

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023
001-12934
(Commission file number)

ImmuCell Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

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

56 Evergreen Drive, Portland, Maine
(Address of principal executive offices)

04103
(Zip Code)

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

Securities registered pursuant to Section 12(b) of the 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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

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 pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) 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, a smaller reporting company or an emerging growth company. 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that require a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates at June 30, 2023 was approximately \$31,165,000 based on the closing sales price on June 30, 2023 of \$5.00 per share.

The number of shares of the registrant's common stock outstanding as of March 8, 2024 was 7,750,864.

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PART I

ITEM 1 – BUSINESS

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

This Annual Report on Form 10-K (Annual Report) contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts, and will often include words such as “expects”, “may”, “anticipates”, “aims”, “intends”, “would”, “could”, “should”, “will”, “plans”, “believes”, “estimates”, “targets”, “projects”, “forecasts”, “seeks” and similar words and expressions. Such statements include, but are not limited to, any forward-looking statements relating to: our plans and strategies for our business; projections of future financial or operational performance; the timing and outcome of pending or anticipated applications for regulatory approvals; future demand for our products; the 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) and the war in the Middle East on the world economy including inflation and the price and availability of grain and oil; the impact of the global supply-chain disruptions on our ability to obtain, in a timely and cost-effective fashion, all the supplies and components we need to produce our products; the impact of inflation and rising interest rates on our operating expenses and financial results; the scope and timing of ongoing and future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis and producers’ level of interest in treating subclinical mastitis given the current economic and market conditions; the expected efficacy of new products; estimates about the market size for our products; future market share of and revenue generated by current products and products still in development; our ability to increase production output and reduce costs of goods sold per unit; the adequacy of our own manufacturing facilities or those of third parties with which we have contractual relationships to meet demand for our products on a timely basis; the impacts of backlogs on customer relationships; the efficacy, success and timeline to complete our contamination remediation efforts; the likelihood, severity or impact of future contamination events; the anticipated costs of (or time to complete) planned expansions of our manufacturing facilities and the adequacy of our funds available for these projects; the robustness of our manufacturing processes and related technical issues; estimates about our production capacity, efficiency and yield; future regulatory requirements relating to our products; future expense ratios and margins; the efficacy of our investments in our business; future compliance with bank debt covenants; anticipated changes in our manufacturing capabilities and efficiencies; our effectiveness in competing against competitors within both our existing and our anticipated product markets; projections about depreciation expense and its impact on income for book and tax return purposes; and any other statements that are not historical facts. These statements are intended to provide management’s current expectation of future events as of the date of this earnings release, are based on management’s estimates, projections, beliefs and assumptions as of the date hereof; and are not guarantees of future performance. Such statements involve known and unknown risks and uncertainties that may cause the Company’s actual results, financial or operational performance or achievements to be materially different from those expressed or implied by these forward-looking statements, including, but not limited to, those risks and uncertainties relating to: difficulties or delays in development, testing, regulatory approval, production and marketing of our products (including the **First Defense**[®] product line and **Re-Tain**[®]), competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand (including the consequences of backlogs), uncertainty associated with the timing and volume of customer orders as we come out of a prolonged backlog, adverse impacts of supply chain disruptions on our operations and customer and supplier relationships, commercial and operational risks relating to our current and planned expansion of production capacity, and other risks and uncertainties detailed from time to time in filings we make with the Securities and Exchange Commission (SEC), including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements involve risks and uncertainties and are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized under **PART I: ITEM 1A – RISK FACTORS** of this Annual Report and uncertainties otherwise referred to in this Annual Report. In addition, there can be no assurance that future risks, uncertainties or developments affecting us will be those that we anticipate. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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OUTLINE TO ITEM 1 – BUSINESS:

- **Summary**
- **Production Capacity Increase and Product Contamination**
- **Animal Health Products**
- **Sales and Markets**
- **Product Development**
- **Competition**
- **Intellectual Property**
- **Government Regulation**
- **Employees**
- **Public Information**

Summary

ImmuCell Corporation was founded in 1982 and completed an initial public offering of common stock in 1987. After achieving approval from the Center for Veterinary Biologics, U.S. Department of Agriculture (USDA) to sell **First Defense**[®] in 1991, we focused most of our efforts during the 1990's attempting to develop human product applications of the underlying milk protein purification technology. Beginning in 1999, we re-focused our business strategy on the **First Defense**[®] product line and other products that improve the health and productivity of dairy and beef cattle. We support the dairy and beef industries' purpose to produce nutritious, protein-rich food efficiently while ensuring food quality and safety. Our products help address the growing human health concern about using less antibiotics in food-producing animals. We aim to capitalize on the growth in sales of the **First Defense**[®] product line (a product that provides significant **Immediate Immunity**[™] to newborn dairy and beef livestock) and to revolutionize the mastitis treatment paradigm with **Re-Tain**[®], a novel product we are developing to treat this most significant cause of economic loss to the dairy industry.

During 2000, we began the development of **Re-Tain**[®], our purified Nisin treatment for subclinical mastitis in lactating dairy cows. No sales of this product can be made without prior approval of our New Animal Drug Application (NADA) by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA). We have achieved FDA approval for four out of five of the significant Technical Sections required for product approval, and we have made our third submission of the fifth Technical Section. We expect a response to this third submission from the FDA by May of 2024. Regulatory achievements to date have significantly reduced the product development risks in the areas of safety and effectiveness. Our primary product development focus has now turned to completion of the manufacturing objectives required for FDA approval.

Since 2006, we have made ongoing efforts to maintain compliance with current Good Manufacturing Practice (cGMP) regulations in all of our manufacturing operations, which requires a sustained investment that further enhances the quality of all of our products and our operating efficiency. As we make process improvements, we continue to invest in personnel, equipment and facility modifications to increase the efficiency and quality of our operations.

During the eight-year period beginning January 1, 2016 and ended December 31, 2023, we funded our operations, constructed an FDA-regulated Drug Substance (DS) manufacturing facility for **Re-Tain**[®] and invested capital to increase our production capacity for the **First Defense**[®] product line. We have also initiated another capital investment (which investment is currently paused) to bring the formulation and aseptic filling capabilities for **Re-Tain**[®] in house in order to end our present reliance on an outside contractor. From the first quarter of 2016 through the second quarter of 2021, we issued an aggregate of 4,553,017 shares of common stock, raising gross proceeds of approximately \$26.7 million in six separate transactions. In order to minimize the dilutive effects of these transactions on our existing stockholders, we chose not to issue any form of convertible or preferred securities and issued these common shares without any warrants. Net of debt issuance and debt discount costs, we had approximately \$12 million in outstanding debt as of December 31, 2023 compared to approximately \$3.2 million as of December 31, 2015. This equity and debt capital has been, and is being, used to increase the production capacity for the **First Defense**[®] product line and complete the development of **Re-Tain**[®] without relying on funding from a partner or licensee, thereby keeping control over all product rights and future revenues. During this time, our total assets have increased to \$43.8 million as of December 31, 2023 from \$14.6 million as of December 31, 2015, and our stockholders' equity has increased to \$25 million as of December 31, 2023 from \$10.6 million as of December 31, 2015. This represents a 200%, or \$29 million, increase in total assets and a 135%, or \$14.4 million, increase in stockholders' equity over this eight-year period.

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Production Capacity Increase and Product Contamination

During 2018, it became clear that demand for **Tri-Shield First Defense**[®] was outpacing production. In response to this increasing demand, we began a series of investments during 2019 to increase our production capacity for the **First Defense**[®] product line to approximately \$30 million per year. The necessary facility expansions and new equipment needed to increase production capacity were in place by the end of 2022. See **PART II: ITEM 7 – MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**, for more detail about our investments to increase production capacity.

As this increased production capacity was coming online, a product contamination event was detected by standard in-process quality control testing around the end of the third quarter of 2022. Scrapped product from contamination events (largely this one around the end of the third quarter) and other production process losses resulted in a total charge to costs of goods sold of approximately \$589,000 during 2022. We took immediate steps to address the contamination, and production ran without issue during the balance of the fourth quarter of 2022. Then during the first quarter of 2023, our standard in-process quality control testing detected a second contamination event. We slowed down our production output to take the necessary steps to assess and remediate the issues and perform a deep sanitization of our facilities and process equipment. After several months of processing without further contamination, we experienced a third contamination event during the third quarter of 2023. Scrapped product from contamination events and other production process losses resulted in a total charge to costs of goods sold of approximately \$527,000 during 2023. We believe that the ongoing implementation of our capacity expansion plans and the corrective actions being taken in response to these contamination events should allow us to operate at the higher level of production output going forward without further significant contaminations. We worked diligently to address the situation and believe we are taking the appropriate steps to emerge from this problem stronger with the production capacity in place to produce approximately \$30 million of product per year going forward, while continuing to ensure that any product that is put to market meets all quality standards.

We believe that our efforts to increase production capacity for the **First Defense**[®] product line are linked to our product contaminations. It was relatively simple to run at lower production capacities for the 30 years between 1991 (the original USDA approval of **First Defense**[®]) and 2021. The contamination events we suffered during 2022 and 2023 were largely the result of us processing more milk (colostrum) than ever before in order to meet increasing customer demand. As we enter 2024, we believe that we have much improved processes and controls in place to better support large-scale production from our raw material source farms through liquid processing. Our most important customer-focused objectives going forward are to fulfill the large backlog of orders and then again be a reliable supplier of a very effective product to the dairy and beef calf market.

Animal Health Products

The **First Defense**[®] product line is manufactured from hyperimmunized cows’ colostrum (the antibody rich milk that a cow produces immediately after giving birth) utilizing our proprietary vaccine and milk protein purification technologies. The **First Defense**[®] product line provides bovine antibodies that newborn calves need but are unable to produce on their own immediately after birth. The target disease, calf scours (bovine enteritis), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. The **First Defense**[®] product line is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against *E. coli*, coronavirus and rotavirus (three leading causes of scours). A single dose of our product provides a measured level of protection proven to reduce mortality and morbidity. Our pre-formed antibody products provide **Immediate Immunity**[™] during the first few critical weeks of life when calves need this protection most. Studies have shown calves that scour are more susceptible to other diseases later in life and under-perform calves that do not contract scours. The direct, two-part mode-of-action of the **First Defense**[®] product line delivers specific immunoglobulins at the gut level to immediately protect against disease, while also providing additional antibodies that are absorbed into the bloodstream. These circulating antibodies function like a natural timed-release mechanism, as they are re-secreted into the gut later to provide extended protection. The **First Defense**[®] product line is convenient to use. A calf needs to receive only one dose of **First Defense**[®] within the first twelve hours after birth. Our capsule format of this product, which requires no mixing, is stored at room temperature, while the gel tube formats of this product require refrigeration in accordance with product label indications. We are the market leader (in terms of both unit volume and dollar sales) when compared to other calf-level scours preventatives and have greater market potential as we gain market share from the dam-level (pre-calving scour vaccines) competitors. The third quarter of 2023 marked the 32nd anniversary of the original USDA approval of this product in 1991. During the fourth quarter of 2023, our cumulative sales of **First Defense**[®] since inception exceeded 33 million doses.

The product line extension, **Tri-Shield First Defense**[®], is the first calf-level, passive antibody product on the market with USDA-approved disease claims providing **Immediate Immunity**[™] against each of the three leading causes of calf scours (*E. coli*, coronavirus and rotavirus). This product achieved USDA approval during the fourth quarter of 2017 and was listed with the Organic Materials Research Institute (OMRI) during the first quarter of 2019, which means it can be used on organic farms. **Tri-Shield**[®] combines the *E. coli* and coronavirus antibodies contained in our bivalent product with rotavirus antibodies in a single-dose gel tube delivery format. This unique breadth of claims further differentiates our product from calf-level competitive products on the market that contain

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only one or two of these label claims. The unique virus-like particle (VLP) technology that is used in our production process increases rotavirus titers in colostrum to a level much greater than traditional vaccine technology can. Because it is possible that some farms may not have (or perceive to have) a rotavirus problem, we are continuing to sell the bivalent formats of the **First Defense**[®] product line as options for customers.

The **First Defense**[®] product line continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent scours in newborn calves, which is the leading cause of death in preweaned calves. Our **Beyond Vaccination**[®] marketing campaign focuses on providing antibodies without vaccination. A 100% vaccine protection rate is biologically impossible. The **First Defense**[®] product line removes the variability associated with a scour vaccine response and instead provides a measured level of pre-formed antibodies, protecting each calf with an equal level of scours protection. There is a strong link between how we sell our product and the challenges we face in producing it. We know better than most how variable a cow's response is to any vaccine. We see this in every batch of **First Defense**[®] that we produce. The value in **First Defense**[®] is that we adjust for this variability by standardizing the antibody content, as needed, so the newborn is given a steady, equal level of protection with each dose. This technology removes a producer's reliance on variable vaccine responses to generate passive antibody protection and instead protects every calf equally with a measured dose of **Immediate Immunity**[™] against the most common scour pathogens. Preventing newborn calves from becoming sick helps them to reach their genetic potential and reduces the need to use treatment antibiotics later in life. Plus, an effectively treated calf is much less likely to require expensive antibiotic treatments or build antibiotic resistance. We are the only manufacturer within the scour prevention space offering polyclonal multi-pathogen antibodies. The market is learning that the best preventative for scours may not be a vaccine, and we are continuing to educate the market about the health benefits of a measured dose of pre-formed antibodies.

Historically, the most common tool to help combat scours has been to vaccinate the mother cow (dam) with a scours vaccine and deliver the antibodies that she produces in her milk to the newborn. It is generally believed that only 80% of animals respond to a vaccine, which could leave about 20% of calves unprotected. We believe that the variability in a cow's immune response to vaccines creates a sales opportunity for our product. Additionally, our research suggests that treatment protocols for dam-level scours vaccine programs are not always followed, leaving even more calves compromised. We are competing effectively against these dam-level vaccine products. Our marketing campaign, **Beyond Vaccination**[®], emphasizes that by delivering **Immediate Immunity**[™] directly to the calf via the **First Defense**[®] product line, producers can reduce stress-causing injections to the cow. Reliance on a dam-level scours vaccine requires that money be spent before it is known whether the cow is carrying a viable, valued calf. With the **First Defense**[®] product line, that investment can be targeted to the calves that are most critical to the operation. This, in turn, can free up space in the cow's vaccination schedule to improve her immune response to vaccines that are critical to her health.

First Defense Technology[®] is a unique whey protein concentrate that is processed utilizing our proprietary colostrum (first milk) protein purification methods, for the nutritional and feed supplement markets without the claims of our USDA-licensed product. During 2012, we initiated a limited launch of a gel tube delivery format of our **First Defense Technology**[®] in a gel solution. We achieved USDA claims for this product format during the fourth quarter of 2018 and Canadian approval during the first quarter of 2019, and it is now being sold as **Dual-Force First Defense**[®]. We are selling the same concentrated whey proteins in a bulk powder format (no capsule), which is delivered with a scoop and mixed with colostrum for feeding to calves. We are working to achieve USDA claims for this product format. During 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start[®] 150 Plus and certain similar private label products, which are colostrum replacers with **First Defense Technology**[®] Inside.

During 2001, we began to offer our own, internally developed **California Mastitis Test (CMT)**. CMT is most often used as a quick on-farm diagnostic to determine which quarter of the udder is mastitic. This test can be performed at cow-side for early detection of mastitis. CMT products are also made by other manufacturers and are readily available to the dairy producer.

Sales and Markets

We believe that the long-term growth in sales of the **First Defense**[®] product line may reflect, at least in part, the success of our strategic decision to invest in additional sales and marketing efforts to help us introduce the expanding **First Defense**[®] product line to new customers. Our communications campaign continues to emphasize how the unique ability of the **First Defense**[®] product line to provide **Immediate Immunity**[™] generates a dependable and competitive return on investment for dairy and beef producers. Our sales and marketing team consists of one vice president, one commercial research and technical services veterinarian, one commercial leader of stakeholder engagement, one director of marketing and eight regional sales managers. The **First Defense**[®] product line and CMT are sold primarily through major animal health distributors who, in turn, sell to veterinary clinics, fleet stores and direct to farms. Our expanded sales and marketing team has proven to be a worthy investment, validating that our message resonates well with customers. Now that our increased production capacity is in place, we anticipate being able to escalate our growth curve after we recover from the brand damage that can come with an extended duration of short supply.

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Sales of the **First Defense**[®] product line are normally seasonal, with higher sales expected during the first quarter, largely driven by the beef calving season, which runs primarily from January to April, unlike the dairy industry in which operations generally calve year round. Warm and dry weather reduces the producer's perception of the need for a disease preventative product like the **First Defense**[®] product line. However, heat stress on calves caused by extremely hot summer weather can increase the incidence of scours, just as harsher winter weather benefits our sales. Other competition for resources that dairy producers allocate to their calf enterprises has been increased by the many new products (principally feed supplements) that have been introduced to the calf market.

We estimate that the total U.S. market for scours preventative products (including sales of our product) that are given to newborn calves (the calf-level market) is approximately \$25.6 million per year. With the additional claim for our new product (**Tri-Shield First Defense**[®]) against rotavirus, we are now also competing against the dam-level vaccine products that are given to the mother cow to increase the antibody level against specific scours-causing pathogens in the colostrum that she produces for her newborn. We estimate that the dam-level product category covers approximately twice as many calves as the calf-level product segment reaches. We estimate that the total domestic addressable market (both calf and dam levels) is approximately \$75.4 million per year.

Based on market share information that we purchase from the leading source of this data for the animal health sector, we believe that we are gaining market share in the United States year after year. We aim to continue these market share gains in both the dairy and beef segments. Our share of the dairy and beef market (calculated on the basis of calves treated) of the scour preventative products administered at the calf-level was approximately:

2019	2020	2021	2022	2023
36%	41%	43%	44%	48%

Our share of the dairy and beef market (calculated on the basis of calves treated) of both products administered at the calf-level and vaccines administered to the dam prior to calving (adjusting for two doses of dam-level scour vaccines required for primary vaccination of first-calf heifers) was approximately:

2019	2020	2021	2022	2023
11%	13%	13%	14%	14%

We continue our efforts to grow sales of the **First Defense**[®] product line in North America, where there are approximately 40 million dairy and beef cows in the United States and approximately 4.5 million dairy and beef cows in Canada. We believe that significant market opportunities exist in other international territories. The majority of our international sales are to Canada. We price our products in U.S. dollars. To the extent that the value of the dollar declines with respect to any other currency, our competitive position may be enhanced. Conversely, an increase in the value of the dollar in any country in which we sell products may have the effect of increasing the local price of our products, thereby leading to a potential reduction in demand. Generally, our international sales have been generated through relationships with in-country distributors that have knowledge of the local regulatory and marketing requirements. We are initiating our plan to expand the number of countries to which our **First Defense**[®] product line is approved for export. Generally, it is our intent to be the holder of these product registrations for each country rather than rely on distribution partners to gain and hold these registrations. This is a long regulatory process but allows us to maximize the use of our product label claims. Industry practices, economic conditions, cause of disease, distribution channels and regulatory requirements may differ in these international markets from what we experience in North America, potentially making it more difficult or costly for us to generate and sustain sales volumes at profitable margins in these markets.

We introduced **First Defense**[®] into South Korea in 2005 through Medexx Co., Ltd of Gyeonggi-do, Korea and its equivalent into Japan in 2007 through NYS Co., Ltd of Iwate, Japan. We are working with Medexx to expand our business in South Korea to include the registration of **Tri-Shield First Defense**[®]. The business in Japan is currently not active, but we are working to resume sales in this territory. We entered into distribution contracts covering certain Middle Eastern countries with Triplest for Drugs and Trade of Madaba, Jordan during the first quarter of 2017 (no sales have yet been achieved under this contract) and covering Iran with Senicko, LLC of Laguna Niguel, California during the fourth quarter of 2016 (sales have been initiated under this contract). We are investigating the requirements to sell the **First Defense**[®] product line in Mexico, Pakistan and India.

With **Re-Tain**[®], we are working to expand our product portfolio to include an intramammary infusion for the treatment of subclinical mastitis in lactating dairy cows. Mastitis is inflammation of the mammary gland typically associated with a bacterial infection. It is estimated to cost the U.S. dairy industry approximately \$2 billion in economic harm per year. It is the most costly and common disease affecting the dairy industry. This illness is categorized as either clinical mastitis or subclinical mastitis. Clinical mastitis infections cause visibly abnormal milk which cannot be sold. On the other hand, subclinical mastitis infections do not cause any visible changes in milk or udder appearance, making it difficult to detect. Most mastitis cases treated today are those that reach the clinical stage even though it is understood that clinical cases are only the tip of the mastitis iceberg. Milk from cows with subclinical

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mastitis can still be sold if not treated with traditional antibiotics. Milk from cows treated with traditional antibiotics must be discarded for the duration of the treatment and for 1.5 to 4 days after the last treatment, depending on the antibiotic that was used. The cost of that milk discard along with the stress and risk in moving the cow to the hospital pen is thought to be a primary reason more subclinical mastitis cases are not treated today. However, the cascade of negative events triggered by subclinical mastitis for both the dairy producer and the milk processor are significant. These include lower milk production (some have estimated approximately 1,500 pounds of lost milk, or about \$270 at \$18.00 per hundredweight per infected cow per lactation), higher rates of clinical mastitis, lower conception rates, increased abortions, increased cull rates, reduced or foregone milk quality premiums, shorter shelf life for fluid milk, and both lower yields and less flavor for cheese. Cows with subclinical mastitis maintain a reservoir of infection within the herd and increase exposure of healthy cows to contagious pathogens. Subclinical mastitis also increases the risk of various quality defects on a variety of final dairy products.

The active ingredient in **Re-Tain**[®] is pharmaceutical-grade Nisin-A. FDA approval for this drug would establish an entirely new class of anti-infective that is different from those currently available to treat mastitis. This new class, called bacteriocins, are antimicrobial polypeptides with no resistance risk for human health. Bacteriocins selectively target Gram+ bacteria, the same bacteria that commonly cause mastitis. We expect **Re-Tain**[®] will be the first FDA-approved intramammary treatment for subclinical mastitis without an FDA-required milk discard or meat withhold. This gives us the opportunity to revolutionize the way mastitis is treated, since **Re-Tain**[®] is specifically designed to treat ahead of clinical signs without an FDA-required milk discard or meat withhold. As a result, we believe that our product can help cows reach their peak milk production and not be sent to the hospital pen.

Referencing the big picture, we are introducing an entirely new class of socially-responsible antimicrobials as an animal drug, a bacteriocin, that does not promote resistance against antibiotics used in human medicine. 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 product to treat mastitis has not been developed in years (other than new formulations of the same old stuff). 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. The industry could keep treating this very significant disease with traditional antibiotics, but it takes innovation to bring a bacteriocin like Nisin to market. We believe that societal animal welfare objectives will put more and more pressure on the industry to treat cows with subclinical infections.

Because Nisin is a naturally occurring bacteriocin that is not used in human medicines, it could alleviate some of the social and public health concerns that the widespread use of antibiotics encourages the growth of antibiotic-resistant bacteria. For example, there is a fear that the possible overuse of antibiotics in livestock undermines the effectiveness of these drugs to combat human illnesses and contributes to a rising number of life-threatening human infections from antibiotic-resistant bacteria, commonly known as "superbugs". The FDA has expressed a commitment to addressing this public health risk. Citing concerns about untreatable, life-threatening infections in humans, new FDA and European regulations are aimed at restricting the use of antibiotics (such as penicillin and cephalosporins) in food animals and at improving milk quality. By reducing the risk of antibiotic residues and slowing the development of antibiotic-resistant organisms, we believe that we can improve food quality and preserve medically important antibiotics for human disease treatment. This current environment is favorable to the introduction of our new product as an alternative to traditional antibiotics. We believe that this changing environment of new regulations and public opinion supports the value of our ongoing development and commercialization efforts for **Re-Tain**[®]. Additionally, we believe that the use of our **First Defense**[®] product line is consistent with this trend of reducing the use of antibiotics because the prevention of calf scours early in life with our purified colostrum antibodies can reduce the need to use treatment antibiotics later in a calf's life.

We estimate that the approximate cost to the U.S. dairy industry of discarded milk associated with the use of traditional antibiotic products currently on the market 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 an FDA-required milk discard or meat withhold cost, we expect producers to be more motivated to identify and treat cows at the subclinical stage. In addition, we expect that **Re-Tain**[®] likely will be priced at a premium to the traditional antibiotic products currently on the market, which are all sold subject to milk discard and meat withhold requirements. To validate our confidence in the value proposition of our product, we initiated a stochastic model led by researchers at Michigan State University. This model simulated the dynamics of subclinical mastitis detected during the first week of lactation. The study involved assessing probabilities of events, both production and health related, and their associated costs using a model grounded in pathogen-specific assumptions drawn from peer-reviewed literature. The study indicated that treatment with our product generated a positive economic benefit and was the optimal economic strategy for treating subclinical mastitis in most herds. The extent of the economic benefit varies depending on factors such as bacteriological cure rates, parity of the animal and the cost of **Re-Tain**[®]. These findings, which were subsequently published in the Journal of Dairy Science in January 2024, will guide our pricing strategies.

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It is difficult to accurately estimate the potential size of the subclinical mastitis market because presently this disease is largely left untreated. We believe that approximately 20% to 40% of the U.S. dairy herd is infected with subclinical mastitis at any given time. This compares to approximately 2% of the U.S. herd that is thought to be infected with clinical mastitis, where approximately \$65 million per year is spent on drug treatments. Rarely is an industry revolutionized overnight. Getting producers to change protocols to make subclinical mastitis treatment a standard and routine procedure is going to take initiative, but we believe producers are eager for something new and better since the FDA has not approved an intramammary treatment within the last 20 years. 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. We also believe there may be a market for **Re-Tain**[®] in small ruminants, 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 18 to 24 months after FDA approval, as we seek to transform the way that mastitis is treated in the dairy industry over the long term, which we refer to as our “Controlled Launch” strategy. 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 with our available resources. 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 is also prudent since our saleable inventory is fixed until an FDA-approved alternative contract manufacturer for aseptic filling is identified or our own aseptic filling capability is developed and approved by the FDA. While we are dedicated to increasing our sales revenue, we must consider the damage a mass market strategy could cause to the long-term value of the product. We have seen products sold by much larger companies that were substantially damaged by such failed market launch strategies. We continue to develop detailed launch plans, focusing on the readiness of dairy operators to successfully introduce **Re-Tain**[®] to their herds. We believe that these prudent steps, while potentially leading to lower initial **Re-Tain**[®] revenues, may create a smooth and successful launch and could safeguard the longer-term performance of our investment in **Re-Tain**[®].

We expect the DS production facility that we constructed to have initial annual production capacity sufficient to meet approximately \$7 million to \$10 million in sales of **Re-Tain**[®] at current production yields without factoring in potential yield improvements, but our supply of finished Drug Product (DP) will be limited until we find an alternative aseptic formulation and filling capability, as discussed above. This production capacity estimate does not yet reflect any inventory build strategies or ongoing yield improvement initiatives. We have available space in our existing facilities to double the production capacity by installing a second equipment train. A decision on whether to use this space for a doubling of the DS production capacity or for in-house aseptic formulation and filling DP equipment will be made post-approval. Our objective is to supply initial market launch with approximately 100,000 to 150,000 doses of **Re-Tain**[®] (enough to treat up to 50,000 cows with three doses per cow) that would be aseptically formulated and filled by our DP manufacturer. The expiry dates on this product would be 18-24 months after the date of production, meaning that product expiry could be approximately between September of 2025 and March of 2026. We may not reach 50,000 cows during the Controlled Launch. Further, early adopters may be offered discounted or promotional goods as an incentive to collaborate with us on data collection during the Controlled Launch. We are expecting a pause in supply to the market after the Controlled Launch after goods produced by our contract DP manufacturer are consumed and before we obtain FDA approval of an alternative DP manufacturing option. Although these projections are subject to many risks and uncertainties (some of which are detailed in this Annual Report), if executed correctly, we believe this strategy will lend itself to a more gradual adoption curve but higher and more sustainable sales over the long-term. In an effort to provide greater visibility into the launch of **Re-Tain**[®], we have expanded Note 17, “Segment Information”, to the accompanying audited financial statements to now display a break-out of our financial results among the following three components of our business: i) Scours, ii) Mastitis and iii) Other, in order to allow investors to see our progress with both products.

