results. Territories outside of the United States may require additional regulatory oversight that we may not be able to meet with our current facilities, processes and resources.

*Regulatory requirements for **Re-Tain®**:* The commercial introduction of this product in the United States requires us to obtain FDA

approval. We have disclosed a timeline of events that could lead to product approval during the fourth quarter of 2022. Completing the development through to approval of the NADA by the FDA involves risk. While four of the five required Technical Sections have been approved, the regulatory development process timeline has been extensive (approximately 13 years from the first FDA submission) and has involved multiple commercial production strategies. The first-phased Chemistry, Manufacturing and Controls Technical Section was submitted for the Nisin Drug Substance during the first quarter of 2019, and the FDA response was received during the third quarter of 2019. We filed the second-phased Drug Substance and Drug Product submission during the first quarter of 2021 and received a Technical Section Incomplete Letter from the FDA during the third quarter of 2021. We made a new submission during the first quarter of 2022 and expect to have the FDA's response six months later. To reduce the risk associated with this process, we worked with a qualified contract manufacturer for alignment of the required validations and Drug Product manufacture and have met with the FDA to clarify filing strategy and requirements. Our efforts are subject to inspection and approval by the FDA. There remains a risk that the required FDA approvals of our product and facilities could be delayed or not obtained. International regulatory approvals would be required for sales of **Re-Tain®** outside of the United States.

**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 to reach 94,800,000 as of January 1, 2019 before declining to 93,800,000 as of both January 1, 2020 and January 1, 2021. As of January 1, 2022, this figure decreased to 91,900,000. Reflecting seasonal trends, this figure was equal to 101,000,000 and 102,000,000 as of July 1, 2021 and 2020, respectively.

*Herd size:* Prior to 1957, there were over 20,000,000 cows in the U.S. dairy herd. Prior to 1986, there were over 10,000,000 cows in the U.S. dairy herd. From 1998 through 2021, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 in 2004 to the high of 9,448,000 in 2021. This average declined to 9,381,000 during the first quarter of 2022.

*Milk price and feed costs:* The dairy market, similar to many others, has been unstable as a result of the pandemic. The price paid to producers for milk has been very volatile. Milk was dumped on farms during the first half of 2020 largely because of the loss of demand for dairy products from closed restaurants and school lunch programs and other negative impacts of the pandemic, but conditions have improved since then. The Class III milk price (an industry benchmark that reflects the value of product used to make cheese) is an important indicator because it defines our customers' revenue level. This annual average milk price level (measured in dollars per hundred pounds of milk) reached its highest point (since these prices were first reported in 1980) during 2014 at $22.34 (peaking at $24.60 in September 2014), which price level has never been repeated. During 2019, this milk price average increased by 16% over 2018 to $16.96. The low price level during 2018 and into the beginning of 2019 was very challenging to the profitability of our customers. During the year ended December 31, 2020, this average milk price was equal to $18.16, but it was extremely volatile during the year due largely to disruption in demand related to the COVID-19 pandemic. The one-month fluctuation of 73% from a low of $12.14 in May 2020 to $21.04 in June 2020 set an all-time record for variability. The average price for 2021 decreased by 6% to $17.08. With a significant jump to $24.42 during April, this price average increased by 29% to $22.04 during the first four months of 2022. The annual fluctuations in this milk price level are demonstrated in the following table:

| Average Class III Milk Price During the Years Ended December 31, | | (Decrease) Increase |
|---|---|---|
| 2014 | $22.34 | |
| 2015 | $15.80 | (29%) |
| 2016 | $14.87 | (6%) |
| 2017 | $16.17 | 9% |
| 2018 | $14.61 | (10%) |
| 2019 | $16.96 | 16% |
| 2020 | $18.16 | 7% |
| 2021 | $17.08 | (6%) |

The actual level of milk prices may be less important than its level relative to feed costs. One measure of this relationship is known as the milk-to-feed price ratio, which represents the amount of feed that one pound of milk can buy. An increase in feed costs also has a negative impact on the beef industry. This ratio varies farm-to-farm based on individual operating parameters. The highest annual average this ratio has reached since this ratio was first reported in 1985 was 3.64 in 1987. The annual average for this ratio of 1.52 in 2012 was the lowest recorded since it was first reported in 1985. Since this ratio reached 3.24 in 2005, it has not exceeded 3.00. The annual average of 2.54 for 2014 was the highest this ratio has been since it was 2.81 in 2007. This ratio averaged 1.76 for 2021, amounting to

a significant decline of 24% from the 2020 average of 2.31. This average has not been lower since 2013. During the first quarter of 2022, this ratio improved by 19% to 2.10. The following table demonstrates the annual volatility and the low values of this ratio recently:

| Average Milk-To-Feed Price Ratio During the Years Ended December 31, | | (Decrease) Increase |
|---|---|---|
| 2014 | 2.54 | |
| 2015 | 2.14 | (16%) |
| 2016 | 2.26 | 6% |
| 2017 | 2.42 | 7% |
| 2018 | 2.05 | (15%) |
| 2019 | 2.25 | 10% |
| 2020 | 2.31 | 3% |
| 2021 | 1.76 | (24%) |

*Milk cow price:* The all-time high value (annual average) for a milk cow was $1,993 during 2015. Since then, this annual average value steadily declined to $1,205 during 2019 before increasing to $1,300 during 2020 and to $1,363 during 2021.