Through our anticipated growth in sales of the **First Defense**[®] product line, and as additional resources are dedicated to production, sales, marketing and technical services, it is our objective to exceed our total product sales of approximately \$17.5 million achieved during the year ended December 31, 2023 as soon as possible. Our longer-term goal is to exceed \$35 million of annual total product sales as soon as possible during the four-year period after the market launch of **Re-Tain**[®].

Product Development

Most of our product development spending has been focused on the development of **Re-Tain**[®], our purified Nisin treatment for subclinical mastitis in lactating cows. During the 24-year period that began on January 1, 2000 and ended on December 31, 2023, we invested an aggregate of approximately \$28.1 million (excluding depreciation and the capital cost of our DS production facility) in the development of this product. This estimation reflects only direct expenditures and includes no allocation of product development or administrative overhead expenses. Approximately \$2.9 million of this investment was offset by related product licensing revenues and

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grant income, most of which was earned from 2001 to 2007.

During 2000, we acquired an exclusive license from Nutrition 21, Inc. (formerly Applied Microbiology Inc. or AMBI) to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Re-Tain**[®]. In 2004, we paid Nutrition 21 approximately \$965,000 to buy out this royalty and milestone-based license to Nisin, thereby acquiring control of the animal health applications of Nisin. Nisin is a well characterized substance, having been used in food preservation applications for over 50 years. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. A much less pure preparation of our active ingredient, Nisin, is commonly used as a food preservative and has been given “Generally Regarded as Safe” (GRAS) status by the FDA. We are also investigating potential applications of Nisin for other animal health applications as well as for humans. Our Nisin technology includes patented processing and purification methods to achieve pharmaceutical-grade purity.

During 2004, we entered into a product development and marketing agreement with Zoetis (formerly Pfizer Animal Health, a division of Pfizer, Inc.) covering this product. That company elected to terminate the agreement in 2007. We believe that this decision was not based on any unanticipated efficacy or regulatory issues. Rather, we believe the decision was primarily driven by a marketing concern relating to their fear that the milk from treated cows could interfere with the manufacture of certain cultured dairy products. Due to the zero-milk discard feature, there is a risk that Nisin from the milk of treated cows could interfere with the manufacture of certain (but not all) commercial cultured dairy products, such as some kinds of cheese and yogurt, if a process tank contains a high enough percentage of milk from treated cows. The impact of this potential interference ranges from a delay in the manufacturing process (which does happen at times for other reasons) to the less likely stopping of a cheese starter culture. Milk from cows that have been treated with our product that is sold exclusively for fluid milk products presents no such risk. We worked with scientists and mastitis experts to conduct a formal risk assessment to quantify the impact that milk from treated cows may have on cultured dairy products. This study concluded that the dilution of milk from treated cows through comingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when the product is used in accordance with the product label. Further, we believe that such a premium-priced product will be used selectively, which reduces the risk of cheese interference and is consistent with modern “precision dairying” practices that discourage the indiscriminate use of drug treatments. Among the measures that we intend to deploy will be detailed guidance on limiting the portion of a herd that is treated with **Re-Tain**[®] at any one time in order to avoid concentration levels in the milk that could lead to the rejection of the contents in a cheese tank.

Our second most important product development initiatives (in terms of dollars invested and, we believe, potential market impact) have been focused on other improvements, extensions or additions to our **First Defense**[®] product line. During the second quarter of 2009, we entered into a perpetual, exclusive license with the Baylor College of Medicine covering the underlying rotavirus vaccine technology used to generate the specific antibodies for use with animals. We achieved product license approval and initiated market launch of this product, **Tri-Shield First Defense**[®], during the fourth quarter of 2017. During the third quarter of 2018, we obtained approval from the Canadian Food Inspection Agency to sell **Tri-Shield**[®] in Canada. We initiated sales in Canada through our in-country distributor during the fourth quarter of 2019. We achieved USDA approval of our bivalent gel tube formulation (formerly marketed as **First Defense Technology**[®]) during the fourth quarter of 2018 and have re-branded this product format as **Dual-Force First Defense**[®]. We are currently working to establish USDA claims for our bivalent bulk powder formulation of **First Defense Technology**[®].

We are also working to expand our product development pipeline of antimicrobials that can be used as alternatives to traditional antibiotics through expansions of our Nisin technology and yield improvements. 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 when we have adequate cash reserves.

Competition

Our competition in the animal health market includes other biotechnology companies and major animal health companies. Most, if not all, of these competitors have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do.

There are several other products on the market (some with claims and some without) that are delivered to newborn calves to prevent scours. We believe that the **First Defense**[®] product line offers two significant competitive advantages. First, the **First Defense**[®] product line is the only calf-level product that provides protection against *E. coli*, coronavirus and rotavirus, three of the leading causes of calf scours. Second, being derived from colostrum, our product offers **Immediate Immunity**[™] through antibodies that both function at the gut level and are absorbed into the blood stream for future protection. All formats of our product can be administered immediately after birth and are not negatively affected by maternal colostrum.

Zoetis sells a product (Calf-Guard[®]) that competes directly with the **First Defense**[®] product line in preventing scours via oral delivery to newborn calves. Their product is a modified-live virus vaccine. Newborn calves respond poorly to vaccines and the immune system must be given time to develop a response to vaccines. Both our product and Calf-Guard[®] carry claims against

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coronavirus and rotavirus infections, but this competing product does not carry a claim against *E. coli* infections like our product does. It is common practice to delay colostrum feeding when dosing a calf with Calf-Guard® so that the antibodies in the colostrum do not inactivate this vaccine product. There is no nutritional or health benefit to withholding milk from newborn calves. In contrast, we encourage the feeding of four quarts of high quality colostrum immediately after birth when dosing a calf with our product, which is standard practice for good calf health. Because the antibodies in our product would likely work to inactivate a modified-live virus vaccine, rendering it useless or less useful, our product label historically included a precaution that **First Defense**® should not be used within five days of such a vaccine. During the first quarter of 2015, the USDA granted us permission to remove this precaution from our label, and we have done so. We believe that this precaution should be required on the Calf-Guard® label to prevent inactivation of that product by **First Defense**® antibodies or by colostrum. Our product is priced at a premium to Calf-Guard®.

During the fourth quarter of 2016, Merck launched a new competing product into this market space. This product (BOVILIS® Coronavirus) is a modified-live virus intranasal vaccine that carries a claim against coronavirus only. Around the end of 2019, Elanco Animal Health gave notice to the market that it had discontinued the manufacture of its competing products, Bovine Ecolizer® and Bovine Ecolizer + C20, and subsequently exited the market during the first quarter of 2021. This product was the smallest of our three significant calf-level competitors.

When compared to the other USDA-approved calf-level scours preventatives, we lead in both sales dollars and calves treated within the U.S. market. This product category is comprised of the three primary brands discussed above that are given either orally or intranasally to newborn dairy and beef calves immediately after birth. With the rotavirus claim for our product (**Tri-Shield First Defense**®), we are now also competing against dam-level vaccine products that are given to the mother cow to increase the antibody level against scours-causing pathogens in the colostrum that she produces for her newborn. Those products are sold by Elanco (Scour Bos™), Merck (Guardian®) and Zoetis (ScourGuard®). Despite the best-managed dam vaccine program, colostrum quality is naturally variable and newborn calves do not always get the antibodies they need from maternal colostrum. We believe that the measured dose of antibodies in our product provides more consistent protection than such vaccine products.

We would consider any company that sells an antibiotic to treat mastitis, such as Boehringer Ingelheim, Merck Animal Health and Zoetis, to be among the potential competitors with respect to **Re-Tain**®. We expect the FDA to grant a period of five years of market exclusivity for our product (meaning the FDA would not grant approval to a second NADA with the same active drug for a period of five years after the first NADA approval is granted) under Section 512(c)(2)F of the Federal Food, Drug, and Cosmetic Act. Our Nisin A is produced from our high-yielding, proprietary *L. lactis* strain and purified to a high level, providing us with a level of protection over a competitor that might try to develop a similar product.

We may not be aware of competition that we face, or may face in the future, from other companies. Our competitive position will be highly influenced by our ability to attract and retain key scientific, manufacturing, managerial and sales and marketing personnel, to develop and effectively produce and market proprietary technologies and products. We need to obtain USDA, FDA or foreign approvals for new products to effectively promote and market our products. We must have available properly-licensed, efficient and effective raw material and finished product manufacturing resources to continue to profitably sell our current products. We currently compete on the basis of product performance, price, distribution capability and customer support. We continue to monitor our network of independent distributors to maintain our competitive position.

Intellectual Property

We own a broad collection of registered and unregistered intellectual property rights relating to our research, products and processes. These rights include patents, copyrights, trademarks, trade dress, trade secrets, know-how and other intellectual property rights in the United States and other countries. We believe the ownership of our intellectual property rights is an important factor in our business and that our success depends in part on such ownership. We also rely heavily on the innovative skills, technical competence and marketing abilities of our personnel. The Nisin A that is produced from our proprietary strain of *L. lactis* is an essential component of our **Re-Tain**® product and related intellectual property. We enter into and rely on confidentiality and proprietary rights agreements with our employees, contractors and business partners to protect our trade secrets, proprietary developments and confidential information.

We own U.S. Patent No. 10,023,617 entitled “Methods and Systems of Producing Pharmaceutical Grade Lantibiotics”, which covers key, novel and proprietary aspects of our manufacturing process for preparing pharmaceutical-grade Nisin and was issued during the third quarter of 2018. In the future, we may file additional patent applications for certain products under development. There can be no assurance that patents will be issued with respect to any pending or future applications. In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. In those instances, we have sought (and may seek in the future) to maintain the confidentiality of any relevant intellectual property and other proprietary rights through operational measures and contractual agreements.

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We own numerous trademarks and trade dress that are very important to our business and have several trademark and trade dress registrations in the United States, Canada and Iran. We own the following U.S. trademark registrations: **IMMUCELL**, **FIRST DEFENSE**, **FD FIRST DEFENSE (& Design)**, **FIRST DEFENSE TECHNOLOGY**, **TRI-SHIELD FIRST DEFENSE**, **TRI-SHIELD FIRST DEFENSE (& Design)**, **YOUR CALF CREW**, **BEYOND VACCINATION**, **BEYOND VACCINATION (& Design)**, **CALF HERO**, **DUAL-FORCE**, **TRI-SHIELD** and **RE-TAIN**. We also own U.S. registrations claiming rights in the color blue for our blue gel and blue bolus **FIRST DEFENSE** products. We also own common law rights in the **IMMEDIATE IMMUNITY** trademark and other trademarks.

Government Regulation

We believe that we are in compliance with current regulatory requirements relating to our business and products. The manufacture and sale of animal health biologicals within the United States is generally regulated by the USDA. We have received USDA and Canadian Food Inspection Agency approval for the bolus format of **First Defense**[®] and for the gel tube formats of **Tri-Shield First Defense**[®] and **Dual-Force First Defense**[®]. **Re-Tain**[®] is regulated by the FDA, which regulates veterinary drugs. Regulations in the European Union will likely require that **Re-Tain**[®] be sold subject to a milk discard requirement in that territory, although the duration of the milk discard requirement may be shorter than the discard requirement applicable to competing antibiotic products in that market. Comparable agencies exist in foreign countries, and foreign sales of our products will be subject to regulation by such agencies. Many countries have laws regulating the production, sale, distribution or use of biological products, and we may have to obtain approvals from regulatory authorities in countries in which we propose to sell our products. Depending upon the product and its applications, obtaining regulatory approvals may be a relatively brief and inexpensive procedure or it may involve extensive clinical tests, incurring significant expenses and an approval process of several years' duration. We generally rely on in-country experts to assist us with or to perform international regulatory applications.

Employees

We currently employ 79 employees (including 5 part-time employees) in comparison to 74 employees (including 7 part-time employees) approximately a year ago. Approximately 51 full-time equivalent employees are engaged in quality and manufacturing operations, 13 full-time equivalent employees in sales and marketing, 7 full-time equivalent employees in product development activities (primarily supporting facility maintenance and operation, regulatory filings and commercial scale-up for **Re-Tain**[®]) and 6 full-time equivalent employees in finance and administration. As needed, we augment our staff with contracted temporary employees. All of our employees are required to execute non-disclosure and invention assignment agreements (and some are required to execute non-compete agreements) intended to protect our rights in our proprietary products. We are not a party to any collective bargaining agreement and consider our employee relations to be excellent.

Public Information

As a reporting company, we file quarterly and annual reports with the Securities and Exchange Commission (SEC) on Form 10-Q and Form 10-K, respectively. We also file current reports on Form 8-K, whenever events warrant or require such a filing. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information about us that we file electronically with the SEC at <http://www.sec.gov>. Our internet address is <http://www.immucell.com>. References to our website in this Annual Report are inactive textual references only and the content of our website should not be deemed incorporated by reference for any purpose.

ITEM 1A— RISK FACTORS

OUTLINE TO ITEM 1A – RISK FACTORS

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

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- Risk Pertaining to Common Stock
- Other Risks

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 45% or more 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 Annual Report (including inflation, cost increases, supply-chain disruptions and the rising price of oil and other commodities and supplies) impact our costs of goods sold. There is a risk that we are not able to achieve our gross margin goals, which would adversely affect our operating results and could impact our future operating plans. We missed our gross margin goals in 2023 and 2022 with realized gross margins of 22% and 41%, respectively. There is also a risk that our plans to maintain or improve our gross margin may not be realized due to cost increases, additional manufacturing contamination events, production equipment failures, the inability to raise our selling prices, or any combination of these factors. In addition, such negative events, depending on their severity, could deplete our cash resulting in an inability to fund our business.

Exposure to interest rates and debt service obligations: Rising interest rates could negatively affect the operating costs of dairy and beef producers and thus put further financial pressure on an already stressed business sector, which could indirectly, but materially and adversely, affect our business. During the first quarter of 2020, we removed the direct aspect of this particular exposure to our business by refinancing our bank debt (with the exception of our line of credit) with fixed rate notes. Our mortgage debt outstanding as of December 31, 2023 was \$5.8 million bearing interest at the fixed rate of 3.53% per annum. Our equipment loans outstanding as of December 31, 2023 were \$2.6 million bearing interest at the fixed rate of 3.5% per annum. The two State of Maine loans aggregating \$754,000 as of December 31, 2023 bear interest at the fixed rate of 5% per annum. The \$3 million in debt that we secured during the third quarter of 2023 bears interest at the blended fixed rate of 7.33% per annum with an outstanding balance of \$2.9 million as of December 31, 2023. Our outstanding debt as of December 31, 2023 aggregating \$12.1 million bears interest at the blended fixed rate of 4.51% per annum. Increasing interest rates would negatively impact the cost of any future borrowings. This was experienced on the new debt facilities aggregating \$3 million that we closed during the third quarter of 2023. A decline in sales or gross margin, coupled with this debt service burden, could impair our ability to fund our capital and operating needs and objectives. The additional debt we incurred to fund our growth objectives has significantly increased our total debt service costs. We are obligated to make principal and interest payments aggregating approximately \$2.0 million during both of the years ending December 31, 2024 and 2025. See Note 10 to the accompanying audited financial statements for more details about our debt.

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

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

Inflation and supply disruptions: Inflation is having a material and adverse impact on almost all supplies we purchase and labor we hire and retain. Continuing or increasing inflationary trends could materially reduce our gross margin on product sales if we are unable or unwilling to impose offsetting price increases on our customers. The Consumer Price Index for All Urban Consumers (CPI-U) during the year ended December 31, 2023, improved to 3.4% for all items before seasonal adjustment. This is down from 6.5% and 7.0% during the years ended December 31, 2022 and 2021, respectively. We are facing significant production constraints, supply

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disruptions and inflationary increases which were initially triggered, in large part directly or indirectly, by the COVID-19 pandemic. The extent and duration of the negative impact of the pandemic on the economics of our customers and on the demand for our products going forward are very difficult to assess. The dairy market, similar to many others, has been unstable as a result of the pandemic. The price paid to producers for milk has been very volatile. The Class III milk price has been extremely volatile since the onset of the pandemic. Market conditions have improved somewhat, but this volatility remains a concern. Additionally, like most input costs, the cost of grain and other feed is rising, which puts a strain on the profitability of our customers. There is also economic uncertainty for beef producers, as the supply chain is interrupted or otherwise adversely affected due to closures of processing plants and reduced throughput. This is a very unusual situation for farmers who work so hard to improve production quality and efficiency in order to help feed a growing population with high-quality and cost-effective proteins. The pandemic created risk and continues to create uncertainty and challenges for us and has created or contributed to global supply-chain disruptions and has affected international trade, while creating a worldwide health and economic crisis. Stock market valuations have declined and recovered somewhat but remain very volatile. Inflation has increased significantly, and tax rates may increase. There is a risk of a period of economic downturn, the severity and duration of which are difficult to know. Prior to the pandemic and the responsive federal economic stimulus programs, many feared the United States had taken on too much national debt. Now the debt load is significantly higher. A combination of the conditions, trends and concerns summarized above could have a corresponding negative effect on our business and operations, including the supply of the colostrum we purchase to produce our **First Defense**[®] product line, the demand for our products in the U.S. market and our ability to penetrate or maintain a profitable presence in international markets. We are experiencing shortages in key components and needed products, backlogs and production slowdowns due to difficulties accessing needed supplies and labor and other restrictions which increase our costs and affect our ability to consistently deliver our products to market in a timely manner. Our exposure to this risk is mitigated to some extent by the fact that our supply chain is not heavily dependent on foreign manufacturers, by our on-going cross-training of our employees, by qualifying alternate suppliers and components and by our early and continued compliance with recommended hygiene.

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

*Risks associated with our funding strategy for **Re-Tain**[®]:* The inability to maintain adequate cash and liquidity to support the commercialization of **Re-Tain**[®] is a risk to our business. Achieving FDA approval of our pharmaceutical-grade Nisin produced at commercial-scale is the most critical action remaining in front of us on our path to U.S. regulatory approval of **Re-Tain**[®]. Having completed the construction and equipping of the DS production facility (as described in more detail in **ITEM 7** of this Annual Report) at a cost of approximately \$20.8 million, we will continue to incur product development expenses to operate and maintain this facility until commercialization. Absent sufficient sales of **Re-Tain**[®] at a profitable gross margin, we would be required to fund all debt service costs from available cash and sales of the **First Defense**[®] product line, which would reduce, and could eliminate, our expected profitability going forward and significantly reduce our cash flows.

Uncertainty of market size and product sales estimates: Estimating the size of the total addressable market and future sales growth potential for our **First Defense**[®] product line is based on our experience and understanding of market dynamics but is inherently subjective. Estimating the size of the market for any new product, such as **Re-Tain**[®], involves more uncertainties than do projections for established products. We do not know whether, or to what extent, our products will achieve, maintain or increase market acceptance and profitability. Some of the uncertainties surrounding **Re-Tain**[®] include the product's effectiveness against currently prevalent pathogens, market acceptance, the effect of a premium selling price on market penetration, cost of manufacture, competition from new and existing products sold by substantially larger competitors with greater market reach and promotional resources and other risks described under "Product Risks" – "Sales risks pertaining to **Re-Tain**[®]" below. Since **Re-Tain**[®] is a novel approach to treating mastitis, there are many uncertainties with regards to how quickly and to what extent we can develop the subclinical mastitis treatment market. We believe that polypeptide antimicrobial technology may be viewed positively (relative to traditional antibiotics). If realized, this may offset some of these risks and result in better overall market acceptance.

Net deferred tax assets: The realizability of our net deferred tax assets is a subjective estimate that is contingent upon many variables. During the second quarter of 2018, we recorded a full valuation allowance against our net deferred tax assets that significantly increased our net loss in comparison to other periods. This non-cash expense could be reversed, and this valuation allowance could be reduced or eliminated, if warranted by our actual and projected profitability in the future. We will continue to assess the need for the valuation allowance each quarter.

Product Risks

Product risks generally: We set objectives for our products that we believe we can achieve, but the achievement of such goals is not a certainty. The sale of our products is subject to production, financial, efficacy, regulatory, competitive and other market risks. Elevated standards to achieve and maintain regulatory compliance required to sell our products continue to evolve. Failure to achieve acceptable biological yields from our production processes can materially increase our costs of goods sold and reduce our production output, leading to lower margins and/or an order backlog that could adversely affect our customer relationships and operating results. **First Defense**[®] is sold, and we expect **Re-Tain**[®] to be sold, at significant price premiums relative to competitive products. There is no assurance that we will continue to achieve market acceptance of the **First Defense**[®] product line, or achieve and sustain market acceptance of **Re-Tain**[®], at a profitable price level or that we can continue to manufacture our products at a low enough cost to result in a sufficient gross margin to justify their continued manufacture and sale. As we bring **Re-Tain**[®] to market, these risks could be heightened by the additional uncertainties associated with introducing a new product requiring a shift in customer behavior.

Contamination events and equipment failures in our production process: During 2023 and 2022, we experienced certain contamination events and equipment failures in our production process that resulted in scrapped inventory and a slowdown of our production process and had a significant impact on our operating results. We are at risk of further such production contaminations or equipment failures resulting in more scrapped inventory if we do not continue to improve our farm operations and implement other necessary improvements from farms to finished goods. The realization of this risk following the above-mentioned contamination events did result in a slowdown of our production output during 2023 to remediate this problem, which led to less sales and gross margin during the year. Additional contamination events or equipment failures causing significantly less production output, depending on their severity, could deplete our cash resulting in an inability to fund our business operations.

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

- 1) A rejection of a tank of milk by a positive milk inhibitor test because too much of the milk in a bulk tank is comprised of milk from cows being treated with **Re-Tain**[®], when tested randomly for inhibitors by a milk hauler, which could create legal liability.
- 2) A failed or stalled cheese tank occurs when a Nisin susceptible cheese starter culture is impacted by residues in milk that exceed our on-farm treatment recommendations, which aims to limit concentrations of bulk tanks or tankers to 1% of milk from cows treated with **Re-Tain**[®] or is not effectively diluted through the milk collection and transportation system. After we study this potential impact during our Controlled Launch of **Re-Tain**[®], we may decide to seek a post-approval label change requiring a short discard of milk, which may be limited to just the treated quarter of the cow.
- 3) Producers' current practice generally is to treat only clinical mastitis, which has the visual indicator of abnormal milk. In order to gain market penetration for **Re-Tain**[®], we will need to change that practice and increase awareness of the importance of treating subclinical disease. This will require the producers' ability and willingness to diagnose without visual indicators. Users of **Re-Tain**[®] could have unsatisfactory treatment outcomes if they lack the equipment needed to measure and monitor somatic cell counts (SCC) of the herd or individual cows (for which data is needed). This risk limits our access to treatment cows because about 40% of farms do not presently have access to this kind of testing at the cow level, and thus are not good candidates for the use of **Re-Tain**[®].
- 4) Lower than anticipated treatment cure rates could be experienced because the product is administered to cows that we would not identify as the best treatment candidates based on SCC data.
- 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 and potential legal liability.
- 7) Producers either do not choose to use it or might use it improperly, rather than follow our label instructions to administer one dose after each of three consecutive milkings, or they may limit use within the herd in an abundance of caution to avoid the negative outcomes described above.

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

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Concentration of sales: Sales of the **First Defense**[®] product line aggregated 99% of our total product sales during both of the years ended December 31, 2023 and 2022. Our primary customers for the majority of our product sales (91% and 92% during the years ended December 31, 2023 and 2022, respectively) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 9% and 8% of our total product sales during the years ended December 31, 2023 and 2022, respectively. The concentration of our sales from one product into just two markets (the dairy and beef markets) is a risk to our business. The animal health distribution segment has been aggressively consolidating over the last few years, with larger distributors acquiring smaller distributors. A large portion of our product sales (79% and 73% during the years ended December 31, 2023 and 2022, respectively) was made to two large distributors. A large portion of our trade accounts receivable (79% and 69% as of December 31, 2023 and 2022, respectively) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us in a manner unfavorable to us.

Production capacity constraints: We invested \$3.7 million from 2019 to the first quarter of 2022 to increase our production capacity (in terms of annual sales dollars) for the **First Defense**[®] product line from approximately \$16.5 million to approximately \$23 million based on current selling prices and estimated production yields. During the fourth quarter of 2021, we reached this new, higher level of production output on an annualized basis. During 2021, we initiated three additional investments aggregating \$4.7 million to increase our estimated annual production capacity for the **First Defense**[®] product line to approximately \$30 million, which we completed at the end of 2022. We are making initial plans and investments to further increase our production capacity in 2024 and after. While this capacity expansion investment has proceeded very close to budget, there is a risk of cost overruns in our ongoing projects and any future production expansions that we may undertake, and a risk that we will not be able to achieve our production capacity growth objectives on a timely basis, resulting in a continuing or increasing shortfall in supply to the market. The inability to meet market demand for our products is a risk to our business. The historically large backlog of orders, as well as any ongoing order backlog, presents a risk that we could lose customers during this period that are not easily regained thereafter, when our production capacity is expected to meet or exceed sales demand. Our long-term capital plan to continue to expand the **First Defense**[®] product line requires ongoing review of equipment capacity and utilization across the manufacturing value stream at the 56 Evergreen Drive facility and our leased facilities at 175 Industrial Way, as well as assessment of costs, functional obsolescence and reliability of equipment. This review and assessment could identify a need to fund unexpected equipment maintenance or replacement costs.

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

Regulatory Risks

*Regulatory requirements for the **First Defense**[®] product line:* **First Defense**[®] is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991, with subsequent approvals of line extensions in 2017 and 2018. As a result, our operations are subject to periodic inspection by the USDA, and we are at risk of an unfavorable outcome from such inspections. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the Reference Standard). Due to the unique nature of the label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product, which could interrupt sales and adversely affect our operating results. Territories outside of the United States may require additional regulatory oversight that we may not be able to meet with our current facilities, processes and resources. During July 2023, the USDA issued a Voluntary Stop Distribution and Sale (VSDS) and a Hold Release on **First Defense**[®] preventing us from shipping product (while not restricting us from continuing to produce inventory) until two inspectional observations were resolved. We promptly responded to the inspectional observations involved. On August 1, 2023, the USDA verbally rescinded the VSDS, and on August 4, 2023, the USDA verbally rescinded the Hold Release, allowing us to resume normal shipping during the week of August 7, 2023. There is a risk that we will become subject to similar or additional regulatory actions in the future. In these cases, the resulting interruption in sales could have a material and adverse effect on our operating results.

*Regulatory requirements for **Re-Tain**[®]:* The commercial introduction of this product in the United States requires us to obtain FDA approval. Completing the development through to approval of the NADA by the FDA involves risk. While four of the five required Technical Sections have been approved, the regulatory development process timeline has been extensive (approximately 16 years from when the product rights were returned to us by a former partner in 2007) and has involved multiple commercial production strategies and multiple submissions of the Chemistry, Manufacturing and Controls (CMC) Technical Section. Most recently, we received an Incomplete

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Letter from the FDA regarding this CMC Technical Section during the third quarter of 2022. This clarifies the required path to product approval. To reduce the risk associated with this process, we are working with a qualified contract manufacturer (Norbrook) for alignment of the required validations and DP manufacture and have met with the FDA to clarify filing strategy and requirements. Our CMC Technical Section submission is currently under review by the FDA as discussed in greater detail in **ITEM 7** of this Annual Report under the caption, **“Product Development Expenses and Strategy”**, below. Early during the first quarter of 2024, the FDA conducted another pre-approval inspection of our DS facility. This resulted in the issuance of one deficiency as identified on the FDA’s Form 483. Since then, we have fully responded with data addressing the inspectional observation. However, our efforts continue to be subject to inspection and approval by the FDA and other factors outside of our control, and there remains a risk that the required FDA approvals of our product and facilities could be delayed or not obtained. The facility of our contract manufacturer is subject to similar inspectional obligations. International regulatory approvals would be required for sales of **Re-Tain**[®] outside of the United States, and there is a risk that these approvals would be or become too costly to pursue or be delayed or not obtained.

Regulatory requirements limiting access to suppliers and customer base: Maine, where our principal executive office and manufacturing facilities are located, has adopted product reporting and phase-out requirements for per- and polyfluoroalkyl substances (“PFAS”). Maine’s statute requires that effective as of January 1, 2025 manufacturers of products with intentionally-added PFAS report the presence of such substances (and requires that such products cannot be sold in Maine unless the required reporting is made) and specifies that (subject to certain exceptions to be promulgated by the Maine Department of Environmental Protection) no product containing intentionally-added PFAS may be sold in Maine after January 1, 2030. This reporting requirement may limit our ability to access supplies from companies which are not in compliance with the state reporting requirements and may limit those customers to whom we may sell our products. The U.S. Environmental Protection Agency also has adopted a PFAS reporting law, which requires that importers of articles that contain PFAS report the presence of such substances to the extent such information is known or reasonably ascertainable. This reporting requirement may limit our ability to import supplies.

Economic Risks Pertaining to the Dairy and Beef Industries

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

Cattle count: The January count of all cattle and calves in the United States had steadily declined from 97,000,000 as of January 1, 2007 to 88,500,000 as of January 1, 2014. Then this figure increased each year, reaching 94,800,000 as of January 1, 2019 before declining to 93,800,000 as of both January 1, 2020 and January 1, 2021. This count continued to decline to 92,100,000 as of January 1, 2022 and to 88,800,000 as of January 1, 2023. This count dropped to 87,200,000 as of January 1, 2024. Reflecting seasonal trends, this figure was equal to 102,000,000, 101,000,000, 98,600,000 and 95,900,000 as of July 1, 2020, 2021, 2022, and 2023, respectively. A significant decline in the cattle count could negatively affect the size of our addressable market.

Herd size: Prior to 1957, there were over 20,000,000 cows in the U.S. dairy herd. Prior to 1986, there were over 10,000,000 cows in the U.S. dairy herd. From 1998 through 2021, the size (annual average) of the U.S. dairy herd ranged from the low of 9,011,000 in 2004 to the high of 9,448,000 in 2021. This average declined to 9,402,000 during the year ended December 31, 2022 and then declined to 9,386,000 during the year ended December 31, 2023. A significant decline in the herd size could negatively affect the size of our addressable market.

Milk cow price: The all-time high value (annual average) for a milk cow was \$1,993 during 2015. Since then, this annual average value steadily declined to \$1,205 during 2019 before increasing to \$1,300 during 2020 and to \$1,363 during 2021. This price for 2022 increased significantly to an average of \$1,598, which is a 17% increase over 2021. The 2023 average price of \$1,763 represents a 10% increase over prior year. A significant decline in the milk cow price could negatively affect the size of our addressable market.

Milk price: The dairy market, similar to many others, has been unstable for several reasons including as a result of the pandemic. The price paid to producers for milk has been very volatile. This market volatility, and the resulting impact on our primary end users, could negatively impact our ability to maintain and grow sales at a profitable level. The Class III milk price (an industry benchmark that reflects the value of product used to make cheese) is an important indicator because it defines our customers’ revenue level. This annual average milk price level (measured in dollars per hundred pounds of milk) reached its highest point (since these prices were first reported in 1980) during 2014 at \$22.34 (peaking at \$24.60 in September 2014), which price level has never been repeated. During the year ended December 31, 2020, this average milk price was equal to \$18.16, but it was extremely volatile during the year due largely to disruption in demand related to the COVID-19 pandemic. The one-month fluctuation of 73% from a low of \$12.14 in May 2020 to \$21.04 in June 2020 set an all-time record for variability. The average price for 2021 decreased by 6% to \$17.08. This price average increased by 29% to \$21.96 during the year ended December 31, 2022. The average price decreased by 22% to \$17.02 during the year ended December 31, 2023. The annual fluctuations in this milk price level are demonstrated in the following table:

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Average Class III Milk Price During the Years Ended December 31,	(Decrease) Increase
2014	\$22.34
2015	\$15.80
2016	\$14.87
2017	\$16.17
2018	\$14.61
2019	\$16.96
2020	\$18.16
2021	\$17.08
2022	\$21.96
2023	\$17.02

Feed Costs: The actual level of milk prices may be less important than its level relative to feed costs. One measure of this relationship is known as the milk-to-feed price ratio, which represents the amount of feed that one pound of milk can buy. An increase in feed costs also has a negative impact on the beef industry and therefore could have a resulting negative impact on our business and results of operations. This ratio varies farm-to-farm based on individual operating parameters. Since this ratio reached 3.24 in 2005, it has not exceeded 3.00. This ratio averaged 1.74 for 2021, amounting to a significant decline of 25% from the 2020 average of 2.32. This average has not been lower since 2012. During 2022, this ratio improved by 10% to 1.91. This ratio dropped to 1.69 during the year ended December 31, 2023. 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
2016	2.26
2017	2.42
2018	2.05
2019	2.25
2020	2.32
2021	1.74
2022	1.91
2023	1.69

Market volatility: While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk, the price for milk is also influenced by very volatile international demand for milk products. Given our focus on the dairy and beef industries, the volatile market conditions and the resulting financial insecurities of our primary end users are risks to our ability to maintain and grow sales at a profitable level. These factors also heighten the challenge of selling premium-priced animal health products (such as **Tri-Shield**[®] and **Re-Tain**[®]) into the dairy market.

Small Size of the Company

Dependence on key personnel: We are a small company with approximately 79 employees (including 5 part-time employees). As such, we rely on certain key employees to support multiple operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained, which could be even more challenging in the present difficult labor market. Our competitive position will be highly influenced by our ability to attract, retain and motivate key scientific, manufacturing, managerial and sales and marketing personnel. We will require increased staffing levels to operate our expanded **First Defense**[®] production capacity and to operate our **Re-Tain**[®] production facility. The cost of attracting and retaining the needed additional personnel in this current job market and inflationary environment could adversely affect our margins and profitability.

Reliance on outside party to provide certain services under contract for us: We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Re-Tain**[®], who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. One example of this outside reliance is Norbrook, our DP contract manufacturer. Because Norbrook notified us of its intent to terminate its supply agreement with us, we initiated an investment of approximately \$4 million during 2022 to construct and equip our own DP formulation and aseptic filling capability for **Re-Tain**[®] in our existing DS facility. Due to the loss in gross margin during 2023 caused by the slowdown in production output necessary to remediate product contamination events, we have decided to defer spending of approximately \$2 million of these funds for the near term. The objective of this investment is to end our reliance on an outside party to perform these services for us. Actual project costs could exceed

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our current estimates. Completion of this project could be delayed due to a number of factors outside our control, including delays in equipment fabrication, equipment delivery or facility construction. In addition, there is a risk that we fail to achieve regulatory approval of the new facility or that such approval is delayed or requires significant additional expenditures to obtain. We are evaluating alternatives for DP supply going forward, which include the resumption of the investment in our own in-house DP services (when prudent based on our cash reserves) or another contract manufacturing agreement or a further extension with Norbrook. We face a supply interruption and adverse effects on the Controlled Launch of **Re-Tain**[®] after the DP supply provided from our contract manufacturer is consumed and until new supply from a new contract manufacturing agreement or our own formulation and aseptic filling facility is implemented.

Competition from others: Many of our competitors are significantly larger and more diversified in the relevant markets than we are and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development and sales/distribution capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. Merck and Zoetis, among other companies, sell products that compete directly with the **First Defense**[®] product line in preventing scours in newborn calves. The scours product sold by Zoetis sells for approximately half the price of our product, although it does not have an *E. coli* claim (which ours does). With **Tri-Shield**[®], we can compete more effectively against vaccines that are given to the mother cow (dam) to improve the quality of the colostrum that she produces for the newborn calf. Elanco, Merck and Zoetis provide these dam vaccine products to the market. There are many companies competing in the mastitis treatment market, most notably Boehringer Ingelheim, Merck and Zoetis. The subclinical mastitis products sold by these large companies are well established in the market and are priced lower than what we expect for **Re-Tain**[®], but all of them involve traditional antibiotics and are sold subject to a requirement to discard milk during and for a period of time after treatment (unlike our product which does not carry an FDA-required milk discard or meat withhold). There is no assurance that our products will compete successfully in these markets. We may not be aware of other companies that compete with us or intend to compete with us in the future.

Global Risks

Russia's unprovoked military invasion of Ukraine and the war in the Middle East: Russia's unprovoked military invasion of Ukraine (and attack on its people) and the war in the Middle East are having a significant negative impact on the world economy, worsening trends that were already moving in an unfavorable direction. Among other exposures, the increasing price of oil is already impacting our transportation-related expenses materially, and we expect this supply stress to increase the cost of petroleum-based products that we purchase (mostly plastics). Both of these military actions could cause more stress on the global economy.

Climate change: Our business, and our activities and the activities of our customers and suppliers, could be disrupted by climate change. Potential physical risks from climate change may include altered distribution and intensity of rainfall, prolonged droughts or flooding, increased frequency of wildfires and other natural disasters, rising sea levels, and a rising heat index, any of which could cause negative impacts to our and our customers' and suppliers' businesses. Increased temperatures and rising water levels may negatively impact our dairy and beef livestock customers by increasing the prevalence of parasites and diseases that affect food animals. The physical changes caused by climate change may also prompt changes in regulations or consumer preferences which in turn could have negative consequences for our and our customers' businesses. Climate change may negatively impact our customers' operations, through climate-related impacts such as increased air and water temperatures, rising water levels and increased incidence of disease in livestock. In addition, concerns regarding greenhouse gas emissions and other potential environmental impacts of livestock production have led to some consumers opting to limit or avoid consuming animal products. If such events affect our customers' businesses, they may purchase fewer of our products, and our revenues may be negatively impacted. Climate driven changes could have a material adverse impact on the financial performance of our business and on our customers. In addition, increased frequency of natural disasters and adverse weather conditions may disrupt our manufacturing processes or our supply chain. These disruptions may have a material adverse effect on our business, financial condition, results of operations and/or cash flows.

Bovine diseases: The potential for epidemics of bovine diseases such as 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: ICCG). Our average daily trading volume (which was 7,950 shares per day during the 20-day period ended March 8, 2024) is lower, our bid/ask stock price

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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 March 8, 2024 was \$5.20. Most companies in the animal health sector have market capitalization values that greatly exceed our market capitalization of approximately \$40 million as of March 8, 2024. Our product sales during the year ended December 31, 2023 were \$17.5 million. This means that our market capitalization as of March 8, 2024 was equal to approximately 2.3 times our sales during the year ended December 31, 2023. 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 Annual 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 will be dependent on one manufacturer for the supply of syringes for **Re-Tain**[®]. We are currently dependent on a contract with Norbrook for the DP formulation and aseptic filling for supply of our Nisin DP through 2024. The facility we may resume 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. We expect to achieve FDA approval for use of our DP facility approximately two years from when this project is restarted. The potential alternative options for these services are narrowed considerably because our

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product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). Any significant damage to or other disruption in the services at any of these third-party facilities or our own facilities (including due to lack of financing, regulatory issues or non-compliance) would adversely affect the production of inventory and result in significant added expenses and potential loss of future sales. We 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 through the end of 2024 (with product expiries that could be approximately between September of 2025 and March of 2026) to align with the new supply from a new contract manufacturing agreement or our own formulation and aseptic filling facility.

Failure to protect intellectual property: The protection and enforcement of our intellectual property rights may require the expenditure of significant financial, managerial and operational resources. We rely on trademark, copyright and patent law, trade secret protection, agreements and other methods with our employees and others to protect our proprietary rights. However, we may be unable to adequately protect our intellectual property rights or prevent third parties from infringing or misappropriating our intellectual property rights. We may not be able to obtain registration for all intellectual property we seek to register, and effective intellectual property protection may not be available in every country in which our products are sold. In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. Instead, we have sought (and may seek in the future) to maintain the confidentiality of any relevant proprietary technology through trade secrets, operational safeguards and contractual agreements. Reliance upon trade secret, rather than patent protection may cause us to be vulnerable to competitors who successfully replicate (knock off) our manufacturing techniques and processes. Further, our confidentiality agreements may not effectively prevent disclosure of our proprietary information, technologies and processes and may not provide an adequate remedy in the event of unauthorized disclosure of such information. Others may independently develop similar trade secrets or technology or obtain access to our unpatented trade secrets or proprietary technology. Others may have filed patent applications and may have been issued patents involving products or technologies potentially useful to us or necessary for us to commercialize our products or achieve our business goals. If that were to be the case, there can be no assurance that we will be able to obtain licenses to such patents on terms that are acceptable to us. Any of our intellectual property rights may be challenged by others or invalidated through administrative process or litigation. Third parties may claim in the future, that we have infringed their intellectual property rights, which could result in significant costs and potential damages and license requirements. We may initiate claims or litigation against others for infringement, misappropriation or violation of our intellectual property rights or other proprietary rights or to establish the validity of such rights. However, we may be unable to discover or determine the extent of any infringement, misappropriation or other violation of our intellectual property rights and other proprietary rights. In addition, we may be unable to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights and other proprietary rights.

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

ITEM 1B — UNRESOLVED STAFF COMMENTS

None

ITEM 1C – CYBERSECURITY

Risk Management and Strategy

We regularly assess risks from cybersecurity threats, monitor our information systems for potential vulnerabilities and test those systems pursuant to our process. Our cybersecurity risk assessment is part of our overall risk management program. We also regularly engage outside consultants to assess, identify and manage material risks from cybersecurity threats, including those threats associated with our use of third-party service providers. These consultants recommend and help implement systems to protect against cybersecurity threats. Based on the information available as of the filing date of this Annual Report, we are not aware of any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect our business strategy, results of operations or financial condition. However, despite our cybersecurity risk management processes, there can be no assurance that we, or the third parties with which we interact, will not experience a cybersecurity incident in the future that may materially affect us. Refer to the risk factor captioned *“Increasing dependence on the continuous and reliable operation of our information technology systems”* under **PART I, ITEM 1A – RISK FACTORS** for additional description of cybersecurity risks and potential related impacts on the Company.

Governance

Our Board of Directors has overall oversight responsibility with respect to our approach to risk management, including risks relating to cybersecurity. Although the Board of Directors has the ultimate responsibility for risk oversight, our management team, including our President and CEO, has operational responsibility for cybersecurity matters, including the day-to-day management of our cybersecurity risks, and oversees processes for the prevention, detection, mitigation and remediation of any cybersecurity incidents. While our management team does not have cybersecurity expertise, we coordinate with expert consultants to assess and manage risks. Our Board of Directors reviews cybersecurity threats and risk controls at quarterly meetings based on information provided by management and outside consultants.

ITEM 2 — PROPERTIES

Building 56:

During 1993, we purchased a 15,000 square foot facility (that included 5,000 square feet of unfinished office space on the second floor) at 56 Evergreen Drive in Portland, Maine. We currently use this space for substantially all of our: i) office and laboratory needs, ii) vaccine manufacturing operations, iii) liquid processing operations and iv) freeze-drying operations for our USDA-regulated product line. All of our powder milling and filling operations, gel formulation operations and assembly services have been relocated out of this building. During 2001, we completed a construction project that added approximately 5,200 square feet of new manufacturing space on the first floor and approximately 4,100 square feet of storage space on the second floor. During 2007, we built out the 5,000 square feet of unfinished space on the second floor into usable office space. After moving offices from the first floor into this new space on the second floor, we modified and expanded the laboratory space on the first floor and added approximately 2,500 additional square feet of storage space on the second floor. During 2009, we added 350 square feet of cold storage space connected to our first floor production area and added an additional 600 square feet to the second floor storage area. During 2015, we completed construction of a two-story addition connected to our facility to provide us with approximately 7,100 additional square feet for cold storage, production and warehouse space for our operations. These additions increased the size of the facility to approximately 34,850 square feet.

Building 33:

During 2015, we exercised an option to acquire land at 33 Caddie Lane in Portland, Maine which is near our facility at 56 Evergreen Drive, on which we initiated construction of our DS production facility for **Re-Tain**[®] during the third quarter of 2016. During the fourth quarter of 2017, we obtained a Certificate of Occupancy from the City of Portland for our 16,202 square foot (9,803 on the first floor and 6,399 on the second floor) DS production facility. Our FDA-regulated operations are conducted in this building.

Building 14:

During 2017, we purchased a 4,080 square foot facility adjacent to the DS production facility for **Re-Tain**[®] at 14 Wedge Way in Portland, Maine. We are using this warehouse space primarily for storage of inventory, materials and equipment. During the middle of 2023, we completed modifications to this facility for packing, shipping and cold storage for **Re-Tain**[®] and other warehousing needs.

Building 175A:

During 2019, we entered into a lease covering approximately 14,300 square feet of office and warehouse space at 175 Industrial

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Way in Portland, Maine to expand our USDA-regulated manufacturing operations. We have renovated this space (a Certificate of Occupancy was issued during the second quarter of 2020) to help us expand our production capacity and improve quality for the **First Defense**[®] product line. This space is being used for all of our powder milling and filling, gel formulation and assembly services. The original lease term was ten years with a right to renew for a second ten-year term and a right of first offer to purchase. During the third quarter of 2022, we entered into a new 20-year lease covering a facility that has been constructed for us by our landlord (**Building 175B**, described below), which is adjacent to (and has been connected to) **Building 175A**. In connection with this new lease, the lease to **Building 175A** was extended by approximately 13 years to match the expiration of the other lease to **Building 175B**.

Building 175B:

During 2022, we committed to lease an additional 15,400 square feet of space at 175 Industrial Way in Portland, Maine, which has been constructed and connected to **Building 175A**, over a 20-year term. The lease commencement date was April 1, 2023. Lease payments began four months after this date. In connection with the lease commitment for space in **Building 175B**, the term of the original lease for **Building 175A** was extended by approximately 13 years. We intend to use this space for the following three purposes: 1) improve product quality by moving powder milling out of **Building 56**, 2) provide much needed additional warehouse space and 3) provide space for additional freeze-drying equipment to increase our production capacity to approximately \$40 million per year. Due to the loss in gross margin on product sales during 2023 caused by the slowdown in production output necessary to remediate product contamination events, we reduced the scope of the investment to build out **Building 175B** at least for the time being. The objective of moving our powder milling operations out of **Building 56** has been achieved by moving powder milling to **Building 175A** for the time being. We have completed Phase I of this build out plan, which included pouring a concrete floor and bringing utilities and heat to the space. Upon issuance of a Certificate of Occupancy by the city, we plan to relocate all shipping and receiving operations from **Building 56** to **Building 175B** and benefit from the new warehouse space. When we have adequate cash, we will initiate Phase II of the build out plan, which includes construction of process rooms and installation of production equipment necessary to further increase our production capacity.

Other:

During March of 2021, we entered into a renewable, two-year lease for approximately 1,300 square feet of office, storage and parking space in New York. Subsequently, we entered into a new two-year lease to the same property through March of 2025 that includes an option to renew for an additional two-year term. We are renting approximately 960 square feet in Winona, Minnesota for a sales office. This lease automatically renews with 4% increases for one-year terms unless we or the landlord give 60-days' notice of a change. The current term expires in June 2024. We do not expect to provide notice of cancellation at this time. We also maintain access to cows (as a source of colostrum used in the production of the **First Defense**[®] product line) through contractual relationships with commercial dairy farms. We maintain property insurance in amounts that approximate replacement cost and a modest amount of business interruption insurance.

ITEM 3 — LEGAL PROCEEDINGS

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

ITEM 4 — MINE SAFETY DISCLOSURES

None

PART II

ITEM 5 — MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock trades on The Nasdaq Capital Market tier of The Nasdaq Stock Market under the symbol ICCG. As of March 8, 2024, we had 15,000,000 common shares authorized and 7,750,864 common shares outstanding, and there were approximately 642 shareholders of record. We have not paid dividends on our common stock and do not have any present plan or expectation to pay dividends.

Purchase of Equity Securities

During 2023, we accepted \$18,760 in cash in consideration for the exercise of 4,000 stock options. During 2022, we accepted

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\$30,670 in cash in consideration for the exercise of 5,000 stock options. In all cases, new shares were issued from treasury stock.

ITEM 6 — [RESERVED]

ITEM 7 — 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 audited financial statements and the related notes and other financial information included in **Part II: ITEM 8 — FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA** of this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual 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 **Part I: ITEM 1A — RISK FACTORS** of this Annual Report for a discussion of some of the important factors that could cause actual results to differ materially from the results, objectives or expectations described in or implied by the forward-looking statements contained in the following discussion and analysis.

OUTLINE TO ITEM 7 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

- **Liquidity and Capital Resources**
- **Results of Operations**
- **Critical Accounting Policies**

Liquidity and Capital Resources

Net cash used for operating activities was \$4.7 million during the year ended December 31, 2023 in comparison to net cash used for operating activities of \$1.5 million during the year ended December 31, 2022. The \$3.1 million increase in cash used for operating activities during the year ended December 31, 2023 compared to the year ended December 31, 2022 was largely caused by the \$3.3 million increase in the net loss which was, in turn, largely the result of \$3.8 million less gross margin being earned during 2023, due to the production contamination events discussed below. Approximately \$1.4 million less cash was received from the collection of accounts receivable, which was largely offset by \$1.2 million less cash being invested in inventory during the year ended December 31, 2023 compared to the prior year. Our inventory balance increased by \$1.8 million to \$7.8 million as of December 31, 2023 from \$6 million as of December 31, 2022. Our total depreciation and amortization expense was approximately \$2.7 million and \$2.5 million during the years December 31, 2023 and 2022, respectively. We anticipate that depreciation expense, while not affecting our cash flows from operations, will be a significant factor in creating annual net operating losses until and unless product sales increase sufficiently to offset these non-cash expenses. Net cash used for investing activities was \$1.9 million during the year ended December 31, 2023 in comparison to net cash used for investing activities of \$4 million during the year ended December 31, 2022 consisting primarily of cash spent to fund the purchase of property, plant and equipment.

Net cash provided by financing activities increased to \$1.8 million during the year ended December 31, 2023 in comparison to net cash provided by financing activities of \$1.1 million during the year ended December 31, 2022. We received gross debt proceeds of \$3 million and \$2 million during the years ended December 31, 2023 and 2022, respectively. We had aggregate debt outstanding (net of debt issuance and debt discount costs) of approximately \$12 million and \$10.2 million as of December 31, 2023 and 2022, respectively. This debt bears interest at fixed rates. The blended interest rate on the debt outstanding as of December 31, 2023 and 2022 is 4.51% and 3.65% per annum, respectively. Debt principal repayments aggregated \$1.2 million and \$897,000 during the years ended December 31, 2023 and 2022, respectively. We anticipate that debt principal repayments will aggregate approximately \$1.5 million during both of the years ending December 31, 2024 and 2025. Interest expense (including amortization of debt issuance and debt discount costs) was \$476,000 and \$349,000 during the years ended December 31, 2023 and 2022, respectively. We anticipate that interest expense (including amortization of debt issuance and debt discount costs) will be \$563,000 and \$492,000 during the years ending December 31, 2024 and 2025, respectively. During the first quarter of 2024, the availability of our \$1.0 million line of credit, which bears interest at the National Prime Rate per annum, was extended until September 11, 2025. There was no outstanding balance under this line of credit as of December 31, 2023 or 2022. See Note 10 to the accompanying audited financial statements for more information about our bank debt.

From the first quarter of 2016 through the second quarter of 2021, we raised gross proceeds of \$26.7 million (net proceeds were \$24.8 million) from six different common equity transactions priced between \$5.25 and \$8.25 per share with a weighted average price of \$5.87 per share. No warrants were issued in connection with any of these transactions, and no convertible or preferred securities were issued. This capital, together with our bank debt and gross margin from product sales, has allowed us to transform the Company. Based on our best estimates and projections, we believe that our cash and cash equivalents, together with gross margin anticipated to

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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	As of	(Decrease) Increase	
	December 31, 2023	December 31, 2022	Amount	%
Cash and cash equivalents	\$979	\$5,792	(\$4,813)	(83%)
Net working capital	\$7,272	\$10,923	(\$3,650)	(33%)
Total assets	\$43,808	\$44,861	(\$1,053)	(2%)
Stockholders' equity	\$24,993	\$30,380	(\$5,387)	(18%)
Common shares outstanding ⁽¹⁾	7,751	7,747	4	<1%

⁽¹⁾ There were 618,500 and 605,000 shares of common stock reserved for issuance for stock options that were outstanding as of December 31, 2023, and 2022, respectively.

We have invested and continue to invest in several different capital expenditure projects to increase our estimated annual full production capacity for the **First Defense**[®] product line from approximately \$16.5 million to approximately \$40 million and to complete the development of **Re-Tain**[®]. When we describe the production capacity for the **First Defense**[®] product line in this Annual Report, it should be noted that the actual value of this capacity varies based on biological and process yields, product format mix, selling price and other factors.

During the three-year period ended December 31, 2016, we invested the aggregate of \$4.2 million to construct a 7,100 square foot facility addition at 56 Evergreen Drive and related equipment (primarily Freeze-Dryer #2) and cold storage capacity increasing our freeze-drying capacity by 100% and making other improvements to our liquid processing capacity, which increased our annual production capacity (in terms of annual sales dollars) to approximately \$16.5 million. During the first quarter of 2016, we completed this investment, which also included the construction and equipping of a pilot plant for small-scale DS production for **Re-Tain**[®] within our **First Defense**[®] production facility at 56 Evergreen Drive. After construction of the DS production facility for **Re-Tain**[®] at 33 Caddie Lane (described in the next paragraph) was completed, this space was converted for use in the production of the gel tube formats of the **First Defense**[®] product line. After construction of **Building 175A** (described below) was completed, this space was converted to double our liquid processing capacity.

During the four-year period ended December 31, 2018, we invested the aggregate of \$21.6 million to construct a DS production facility for **Re-Tain**[®] at 33 Caddie Lane. During the fourth quarter of 2017, we completed construction of the DS production facility. We began equipment installation during the third quarter of 2017, and we completed this installation during the third quarter of 2018. The total cost of this investment for the DS production facility and related processing equipment was \$20.8 million plus \$331,000 for the land and \$472,000 for the acquisition of an adjacent 4,080 square foot warehouse facility at 14 Wedge Way, which will be used for packing, shipping and cold storage of **Re-Tain**[®] and other warehousing needs.

During 2019, we initiated several additional capital expenditure investments in **First Defense**[®] and **Re-Tain**[®] as detailed in the following table (in thousands):

Paid During	First Defense [®]	Re-Tain [®]	Other	Total
Year Ended December 31, 2019	\$279	\$538	\$574	\$1,391
Year Ended December 31, 2020	2,938	581	554	4,073
Year Ended December 31, 2021	1,633	976	-	2,609
Year Ended December 31, 2022	3,513	415	47	3,975
Year Ended December 31, 2023	1,097	796	-	1,893
Total Paid through December 31, 2023	9,460	3,306	1,175	13,941
Estimate to Complete ⁽¹⁾	3,500	2,000	900	6,400
Total Project Cost	\$12,960	\$5,306	\$2,075	\$20,341

⁽¹⁾ The investment of approximately \$5.5 million of these funds for **First Defense**[®] and **Re-Tain**[®] projects has been deferred for the time being. These figures are rough estimates for the work to be completed that have not been put out to bid for firm cost quotations or contracts at this time.