*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 First Defense®** and **Re-Tain®**) into the dairy market.

**Small Size of Company**

*Dependence on key personnel:* We are a small company with 67 employees (including 7 part-time employees). As such, we rely on certain key employees to support multiple operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained, which could be even more challenging in the present very difficult labor market. Our competitive position will be highly influenced by our ability to attract, retain and motivate key scientific, manufacturing, managerial and sales and marketing personnel. With increased manufacturing staffing required to operate our expanded **First Defense®** production capacity and to operate our **Re-Tain®** production facility, we anticipate that our employment level could grow to approximately 80 employees during 2022. The cost of attracting and retaining the needed additional personnel in this current job market and inflationary environment could adversely affect our margins and profitability.

*Reliance on outside party to provide certain services under contract for us:* We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Re-Tain®**, who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. One example of this outside reliance is Norbrook, our Drug Product (DP) contract manufacturer. We face the risk of potential supply interruption and adverse effects on the market launch of **Re-Tain®** if we do not effectively manage the end of the DP supply provided from our contract manufacturer for orders scheduled for delivery during 2022 to align with the new supply from our own formulation and aseptic filling facility, which we currently expect to be operational by the second quarter of 2024. Because Norbrook has elected to terminate this supply agreement effective as of the end of 2022, we are investing approximately $4 million of the additional capital we raised during the first quarter of 2019 to construct and equip our own DP formulation and aseptic filling capability for **Re-Tain®** inside our existing Drug Substance facility. The objective of this investment is to end our reliance on an outside party to perform these services for us. Actual project costs could exceed our current estimates. Completion of this project could be delayed due to a number of factors outside our control, including delays in equipment fabrication, equipment delivery or facility construction. In addition, there is a risk that we fail to achieve regulatory approval of the new facility or that such approval is delayed or requires significant additional expenditures to obtain.

*Competition from others:* Many of our competitors are significantly larger and more diversified in the relevant markets than we are and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development and sales/distribution capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. Merck and Zoetis, among other companies, sell products that compete directly with the **First Defense®** product line in preventing scours in newborn calves. The scours product sold by Zoetis sells for approximately half the price of our product, although it does not have an *E. coli* claim (which ours does). With **Tri-Shield First Defense®**, we can now compete more effectively against vaccines that are given to the mother cow (dam) to improve the quality of the colostrum that she produces for the newborn calf. Elanco, Merck and Zoetis provide these dam vaccine products to the market. There are many companies competing in the mastitis treatment market, most notably Boehringer Ingelheim, Merck and Zoetis. The subclinical mastitis products sold by

these large companies are well established in the market and are priced lower than what we expect for **Re-Tain®**, but all of them involve traditional antibiotics and are sold subject to a requirement to discard milk during and for a period of time after treatment (unlike our product which carries zero milk discard and zero milk withhold claims). There is no assurance that our products will compete successfully in these markets. We may not be aware of other companies that compete with us or intend to compete with us in the future.

**Global Risks**

*Russia's unprovoked military invasion of Ukraine:* Russia's unprovoked military invasion of Ukraine and attack on its people is having a significant negative impact on the world economy, worsening trends that were already moving in an unfavorable direction. Among other exposures, the increasing price of oil is already impacting our transportation-related expenses materially, and we expect this supply stress to increase the cost of petroleum-based products that we purchase (most plastics etc.). Further, the increasing cost of grain is a risk to our customers' profitability.

*Global COVID-19 pandemic (novel coronavirus, technically known as SARS-CoV-2):* The global COVID-19 pandemic has created, and continues to create, uncertainty and challenges for us. The emergence of the Delta and Omicron variants and the resulting rising number of positive cases during the latter part of 2021 and into early 2022 has been a more recent concern. The COVID-19 pandemic has created or contributed to global supply-chain disruptions and has affected international trade, while creating a worldwide health and economic crisis. While presently there are some indications that suggest the situation may be improving, the full impact of this viral outbreak on the global economy, and the duration of such impact, remains very uncertain at this time. Stock market valuations have declined and recovered and remain volatile. Inflation has begun to increase 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. 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. There is also economic uncertainty for beef producers, as the supply chain is interrupted or otherwise adversely affected due to closures of processing plants and reduced throughput caused by, among other things, restaurants closing or curtailing their operations. This is a very unusual situation for farmers that work so hard to improve production quality and efficiency in order to help feed a growing population with high-quality and cost-effective proteins. A combination of the 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 our implementation of remote work practices (where feasible) and by our early and continued compliance with recommended hygiene and social distancing practices. Despite our best efforts and intentions, there is a risk that an employee could become infected and could infect others.