The primary purpose of the additional investment in **First Defense**[®] is to fulfill the current backlog and materially reduce the risk of another order backlog. Operating at very close to 100% of available capacity is not efficient or sustainable. Our objective is to be in position to operate without significant contaminations at the capacity level we choose to cover sales with adequate buffer stock,

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which would allow more time for necessary preventative maintenance, and to have redundancy in place for when equipment failures occur. In addition to running without significant product contaminations or equipment failures, we need to meet or exceed our production yield assumptions to succeed.

The first phase of the additional investments in **First Defense**[®] included significant renovations to a 14,300 square foot leased facility at 175 Industrial Way (**Building 175A**), some facility modifications at 56 Evergreen Drive and the necessary production equipment (including Freeze-Dryer #3) to increase our freeze-drying capacity by 50% and our liquid processing capacity by 100%. This resulted in increasing the annual production capacity of the **First Defense**[®] product line (in terms of annual sales dollars) from approximately \$16.5 million to approximately \$23 million. Renovations of **Building 175A** to enable this expansion were completed during the second quarter of 2020. By moving our powder and gel filling and assembly services from 56 Evergreen Drive into this new space, we created space at 56 Evergreen Drive for the installation of the expanded freeze-drying capacity. The new facilities are built to contemporary current Good Manufacturing Practices (cGMP) standards with efficient material and people flows. A site license approval for this new facility was issued by the USDA during the third quarter of 2020. During the second quarter of 2021, we completed the relocation of our gel formulation equipment from 56 Evergreen Drive to **Building 175A**, which created the space necessary to double our liquid processing capacity at 56 Evergreen Drive. We obtained site license approval of the expanded freeze-drying capacity (Freeze-Dryer #3) at 56 Evergreen Drive from the USDA during the third quarter of 2021, and we obtained site license approval of the expanded liquid processing capacity at 56 Evergreen Drive from the USDA during the third quarter of 2022. This investment also included equipment and vehicle investments necessary to expand and improve our colostrum collection capabilities and logistics.

The second phase of the additional investments in **First Defense**[®] included the installation of Freeze-Dryer #4 to further increase the estimated annual production capacity of the **First Defense**[®] product line (in terms of annual sales dollars) by an additional 33% from approximately \$23 million to approximately \$30 million. Due to supply disruptions affecting key components and equipment, this investment was not completed until the end of 2022. This investment also includes equipment and facility modifications to scale-up and upgrade our vaccine manufacturing capacity, improve our quality laboratories and install new equipment for our gel filling operations for **First Defense**[®] at 56 Evergreen Drive and **Building 175A**. This phase included the automation of our gel filling operations.

The third phase of the additional investments in **First Defense**[®] involves the initiation of a new investment in building modifications and equipment to further increase our estimated annual **First Defense**[®] production capacity from approximately \$30 million to approximately \$40 million with options for further expansion. Given the long lead time required for investments like this, we initiated this project by entering into a lease amendment during the third quarter of 2022 covering a to-be-constructed 15,400 square foot building shell connected to **Building 175A** for approximately \$250,000 per year. Construction of the building shell by our landlord was substantially complete as of April 1, 2023, and rent payments commenced as of August 1, 2023. We made this lease commitment because of the unique proximity of the land adjacent to our currently leased space and the high level of demand for properties of this type in the Portland market. We did not want to risk losing this opportunity to others. The anticipated benefits to us from this new lease include: i) space for the potential to install Freeze-Dryers #5, #6, #7 and #8 if justified by market demand in the future, ii) improved space and quality for our powder milling operations by separating our upstream processes (liquid processing) at 56 Evergreen Drive from our clean downstream processes (milling, formulation, filling and packaging) and iii) much needed additional warehouse space. Freeze-Dryer #5 is the key piece of equipment required to allow us to increase our estimated annual production capacity to above \$30 million. Based on past experience, we are planning for approximately 18 to 24 months of lead time for fabrication, installation, qualification and implementation of Freeze-Dryer #5. We have been running our equipment and staff close to 100% of capacity in order to fill the backlog of orders. One of our objectives is to create a more sustainable production schedule. However, due to the loss in gross margin during 2023 caused by the slowdown in production output necessary to remediate the product contamination events discussed below, we have decided to defer most of this investment, for the time being. During the third quarter of 2023, we initiated the initial steps of this project with a budget of approximately \$700,000. We completed this work during the first quarter of 2024, which will provide additional warehousing space and allow us to move all shipping and receiving functions out of 56 Evergreen Drive to create more space for liquid processing. In consideration for our landlord agreeing to pay for the cost of those certain tenant improvements, we are obligated to make additional rent payments of \$20,000 per month from November 2023 through June 2024 and a one-time additional rent payment of \$488,743 in July 2024.

The purpose of the additional investments in **Re-Tain**[®] is to bring the formulation and aseptic filling capabilities for **Re-Tain**[®] DP into available space in our DS facility to end our reliance on third-party DP manufacturing services as well as to build out warehouse space at 14 Wedge Way for packing and shipping facilities for **Re-Tain**[®]. We began initial installation of the filling equipment during the first quarter of 2022. Then we paused this installation work pending concurrence with the FDA pertaining to our third submission of the Chemistry, Manufacturing and Controls (CMC) Technical Section, which is discussed in greater detail below. Due to the loss in gross margin during 2023 caused by the slowdown in production output necessary to remediate the product contamination events discussed below, we have decided to defer the spending of approximately \$2 million of these funds, for the time

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being. At the same time, we are investigating other potential relationships with contract manufacturers that might do this work for us so that we can avoid this use of funds. If we decide to resume the in-house strategy, we would anticipate FDA approval of this facility (which is a requirement for commercial manufacturing) at least two years after we resume spending on this project.

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

Assessed Value	Twelve-Month Period Ended	Total New Taxes Generated by the Project	Less: TIF Credit	Net Amount Paid by ImmuCell
\$1.7 million @ April 1, 2017	June 30, 2018	\$36,000	\$22,000	\$13,000
\$4.0 million @ April 1, 2018	June 30, 2019	\$90,000	\$58,000	\$32,000
\$4.0 million @ April 1, 2019	June 30, 2020	\$94,000	\$60,000	\$34,000
\$4.0 million @ April 1, 2020	June 30, 2021	\$94,000	\$60,000	\$34,000
\$4.3 million @ April 1, 2021	June 30, 2022	\$55,000	\$36,000	\$20,000
\$4.3 million @ April 1, 2022	June 30, 2023	\$58,000	\$37,000	\$21,000
\$4.3 million @ April 1, 2023	June 30, 2024	\$61,000	\$39,000	\$22,000
Total		<u>\$488,000</u>	<u>\$312,000</u>	<u>\$176,000</u>

Results of Operations

Business Segments

As detailed in Note 17, "Segment Information", to the accompanying audited financial statements, we operate in two business segments. The Scours segment is dedicated to manufacturing and selling **First Defense**[®], a product used to prevent scours in newborn calves, which is regulated by the United States Department of Agriculture (USDA). The Mastitis segment is focused on developing and commercializing **Re-Tain**[®], a product to treat subclinical mastitis in lactating dairy cows, which is regulated by the United States Food and Drug Administration (FDA).

Production Capacity Increase, Product Contamination and Related Events

During 2018, it became clear that demand for **Tri-Shield First Defense**[®] was outpacing production. In response to this increasing demand, we began a series of investments during 2019 to increase our production capacity for the **First Defense**[®] product line to an estimate of approximately \$30 million per year. Over recent years, we have invested more than \$12.4 million to increase our production capacity to meet the still-growing demand. This investment in equipment and facilities represents approximately 50% of our stockholders' equity as of December 31, 2023. Although we have not yet been able to achieve our production output goals, we remain deeply committed to continuing to supply **First Defense**[®] to the market over the long term, despite the current short supply. Our production process is a very complicated one, which makes it difficult to scale-up quickly. We can't just flip a switch and pump out more widgets.

The past year or so has been considerably challenging for us. As of July 2022, we had completed almost all of the facility expansion work and new equipment installations needed to significantly increase our production capacity. However, the most critical piece of new equipment (being Freeze-Dryer #4) was delivered six months late by the fabricator. As this increased production capacity was coming online, a product contamination event was detected by standard in-process quality control testing around the end of the third quarter of 2022. Scrapped product from contamination events and other production process losses during 2022 (largely due to the contamination event around the end of the third quarter) resulted in a total charge to costs of goods sold of \$589,000 during 2022. We took immediate steps to address the contamination, and production ran without issue during the balance of the fourth quarter of 2022. By the end of 2022, we had Freeze-Dryer #4 approved for use by the USDA. Just as we began to operate at this higher level of capacity at the beginning of 2023, we were forced to slow down production to remediate a second contamination event related to our incoming raw material. In response to this contamination event, we slowed down our production output as we took the necessary steps to assess and remediate the issues to ensure that any product that is released to market continues to meet all quality standards. At the same time, Freeze-Dryer #2 stopped operating requiring a six-month repair, netting us back to three operating freeze dryers. As of early July 2023, we were back to four operating freeze dryers, and we believed that the contamination events were largely behind us. We subsequently experienced a third contamination event in September 2023 impacting two lots of work-in-progress inventory. Although all of the incoming material utilized in this production phase had passed quality control testing, the product failed the quality control tests later in the production process. The production pause necessary to remediate the problem reduced our production output

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during September and October of 2023. Scrapped product from contamination events and other production process losses during 2023 resulted in a total charge to costs of goods sold of \$527,000 during 2023.

The production slowdown during the first ten months of 2023, has, in part, caused an increase in the amount of our order backlog from approximately \$2.5 million as of December 31, 2022 to approximately \$9.4 million as of December 31, 2023. This backlog increased further to \$10.3 million as of March 8, 2024. We cannot be certain that this backlog will be converted to sales because it includes orders that were placed months ago, redundancy in demand and orders that may be cancelled. We believe that the ongoing implementation of our capacity expansion plans and the corrective actions being taken in response to these contamination events should allow us to operate without further significant contaminations going forward with estimated annual production capacity of approximately \$30 million during the latter part of the fourth quarter of 2023 and into 2024. While we produced far less than we needed during 2023, we believe that our remediation efforts are allowing us to steadily ramp back up to full production capacity. With the positive trend in our quality control test results described above, we are building back production. As we resume full production, our goal is to be able to produce at least \$6 million or more worth of product per quarter, which would annualize to about 80% or more of our estimated \$30 million annual production capacity. Finished goods produced increased steadily from approximately \$3.3 million to \$4 million and further to \$5.3 million during the first, second and third quarters of 2023, respectively, before dropping modestly to \$5.1 million during the fourth quarter of 2023. The output levels achieved during the months of November and December of 2023 annualize to approximately \$26.8 million, which equates to an average quarterly production of approximately \$6.7 million.

Since February of 2023, we have been pursuing an insurance claim under our business interruption policy to offset a small portion of the losses that we have incurred related to at least three different product contamination events. While our financial losses are far larger, we are seeking a \$750,000 insurance benefit. To date, we have received \$250,000. The balance of this claim is under review by our underwriter. We cannot estimate the likelihood of our success with this claim.

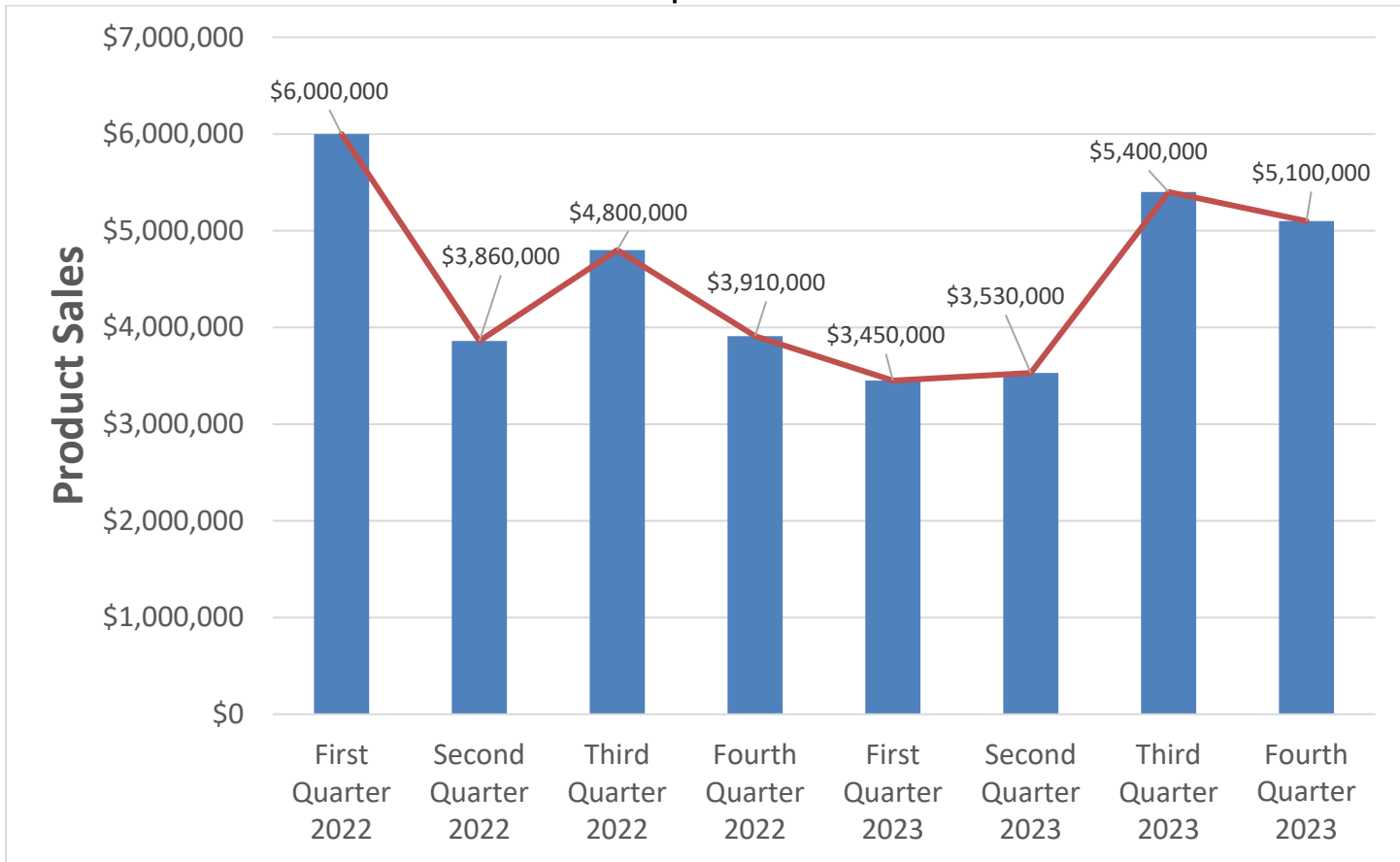
The increase in sales demand for **First Defense**[®] is both exciting and challenging for us. The learnings from the remediation of the contamination events have improved our production processes going forward. We have implemented several important improvements at the source farm level including more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

Product Sales

Our near-term goal is to increase and stabilize supply, regain lost business and re-establish our growth curve. However, the 2023 production shortage caused largely by certain contamination events may prove to be more detrimental to our growth curve than any prior production shortage because it impacted more customers for a longer period of time. Through continued growth in sales of the **First Defense**[®] product line, and the dedication of additional resources to production, sales, marketing and technical services, it is our objective to exceed our total product sales of approximately \$17.5 million and \$18.6 million achieved during the years ended December 31, 2023 and 2022, respectively, as soon as possible. Our longer-term goal is to exceed \$35 million of annual total product sales as soon as possible during the four-year period after the market launch of **Re-Tain**[®]. We do not solely benchmark our sales expectations off trailing twelve-month sales results. Instead, we look at the sales of competitive products to assess the size of the addressable market and plan for growth when projecting our future production capacity needs.

The production slowdown necessary to remediate the contamination events described above resulted in significantly reduced sales during the first ten months of 2023. During this period of short supply when we have been selling product as soon as it is produced, our sales are less impacted by the historically high seasonality during the first quarter of each year. Sales during the three-month period ended March 31, 2023 were \$3.45 million, representing a 12%, or \$464,000, decrease from sales of \$3.9 million during the fourth quarter of 2022. Sales during the three-month period ended June 30, 2023 were \$3.53 million, representing a 2%, or \$86,000, increase over sales during the first quarter of 2023. Sales during the three-month period ended September 30, 2023 were \$5.4 million, representing a 53%, or \$1.9 million, increase over sales during the second quarter of 2023. Sales during the three-month period ended December 31, 2023 were \$5.1 million, representing a 6%, or \$301,000, decrease from sales during the third quarter of 2023. Sales during the second half of the year were stronger as we were able to increase production. Sales during the six-month period ended December 31, 2023 were \$10.5 million, representing a 50%, or \$3.5 million, increase over sales of \$7 million during the six-month period ended June 30, 2023. Quarter to quarter sales over the past two years are displayed in the following table:

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Sales increased by 30%, or \$1.2 million, to \$5.1 million during the three-month period ended December 31, 2023, in comparison to \$3.9 million during the three-month period ended December 31, 2022. Domestic sales during the three-month period ended December 31, 2023 increased by 29%, and international sales increased by 46%, in comparison to the three-month period ended December 31, 2022. International sales aggregated 6% of total sales during both of the three-month periods ended December 31, 2023 and 2022. The quarterly sales results are summarized in the following table (in thousands, except for percentages):

	During the Three-Month Periods Ended December 31,		Increase	
	2023	2022	Amount	%
Total product sales	\$5,096	\$3,911	\$1,185	30%

Our lack of product supply drove a sales decrease of 6%, or \$1.1 million, to \$17.5 million during the year ended December 31, 2023, in comparison to \$18.6 million during the year ended December 31, 2022. Domestic sales during the year ended December 31, 2023 decreased by 6%, and international sales decreased by 2%, in comparison to the year ended December 31, 2022. International sales aggregated 9% and 8% of total sales during the years ended December 31, 2023 and 2022, respectively. The sales results for the annual periods are summarized in the following table (in thousands, except for percentages):

	During the Years Ended December 31,		(Decrease)	
	2023	2022	Amount	%
Total product sales	\$17,472	\$18,568	(\$1,096)	(6%)

Sales of the **First Defense**[®] product line aggregated 99% of our total sales during both of the years ended December 31, 2023 and 2022. Our sales are generally seasonal with highest demand expected during the first quarter of each year. However, as we fulfill our large backlog of orders, we do not expect to see as much of this seasonal demand swing in our product sales. Most of our growth (when not limited by backlog) is being realized through increased demand and a deliberate strategy to prioritize production capacity towards **Tri-Shield First Defense**[®] (the trivalent format of our product delivered via a gel tube), which provides broader protection to calves. The compound annual growth rate (CAGR) of our total product sales was 10.8%, 9.7% and 6.2% during the twelve-year, five-year, and four-year periods ended December 31, 2023, respectively.

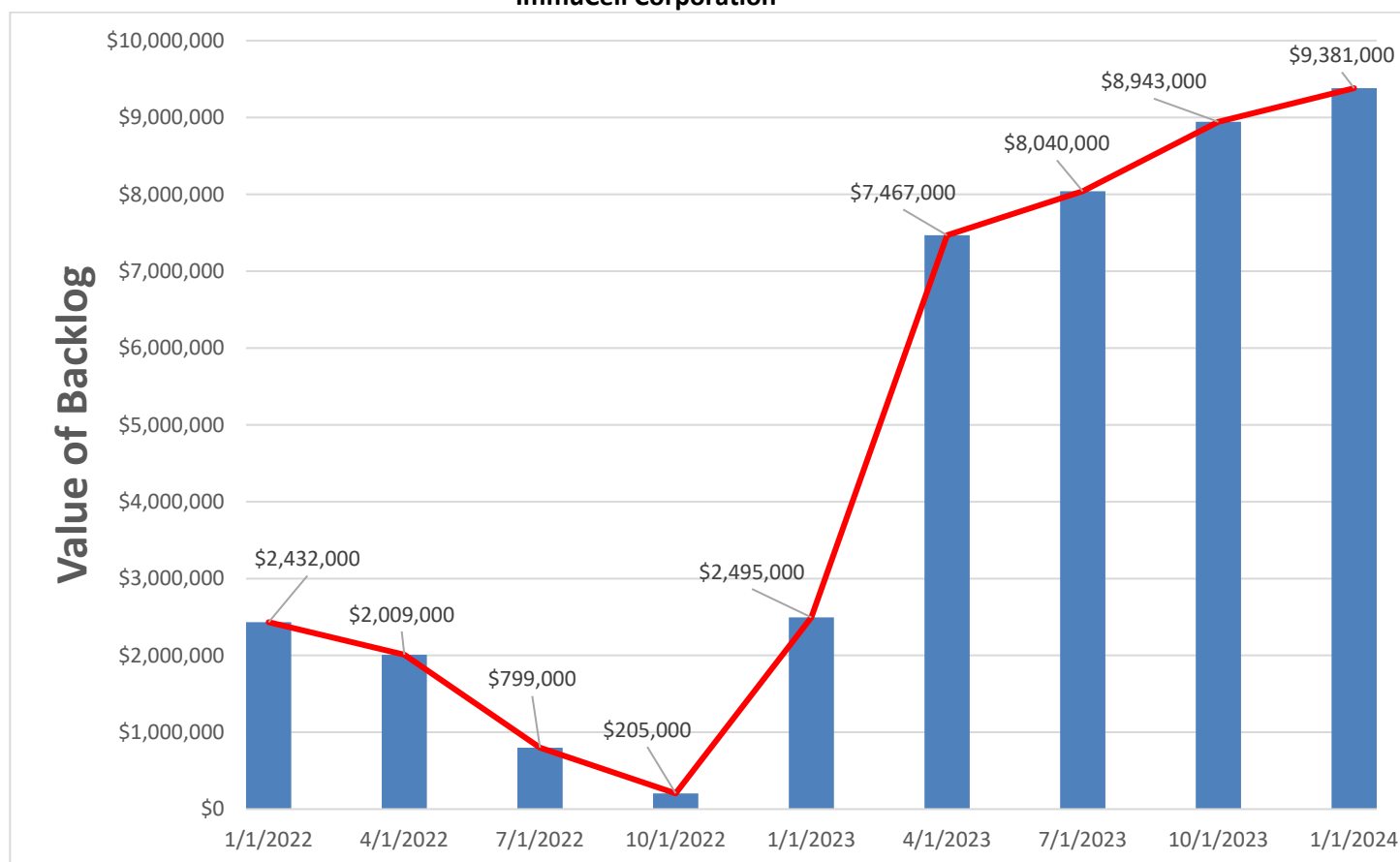
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We likely lost some business during 2022 and 2023 as a result of the backlog. During the first half of 2023, the impact of tight supplies hit even harder leaving our customers without product during their busiest calving season. Our inability to timely meet the needs of our customers could result in the loss of some customers who seek alternative scours management products during this period of short supply and some of these customers may not resume purchasing our product when we have eliminated the backlog. While we worked to allocate product directly to certain large customers during this period of short supply, we likely lost some customers that could not access product. While backlog is a better problem to have than seeing product expiring on our shelves, it is nonetheless a significant challenge when we do not get our customers everything that they want. Our sales team is preparing to resume more normal sales growth initiatives as we expect inventory to become available. We will work to regain end-user customers that we may have lost while we were short on product and will aggressively compete for new business. As we emerge from an extended period of time on backlog, we anticipate higher than normal sales fluctuations quarter to quarter. What is most important to us at this time is that we achieve sales growth over the longer periods of time, even if we experience some quarter-to-quarter fluctuations.

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. Quantification of the backlog during the current periods has become far less comparable to prior periods. At times, customers have placed orders for more than a month's worth of their demand, perhaps in reaction to our ongoing backlog situation, whereas in the past they ordered more closely in line with their current demand. We are reporting this figure because it reflects the orders on our books presently that we cannot ship. We are concerned that this backlog amount may not be highly relevant at this time as it includes very old orders, redundancy in demand and orders that may be cancelled given the time that has passed since they were originally placed. However, when we required all distributors to replace their orders around November 15, 2023 to reflect an 8% price increase, the amount of the backlog, in fact, increased rather than decreased. We believe this reflects strong demand for our product.

The backlog was reduced from approximately \$2.4 million as of December 31, 2021 to approximately \$205,000 as of September 30, 2022. In part because of a first contamination event experienced around the end of the third quarter of 2022, our backlog increased to approximately \$2.5 million as of December 31, 2022. In part because of a second contamination event experienced during the first quarter of 2023, the backlog increased further to approximately \$7.5 million as of March 31, 2023 and increased to approximately \$8 million as of June 30, 2023 and increased to approximately \$8.9 million as of September 30, 2023 and increased to approximately \$9.4 million as of December 31, 2023 (as demonstrated in the table below). As of March 8, 2024, the backlog of orders was approximately \$10.3 million. As sales demand increased while our production output was reduced, the value of our order backlog has fluctuated as demonstrated in the following table:

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We believe that we are on the right track to increase production output, but we still have more work to do to catch up to product demand. We anticipate that we are in good position to move past the contamination events that materially affected our output during late 2022 and through the first ten months of 2023 and are positioned to execute on our plan to resume sales growth in 2024. Finished goods produced increased steadily from approximately \$3.3 million to \$4 million and further to \$5.3 million during the first, second and third quarters of 2023, respectively, but then dropped off slightly to \$5.1 million during the fourth quarter of 2023. Our objective is to produce finished goods with an approximate sales value of \$6 million or more per quarter, as we implement and optimize recent investments to increase its production capacity. Fourth quarter 2023 production was limited by lower output during the month of October, which was caused by a contamination event in September 2023. After remediating this event, we achieved full production during the balance of the quarter. The output levels achieved during the months of November and December 2023 annualize to approximately \$26.8 million, which equates to an average quarterly production of approximately \$6.7 million.

We implemented an average price increase of approximately 8% on the **First Defense**[®] product line effective November 15, 2023. The backlog of orders was worth approximately \$9 million just before this price change. We had some concern that the value of the backlog might decrease materially if customers chose not to replace all orders at the new price given that many of those orders were dated. However, we did not see a decrease in the backlog after the price increase which validated the strength of the order demand.

We acquired a private label product 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**, which is used to detect somatic cell counts in milk. Sales of these products (other than the **First Defense**[®] product line) increased by 53%, or \$19,000, to \$56,000 during the three-month period ended December 31, 2023, in comparison to the three-month period ended December 31, 2022. Sales of these other products aggregated 1% of our total product sales during both of the three-month periods ended December 31, 2023 and 2022. Sales of these products increased by 14%, or \$22,000, to \$178,000 during the year ended December 31, 2023, in comparison to the year ended December 31, 2022. Sales of these other products aggregated 1% of our total product sales during both of the years ended December 31, 2023 and 2022.

Effective January 1, 2022, we increased our selling price of the **First Defense**[®] product line by approximately 5% and **CMT** by approximately 7%. Effective January 1, 2023, we increased our selling price of the **First Defense**[®] product line by approximately 4% (range of 2% to 8%) and **CMT** by approximately 5%. Effective November 15, 2023, we increased our selling price for the **First**

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Defense[®] product line by an average of 8% and for **CMT** by approximately 12%.

Gross Margin

The change in our gross margin (product sales less costs of goods sold) and our gross margin as a percentage of product sales during the three-month periods and years ended December 31, 2023 and 2022 are summarized in the following tables (in thousands, except for percentages):

	During the Three-Month Periods Ended December 31,		Increase (Decrease)	
	2023	2022	Amount	%
Gross margin	\$1,258	\$992	\$266	27%
Percent of product sales	25%	25%	(1%)	(3%)

	During the Years Ended December 31,		(Decrease)	
	2023	2022	Amount	%
Gross margin	\$3,869	\$7,649	(\$3,779)	(49%)
Percent of product sales	22%	41%	(19%)	(46%)

The very significantly reduced gross margin (on both a dollar and percentage of sales basis) during the year ended December 31, 2023 was largely the result of the significant decrease in sales during the first ten months of 2023, which was caused by a reduction in production output, not by a reduction in demand. The reduction in production output was, in turn, the result of our decision to slow down our production rate while remediating the production contamination events, while not yet operating at our anticipated increased production output level. During 2023, we did not benefit from spreading our fixed costs over higher volumes as we normally do. Further, we did not furlough any labor during this production slowdown. The gross margin as a percentage of product sales was 41%, 45%, 45%, 49%, 47% and 50% during the years ended December 31, 2022, 2021, 2020, 2019, 2018 and 2017, respectively. The gross margin during the year ended December 31, 2023 was significantly less than what we have experienced historically and significantly less than what we anticipate going forward. The product contamination events and other production process losses experienced during 2023 and 2022 resulted in scrapped inventory valued at approximately \$527,000 and \$589,000, respectively. Absent these write-offs, our gross margin as a percentage of product sales would have been approximately 25% and 44% during the years ended December 31, 2023 and 2022, respectively. Although these types of losses are expected to happen from time to time in the production of a biological product such as ours, we believe we have mitigated the risk of reoccurrence of such losses through the implementation of certain new quality control steps and manufacturing processes and facility improvements.

The significant global supply-chain disruptions that almost all industries are experiencing presently are a challenge to us. The costs of our supplies, components, raw materials, and services increased significantly during 2021 and that trend continued during 2022 and 2023. Prices for raw materials and critical supplies are increasing significantly, and it is becoming increasingly more difficult to obtain timely delivery of the orders that we place. Therefore, we have little choice but to pay the higher prices and try to take on more months of supply than we would have held previously if we could get our orders fulfilled timely.

While our biological and process yields can be variable, we have seen a favorable improvement to our finished goods yield recently, but these yields continue to be variable. The **Tri-Shield**[®] product format is more complex (i.e., three antibodies versus two antibodies for **Dual-Force**[®]) making it more costly to produce, and both the bivalent and trivalent gel product formats are more expensive to produce than the bolus format. These new formats are creating sales growth for us, and we are focused on increasing total gross margin dollars, even if that is accomplished with a lower gross margin as a percentage of sales. A number of other factors contribute to the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter and from year to year. We also invest to sustain compliance with current Good Manufacturing Practices (cGMP) in our production processes. Increasing production can be more expensive in the initial stages. To achieve our inventory production growth objectives, we continue to acquire more raw material (colostrum) from many more cows at several new farms. During this expansion phase, colostrum quality can be more variable. Additionally, the biological yields from our raw material are always variable, which impacts our costs of goods sold in a similar way. Just as our customers' cows respond differently to commercial dam-level vaccines, depending on the time of year and immune competency, our source cows have similar biological variances in response to our proprietary vaccines. As is the case with any vaccine program, animals respond less effectively to their first exposure to a new vaccine, and thereafter the effectiveness of their immune response improves in response to subsequent immunizations. While this variability impacts our costs of producing inventory, the commercial value of our **First Defense**[®] product line is that we compensate for the variability in a cow's immune response by standardizing each dose of finished product. This ensures that every calf is equally protected, which is something that dam-level commercial scours vaccines cannot offer. We continue to work on processing and yield improvements and other opportunities to reduce costs, while enhancing process knowledge and robustness. Over time, we have been able to reduce the impact

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of cost increases by implementing yield improvements. We believe that gross margin results going forward should be viewed over longer periods of time than just one quarter. As we fully integrate and utilize our increased capacity and evaluate our product costs and selling price, one of our goals is to achieve a gross margin (before related depreciation and amortization expenses) as a percentage of total sales approaching 48%.

Product Development Expenses and Strategy

Overview: The majority of our product development expenses pertain to the development of **Re-Tain**[®]. During the year ended December 31, 2023, product development expenses decreased by 2%, or \$99,000, to \$4.4 million in comparison to \$4.5 million during the year ended December 31, 2022. Product development expenses aggregated 25% and 24% of product sales during the years ended December 31, 2023 and 2022, respectively. Product development expenses included non-cash depreciation and stock-based compensation expenses of \$1.5 million and \$1.4 million during the years ended December 31, 2023 and 2022, respectively. Approximately \$1.3 million of these non-cash expenses were comprised of depreciation expenses pertaining to our DS facility for **Re-Tain**[®] during both of the years ended December 31, 2023 and 2022. We began depreciating this asset when the Certificate of Occupancy for the new construction was issued during the fourth quarter of 2017, but sales of our new product cannot be realized until we achieve FDA approval. We expect our product development expenses to decrease modestly during 2024 as we produce less product for commercial launch and somewhat further after **Re-Tain**[®] is commercialized and some of the costs incurred to maintain and run our DS production facility become part of our costs of goods sold.

Development objective: As we work to change the way that mastitis is managed in the dairy industry, we aim to demonstrate that our bacteriocin, Nisin A, which is designed specifically for subclinical mastitis, can provide producers the freedom to change when and how mastitis is treated. **Re-Tain**[®] is not a broad-spectrum antibiotic used in human health. Rather, it consists of a highly targeted active ingredient without an FDA-required milk discard or meat withhold. While milk prices vary, the cost of the milk discard associated with traditional antibiotics ranges from approximately \$36.00 (for 3.5 days of milk at 60 pounds per day at the Class III milk price average of \$17.02 per hundredweight during 2023) to approximately \$150.00 (for 11 days of milk at 80 pounds per day at the Class III milk price average of \$17.02 per hundredweight during 2023) per treated animal. These high milk discard costs associated with traditional antibiotic treatments lead producers to only treat mastitis after clinical signs develop. We expect that **Re-Tain**[®] will be a first-of-its-kind product that can be used to economically treat at the earliest stage of infection, giving producers the ability to get ahead of mastitis before clinical signs develop so the best cows stay at their best performance level and in the herd longer. The final and most critical development objective for **Re-Tain**[®] is to achieve regulatory approval of our manufacturing operations.

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

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

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

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

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

4) **Human Food Safety:** During the third quarter of 2018, we received the Human Food Safety Technical Section Complete

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

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

Under the FDA's phased submission process, we made a first-phased submission covering just the DS during the first quarter of 2019. The first-phased DS submission included data from the DS Registration Batches produced at commercial scale in our new DS manufacturing facility. This first-phased submission was followed by a second-phased submission covering both DS and DP, during the first quarter of 2021. The second-phased DS and DP submission responded to comments raised by the FDA regarding the first-phased DS submission and included detailed information about the manufacturing process and controls for DP. One of the key components of the second-phased DS and DP submission was also demonstrating stability of the product through expiry. During the third quarter of 2021, the FDA issued a Technical Section Incomplete Letter with regard to this second-phased DS and DP submission. This response was not unexpected as it is common for the FDA to issue queries and comments, especially related to an aseptic DP submission. We made a second submission of the DS and DP Technical Section during the first quarter of 2022. During the third quarter of 2022, we received a Technical Section Incomplete Letter from the FDA with regards to this second DS and DP submission of the CMC Technical Section. The submission required that internal and external laboratories re-develop and qualify several analytical tests and associated controls. We made this third DS and DP submission of the CMC Technical Section during the third quarter of 2023. In late October of 2023, the FDA notified us that it was refusing to review our submission because Norbrook was identified as the DP manufacturer in our submission, but the FDA was expecting that we would identify our own in-house services as the DP manufacturer (instead of Norbrook). This miscommunication was due to a statement in our April 2022 response to an FDA 483 inspectional observation in which we noted that Norbrook was expected to exit the DP manufacturing agreement with us at the end of 2022, which would have required us to procure and install some long lead time equipment (filler and labeler) in our DS suite in late 2022. Instead, we were able to extend the agreement with Norbrook to complete the manufacture of DP inventory for the initial commercial sales under our Controlled Launch strategy. As a result, we continued to identify Norbrook as our DP manufacturer. In fact, Norbrook has recently initiated production of the launch goods, and this work has been extended into 2024 with labeling and final packaging occurring post-approval. As a result of this miscommunication, we were required to re-submit the CMC Technical Section. If the FDA issues a Technical Section Complete Letter in response to this re-submission, we believe that we could commence commercial sales approximately ten months from the November of 2023 re-submission date, allowing for the re-setting of the six-month CMC review period by the FDA followed by a two-month administrative review period and approximately two additional months for labeling, packaging and shipping.

While being prudent with how much cash we invest into inventory that would have short expiry dating if market launch is delayed, we have built and are building more DS inventory during 2022 and 2023 to support the initial commercial sales of **Re-Tain**[®].

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As discussed above, our contract manufacturer has agreed to convert this DS to DP during the fourth quarter of 2023 and into 2024 with associated product expirations of 18 to 24 months from the date of manufacture. We anticipate a pause in the supply of product to market after the initial launch goods are sold and before the product is re-launched with DP produced by our in-house aseptic filling operations (if that investment is re-funded) or by an alternative contractor that we have not identified to date.

Our DS manufacturing facility and that of our DP contract manufacturer (and our potential future DP manufacturing facility) are subject to ongoing FDA inspections. During the third quarter of 2019, the FDA conducted a pre-approval inspection of our DS facility. This resulted in the issuance of certain deficiencies as identified on the FDA's Form 483. We submitted responses and data summaries in a phased manner over the fourth quarter of 2019 and first quarter of 2020. During the first quarter of 2022, the FDA conducted another pre-approval inspection of our DS facility. This also resulted in the issuance of certain deficiencies as identified on the FDA's Form 483. We have responded to all of the queries. Early during the first quarter of 2024, the FDA conducted another pre-approval inspection of our DS facility. This resulted in the issuance of one deficiency as identified on the FDA's Form 483. Since then, we have fully responded to this inspectional observation. The facility of our DP contract manufacturer is subject to similar inspectional compliance obligations.

We have always believed that the fastest route to FDA approval and market launch is with the services of Norbrook (an FDA-approved DP manufacturer), reducing our risk by benefiting from their demonstrated expertise in aseptic filling. From 2010 to the present, we have worked with Norbrook under several amended contract manufacturing agreements covering the DP formulation, aseptic filling and final packaging services. Under our current agreement, Norbrook will provide DP for the Controlled Launch with production in the fourth quarter of 2023 and into 2024. We believe this will enable us to commence sales of **Re-Tain**[®] without delay upon receipt of the anticipated FDA approval.

Our potential alternative third-party options for the formulation and aseptic filling services that are presently being performed by Norbrook are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). During the first quarter of 2022, we initiated an investment in the installation of equipment to produce DP at our own facility at 33 Caddie Lane. Given the loss in gross margin during the first ten months of 2023 caused by the slowdown in production output that was necessary to remediate the production contamination events, we have decided to defer the completion of this investment for the time being. Subject to the timing of our installation and validation work, we anticipate FDA approval of this facility (which is a requirement for commercial manufacturing) at least two years from when this project is restarted allowing for two six-month review cycles. This will be a post-approval submission. If we decide to complete our potential future DP manufacturing facility, such facility will, upon completion, be subject to FDA inspection and approval. We anticipate it would have enough formulation and aseptic filling capacity to exceed the expected production capacity of our DS facility, which is approximately \$7 million to \$10 million in annual sales. This production capacity estimate is based on our assumptions as to product pricing and does not yet reflect inventory build strategies in advance of product approval or ongoing yield improvement initiatives. Establishing our own DP formulation and aseptic filling capability 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, if completed, will be located in existing facility space that we had intended to utilize to double our DS production capacity if warranted by sales volumes following market launch. As a result, if we decide to complete this DP facility (rather than utilizing a third party for these services), we would need to explore alternative strategies (in parallel with ongoing DS yield improvement initiatives) to expand our DS production capacity. This integrated manufacturing capability for **Re-Tain**[®] would substantially reduce our dependence on third parties. Upon completion of our formulation and aseptic filling facility, the only significant third-party input for **Re-Tain**[®] would be the DP syringes. It is anticipated that Hubert De Backer of Belgium (HDB) will supply these syringes in accordance with purchase orders that we submit. HDB is a syringe supplier for many of the largest participants in the human and veterinary medical industries, and with whom Norbrook presently works. Based on HDB's performance history and reputation in the industry, we are confident that HDB will be a dependable supplier of syringes in the quantity and of the quality needed for **Re-Tain**[®].

Other product development initiatives: Our second most important product development initiative has been focused on other improvements, line extensions or additions to our **First Defense**[®] product line. 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 Expenses and Selling Strategy

We see ourselves as the “non-pharma” pharma company. Rather than offering variations of “copy-cat” technology like vaccines and antibiotics, we have taken the path less traveled by developing first-of-their kind products fueled by novel active ingredients such as polyclonal antibodies (for **First Defense**[®]) and bacteriocins (for **Re-Tain**[®]). While we expect that **Re-Tain**[®] could be a significant

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market disrupter, we project the **First Defense**[®] market could be larger, especially during the first years of the commercial launch of **Re-Tain**[®]. We anticipate that these category developing innovations will drive greater value for the livestock industry and, in turn, for our stockholders.

During the year ended December 31, 2023, sales and marketing expenses decreased by 3%, or \$102,000, to \$3.1 million in comparison to \$3.2 million during the year ended December 31, 2022, amounting to 18% and 17% of product sales during the years ended December 31, 2023 and 2022, respectively. Sales and marketing expenses included non-cash depreciation and stock-based compensation expenses of \$182,000 and \$158,000 during the years ended December 31, 2023 and 2022, respectively. Our budgetary guideline for 2023 and after is to keep these expenses under 20% of total sales. By decreasing sales and marketing expenses by \$321,000 during the fourth quarter of 2023 in comparison to the fourth quarter of 2022, we were able to reduce sales and marketing expenses by \$102,000 for the year ended December 31, 2023. We continue to leverage the efforts of our small sales force by using animal health distributors.

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

During the twelve-month period ended December 31, 2023, we treated more calves than our next largest calf-level competitive product, which is a vaccine administered to the newborn at birth. Compared to the dam-level competitive products (which are vaccines given to the cow pre-calving), we are second in sales dollars to the market leader. Despite these successes, there remains significant opportunity to displace more competition within North America. There is also opportunity to grow our sales by expanding into international markets. We are being strategic in how we invest in international market development in order not to divert our limited resources away from achieving domestic growth, which is often more efficient to obtain.

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

Re-Tain[®] could increase the lifetime profitability of a cow and reduce disease transfer to herd mates. It is common practice to move sick cows from their regular herd group to a sick cow group for treatment and the related milk discard. This movement causes stress on the cow and a reduction in milk production. While practices may vary farm-to-farm, there would be no requirement to move cows treated with our product, allowing this costly drop in production to be avoided. It is generally current practice to treat mastitis only when the disease has progressed to the clinical stage where the milk from an infected cow cannot be sold, leaving most subclinically infected cows untreated. Without a milk discard cost, we expect producers to be more motivated to identify and treat cows at the subclinical stage. This creates a substantial animal welfare benefit. By treating mastitis early at the subclinical level, producers could preserve optimal milk yields. We also know that animals infected with subclinical mastitis have higher abortion rates and often progress to the clinical disease state requiring antibiotic treatment and milk discard. We believe that societal animal welfare objectives will put more and more pressure on the industry to treat cows with subclinical infections.

The over-use of antibiotics that are medically important to human healthcare is a growing public health concern of our society and an active issue with the FDA, largely because of the growing evidence that this over-use contributes to antibiotic resistance and the rise of "super-bugs". Sustainability objectives require that less antibiotics be used in food producing animals, yet a new FDA-approved drug to treat mastitis has not been developed in years. Our product improves sustainability by utilizing a bacteriocin as an alternative to traditional antibiotics that are used in human medicine. In the big picture, we are introducing an entirely new class of antimicrobial as an animal drug, a bacteriocin, that does not promote resistance against antibiotics used in human medicine making it

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more socially responsible. The industry could keep treating this very significant disease with traditional antibiotics, but it takes innovation to bring a bacteriocin like Nisin to market. **Re-Tain**[®] would, when introduced, offer a needed alternative to these traditional antibiotics, while at the same time improving milk quality and the quantity of milk produced by treated cows. We believe our product fits very well with where the industry is going to be in the coming years.

As with all new products, the market determines the value. Our objective is to gain market acceptance of this new product concept as we develop a new product category. Despite our product's exciting benefits, it will take time to change this longstanding treatment paradigm and develop this new market. It will take time for the market to understand, evaluate, implement and adapt to the use and benefits of **Re-Tain**[®]. Based on consultations with industry experts and key opinion leaders, we have opted to carefully control the launch of this novel product over the first 18 to 24 months after FDA approval, as we seek to transform the way that mastitis is treated in the dairy industry over the long term. Our goal is to help early adopters select treatment candidates, develop easy to use protocols, optimize treatment results and realize a positive return on their investment. We intend to limit initial distribution of **Re-Tain**[®] to a level that enables our sales team to select the optimal dairy farms at which to introduce **Re-Tain**[®] and to limit the initial number of participating farms so that the desired levels of support and guidance relating to effective usage of **Re-Tain**[®] can be provided with our available resources. We recognize that it will be important to manage expectations from the producer to the milk processor because it is possible that processors may express reservations with regards to the zero milk discard claim. Our Controlled Launch strategy reduces the amount of inventory that we would need to build at risk before regulatory approval is achieved. This strategic choice means that we have elected not to pursue an alternative strategy that might have maximized short-term, initial sales quickly through a mass market approach where we provide product to distribution and let them sell it to as many farms as possible. While we are dedicated to increasing our sales revenue, we must consider the damage a mass market strategy could cause to the long-term value of the product. We have seen products sold by much larger companies that were substantially damaged by such failed market launch strategies. We continue to develop detailed launch plans, focusing on the readiness of dairy operators to successfully introduce **Re-Tain**[®] to their herds. We believe that these prudent steps, while potentially leading to lower initial **Re-Tain**[®] revenues, may create a smooth and successful launch and could safeguard the longer term performance of our investment in **Re-Tain**[®]. We also believe that the operational adjustments and accommodations that dairy farmers will need to make to effectively use **Re-Tain**[®] and avoid the potential problems described under **PART I: ITEM 1A – RISK FACTORS**, to this Annual 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**[®].

Administrative Expenses

During the year ended December 31, 2023, administrative expenses decreased by 6%, or \$130,000, to \$2.1 million in comparison to \$2.3 million during the year ended December 31, 2022. Administrative expenses included the accrual of \$222,000 in deferred compensation expense (consisting of earned and unused paid time off) during the first quarter of 2022. This accrual was increased by \$8,000 during 2023 reflecting current wage rates. Administrative expenses amounted to 12% of product sales during both of the years ended December 31, 2023 and 2022. Administrative expenses included non-cash depreciation and stock-based compensation expenses of \$210,000 and \$148,000 during the years ended December 31, 2023 and 2022, respectively. We strive to be efficient with these expenses while funding all the legal, audit and other costs associated with being a publicly-held company. Given the growth in our business, our administrative staff has increased to four employees reporting to our CEO. Prior to 2014, we had limited our investment in investor relations spending. Beginning in the second quarter of 2014, we initiated an investment in a more active investor relations program. Given travel restrictions related to the COVID-19 pandemic, this initiative has pivoted to a virtual meeting format, which is less expensive. Having experienced this efficiency, it is our intent to continue with the same strategy, for the most part, even as travel restrictions have been largely eliminated. At the same time, we continue to provide full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as in Current Reports on Form 8-K when legally required or deemed appropriate by management. We believe these efforts have helped us access the capital markets to fund our growth objectives. Considering inflation and all the necessary support services that fit into this category, we believe that approximately \$2 million to \$2.5 million per year is an efficient budget goal to fund the administrative expenses of a publicly-held company.

Net Operating Loss

During the year ended December 31, 2023, our net operating loss of \$5.7 million was significantly larger than our net operating loss of \$2.3 million during the year ended December 31, 2022. The \$3.4 million increase in our net operating loss during the year ended December 31, 2023 was caused by the \$3.8 million decrease in gross margin, offset, in part, by a \$330,000 reduction in operating expenses.

Other Expenses, net

During the year ended December 31, 2023, other expenses, net, aggregated \$22,000 in comparison to other expenses, net, of \$187,000 during the year ended December 31, 2022. During the year ended December 31, 2023, other income included insurance

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recovery income of \$365,000 paid under our business interruption policy related to the product contamination losses previously described and a recovery from a vendor's insurance policy related to an equipment malfunction that were received during the third quarter of 2023. No such insurance recoveries were received during 2022. Interest expense increased to \$476,000 during the year ended December 31, 2023 from \$349,000 during the year ended December 31, 2022. Non-cash amortization of debt issuance and debt discount costs (which is included as a component of interest expense) was \$23,000 and \$8,000 during the years ended December 31, 2023 and 2022, respectively. We anticipate that our interest expense will be \$563,000 and \$492,000 during the years ending December 31, 2024 and 2025, respectively. Interest income was \$97,000 and \$153,000 during the years ended December 31, 2023 and 2022, respectively. The loss (gain) on disposal of property, plant and equipment was \$8,000 and (\$7,000) during the years ended December 31, 2023 and 2022, respectively.

Loss Before Income Taxes

During the year ended December 31, 2023, our loss before income taxes was \$5.8 million in comparison to our loss before income taxes of \$2.5 million during the year ended December 31, 2022.

Income Taxes and Net Loss

During the years ended December 31, 2023 and 2022, we recorded income tax expense of \$5,000 and \$8,000, respectively, which is comprised of minimum state tax liabilities. Our net loss of \$5.8 million, or \$0.75 per basic share, during the year ended December 31, 2023 was in comparison to net loss of \$2.5 million, or \$0.32 per basic share, during the year ended December 31, 2022.

We have substantial net operating loss carryforwards that largely offset future income tax expense. As of December 31, 2023, our federal net operating loss carryforward was \$17.8 million. As of December 31, 2023, our state net operating loss carryforward was \$4.7 million. On December 22, 2017, the Tax Cuts and Jobs Act was signed into law. This legislation made significant changes in the U.S. tax laws, including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from 34% to 21%. Our income tax rate differs from this statutory tax rate primarily because we are currently providing for a full valuation allowance against our deferred tax assets. While we are recording this full valuation allowance, we are not recognizing the benefit of our tax losses.

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

Critical Accounting Policies and Estimates

The audited 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 December 31, 2023 have been taken into consideration in preparing the financial statements. The preparation of financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates. Significant estimates include our valuation of inventory, long-lived assets, deferred tax assets and costs of goods sold. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have chosen to highlight certain policies that we consider critical to the operations of our business and understanding of our financial statements. These critical accounting estimates have been consistently applied.

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

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

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ITEM 7A— QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

None

ITEM 8— FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements, together with the notes thereto and the reports of the independent registered public accounting firms thereon, are set forth on Pages F-1 through F-26 at the end of this Annual Report. The index to these financial statements is as follows:

Report of Wipfli LLP, Independent Registered Public Accounting Firm (PCAOB ID#344)	F-1 to F-2
Balance Sheets as of December 31, 2023 and 2022	F-3
Statements of Operations during the years ended December 31, 2023 and 2022	F-4
Statements of Stockholders' Equity during the years ended December 31, 2022 and 2023	F-5
Statements of Cash Flows during the years ended December 31, 2023 and 2022	F-6 to F-7
Notes to Audited Financial Statements	F-8 to F-26

ITEM 9— CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

ITEM 9A— 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 defined in Exchange Act Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of December 31, 2023. 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 Annual Report on Internal Control Over Financial Reporting: The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Our 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. This Annual Report does not include an attestation report from our 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 our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report.

Material Weaknesses in Internal Controls Over Financial Reporting: Management assesses the effectiveness of the Company's internal control over financial reporting at the end of each quarter. During our assessment for the second quarter of 2023, we identified one material weakness where we did not properly capitalize non-cash depreciation expense as a component of inventory, which would have understated the value of our inventory as of June 30, 2023 by approximately \$387,000 if the error had not been detected before we issued our Quarterly Report on Form 10-Q. This error had no impact on our product sales or cash position. We do believe that the design of our internal controls is effective, but those internal controls were not effectively operating. We have implemented some changes to our internal controls over financial reporting, including seeking additional consulting with subject matter experts on this matter. We remediated this material weakness in internal controls during the third quarter of 2023. Based on our assessment for the fourth quarter of 2023, we have concluded that our internal controls over financial reporting were effective as of December 31, 2023.

Changes in Internal Controls over Financial Reporting: Our principal executive and principal financial officer and our Director of Finance and Administration periodically evaluate any change in internal control over financial reporting which has occurred during

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the prior fiscal quarter. With the exception of the improvements to our internal controls described in the previous paragraph, we have concluded that there was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B — OTHER INFORMATION

None

ITEM 9C — DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable

PART III

ITEM 10 — DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

LEADERSHIP STRUCTURE OF THE BOARD OF DIRECTORS

With approval from the Board of Directors, the Compensation and Stock Option Committee determined that the title of President and CEO should be given to an individual not being the same person holding the title of Chair. The objective of this policy is to avoid a concentration of authority in any one person. Mr. Michael F. Brigham has served as President and CEO since February 2000. He also serves as the Company's Principal Financial Officer. Mr. Brigham is responsible for the day-to-day operations of the Company and for managing the actions of the two other executive officers, as well as those of several senior managers. Since February 2013, Dr. David S. Tomsche has served as Chair of the Board of Directors, leading the Company as its independent non-executive board chair. Dr. Tomsche works with the CEO in preparing the agenda for each board meeting and presides over all board meetings and meetings of the non-employee directors. He provides advice to the CEO and serves as principal liaison between the board and the CEO. Ms. Bobbi Jo Brockmann has served as Vice President of Sales and Marketing since February 2015. Ms. Elizabeth L. Williams has served as Vice President of Manufacturing Operations since April 2016. Dr. Joseph H. Crabb served as Vice President and Chief Scientific Officer from December 1998 to February 2022, and he also served as Chair of the Board of Directors from June 2009 to February 2013. It is the policy of the Board of Directors to have a portion of the meeting without the presence of the executive officers each time that the board or any of its committees meets to assure that candid discussions of business matters are conducted with and without the influence of the executive officers. The board delegates certain authority and responsibility to its committees, as described below.

THE BOARD OF DIRECTORS AND ITS COMMITTEES

During the year ended December 31, 2023, the Board of Directors of the Company held four regular meetings and two special meetings and took action by unanimous written consent four times. The committees of the Board of Directors are the Audit Committee, the Compensation and Stock Option Committee and the Nominating Committee. During the year ended December 31, 2023, each director attended at least 75 percent of the aggregate of (i) the total number of meetings of the Board of Directors and (ii) the total number of meetings held by all committees of the board on which he or she served (during the periods that he or she served). The board has not set a formal policy for required meeting attendance. A high level of attendance and participation is expected, and to date directors have fulfilled this expectation. At the first meeting of the board following this year's Annual Meeting, executive officers will be appointed and, effective upon the election of directors at this year's Annual Meeting, directors will be appointed to serve on the various board committees until the next Annual Meeting and until their successors are elected.