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

**Risks Pertaining to Common Stock**

*Stock market valuation and liquidity:* Our common stock trades on The Nasdaq Stock Market (Nasdaq: ICCC). Our average daily trading volume 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 May 6, 2022 was $8.75. Most companies in the animal health sector have market capitalization values that greatly exceed our current market capitalization of approximately $68 million as of May 6, 2022. Our product sales during the twelve-month period ended March 31, 2022 were $21.1 million. This means that our market valuation as of May 6, 2022 was equal to approximately 3.2 times our sales during the twelve-month period ended March 31, 2022. Before gross margin from the sale of new products is achieved, our market capitalization may be heavily dependent on the perceived potential for growth from our product under development and may therefore be negatively affected by the related uncertainties and risks.

*Certain provisions might discourage, delay or prevent a change in control of our Company or changes in our management:* Provisions of our certificate of incorporation, our bylaws, our Common Stock Rights Plan or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

- limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the ability of our Board of Directors to alter or repeal our bylaws;
- the ability of our Board of Directors to refuse to redeem rights issued under our Common Stock Rights Plan or otherwise to limit or suspend its operation that would work to dilute the stock ownership of a potential hostile acquirer, potentially preventing acquisitions that have not been approved by our Board of Directors; and
- Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner.

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

*No expectation to pay any dividends or repurchase stock for the foreseeable future:* We do not anticipate paying any dividends to, or repurchasing stock from, our stockholders for the foreseeable future. Instead, we expect to use cash to fund product development costs and investments in our facilities and production equipment, and to increase our working capital and to reduce debt. Stockholders must be prepared to rely on market sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, contractual restrictions, restrictions imposed by applicable laws, current and anticipated needs for liquidity and other factors our Board of Directors deems relevant.

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

**Other Risks**

*Access to raw materials and contract manufacturing services:* Our objective is to maintain more than one source of supply for the components used to manufacture and test our products that we obtain from third parties. However, we are experiencing difficulty in efficiently acquiring essential supplies. We have significantly increased the number of farms from which we purchase colostrum for the **First Defense®** product line. A significant reduction in farm capacity could make it difficult for us to produce enough inventory to meet customer demand. The specific antibodies that we purify from colostrum for the **First Defense®** product line are not readily available from other sources. We are and will be dependent on our manufacturing facilities and operations in Portland for the production of the **First Defense®** product line and **Re-Tain®**. We are currently dependent on one manufacturer for the supply of the syringes used for our gel tube formats of **Dual-Force First Defense®** and **Tri-Shield First Defense®**. We are actively investigating a second supplier. We will be dependent on one other manufacturer for the supply of syringes for **Re-Tain®**. We are dependent on a contract with Norbrook for the Drug Product formulation and aseptic filling of our Nisin Drug Substance for orders scheduled for delivery in 2022. We expect to complete the investment to perform these services in-house during 2022 and achieve the required regulatory approval for use by the fourth quarter of 2023 or the second quarter of 2024. The facility we are constructing to perform these services in-house will be subject to FDA inspection and approval, the outcome and timing of which are not within our control. The potential alternative options for these services are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). Any significant damage to or other disruption in the services at any of these third-party facilities or our own facilities (including due to regulatory issues or non-compliance) would adversely affect the production of inventory and result in significant added expenses and potential loss of future sales.

*Failure to protect intellectual property:* In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. Instead, we have sought (and may seek in the future) to maintain the confidentiality of any

relevant proprietary technology through trade secrets, operational safeguards and contractual agreements. Reliance upon trade secret, rather than patent, protection may cause us to be vulnerable to competitors who successfully replicate (knock off) our manufacturing techniques and processes. Additionally, there can be no assurance that others may not independently develop similar trade secrets or technology or obtain access to our unpatented trade secrets or proprietary technology. Other companies may have filed patent applications and may have been issued patents involving products or technologies potentially useful to us or necessary for us to commercialize our products or achieve our business goals. If that were to be the case, there can be no assurance that we will be able to obtain licenses to such patents on terms that are acceptable to us. There is also a risk that competitors could challenge the claims in patents that have been issued to us.

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

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

None

**ITEM 3 - DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4 - MINE SAFETY DISCLOSURES**

None

**ITEM 5 - OTHER INFORMATION**

None

**ITEM 6 – EXHIBITS**

| | |
|---|---|
| Exhibit 31 | Certifications required by Rule 13a-14(a). |
| Exhibit 32 | Certification pursuant to Section 1350, as adopted pursuant to Section 906 of the |

| | |
|---|---|
| | Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document-the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document. |
| 104 | Cover Page Interactive Data File-the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |

## SIGNATURE

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

ImmuCell Corporation
Registrant

Date: May 12, 2022

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

**ImmuCell Corporation**

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

I, Michael F. Brigham, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 12, 2022

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

**ImmuCell Corporation**

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

In connection with the Quarterly Report on Form 10-Q of ImmuCell Corporation (the "Company") for the period ended March 31, 2022, 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
May 12, 2022

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.