The Board of Directors has established an Audit Committee for the purpose of overseeing the accounting and financial reporting processes of the Company and the audits and reviews of its financial statements. The Audit Committee engages the Company's Independent Registered Public Accounting Firm, consults with such auditors with regard to audit plans, reviews the annual reports of the independent auditors, oversees the adequacy of the Company's internal operating procedures and controls, meets with management and the auditors to review quarterly and annual financial results, authorizes the public release of press releases covering financial results, reviews and authorizes quarterly and annual reports filed with the SEC and otherwise oversees compliance with certain legal, ethical and regulatory matters. The development and manufacture of efficacious products with and without regulatory approval is subject to considerable risk. The Audit Committee takes the lead on oversight of credit, liquidity and operational risk, but the entire board, in conjunction with the executive officers, is very involved with reviewing Audit Committee recommendations and making independent assessments of risks in all areas of the Company's business. The Company does not have a specific risk management department, but the Company's Director of Finance and Administration and its President and CEO manage and contract for the Company's insurance coverages in consultation with outside experts, in addition to identifying, managing and monitoring risk in areas not specifically covered by insurance. The Director of Finance and Administration reports to the President and

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CEO, who reports to the board. The Audit Committee's current members are Mr. Gathagan, Mr. Rosgen, Dr. Tomsche and Mr. Wainman. Mr. Wainman serves as Chair of the Audit Committee. All members of the Audit Committee meet the heightened independence and expertise requirements for audit committees under applicable SEC and NASDAQ Stock Market rules. The Audit Committee held eight meetings during the year ended December 31, 2023. The Audit Committee Report can be found later in this Annual Report, and the "Charter and Powers of the Audit Committee" has been posted on the Company's website (<http://immucell.com/wp-content/uploads/2017/05/charter.pdf>). Information on the Company's website does not constitute part of this Annual Report.

Mr. Paul R. Wainman, who joined our Board of Directors in March of 2014 and currently serves as Chair of the Audit Committee, and Mr. Bryan K. Gathagan, who joined our Board of Directors in June of 2023, both meet the criteria for "audit committee financial expert" as defined by SEC rules. It is the opinion of the Company's Board of Directors that the Company addresses its audit functions with a depth of penetration and rigor that meets the intent of the requirements of the Sarbanes-Oxley Act for the following reasons:

- All four members of the Audit Committee are independent directors, as defined by the SEC and NASDAQ.
- The four members of the Audit Committee have knowledge of accounting for both their own businesses as well as for the Company.
- Internal audit work of the Company is performed by its Director of Finance and Administration, two Finance and Administrative Associates and one Manager of Administrative Operations.
- The Company also continuously reviews, at its own initiative, the expertise of the members of its Board of Directors and its Audit Committee.

The Board of Directors has established a Compensation and Stock Option Committee (Compensation Committee) for the purpose of reviewing and recommending salary, bonus and other benefits for executive officers and directors of the Company. The Compensation Committee is responsible for administering the Company's 2010 Stock Option and Incentive Plan and the 2017 Stock Option and Incentive Plan. The Compensation Committee's current members are Ms. Basse and Mr. Rosgen, each of whom are independent directors. Mr. Rosgen serves as Chair of the Compensation Committee. The Compensation Committee held six meetings during the year ended December 31, 2023. The Compensation Committee does not have a charter but instead operates within the authority provided by the Company's By-laws and authorizing resolutions adopted by the board. Its recommendations on executive and director compensation are subject to review and final approval by the Board of Directors, a majority of whose members are independent directors. The Compensation Committee considers recommendations from Mr. Brigham, the Company's President and CEO, relevant to a determination of executive and director compensation, but neither he nor Ms. Brockmann participates in votes of the Compensation Committee or the board in this regard. In recent years, the Compensation Committee has not retained or relied upon outside consultants to assist in its determination of executive or director compensation but does consider available compensation data. During the end of 2021 and beginning of 2022, the Compensation Committee did consider certain information provided by a consultant.

The Board of Directors has established a Nominating Committee for the purpose of recommending to the full board the number of directors to serve on the board, criteria for board membership and nominees for election to the board. In doing so, the Nominating Committee considers the integrity and relevant business experience of each nominee. The Nominating Committee values diversity, believing that the Company benefits from decision making that includes a range of opinions, points of view and experience. For instance, the Nominating Committee would not want a board comprised only of directors having principally financial expertise or only of directors whose principal experience is in the dairy and beef industries. Likewise, the Nominating Committee believes that a board consisting of all men or all women would not be as strong as a gender-diverse board. While there is always room for improvement, the Nominating Committee believes that it has made substantial progress towards achieving these board diversity goals. To be considered for nomination to the board, a candidate must meet the following minimum criteria: 1) reputation for integrity and high ethical standards, 2) willingness and ability to contribute positively to the Company's decision-making process, 3) absence of any conflict of interest, or appearance of conflict of interest and 4) commitment to understanding the Company's business and associated business risks and to devoting adequate time and effort to create value for the Company and its stockholders. All director nominees are recommended by the Nominating Committee and then approved by a vote of the board. The Committee's current members are Ms. Basse and Mr. Wainman, each of whom are independent directors. Ms. Basse serves as Chair of the Nominating Committee. The Nominating Committee held three meetings during the year ended December 31, 2023. Upon recommendation of the Nominating Committee, the Board of Directors adopted a charter for the Nominating Committee in December 2012. This charter sets forth the policy to be utilized by the Nominating Committee in considering nominees identified by management to serve as directors for the Company. The Charter of the Nominating Committee has been posted to the Company's website (<http://immucell.com/wp->

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content/uploads/2019/04/Nominating-Committee-Charter.pdf). The Nominating Committee applies the same evaluation standards in considering nominees for director recommended by stockholders.

BOARD OF DIRECTORS

GLORIA J. BASSE

Age: 63
Director since: June 2020

Ms. Basse was first elected to our Board of Directors at the 2020 Annual Meeting of Stockholders. Ms. Basse has been the senior executive director of Tonisity International, an animal nutrition company with offices in Ireland, Brazil and the United States, from 2017 to the present. Since 2016, Ms. Basse has been a Senior Associate at the Context Network, a business management and strategy consulting firm providing services to agriculture, biotechnology and food companies. She held various positions at Zoetis Inc. (formerly Pfizer Animal Health) from 1985 to 2015 and most recently served as Vice President of its U.S. pork business. Ms. Basse is a graduate of the University of Wisconsin and earned her Masters in Business Administration from the University of Rochester.

MICHAEL F. BRIGHAM

Age: 63
Officer since: October 1991
Director since: March 1999

Mr. Brigham was appointed to serve as President and Chief Executive Officer in February 2000, while maintaining the titles of Treasurer and Secretary, and was appointed to serve as a Director of the Company in March 1999. He previously had been elected Vice President of the Company in December 1998 and had served as Chief Financial Officer since October 1991. He has served as Secretary since December 1995 and as Treasurer since October 1991. Prior to that, he served as Director of Finance and Administration since originally joining the Company in September 1989. Mr. Brigham served as a member of the Board of Directors of the United Way of York County from 2012 to 2019, serving as its Treasurer until June 2016 and as Chair of the Board of Directors for one year and as a member of its Executive Committee. Mr. Brigham served as the Treasurer of the Board of Trustees of the Kennebunk Free Library from 2005 to 2011. He re-joined the Finance Committee of the library in 2012. Prior to joining the Company, he was employed as an audit manager for the public accounting firm of Ernst & Young in New York City. Mr. Brigham earned his Masters in Business Administration from New York University in 1989 and a Bachelor of Arts degree (with a double major in Economics and Spanish) from Trinity College in Hartford, Connecticut in 1983.

BOBBI JO BROCKMANN

Age: 48
Officer since: February 2015
Director since: March 2017

Ms. Brockmann served as a Director of the Company from March 2017 to September 2017 and from January 2018 to the present. She was promoted to Vice President of Sales and Marketing in February 2015. She joined the Company as Director of Sales and Marketing in January 2010. Prior to that, she had been employed as Director of Sales since May 2008 and Sales Manager from February 2004 to April 2008 at APC, Inc. of Ankeny, Iowa, a developer and marketer of functional protein products for animal health and nutrition. Prior to that, she held other sales and marketing positions at APC, W & G Marketing Company, Inc. of Ames, Iowa, The Council for Agricultural Science and Technology of Ames, Iowa and Meyocks Group Advertising of West Des Moines, Iowa after graduating from Iowa State University.

BRYAN K. GATHAGAN

Age: 56
Director since: June 2023

Mr. Gathagan is the owner and a managing member of broad Thinking, LLC, a management consulting firm and has 25 years of animal health experience. He is a founding member of Animalytix LLC and has served as its Chief Financial and Chief Technology Officer since it began operations in 2010. Prior to Animalytix, he was a senior executive and Vice President of IT and Finance for Intervet, Inc. and oversaw various finance, IT, and general business functions between 1998 to 2008, including 3 years in a global role based in The Netherlands. Before entering the animal health industry, he served as a Vice President at MBNA and Norwest Bank responsible for various IT functions and started his career in IT roles at the University of Maryland, Baltimore County (UMBC). He holds a BS in Information Systems Management from UMBC and an MS in Business from Johns Hopkins University.

STEVEN T. ROSGEN

Age: 58
Director since: January 2018

Mr. Rosgen joined the Board of Directors in January 2018 and the Audit Committee of the Board of Directors effective April 1, 2018. He is President of Strategem Research Inc., founded in 2005. Strategem's mission is to capture and leverage customer insights when launching new technologies and revitalizing brands that have struggled in the market. Mr.

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Rosgen specializes in value proposition development and pricing strategy. He has worked with global brands across a range of industries including multiple agricultural sectors (ag informatics, animal health, biotechnology, crop protection, fertilizer, equipment, finance, grain marketing, livestock production, retail and seed technology). Before founding Strategem, Mr. Rosgen was a senior partner with Street Smart Strategic Planning and Research Coordinator for Baker Lovick/BBDO Advertising. He holds a Bachelor of Commerce Degree from the University of Calgary.

DAVID S. TOMSCHE, D.V.M.

Age: 67

Director since: December 2006

Dr. Tomsche was appointed to serve as Chair of the Board of Directors in February 2013. He served on the Nominating Committee of the Board of Directors until September 2017. He served on the Audit Committee from February 2014 through March 2014 and rejoined this committee in June 2021. He is a large animal veterinarian and owner of Leedstone Inc. (formerly Stearns Veterinary Outlet, Inc., an animal health distribution and milking system installation company) and of J-t Enterprises of Melrose, Inc., an exporter of ImmuCell products. He also is a dairy producer. He obtained his degrees from the University of Minnesota.

PAUL R. WAINMAN

Age: 59

Director since: March 2014

Mr. Wainman was appointed to the Board of Directors on March 31, 2014 and is a member of the Audit and Nominating Committees and serves as Chair of the Audit Committee. He qualifies to serve as a “financial expert” given his background in accounting and finance. Mr. Wainman served as Chief Financial Officer of Hancock Lumber, a 725-employee lumber and building products company located in Casco, Maine, from February 2016 and its President and CFO from January 2020 until, most recently, becoming President and CEO in January 2023. From April 2015 until February 2016, he was a business strategy and financial consultant specializing in the paper and greeting card industry. Prior to that, he was President of Kleinfeld, a personalized wedding stationery company, from September 2013 until April 2015. From 2005 to 2012, he was President and CEO of William Arthur, Inc., a division of Hallmark Cards, where he led a 275-employee manufacturer of luxury stationery products. Prior to that, he served another division of Hallmark Cards as CFO and COO from 1998 to 2004. He obtained a degree in Accounting and Financial Control from Sheffield City University in England and qualified as a Chartered Accountant of England and Wales in 1990.

Each of these individuals brings distinct skills, perspectives and attributes to the Board of Directors. Ms. Basse has extensive animal health marketing experience. Mr. Brigham is an executive officer who has been employed by the Company since 1989 and has a financial and accounting background. Ms. Brockmann is an executive officer who has been employed by the Company since 2010 and has extensive experience in the sales and marketing of products to the dairy and beef industries. Mr. Gathagan has significant experience with information systems and finance as well as relevant animal health industry experience. Mr. Rosgen has a depth of experience in sales and marketing and product branding. Dr. Tomsche is a veterinarian and owner of a distribution outlet of products and services for animals, as well as an investor in and owner of dairy farms, and brings to the board substantial expertise in our industry. Mr. Wainman has extensive managerial and financial training and expertise.

EXECUTIVE OFFICERS OF THE COMPANY

Our executive officers as of March 8, 2024 were as follows:

MICHAEL F. BRIGHAM

See Biography above.

BOBBI JO BROCKMANN

See Biography above.

ELIZABETH L. WILLIAMS

(Age: 68, Officer since April 2016) joined the Company in April 2016 as Vice President of Manufacturing Operations. Previously, she led the U.S. Region for Zoetis as Vice President, Global Manufacturing and Supply. Prior to that, she held multiple Site Leader positions at Pfizer Animal Health facilities in Lincoln, Nebraska (2008-2011), Conshohocken, Pennsylvania (2006-2008) and Lee’s Summit, Missouri (2003-2006). She led the manufacturing organization (1999-2003) and the Process and Product Development group (1995-1999), achieving registration, approval and successful scale-up of five new products at the Lee’s Summit facility. She earned her Masters of Business Administration from Rockhurst University in Kansas City, Missouri and her Bachelor’s degree in Biology from the University of Missouri.

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There is no family relationship between any director, executive officer or person nominated or chosen by the Company to become a director or executive officer. Except for Mr. Brigham and Ms. Brockmann (both of whom are Company employees), each of the Company's existing directors or nominees qualifies as an "independent director" as defined under applicable NASDAQ Stock Market rules. In evaluating the independence of directors, the board did consider related party transactions described elsewhere in this Annual Report. Any vacancies that may occur during the year may be filled by the Board of Directors to serve until the next Annual Meeting.

CODE OF BUSINESS CONDUCT AND ETHICS

In December 2003, the Board of Directors of the Company adopted a Code of Business Conduct and Ethics (the Code) that applies to all employees of the Company, including the Company's President and CEO and Director of Finance and Administration. This Code is a set of written standards that are designed to deter wrongdoing and to promote: (i) honest and ethical conduct, (ii) full, fair, accurate, timely and understandable disclosure in reports filed with the SEC, (iii) compliance with applicable laws, (iv) prompt internal reporting of violations of the Code and (v) accountability for adherence to the Code. On March 19, 2014, the Board of Directors approved several minor revisions to this Code. This Code has been posted on the Company's website (<http://immucell.com/wp-content/uploads/2017/05/2014-Code-of-Business-Conduct-and-Ethics-revision.pdf>) and was filed as Exhibit 14 to the Company's Current Report on Form 8-K dated March 20, 2014. The Company will mail a copy of its Code of Business Conduct and Ethics to any interested party without charge, upon request. Such requests may be made by mail to the Company's Secretary at ImmuCell Corporation, 56 Evergreen Drive, Portland, Maine 04103.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16 of the Securities Exchange Act of 1934 requires the Company's directors, executive officers and persons who own more than ten percent of a registered class of the Company's equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) reports they file. To the best of the Company's knowledge, based solely on review of the copies of such reports furnished to the Company and written representations that no other reports were required, during the year ended December 31, 2023, the Company's directors, executive officers and greater than ten percent beneficial owners complied on a timely basis with all applicable Section 16(a) filing requirements.

ITEM 11 — EXECUTIVE COMPENSATION

The following table contains information as to the compensation paid by the Company to its non-executive directors for services rendered during the year ended December 31, 2023:

Name	Fees Earned or Paid in Cash	Stock Option Awards⁽¹⁾⁽²⁾	All Other Compensation	Total
Gloria J. Basse	\$ 28,000	\$ 0	\$ 0	\$ 28,000
David S. Cunningham	\$ 14,000	\$ 0	\$ 0	\$ 14,000
Bryan K. Gathagan	\$ 15,000	\$ 35,700	\$ 0	\$ 50,700
Steven T. Rosgen	\$ 30,000	\$ 0	\$ 0	\$ 30,000
David S. Tomsche, D.V.M.	\$ 42,000	\$ 0	\$ 0	\$ 42,000
Paul R. Wainman	\$ 30,000	\$ 0	\$ 0	\$ 30,000

- (1) This amount represents the total non-cash compensation expense related to stock options granted during the year ended December 31, 2023, which is being expensed over the three-year vesting period from grant date.
- (2) As of December 31, 2023, Ms. Basse had 35,000 stock options outstanding; Mr. Cunningham had no stock options outstanding; Mr. Gathagan had 15,000 stock options outstanding; Mr. Rosgen had 20,000 stock options outstanding; Dr. Tomsche had 20,000 stock options outstanding; and Mr. Wainman had 20,000 stock options outstanding.

Officers of the Company, who are also directors, do not receive additional compensation for attendance at Board of Directors' meetings or committee meetings (and no such employee directors are members of any of the Company's Committees). Effective January 1, 2022, this annual fee paid to non-employee directors was increased from \$24,000 to \$28,000. Effective January 1, 2022, compensation for members of the Audit Committee was set at \$2,000 per year. Effective January 1, 2013, the additional compensation for the Chair of the Board of Directors was set at \$12,000 per year (Dr. Tomsche served as Chair during 2023). All fees paid to directors are paid quarterly. Historically, fees paid to directors were payable on the first day of the quarter during which they

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were earned. However, beginning in the first quarter of 2023 fees paid to directors become payable at the end of the quarter during which they are earned. No other increases in these fees have been made since those noted above.

On March 19, 2018, each of the then serving outside directors were granted non-qualified stock options to purchase 15,000 shares of common stock under the 2017 Stock Option and Incentive Plan. These options had an exercise price equal to \$7.08 per share, which was the fair market value of the common stock on the date of grant, and they vested on March 18, 2021. These options expired March 18, 2023. At the time first appointed to the board, Ms. Basse was granted a non-qualified stock option to purchase 15,000 shares of common stock under the 2017 Stock Option and Incentive Plan with terms similar to those previously granted to all other directors. Ms. Basse’s options have an exercise price equal to \$4.81 per share, which was the fair market value of the common stock on the date of grant (June 29, 2020), and vest on June 28, 2023. These options expire if not exercised by June 28, 2025 or, if earlier, within one month (twelve months if in the case of death or disability) after termination of service as a director. On June 17, 2021, each of the then serving outside directors were granted non-qualified stock options to purchase 10,000 shares of common stock under the 2017 Stock Option and Incentive Plan. These options have an exercise price equal to \$10.04 per share, which was the fair market value on the date of grant, and they vest on June 16, 2024. These options expire if not exercised by June 16, 2026 or, if earlier, within one month (twelve months in the case of death or disability) after termination of service as a director. On December 15, 2022, each of the then serving outside directors were granted non-qualified stock options to purchase 10,000 shares of common stock under the 2017 Stock Option and Incentive Plan. These options have an exercise price equal to \$6.52 per share, which was the fair market value on the date of grant, and they vest on December 14, 2025. These options expire if not exercised by December 14, 2027 or, if earlier, within one month (twelve months in the case of death or disability) after termination of service as a director. At the time first appointed to the board, Mr. Gathagan was granted a non-qualified stock option to purchase 15,000 shares of common stock under the 2017 Stock Option and Incentive Plan with terms similar to those previously granted to all other directors. Mr. Gathagan’s options have an exercise price equal to \$5.11 per share, which was the fair market value of the common stock on the date of grant (June 28, 2023), and vest on June 27, 2026. These options expire if not exercised by June 27, 2028 or, if earlier, within one month (twelve months if in the case of death or disability) after termination of service as a director.

INDEMNIFICATION AGREEMENTS

The Company has entered into indemnification agreements with its directors and executive officers in substantially the form approved by the stockholders at the 1989 Annual Meeting, as recently updated. The agreements include procedures for reimbursement by the Company of certain liabilities and expenses which may be incurred in connection with service as a director or executive officer. The Company expects to enter into indemnification agreements with individuals who become directors in the future, as well as such executive officers of the Company as the Board of Directors may from time to time determine.

EXECUTIVE COMPENSATION

Under the By-laws, executive officers are elected by the Board of Directors at its first meeting following each Annual Meeting of Stockholders of the Company, and each serves for a one-year term and until his or her successor is chosen and qualified, but all officers are employees of the Company “at will”, and their service may be terminated at any time without payment of severance or similar benefits, except as described under **EMPLOYMENT AGREEMENTS** below.

SUMMARY COMPENSATION TABLE

The following table contains information as to the total compensation paid by the Company to its named executive officers for services rendered during the years ended December 31, 2023 and 2022:

Name and Principal Position	Year	Salary	Bonus ⁽¹⁾	Stock Option Awards ⁽²⁾	All Other Compensation ⁽³⁾	Total
Michael F. Brigham President, Chief Executive Officer, Treasurer and Secretary	2023	\$ 355,267	\$ 0	\$ 0	\$ 39,968	\$ 395,235
	2022	\$ 342,944	\$ 0	\$ 4,500	\$ 252,500	\$ 599,944
Bobbi Jo Brockmann Vice President of Sales and Marketing	2023	\$ 268,846	\$ 25,000	\$ 0	\$ 29,675	\$ 323,521
	2022	\$ 259,522	\$ 0	\$ 0	\$ 28,159	\$ 287,681
Elizabeth L. Williams Vice President of Manufacturing Operations	2023	\$ 264,173	\$ 25,000	\$ 0	\$ 22,899	\$ 312,072
	2022	\$ 254,678	\$ 0	\$ 4,500	\$ 20,760	\$ 279,938

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- (1) Bonus (or variable compensation) is reported in the year earned, even if paid in the beginning of the next year.
- (2) This amount represents the total non-cash compensation expense related to stock option awards granted during the year that they were earned, which is being expensed over the three-year vesting period from grant date.
- (3) This amount includes Company-paid contributions to a 401(k) Plan, health insurance premiums and life insurance premiums that are available to all employees of similar employment status, if elected. For Mr. Brigham, this amount includes approximately \$8,000 and \$222,000 worth of earned and unused paid time off described under **EMPLOYMENT AGREEMENTS** below that was accrued during the first quarter of 2023 and 2022, respectively, and is due to be paid to Mr. Brigham upon his separation from the Company. For Ms. Brockmann, this amount also includes the personal use of a Company-owned vehicle.

Generally during the first quarter of each year, annual salaries and bonuses for these named executive officers are determined at the discretion of the Compensation and Stock Option Committee. Effective January 30, 2021, the annual salary for Mr. Brigham was increased by 2% to \$332,212. Effective February 26, 2022, the annual salary for Mr. Brigham was increased by 4% to \$345,500. Effective February 25, 2023, the annual salary for Mr. Brigham was increased by 3.5% to \$357,592. No such annual increase was provided to Mr. Brigham for 2024. Effective January 30, 2021, the annual salary for Ms. Brockmann was increased by 2% to \$251,400, and she was paid \$12,645 in variable compensation related to her 2020 performance. Effective February 26, 2022, the annual salary for Ms. Brockmann was increased by 4% to \$261,456, and she was paid \$22,500 and awarded 18,000 stock options with an exercise price of \$8.15 per share in variable compensation related to her 2021 performance. Effective February 25, 2023, the annual salary for Ms. Brockmann was increased by 3.5% to \$270,606, and she was paid a discretionary bonus of \$25,000 on March 1, 2023. Effective February 10, 2024, the annual salary for Ms. Brockmann was increased by 4% to \$281,430. Effective January 30, 2021, the annual salary for Ms. Williams was increased by 4% to \$246,707. Effective February 26, 2022, the annual salary for Ms. Williams was increased by 4% to \$256,575. Effective February 25, 2023, the annual salary for Ms. Williams was increased by 3.5% to \$265,555, and she was paid a performance bonus of \$25,000 on August 30, 2023. Effective February 10, 2024, the annual salary for Ms. Williams was increased by 4% to \$276,177.

Effective December 1, 2022 through November 30, 2023, the Company contributed approximately \$18,400 per year towards the cost of family health insurance coverage for each full-time employee electing this coverage. Effective December 1, 2023 through November 30, 2024, this annual contribution is \$20,755. Mr. Brigham and Ms. Brockmann elected this coverage. Effective December 1, 2022 through November 30, 2023, the Company contributed approximately \$12,600 per year towards the cost of employee and spouse health insurance coverage for each full-time employee electing this coverage. Effective December 1, 2023 through November 30, 2024, this annual contribution is \$14,250. Ms. Williams elected this coverage.

EMPLOYMENT AGREEMENTS

We enter into compensation agreements (which are publicly filed) with our three executive officers. Effective March 28, 2022, we entered into an Amended and Restated Separation and Deferred Compensation Agreement (the “Deferred Compensation Agreement”) with Mr. Brigham (our President and CEO) that superseded and replaced in its entirety a March 2020 severance agreement between the Company and Mr. Brigham. Upon separation from the Company for any reason, Mr. Brigham’s Deferred Compensation Agreement allows Mr. Brigham to be paid, among other amounts, all earned and unused paid time off (which expense totaling \$222,379 was accrued during the first quarter of 2022 and \$230,162 and \$222,379 was included in accounts payable and accrued expenses on the accompanying balance sheets as of December 31, 2023 and 2022, respectively) and to receive up to an additional \$300,000 in deferred compensation (which amount is being accrued over the three-year period ending in January 2025). This deferred compensation payment vested as to \$100,000 on January 1, 2023 and an additional \$100,000 on January 1, 2024. An additional \$100,000 will vest on January 1, 2025, provided that Mr. Brigham is employed by the Company as of January 2025. The vested amounts would be paid upon the earlier of January 31, 2025 or within thirty (30) days following his separation from the Company. As of December 31, 2023 and 2022, \$200,000 and \$100,000, respectively, was included in accounts payable and accrued expenses on the accompanying balance sheets. In addition, upon termination of Mr. Brigham’s employment (a) by the Company other than for cause, (b) due to death or disability or (c) by Mr. Brigham for good reason, in each case as described and defined in the Deferred Compensation Agreement, the Company agrees to pay Mr. Brigham 100% of his then current annual base salary and a lump sum payment equal to the employer portion of the costs of continued health benefits for Mr. Brigham and his covered dependents for a twelve-month period following termination, and certain equity incentive awards granted to Mr. Brigham would continue to vest following such termination in accordance with the terms of the Deferred Compensation Agreement. Incentive Compensation Agreements with Mr. Brigham, Ms. Brockmann (our Vice President of Sales and Marketing) and Ms. Williams (our Vice President of Manufacturing Operations) allow these executives to earn incentive compensation if certain regulatory and financial objectives are met during the year to which the agreement relates, as specified in their agreements. Amounts related to these incentive compensation agreements are accrued over the period they are earned (when it is probable that the amounts will be earned) based on our best estimate of the amounts expected to be earned.

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OUTSTANDING EQUITY AWARDS

Stock options are the only outstanding form of equity awards to the Company's employees and directors. The following table contains information on stock options held by the Company's named executive officers that were outstanding as of December 31, 2023:

<u>Name</u>	<u>Number of Shares Underlying Unexercised Stock Options - Exercisable</u>	<u>Number of Shares Underlying Unexercised Stock Options - Unexercisable⁽¹⁾</u>	<u>Stock Option Exercise Price</u>	<u>Date of Grant</u>	<u>Expiration Date</u>
Michael F. Brigham	25,000	0	\$ 5.84	02/10/2017	02/09/2027
	20,000	0	\$ 7.80	01/08/2018	01/07/2028
	0	1,000	\$ 8.15	06/15/2022	06/14/2032
Bobbi Jo Brockmann	10,000	0	\$ 7.54	12/16/2015	12/15/2025
	10,000	0	\$ 5.84	02/10/2017	02/09/2027
	7,500	0	\$ 7.80	01/08/2018	01/07/2028
	10,000	0	\$ 5.18	12/11/2019	12/10/2029
	0	18,000	\$ 8.15	01/31/2022	01/30/2032
Elizabeth L. Williams	25,000	0	\$ 6.70	04/04/2016	04/03/2026
	10,000	0	\$ 5.84	02/10/2017	02/09/2027
	7,500	0	\$ 7.80	01/08/2018	01/07/2028
	10,000	0	\$ 5.18	12/11/2019	12/10/2029
	0	1,000	\$ 8.15	06/15/2022	06/14/2032

(1) These stock options become exercisable three years after the date of grant.

ITEM 12 — SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information known to the Company regarding beneficial ownership of the Company's common stock as of April 15, 2024 of (i) each person known to the Company to be the beneficial owner of more than five percent of the Company's common stock, (ii) each of the Company's directors, (iii) each of the Company's executive officers named in the "SUMMARY COMPENSATION TABLE" above, (iv) the five largest stockholders listed in this table as a group and (v) all directors and executive officers of the Company as a group:

<u>Name of Beneficial Owner</u>	<u>Shares of the Company's Common Stock Beneficially Owned (1)</u>	<u>Percent of the Company's Common Stock Beneficially Owned</u>
Sandra F., Norman H. and Brian L. Pessin (2)	1,182,720	15.3 %
Jonathan E. Rothschild (3)	514,003	6.6 %
Michael F. Brigham (4)	260,752	3.3 %
Joseph H. Crabb, Ph.D. (5)	142,845	1.8 %
David S. Tomsche D.V.M. (6)	113,606	1.5 %
Elizabeth Williams (7)	52,500	0.7 %
Bobbi Jo Brockmann (8)	46,021	0.6 %
Gloria J. Basse (9)	25,000	0.3 %
Paul R. Wainman (10)	16,269	0.2 %
Steven T. Rosgen (11)	10,000	0.1 %
Bryan K. Gathagan (12)	0	0.0 %
Directors and executive officers as a group (8 persons) (13)	524,148	6.6 %
The five largest stockholders listed in this table as a group (14)	2,213,926	28.4 %

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- (1) The persons named in the table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, subject to the information contained in the footnotes to this table. The figures in the table include shares of common stock covered by stock options which are currently exercisable or will become exercisable on June 16, 2024.
- (2) The address for the Pessins is 400 East 51st Street, PH31, New York, NY 10022. The Pessins have indicated that each of them has sole voting and dispositive/investment power with respect to the shares of common stock owned by them individually: Norman H. Pessin—644,019 shares (8.3%), Sandra F. Pessin—401,819 shares (5.2%) and Brian L. Pessin—136,882 shares (1.8%).
- (3) The address for Mr. Rothschild is c/o Arterio, Inc., 1061-B Shary Circle, Concord, CA 94518. This figure includes 226,416 shares of common stock held by Arterio Inc., a corporation owned solely by Mr. Rothschild.
- (4) This figure includes 45,000 vested stock options that are described in the “**OUTSTANDING EQUITY AWARDS**” table and 11,000 shares of common stock held by the mother of Mr. Brigham. Mr. Brigham also holds 1,000 unvested stock options that were granted during 2022.
- (5) Dr. Crabb holds these shares of common stock jointly with his former spouse. He is listed in this table for informational purposes because he is one of the five largest stockholders.
- (6) This figure includes 6,987 shares of common stock held by immediate family members of Dr. Tomsche. This figure includes 10,000 stock options that vest on June 16, 2024. Dr. Tomsche also holds 10,000 unvested stock options.
- (7) This figure is comprised of 52,500 vested stock options that are described in the “**OUTSTANDING EQUITY AWARDS**” table. Ms. Williams also holds 1,000 unvested stock options that were granted during 2022.
- (8) This figure includes 7,466 shares of common stock held by Ms. Brockmann and 1,055 shares of common stock held jointly with her spouse and 37,500 vested stock options that are described in the “**OUTSTANDING EQUITY AWARDS**” table. Ms. Brockmann also holds 18,000 unvested stock options that were granted during 2022.
- (9) This figure is comprised of 15,000 vested stock options and 10,000 stock options that vest on June 16, 2024. Ms. Basse also holds 10,000 unvested stock options.
- (10) This figure includes 10,000 stock options that vest on June 16, 2024. Mr. Wainman also holds 10,000 unvested stock options.
- (11) This figure includes 10,000 stock options that vest on June 16, 2024. Mr. Rosgen also holds 10,000 unvested stock options.
- (12) Mr. Gathagan holds 15,000 unvested stock options.
- (13) This figure includes 150,000 vested stock options and 40,000 stock options that vest on June 16, 2024.
- (14) This figure includes 45,000 vested stock options and 10,000 stock options that vest on June 16, 2024.

The Company does not permit employees or directors to engage in hedging transactions with respect to the Company’s stock.

Equity Compensation Plan Information

The table below summarizes the common stock reserved for issuance upon the exercise of stock options outstanding as of December 31, 2023 or that could be granted in the future:

	Number of shares to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of shares remaining available for future issuance under stock-based compensation plans (excluding shares reflected in first column of this table)
Equity compensation plans approved by stockholders	618,500	\$6.82	202,000
Equity compensation plans not approved by stockholders	—	—	—
Total	618,500	\$6.82	202,000

ITEM 13 — CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone Inc., a domestic distributor of our products (the **First Defense**[®] product line and **CMT**). His affiliated company purchased \$231,405 and \$587,677 of products from us during the years ended December 2023 and 2022, respectively, all on terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from this affiliated company aggregated \$42,507

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and \$46,426 as of December 31, 2023 and 2022, respectively.

The President and CEO of the Company is responsible for reviewing related party transactions. To assist with this process, each director is asked to complete an annual questionnaire covering transactions of this nature and other related matters. Regardless of dollar value, all related party transactions are reviewed with the relevant director and with the entire Board of Directors, if necessary.

Except for Mr. Brigham and Ms. Brockmann (both of whom are Company employees), each of the Company's existing directors qualifies as an "independent director" as defined under the applicable NASDAQ Stock Market rules. Each member of the Company's Audit Committee, Nominating Committee, and Compensation and Stock Option Committee are independent under the applicable NASDAQ Stock Market rules.

ITEM 14 — PRINCIPAL ACCOUNTANT FEES AND SERVICES

Principal Accounting Fees and Services

On April 12, 2019, the Company engaged Wipfli LLP for the first time as its Independent Registered Public Accounting Firm (IRPAF) for the year ended December 31, 2019 beginning with a customary review of the Company's financial statements as of and for the quarter ended March 31, 2019. On March 20, 2020, the Company engaged Wipfli LLP as its IRPAF for the year ended December 31, 2020. On March 23, 2021, the Company engaged Wipfli as its IRPAF for the year ended December 31, 2021. On March 23, 2022, the Company engaged Wipfli as its IRPAF for the year ended December 31, 2022. On March 22, 2023, the Company engaged Wipfli as its IRPAF for the year ending December 31, 2023.

Set forth below is a summary of the fees incurred for services rendered by the Company's Independent Registered Public Accounting Firm, Wipfli LLP, for the years ended December 31, 2023 and 2022:

	2023	2022
Audit Fees ⁽¹⁾	\$ 140,000	\$ 130,000
Audit-Related Fees ⁽²⁾	550	19,000
Total	<u>\$ 140,550</u>	<u>\$ 149,000</u>

- (1) The Audit Fees include fees billed by or accrued for the auditors for their reviews of the quarterly financial statements included in the Company's Quarterly Reports on Form 10-Q for the first three quarters of each year and their audits of the annual financial statements included in the Company's Annual Reports on Form 10-K and incidental expenses.
- (2) Audit-Related Fees include fees paid to Wipfli LLP related to the issuance of a consent for a registration statement during 2023 and related to the restatement of the Company's Quarterly Reports on Form 10-Q for the three-month periods ended June 30, 2022 and March 31, 2022 during 2022.

Pre-Approval Policy

In accordance with the procedures set forth in its charter, the Audit Committee pre-approves all auditing services and permitted non-audit services (including the fees and other terms of those services) to be performed for the Company by its Independent Registered Public Accounting Firm. Such approval may be accomplished by approving the terms of the engagement prior to the engagement of the Independent Registered Public Accounting Firm with respect to such services or by establishing detailed pre-approval policies and procedures to govern such engagement. The Audit Committee authorizes management to spend up to \$5,000 per year for services that are not anticipated at the time of the engagement, provided that the Audit Committee is promptly informed of such services.

AUDIT COMMITTEE REPORT

The Audit Committee of the Board of Directors reviews the financial reporting process, the system of internal controls, the audit process and the process for monitoring compliance with certain applicable laws and regulations. The Audit Committee is responsible for selecting and hiring the Independent Registered Public Accounting Firm and meets with those accountants (in person or by telephone) before each quarterly press release concerning the Company's financial results. The Audit Committee approves the public disclosure and filing with the SEC of the related press releases. After reviewing the quarterly and annual reports that are prepared by management, the Audit Committee authorizes the filing of such reports with the SEC. All members of the Audit Committee meet the heightened independence and expertise requirements for audit committees under applicable NASDAQ Stock Market rules. Mr. Wainman joined the Audit Committee in March of 2014 and serves as its Chair. Mr. Rosgen joined the Audit Committee in April of 2018. Dr. Tomsche joined the Audit Committee in June of 2021. Mr. Gathagan joined the Audit Committee in

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June of 2023. The Audit Committee currently operates under a charter adopted by the board in 2004. The Company has a January 1st to December 31st fiscal year. The Audit Committee met eight times during 2023.

The Audit Committee has reviewed the Company's audited financial statements for the year ended December 31, 2023 and discussed such statements with management and Wipfli LLP, the Company's independent registered public accounting firm for 2023. The Audit Committee has discussed with Wipfli LLP various communications that Wipfli LLP is required to provide to the Audit Committee including the matters required to be discussed by Public Company Accounting Oversight Board (PCAOB) Auditing Standards No. 1301 (Communication with Audit Committees). The Audit Committee received from Wipfli LLP the written disclosures and the letter required by applicable requirements of the PCAOB concerning independence and has discussed the auditor's independence with them.

Based on the review and discussions noted above, the Audit Committee recommended to the board that the Company's audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and be filed with the SEC.

This report of the Audit Committee shall not be deemed incorporated by reference by any general statement into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Company specifically incorporates this information by reference and shall not otherwise be deemed filed under such Acts.

Submitted by: Audit Committee

Bryan K. Gathagan

Steven T. Rosgen

David S. Tomsche, D.V.M.

Paul R. Wainman, Chair

PART IV

ITEM 15—EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

- 3.1 Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 of the Company's 1987 Registration Statement No. 33-12722 on Form S-1 as filed with the Commission).
- 3.2 Certificate of Amendment to the Company's Certificate of Incorporation effective July 23, 1990 (incorporated by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
- 3.3 Certificate of Amendment to the Company's Certificate of Incorporation effective August 24, 1992 (incorporated by reference to Exhibit 3.3 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
- 3.4 Certificate of Amendment to the Company's Certificate of Incorporation effective June 16, 2016 (incorporated by reference to Exhibit 3.1 of the Company's Amended Current Report on Form 8-K/A filed on June 16, 2016).
- 3.5 Certificate of Amendment to the Company's Certificate of Incorporation effective June 18, 2018 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on June 18, 2018).
- 3.6 Certificate of Amendment to the Company's Certificate of Incorporation effective June 11, 2020 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on June 11, 2020).
- 3.7 Bylaws of the Company as amended (incorporated by reference to Exhibit 3.4 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
- 4.1 Rights Agreement dated as of September 5, 1995, between the Company and American Stock Transfer and Trust Co., as Rights Agent, which includes as Exhibit A thereto the form of Right Certificate and as Exhibit B thereto the Summary of Rights to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2009).
- 4.1A First Amendment to Rights Agreement dated as of June 30, 2005 (incorporated by reference to Exhibit 4.1A of the Company's Current Report on Form 8-K filed on July 5, 2005).
- 4.1B Second Amendment to Rights Agreement dated as of June 30, 2008 (incorporated by reference to Exhibit 4.1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
- 4.1C Third Amendment to Rights Agreement dated as of August 9, 2011 (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2011).
- 4.1D Fourth Amendment to Rights Agreement dated as of June 16, 2014 (incorporated by reference to Exhibit

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- 4.1D of the Company's Current Report on Form 8-K filed on June 17, 2014).
- 4.1E Fifth Amendment to Rights Agreement dated as of April 15, 2015 (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended March 31, 2015).
- 4.1F Sixth Amendment to Rights Agreement dated as of August 10, 2017 (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2017).
- 4.1G Seventh Amendment to Rights Agreement dated as of August 10, 2022 (incorporated by reference to Exhibit 4.1 of the Company's Amended Quarterly Report on Form 10-Q/A filed on November 21, 2022).
- 4.1H Eighth Amendment to Rights Agreement dated as of August 9, 2023 (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q filed on August 10, 2023).
- 4.2 Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934, as amended (incorporated by reference to Exhibit 4.2 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020).
- 10.1+ Form of Indemnification Agreement (updated) entered into with each of the Company's Directors and Officers (incorporated by reference to Exhibit 10.3A of the Company's Annual Report on Form 10-KSB for the year ended December 31, 2006).
- 10.2+ Amendment to Employment Agreement between the Company and Michael F. Brigham dated March 26, 2010 (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2009).
- 10.3+ 2010 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2010).
- 10.4+ Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2010).
- 10.5+ 2017 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2017).
- 10.6+ Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.9 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019).
- 10.7+ Amendment to the 2017 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2022).
- 10.8+* Fifth Amended and Restated Incentive Compensation Agreement between the Company and Elizabeth L. Williams dated as of March 27, 2024.
- 10.9+ Amended and Restated Separation and Deferred Compensation Agreement between the Company and Michael F. Brigham dated as of March 28, 2022 (incorporated by reference to Exhibit 10.9 of the Company's Annual Report on Form 10-K filed on March 30, 2022).
- 10.10+ Amended and Restated Incentive Compensation Agreement between the Company and Michael F. Brigham dated as of March 28, 2023 (incorporated by reference to Exhibit 10.13 of the Company's Annual Report on Form 10-K for the year ended December 31, 2022).
- 10.11+* Fourth Amended and Restated Incentive Compensation Agreement between the Company and Bobbi Jo Brockmann dated as of March 27, 2024.
- 10.12 Development Services and Commercial Supply Agreement between the Company and Norbrook Laboratories Limited dated as of September 5, 2019 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on September 11, 2019).
- 10.13 Amending Agreement between the Company and Norbrook Laboratories dated as of March 4, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed March 6, 2024).
- 10.14 Indenture of Lease for Premises Located in Portland, Maine between the Company and TVP, LLC (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on September 17, 2019).
- 10.15 Second Amendment of Indenture of Lease for Premises Located in Portland, Maine between the Company and TVP, LLC dated as of August 15, 2022 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on August 17, 2022).
- 10.16 Third Amendment of Indenture of Lease for Premises Located in Portland, Maine between the Company and TVP, LLC dated as of November 14, 2023 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on November 16, 2023).
- 10.17 Term Note for \$5,100,000 between the Company and Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on March 12, 2020).
- 10.18 Loan Agreement for \$5,100,000 between the Company and Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.4 of the Company's Current Report on Form 8-K filed on March 12, 2020).

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- 10.19 Allonge to and Amendment of Term Note, dated March 23, 2022, between the Company and Gorham Savings Bank (incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on March 24, 2022).
- 10.20 Mortgage Modification Agreement, dated March 23, 2022, between the Company and Gorham Savings Bank (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on March 24, 2022).
- 10.21 Term Note for \$3,500,000 between the Company and Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.3 of the Company's Current Report on Form 8-K filed on March 12, 2020).
- 10.22 Loan Agreement for \$3,500,000 between the Company and Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.5 of the Company's Current Report on Form 8-K filed on March 12, 2020).
- 10.23 Line of Credit Agreement for up to \$1,000,000 executed by ImmuCell Corporation in favor of Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on March 12, 2020).
- 10.24 Allonge to and Amendment of Line of Credit Loan for up to \$1,000,000 between the Company and Gorham Savings Bank dated March 23, 2022 (incorporated by reference to Exhibit 10.23 of the Company's Annual Report on Form 10-K for the year ended December 31, 2022).
- 10.25 Allonge to and Amendment of Line of Credit between the Company and Gorham Savings Bank, dated February 22, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on February 27, 2024).
- 10.26 Note Purchase Agreement executed by the Company in favor of the Maine Technology Institute dated June 12, 2020 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on June 16, 2020).
- 10.27 Subordinated Promissory Note for \$500,000 executed by the Company in favor of the Maine Technology Institute dated June 12, 2020 (incorporated by reference to Exhibit 99.3 of the Company's Current Report on Form 8-K filed on June 16, 2020).
- 10.28 Note Purchase Agreement executed by the Company in favor of the Maine Technology Institute dated June 30, 2021 (incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on July 6, 2021).
- 10.29 Subordinated Promissory Note for \$400,000 executed by the Company in favor of the Maine Technology Institute dated June 30, 2022 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on July 6, 2021).
- 10.30 Term Note for \$1,500,000 executed by the Company in favor of Gorham Savings Bank dated December 15, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 17, 2020).
- 10.31 Loan Agreement for \$1,500,000 executed by the Company in favor of Gorham Savings Bank dated December 15, 2020 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 17, 2020).
- 10.32 Term Note for \$2,000,000 executed by ImmuCell Corporation in favor of Gorham Savings Bank dated July 17, 2023 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on July 21, 2023).
- 10.33 Loan Agreement, by and between ImmuCell Corporation and Gorham Savings Bank dated July 17, 2023 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on July 21, 2023).
- 10.34 Economic Recovery/SSBCI Program Loan Promissory Note for \$1,000,000 executed by ImmuCell Corporation in favor of the Finance Authority of Maine dated July 17, 2023 (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed on July 21, 2023).
- 10.35 Economic Recovery Loan Program Loan Agreement, by and between ImmuCell Corporation and the Finance Authority of Maine dated July 17, 2023 (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed on July 21, 2023).
- 14 Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14 of the Company's Current Report on Form 8-K filed on March 20, 2014).
- 23.1* Consent of Independent Registered Public Accounting Firm.
- 24.1 Power of Attorney (incorporated by reference to the signature page of this Form 10-K).
- 31* Certification Pursuant to Rule 13a-14(a).
- 32* Certification Pursuant to Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 97.1* ImmuCell Corporation Clawback Policy.

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

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

ITEM 16 – FORM 10-K SUMMARY

None

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of ImmuCell Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheets of ImmuCell Corporation (the “Company”) as of December 31, 2023 and 2022, and the related statements of operations, stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Inventory

Description of the Matter

At December 31, 2023, the Company’s inventory was \$7,811,841. As discussed in Note 2 of the financial statements, inventory is recorded at the lower of cost or net realizable value.

Auditing management’s valuation of inventory is complex and highly judgmental because of the estimates and assumptions used by management to determine the cost accounting and because of the variability of the cost per dose due to fluctuations in the biological yield achieved.

How We Addressed the Matter In Our Audit

The primary procedures we performed to address this critical audit matter included the following. We obtained an understanding of the cost accounting developed by management and the related assumptions and estimates used. We tested the cost accounting by examining the underlying data used by the Company to prepare the cost accounting. We evaluated the effect of the variability of the cost per dose on the inventory value by comparing the biological yield to historical results and by performing a sensitivity analysis of the potential range in inventory value within a corridor of historical results based on minimum and maximum outcomes for the biological yield.

/s/ WIPFLI LLP

We have served as the Company's auditor since 2019.

Radnor, Pennsylvania

April 1, 2024

ImmuCell Corporation

BALANCE SHEETS

	As of December 31,	
	2023	2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$978,741	\$5,791,562
Trade accounts receivable	2,185,383	1,758,600
Inventory	7,811,841	6,038,539
Prepaid expenses and other current assets	493,885	406,055
Total current assets	11,469,850	13,994,756
Property, plant and equipment, net	27,575,683	28,441,726
Operating lease right-of-use asset	4,571,149	2,194,670
Goodwill	95,557	95,557
Intangible assets, net	38,208	57,312
Other assets	57,655	76,628
TOTAL ASSETS	\$43,808,102	\$44,860,649
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of debt obligations	\$1,428,807	\$1,039,447
Current portion of operating lease liability	644,276	31,764
Accounts payable and accrued expenses	2,124,337	2,000,862
Total current liabilities	4,197,420	3,072,073
LONG-TERM LIABILITIES:		
Debt obligations, net of current portion	10,540,496	9,191,109
Operating lease liability, net of current portion	4,077,109	2,217,418
Total long-term liabilities	14,617,605	11,408,527
TOTAL LIABILITIES	18,815,025	14,480,600
CONTINGENT LIABILITIES AND COMMITMENTS (See Note 11)		
STOCKHOLDERS' EQUITY:		
Common stock, \$0.10 par value per share, 15,000,000 shares authorized and 7,814,165 shares issued as of both December 31, 2023 and 2022 and 7,750,864 and 7,746,864 shares outstanding as of December 31, 2023 and 2022, respectively	781,417	781,417
Additional paid-in capital	36,357,239	35,978,364
Accumulated deficit	(12,007,097)	(6,232,499)
Treasury stock, at cost, 63,301 and 67,301 shares as of December 31, 2023 and 2022, respectively	(138,482)	(147,233)
Total stockholders' equity	24,993,077	30,380,049
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$43,808,102	\$44,860,649

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

ImmuCell Corporation

STATEMENTS OF OPERATIONS

	During the Years Ended December 31,	
	2023	2022
Product sales	\$17,471,669	\$18,567,962
Costs of goods sold	13,602,385	10,919,183
Gross margin	3,869,284	7,648,779
Product development expenses	4,394,852	4,493,872
Sales and marketing expenses	3,088,215	3,190,033
Administrative expenses	2,134,295	2,263,817
Operating expenses	9,617,362	9,947,722
NET OPERATING LOSS	(5,748,078)	(2,298,943)
Other expenses, net	21,893	187,190
LOSS BEFORE INCOME TAXES	(5,769,971)	(2,486,133)
Income tax expense	4,627	7,672
NET LOSS	(\$5,774,598)	(\$2,493,805)
Basic weighted average common shares outstanding	7,747,686	7,745,122
Basic net loss per share	(\$0.75)	(\$0.32)
Diluted weighted average common shares outstanding	7,747,686	7,745,122
Diluted net loss per share	(\$0.75)	(\$0.32)

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

ImmuCell Corporation

STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock			Accumulated Deficit	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Additional paid- in capital		Shares	Amount	
BALANCE,							
December 31, 2021	7,814,165	\$781,417	\$35,692,388	(\$3,738,694)	72,301	(\$158,171)	\$32,576,940
Net loss	—	—	—	(2,493,805)	—	—	(2,493,805)
Exercise of stock options	—	—	19,732	—	(5,000)	10,938	30,670
Stock-based compensation	—	—	266,244	—	—	—	266,244
BALANCE,							
December 31, 2022	7,814,165	\$781,417	\$35,978,364	(\$6,232,499)	67,301	(\$147,233)	\$30,380,049
Net loss	—	—	—	(5,774,598)	—	—	(5,774,598)
Exercise of stock options	—	—	10,009	—	(4,000)	8,751	18,760
Stock-based compensation	—	—	368,866	—	—	—	368,866
BALANCE,							
December 31, 2023	7,814,165	\$781,417	\$36,357,239	(\$12,007,097)	63,301	(\$138,482)	\$24,993,077

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

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STATEMENTS OF CASH FLOWS

	During the Years Ended December 31,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	(\$5,774,598)	(\$2,493,805)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	2,697,897	2,468,479
Amortization of intangible assets	19,104	19,104
Amortization of debt issuance costs	13,072	7,658
Amortization of debt discounts	9,547	—
Stock-based compensation	368,866	266,244
Loss (gain) on disposal of property, plant and equipment	8,099	(7,334)
Non-cash rent expense	95,724	28,476
Changes in:		
Trade accounts receivable	(426,783)	935,629
Inventory	(1,773,302)	(2,948,565)
Prepaid expenses and other current assets	(87,830)	(110,858)
Other assets	18,973	(50,513)
Accounts payable and accrued expenses	156,995	341,614
Net cash used for operating activities	(4,674,236)	(1,543,871)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1,892,513)	(3,975,274)
Proceeds from sale of property, plant and equipment	2,474	11,000
Net cash used for investing activities	(1,890,039)	(3,964,274)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from debt issuance	3,000,000	2,000,000
Proceeds from line of credit	2,000,000	—
Debt principal repayments	(1,185,774)	(897,125)
Line of credit repayments	(2,000,000)	—
Payments of debt issuance costs	(35,425)	(19,306)
Payments of debt discounts	(46,107)	—
Proceeds from exercise of stock options	18,760	30,670
Net cash provided by financing activities	1,751,454	1,114,239
NET DECREASE IN CASH AND CASH EQUIVALENTS	(4,812,821)	(4,393,906)
BEGINNING CASH AND CASH EQUIVALENTS	5,791,562	10,185,468
ENDING CASH AND CASH EQUIVALENTS	\$978,741	\$5,791,562

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

ImmuCell Corporation
STATEMENT OF CASH FLOWS
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

	During the Years Ended December 31,	
	2023	2022
CASH PAID FOR:		
Income taxes	\$6,466	\$4,923
Interest expense	\$444,954	\$338,516
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable and accrued expenses	\$50,086	(\$44,998)
Change in payments of debt discounts included in accounts payable and accrued expenses	\$16,566	\$—
Operating lease right-of-use asset and operating lease liability	\$2,472,203	\$1,184,727

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

ImmuCell Corporation
Notes to Audited Financial Statements

1. BUSINESS OPERATIONS

ImmuCell Corporation (the “Company”, “we”, “us”, “our”) was originally incorporated in Maine in 1982 and reincorporated in Delaware in 1987, in conjunction with an initial public offering of common stock. We are an animal health company whose purpose is to create scientifically proven and practical products that improve the health and productivity of dairy and beef cattle. As disclosed in Note 17, “Segment Information”, one of our business segments is dedicated to Scours and the other is focused on Mastitis. We manufacture and market the **First Defense**[®] product line, providing **Immediate Immunity**[™] to prevent scours in newborn dairy and beef calves. We have expanded this line into four different products with formulations targeting *E. coli*, coronavirus and rotavirus pathogens. We are also in the late stages of developing **Re-Tain**[®], a treatment for lactating dairy cows with subclinical mastitis. Mastitis is the most significant cause of economic loss to the dairy industry. These products help reduce the need to use traditional antibiotics in food producing animals. We are subject to certain risks including dependence on key individuals and third-party providers of critical goods and services, competition from other larger companies, the successful sale of existing products and the development of new viable products with appropriate regulatory approvals, where applicable. A combination of the conditions, trends and concerns related to or arising from inflation, rising interest rates and potential recessionary conditions in the United States and/or internationally, could have a corresponding negative effect on our business and operations. We are experiencing price increases in key components, supportive services, transportation and other supplies that are causing our costs of goods sold to increase. We have experienced some contamination events in our production process. We implemented a production slowdown to remediate this problem, which led to the recognition of lower sales and gross margin during the first ten months of 2023.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

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

(b) Cash and Cash Equivalents

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. We hold no cash or cash equivalents in excess of Federal Deposit Insurance Corporation (FDIC) limits of \$250,000 per financial institution per depositor. See Note 3.

(c) Trade Accounts Receivable

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful collection when applicable. Management determines the allowance for doubtful accounts on a monthly basis by identifying troubled accounts and by using historical experience applied to an aging of accounts and other relevant factors. Accounts receivable are considered to be past due if a portion of the receivable balance is outstanding for more than 30 days. Past due accounts receivable are subject to an interest charge. It was not necessary to charge interest on past due accounts during the years ended December 31, 2023 or 2022 because the time past due was not significant. There was no accrual for such interest charges as of December 31, 2023 or 2022. Accounts receivable are written off when deemed uncollectible. No accounts receivable were written off during the years ended December 31, 2023 or 2022. Recoveries of accounts receivable previously written off are recorded as income when received. No such recoveries were recorded during the years ended December 31, 2023 or 2022. As of December 31, 2023 and 2022, 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

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

predictable costs of completion, disposal and transportation). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. At each balance sheet date, we evaluate our ending inventories for excess quantities and obsolescence. Inventories that we consider excess or obsolete are written down to estimated net realizable value. Once inventory is written down and a new cost basis is established, it is not written back up. We believe that supplies and raw materials for the production of our products are available from more than one vendor or farm. Our policy is to maintain more than one source of supply for the components used in our products when feasible. See Note 5.

(e) Property, Plant and Equipment, net

We depreciate property, plant and equipment on the straight-line method by charges to operations and costs of goods sold in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The facility we have constructed at 33 Caddie Lane to produce the Nisin Drug Substance (DS) for **Re-Tain**[®] is being depreciated over 39 years from when a Certificate of Occupancy was issued during the fourth quarter of 2017. We began depreciating the equipment for our Nisin DS facility when it was placed in service during the third quarter of 2018. Approximately 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 (**Building 175A**) over the remainder of the 10-year lease term beginning when a Certificate of Occupancy was issued during the second quarter of 2020. During August of 2022, this lease term was extended to January of 2043 in connection with a new lease covering additional space at 175 Industrial Way (**Building 175B**). As a result, the net book value of these leasehold improvements as of August 31, 2022 is now being depreciated over the remainder of the extended lease term. Significant repairs to property, plant and equipment that benefit more than a current period are capitalized and depreciated over their useful lives. Insignificant repairs are expensed when incurred. See Notes 2(h) and 7 for additional disclosures.

(f) Operating Leases

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

(g) Intangible Assets and Goodwill

We amortize intangible assets on the straight-line method by charges to costs of goods sold in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. We have recorded intangible assets related to customer relationships, non-compete agreements and developed technology, each with defined useful lives. Amounts paid in excess of fair value of the net assets (including tax attributes) are recorded as goodwill under the acquisition method of accounting. We assess the impairment of intangible assets that have indefinite lives (when applicable) and goodwill (at the reporting unit level) on an annual basis (as of December 31st) and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We would record an impairment charge if such an assessment were to indicate that the fair value of such assets was less than the carrying value. Judgment is required in determining whether an event has occurred that may impair the value of goodwill or identifiable intangible assets. Factors that could indicate that an impairment may exist include significant under-performance relative to plan or long-term projections, significant changes in business strategy and significant negative industry or economic trends. Although we believe intangible assets and goodwill are properly stated in the accompanying financial statements, changes in strategy or market conditions could significantly impact these judgments and require an adjustment to

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

the recorded balance in the future. No goodwill impairments were recorded during the years ended December 31, 2023 or 2022. See Notes 2(h) and 8 for additional disclosures.

(h) Valuation of Long-Lived Assets

We periodically evaluate our long-lived assets, consisting principally of property, plant and equipment, operating lease right-of-use asset and amortizable intangible assets, for potential impairment. In accordance with the applicable accounting guidance for the treatment of long-lived assets, we review the carrying value of our long-lived assets or asset group that is held and used, including intangible assets subject to amortization, for impairment whenever events and circumstances indicate that the carrying value of the assets may not be recoverable. Under the held for use approach, the asset or asset group to be tested for impairment should represent the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities. No impairment was recognized during the years ended December 31, 2023 or 2022.

(i) Fair Value Measurements

In determining fair value measurements, we follow the provisions of Codification Topic 820, *Fair Value Measurements and Disclosures*. Codification Topic 820 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. The topic provides a consistent definition of fair value which focuses on an exit price, which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The topic also prioritizes, within the measurement of fair value, the use of market-based information over entity-specific information and establishes a three-level hierarchy for fair value measurements based on the nature of inputs used in the valuation of an asset or liability as of the measurement date. As of December 31, 2023 and 2022, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, prepaid expenses and other current assets, accounts payable and accrued expenses approximate fair value because of their short-term nature. The amount outstanding under our bank debt facilities is measured at carrying value in our accompanying balance sheets. Our bank debt facilities are valued using Level 2 inputs. The three-level hierarchy is as follows:

- Level 1 — Pricing inputs are quoted prices available in active markets for identical assets or liabilities as of the measurement date.
- Level 2 — Pricing inputs are quoted prices for similar assets or liabilities, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data.
- Level 3 — Pricing inputs are unobservable for the assets or liabilities, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the asset or liability.

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

We assess the levels of the investments at each measurement date, and transfers between levels are recognized on the actual date of the event or change in circumstances that caused the transfer in accordance with our accounting policy regarding the recognition of transfers between levels of the fair value hierarchy. During the years ended December 31, 2023 and 2022, there were no transfers between levels. As of December 31, 2023 and 2022, our Level 1 assets measured at fair value by quoted prices in active markets consisted of cash and money market accounts. There were no assets or liabilities measured at fair value on a nonrecurring basis as of December 31, 2023 or 2022. The carrying values of our cash and money market accounts as of December 31, 2023 or 2022 approximated their fair market values. Due to inflation and the changing interest rate environment, the carrying values of our fixed rate bank debt as of December 31, 2023 and 2022 differed from their fair market values. These values are reflected in the following tables:

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

As of December 31, 2023

	Level 1	Level 2	Level 3	Total
Assets:				
Cash and money market accounts	\$978,741	\$—	\$—	\$978,741
Liabilities:				
Bank debt	\$—	\$10,431,817	\$—	\$10,431,817

As of December 31, 2022

	Level 1	Level 2	Level 3	Total
Assets:				
Cash and money market accounts	\$5,791,562	\$—	\$—	\$5,791,562
Liabilities:				
Bank debt	\$—	\$8,897,197	\$—	\$8,897,197

(j) Concentration of Risk

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

	During the Years Ended December 31,	
	2023	2022
Company A	47%	40%
Company B	32%	33%

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

	As of December 31, 2023	As of December 31, 2022
Company A	43%	41%
Company B	36%	28%
Company C	*	12%

* This amount is less than 10%.

(k) Revenue Recognition

We recognize revenue in accordance with Codification Topic 606, *Revenue from Contracts with Customers (ASC 606)*. ASC 606 is a single comprehensive model for companies to use in accounting for revenue arising from contracts with customers. The core principle is that we recognize the amount of revenue to which we expect to be entitled for the transfer of promised goods or services to customers when a customer obtains control of promised goods or services in an amount that reflects the consideration we expect to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. We conduct our business with customers through valid purchase orders or sales orders which are considered contracts and are not interdependent on one another. A performance obligation is a promise in a contract to transfer a distinct product to the customer. The transaction price is the amount of consideration we expect to receive under the arrangement. Revenue is measured based on consideration specified in a contract with a customer. The transaction price of a contract is allocated to each distinct

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

performance obligation and recognized when or as the customer receives the benefit of the performance obligation. Product transaction prices on a purchase or sales order are discrete and stand-alone. We recognize revenue when we satisfy a performance obligation in a contract by transferring control over a product to a customer when product ships to a customer. Amounts due are typically paid approximately 30 days from the time control is transferred. Shipping and handling costs associated with outbound freight are accounted for as a fulfillment cost in costs of goods sold. We do not bill for or collect sales tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We generally have experienced an immaterial amount of product returns. See Note 14 for additional disclosures.

(l) Expense Recognition

We do not incur costs in connection with product sales to customers that are eligible for capitalization. Advertising costs are expensed when incurred, which is generally during the month in which the advertisement is published. All product development expenses are expensed as incurred, as are all related patent costs. We capitalize costs to produce inventory during the production cycle, and these costs are charged to costs of goods sold when the inventory is sold to a customer or is deemed to be in excess or obsolete.

(m) Income Taxes

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. We consider future taxable income and feasible tax planning strategies in assessing the need for a valuation allowance against our deferred tax assets at the end of each quarter. If we determine that it is more likely than not that we will realize our deferred tax assets in the future in excess of the net recorded amount over a reasonably short period of time, a reduction of the valuation allowance would increase income in the period such determination was made. Likewise, if we determine that it is more likely than not that we will not realize all or part of our net deferred tax asset in the future, an increase to the valuation allowance would be charged to income in the period such determination was made.

Codification Topic 740-10 clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position must meet before being recognized in the financial statements. In the ordinary course of business, there are transactions and calculations where the ultimate tax outcome is uncertain. In addition, we are subject to periodic audits and examinations by the Internal Revenue Service and other taxing authorities. With few exceptions, we are no longer subject to income tax examinations by tax authorities for years before 2020. We have evaluated the positions taken on our filed tax returns and have concluded that no uncertain tax positions existed as of December 31, 2023 or 2022. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 16.

(n) Stock-Based Compensation

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock Compensation*, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model. Accordingly, we recorded compensation expense pertaining to stock-based compensation of \$368,866 and \$266,244 during the years ended December 31, 2023 and 2022, respectively. See Note 13.

(o) Net Loss Per Common Share

Net loss per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*. The net loss per share has been computed by dividing the net loss by the weighted average number of common shares outstanding during the period. All stock options have been excluded from the denominator in the calculation of dilutive earnings per share when we are in a loss position because their inclusion would be anti-dilutive. Outstanding stock options that were not included in this calculation because the effect would be anti-dilutive amounted to 618,500 and 605,000 during the years ended December 31, 2023 and 2022, respectively.

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

	During the Years Ended December 31,	
	2023	2022
Net loss attributable to stockholders	(\$5,774,598)	(\$2,493,805)
Weighted average common shares outstanding - Basic	7,747,686	7,745,122
Dilutive impact of share-based compensation awards	—	—
Weighted average common shares outstanding - Diluted	7,747,686	7,745,122
Net loss per share:		
Basic	(\$0.75)	(\$0.32)
Diluted	(\$0.75)	(\$0.32)

(p) Use of Estimates

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

(q) New Accounting Pronouncement Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which was effective for us as of January 1, 2023, using the modified retrospective transition method. This ASU amends the impairment model to utilize an expected loss methodology in place of the incurred loss methodology for financial instruments, including trade receivables. The amendment requires entities to consider a broader range of information to estimate expected credit losses, which may result in earlier recognition of losses. Historically, we have experienced a very low level of bad debt expense, and most of our trade receivables are collected by the due date or within a few days of the due date. Because of this experience, the adoption of ASU 2016-13 did not have a material impact on our financial statements.

(r) New Accounting Pronouncements Not Yet Adopted

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

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

3. CASH AND CASH EQUIVALENTS

Cash and cash equivalents amounted to \$978,741 and \$5,791,562 as of December 31, 2023 and 2022, respectively.

4. TRADE ACCOUNTS RECEIVABLE

Trade accounts receivable amounted to \$2,185,383 and \$1,758,600 as of December 31, 2023 and 2022, respectively. No allowance for bad debt or product returns was recorded as of December 31, 2023 or 2022. We anticipate no future events or conditions that would impact our ability to collect our accounts receivable. Because of the generally short duration from the balance sheet date to

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

the date of collection, our collection rate is not expected to be significantly impacted by events occurring after the balance sheet date. The trade accounts receivable balances included \$42,507 and \$46,426 due from a related party as of December 31, 2023 or 2022, respectively. See Note 18.

5. INVENTORY

Inventory consisted of the following:

	<u>As of</u> <u>December 31, 2023</u>	<u>As of</u> <u>December 31, 2022</u>
Raw materials	\$1,594,028	\$2,419,982
Work-in-process	5,815,194	3,468,702
Finished goods	402,619	149,855
Total	<u>\$7,811,841</u>	<u>\$6,038,539</u>

These inventory figures are net of a \$527,133 and \$589,204 write-off of scrapped inventory during the years ended December 31, 2023 and 2022, respectively, that resulted principally from contamination events and other production process losses.

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	<u>As of</u> <u>December 31, 2023</u>	<u>As of</u> <u>December 31, 2022</u>
Prepaid expenses	\$454,152	\$363,877
Other receivables	39,733	42,178
Total	<u>\$493,885</u>	<u>\$406,055</u>

7. PROPERTY, PLANT AND EQUIPMENT, net

Property, plant and equipment consisted of the following:

	<u>Estimated Useful</u> <u>Lives</u> <u>(in years)</u>	<u>As of</u> <u>December 31, 2023</u>	<u>As of</u> <u>December 31, 2022</u>
Laboratory and manufacturing equipment	3-10	\$20,953,601	\$19,181,960
Buildings and improvements	10-39	20,784,565	20,050,167
Office furniture and equipment	3-10	1,036,374	900,306
Construction in progress	n/a	2,768,224	3,668,046
Land	n/a	516,867	516,867
Property, plant and equipment, gross		46,059,631	44,317,346
Accumulated depreciation		(18,483,948)	(15,875,620)
Property, plant and equipment, net		<u>\$27,575,683</u>	<u>\$28,441,726</u>

As of December 31, 2023 and 2022, 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 \$100,142 and \$127,127 during the years ended December 31, 2023 and 2022, respectively. Depreciation expense was \$2,697,897 and \$2,468,479 during the years ended December 31, 2023 and 2022, 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 \$19,104 during both of the years ended December 31, 2023 and 2022. The net value of these intangibles was \$38,208 and \$57,312 as of December 31, 2023 and December 31, 2022, respectively. Intangible asset amortization expense is estimated to be \$19,104 per year through December 31, 2025.

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

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

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

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

	<u>Gross Carrying Value</u>	<u>Accumulated Amortization</u>	<u>Net Book Value</u>
Developed technology	\$184,100	(\$128,870)	\$55,230
Customer relationships	1,300	(910)	390
Non-compete agreements	5,640	(3,948)	1,692
Total	<u>\$191,040</u>	<u>(\$133,728)</u>	<u>\$57,312</u>

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	<u>As of December 31, 2023</u>	<u>As of December 31, 2022</u>
Accounts payable – trade	\$874,558	\$726,736
Accounts payable – capital	13,175	63,261
Accrued payroll	942,999	966,553
Accrued professional fees	97,800	95,550
Accrued other	192,754	143,872
Income tax payable	3,051	4,890
Total	<u>\$2,124,337</u>	<u>\$2,000,862</u>

10. BANK DEBT

Loans #1 and #2: During the first quarter of 2020, we closed on a debt financing with Gorham Savings Bank (GSB) aggregating \$8,600,000, which was comprised of a \$5,100,000 mortgage note (Loan #1) that bears interest at a fixed rate of 3.50% per annum (with a 10-year term and 25-year amortization schedule and a balloon principal payment of \$3,145,888 due during the first quarter of 2030) and a \$3,500,000 note (Loan #2) that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). The proceeds from the 2020 debt refinancing were used to repay all bank debt outstanding at the time of closing and to provide some additional working capital. During the first quarter of 2022, we closed on an additional \$2,000,000 in mortgage debt, which bears interest at the fixed rate of 3.58% per annum. This was accomplished through an amendment of the original mortgage note (Loan #1) that increased the then outstanding principal balance from \$4,233,957 to \$6,233,957 bearing interest at the blended fixed rate of 3.53% per annum. This increased the balloon payment from \$3,145,888 to \$3,687,479 and extended the due date of the balloon payment from the first quarter of 2030 to the first quarter of 2032.

Line of Credit (LOC): Also during the first quarter of 2020, GSB extended a \$1,000,000 LOC to us that is available, as needed, through September 11, 2025. Interest on borrowings against the LOC is variable at the National Prime Rate per annum. There was no outstanding balance under this LOC as of December 31, 2023 or 2022.

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

Loan #4: During the fourth quarter of 2020, we closed on a \$1,500,000 note with GSB that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). Proceeds of \$624,167 were used to prepay a portion of the outstanding principal on our mortgage note (Loan #1), which reduced the outstanding balance to 80% of the most recent appraised

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

value of the property securing the debt, which allowed GSB to release the \$1,400,000 that had been held in escrow. The remaining proceeds were available for general working capital purposes.

Loan #5: On June 30, 2021, we executed definitive agreements covering a second loan from the MTI in the aggregate principal amount of \$400,000, proceeds from which were received in July 2021. The first two years of this loan were interest-free with no interest accrual or required principal payments. Principal and interest payments at a fixed rate of 5% per annum are due quarterly over the final 5.5 years of the loan, beginning during the third quarter of 2023 and continuing through the fourth quarter of 2028 if not repaid before then.

Loan #6: During the third quarter of 2023, we closed on a \$2,000,000 term loan bearing interest at a fixed rate of 7% per annum from GSB. The Finance Authority of Maine (FAME) provided \$1,000,000 of loan insurance to GSB. This loan is repayable under a 7-year amortization schedule with a balloon payment of \$1,285,072 due during the third quarter of 2026.

Loan #7: Also during the third quarter of 2023, we closed on a \$1,000,000 term loan bearing interest at a fixed rate of 8% per annum from FAME. The loan is repayable under a 7-year amortization schedule with a balloon payment of \$649,235 due during the third quarter of 2026.

Loans #1, #2, #4, #6 and #7 are secured by liens on substantially all of our assets and are subject to certain restrictions and financial covenants. Loan #7 is subordinated to Loans #1, #2, #4 and #6. Reflecting our poor financial performance during 2023, the debt covenant requirements for the twelve-month periods ended December 31, 2023 and June 30, 2024 were waived pre-emptively by our bank. We are required to meet a minimum debt service coverage (DSC) ratio of 1.35 for the twelve-month period ending September 30, 2024 and then annually after that beginning with the year ending December 31, 2024. In connection with these credit facilities, we incurred aggregate debt issuance and debt discount costs of \$168,268 (\$98,098 and \$19,306 of which were incurred during the years ended December 31, 2023 and 2022, respectively). The amortization of these debt issuance and debt discount costs is being recorded as a component of interest expense, included in other expenses, net, and is being amortized on a straight-line basis over the underlying terms of the notes. Loans #3 and #5 are unsecured and subordinated to our indebtedness to GSB and FAME. Failure to make timely payments of principal and interest, or otherwise to comply with the terms of the agreements of Loans #3 and #5, would entitle the MTI to accelerate the maturity of such debt and demand repayment in full. These loans may be prepaid without penalty at any time.

Debt proceeds received and principal repayments made (excluding our \$1,000,000 line of credit) during the years ended December 31, 2023 and 2022 are reflected in the following table by period and by loan:

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

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

Principal payments (net of debt issuance and debt discount costs) due under bank loans outstanding as of December 31, 2023 (excluding our \$1,000,000 line of credit) are reflected in the following table by the year that payments are due:

	During the Years Ending December 31,						Total
	2024	2025	2026	2027	2028	Thereafter	
Loan #1	\$230,879	\$239,876	\$248,604	\$257,649	\$266,537	\$4,598,360	\$5,841,905
Loan #2	512,103	530,738	549,881	140,458	—	—	1,733,180
Loan #3	96,104	101,001	106,146	83,143	—	—	386,394
Loan #4	213,217	220,994	228,965	240,452	—	—	903,628
Loan #5	66,470	69,856	73,415	77,156	81,086	—	367,983
Loan #6	235,369	253,003	1,418,574	—	—	—	1,906,946
Loan #7	114,632	124,364	715,308	—	—	—	954,304
Subtotal	1,468,774	1,539,832	3,340,893	798,858	347,623	4,598,360	12,094,340
Debt issuance cost	(19,076)	(18,976)	(13,579)	(5,420)	(3,513)	(11,347)	(71,911)
Debt discount cost	(20,891)	(20,891)	(11,344)	—	—	—	(53,126)
Total	\$1,428,807	\$1,499,965	\$3,315,970	\$793,438	\$344,110	\$4,587,013	\$11,969,303

11. CONTINGENT LIABILITIES AND COMMITMENTS

Our bylaws, as amended, in effect provide that the Company will indemnify its officers and directors against any liability arising from their responsibilities as officers and directors to the maximum extent permitted by Delaware law. In addition, we make similar indemnity undertakings with each director through a separate indemnification agreement with that director. The maximum payment that we may be required to make under such provisions is theoretically unlimited and is impossible to determine. We maintain directors' and officers' liability insurance, which may provide reimbursement to the Company for payments made to, or on behalf of, officers and directors pursuant to the indemnification provisions. Our indemnification obligations were grandfathered under the provisions of Codification Topic 460, *Guarantees*. Accordingly, we have recorded no liability for such obligations as of December 31, 2023 or 2022. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

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

We enter into agreements with third parties in the ordinary course of business under which we are obligated to indemnify such third parties from and against various risks and losses. The precise terms of such indemnities vary with the nature of the agreement. In many cases, we limit the maximum amount of our indemnification obligations, but in some cases those obligations may be theoretically unlimited. We have not incurred material expenses in discharging any of these indemnification obligations and based on our analysis of the nature of the risks involved, we believe that the fair value of the liabilities potentially arising under these agreements is minimal. Accordingly, we recorded no liabilities for such obligations as of December 31, 2023 or 2022.

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

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

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This deferred compensation payment vested as to \$100,000 on January 1, 2023 and an additional \$100,000 on January 1, 2024. An additional \$100,00 will vest on January 1, 2025, provided that Mr. Brigham is employed by the Company as of January 2025. The vested amounts would be paid upon the earlier of January 31, 2025 or within thirty (30) days following his separation from the Company. As of December 31, 2023 and 2022, \$200,000 and \$100,000, respectively, was included in accounts payable and accrued expenses on the accompanying balance sheets. In addition, upon termination of Mr. Brigham's employment (a) by the Company other than for cause, (b) due to death or disability or (c) by Mr. Brigham for good reason, in each case as described and defined in the Deferred Compensation Agreement, the Company agrees to pay Mr. Brigham 100% of his then current annual base salary and a lump sum payment equal to the employer portion of the costs of continued health benefits for Mr. Brigham and his covered dependents for a twelve-month period following termination, and certain equity incentive awards granted to Mr. Brigham would continue to vest following such termination in accordance with the terms of the Deferred Compensation Agreement. Incentive Compensation Agreements with Mr. Brigham, Ms. Brockmann (our Vice President of Sales and Marketing) and Ms. Williams (our Vice President of Manufacturing Operations) allow these executives to earn incentive compensation if certain regulatory and financial objectives are met during the year to which the agreement relates, as specified in their agreements. Amounts related to these incentive compensation agreements are accrued over the period they are earned (when it is probable that the amounts will be earned) based on our best estimate of the amounts expected to be earned.

In addition to the commitments discussed above, we had committed \$41,000 to increase our production capacity for the **First Defense**[®] product line, \$2,345,000 to the purchase of inventory, \$7,000 related to the commercial manufacture of **Re-Tain**[®] and \$307,000 to other obligations as of December 31, 2023.

12. OPERATING LEASES

On September 12, 2019, we entered into a lease covering approximately 14,300 square feet of office and warehouse space with a possession date of November 15, 2019 and a commencement date of February 13, 2020. The property is located at 175 Industrial Way in Portland (**Building 175A**), which is a short distance from our headquarters and manufacturing facility at 56 Evergreen Drive. We renovated this space to meet our needs in expanding our production capacity for the **First Defense**[®] product line. The original lease term was ten years with a right to renew for a second 10-year term and a right of first offer to purchase. At the time we entered into this lease, we were not reasonably assured that we would exercise this renewal option in place of other real estate options. For that reason, a 10-year period was reflected in the right-of-use (ROU) asset and lease liability on our balance sheet. During the third quarter of 2022, we committed to lease an additional 15,400 square feet of space at 175 Industrial Way (**Building 175B**), which is connected to the original space, over a 20-year term. The ROU asset and lease liability for the committed space at **Building 175B** was recorded as of April 1, 2023 after construction of the building shell was completed in accordance with the lease agreement. Monthly lease payments commenced as of August 1, 2023. In connection with the lease commitment for space at **Building 175B**, the term of the original lease for **Building 175A** was extended by approximately 13 years. On November 14, 2023, we amended this lease further to provide for certain tenant improvements on the leased premises to be paid for by our landlord. These improvements will provide heat to an unfinished space, provide additional warehouse space, and create a new primary shipping and receiving facility. In consideration for the landlord agreeing to pay for the cost of those certain tenant improvements, we are obligated to make additional rent payments of \$20,000 per month from November 2023 through June 2024 and a one-time additional rent payment of \$488,743 in July 2024. The total lease liability for both leases over the amended terms (including inflationary adjustments) aggregates \$4,739,077 as of November 14, 2023. Because of this modification to the lease payments, the ROU asset and lease liability associated with the space at **Building 175B** were remeasured as of the modification date. Our leases include variable non-lease components. Such payments primarily include common area maintenance charges. As of December 31, 2023, the balance of the operating lease ROU asset was \$4,571,149 and the operating lease liability was \$4,721,385. As of December 31, 2022, the balance of the operating lease ROU asset was \$2,194,670 and the operating lease liability was \$2,249,182. The calculated amount of the ROU asset and lease liability is impacted by the length of the lease term and the discount rate used for the present value of the minimum lease payments. We elected not to separate lease and non-lease components for all classes of underlying assets, and instead to account for them as a single lease component. Variable lease cost primarily represents variable payments such as real estate taxes and common area maintenance. The following tables describe our lease costs and other lease information:

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Notes to Audited Financial Statements (continued)

	During the Years Ended December 31,	
	2023	2022
Lease Cost		
Operating lease cost	\$348,929	\$149,176
Variable lease cost	36,774	36,404
Total lease cost	<u>\$385,703</u>	<u>\$185,580</u>
Operating Leases		
Cash paid for operating lease liabilities	\$248,595	\$148,302
Weighted average remaining lease term (in years)	19.1	20.1
Weighted average discount rate	7.11%	5.54%

Future lease payments required under non-cancelable operating leases in effect as of December 31, 2023 were as follows:

	<u>Amount</u>
<u>During the years ending December 31,</u>	
2024	\$946,003
2025	342,880
2026	349,744
2027	356,732
2028	363,870
Thereafter	5,949,488
Total lease payments (undiscounted cash flows)	<u>8,308,717</u>
Less: imputed interest (discount effect of cash flows)	<u>(3,587,332)</u>
Total operating liabilities	<u>\$4,721,385</u>

13. STOCKHOLDERS' EQUITY

Common Stock Issuances

From February 2016 to April 2021, we sold the aggregate of 4,553,017 shares of common stock in six different transactions raising gross proceeds of \$26,714,403 at the weighted average price of \$5.87 per share. These funds have been essential to funding our business growth plans. The details of each transaction are discussed below:

1) During February of 2016, we sold 1,123,810 shares of common stock at a price to the public of \$5.25 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of \$5,900,003 and resulting in net proceeds to the Company of \$5,313,224 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

2) During October of 2016, we sold, in a private placement, 659,880 shares of common stock to nineteen institutional and accredited investors at \$5.25 per share, raising gross proceeds of \$3,464,370 and resulting in net proceeds to the Company of \$3,160,923 (after deducting placement agent fees and other expenses incurred in connection with the equity financing).

3) During July of 2017, we sold 200,000 shares of our common stock at a price of \$5.25 per share in a public, registered sale to two related investors pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of \$1,050,000 and resulting in net proceeds of \$1,034,164 (after deducting expenses incurred in connection with the equity financing).

4) During December of 2017, we sold 417,807 shares of common stock at a price to the public of \$7.30 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of \$3,049,991 and resulting in net proceeds to the Company of \$2,734,173 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

5) During March of 2019, we sold 1,636,364 shares of common stock at a price to the public of \$5.50 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of \$9,000,002

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Notes to Audited Financial Statements (continued)

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

6) During April of 2021, we sold 515,156 shares of our common stock at a price of \$8.25 per share in a public, registered sale to seven investors pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of \$4,250,038 and resulting in net proceeds of \$4,233,026 (after deducting expenses incurred in connection with the equity financing).

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. There were 188,500 and 202,500 options outstanding under the 2010 Plan as of December 31, 2023 and 2022, respectively.

In June 2017, our stockholders approved the 2017 Stock Option and Incentive Plan (the “2017 Plan”) pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company’s common stock at no less than fair market value on the date of grant. At that time, 300,000 shares of common stock were reserved for issuance under the 2017 Plan. An amendment to the 2017 Plan increasing the number of shares reserved for issuance under the 2017 Plan from 300,000 shares to 650,000 shares was approved by a vote of stockholders at the Annual Meeting of Stockholders in June 2022. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case-by-case basis. All options granted under the 2017 Plan expire no later than 10 years from the date of grant. The 2017 Plan expires in March 2027, after which date no further options can be granted under the 2017 Plan. However, options outstanding under the 2017 Plan at that time can be exercised in accordance with their terms. As of December 31, 2023 and 2022, there were 430,000 and 402,500 options outstanding under the 2017 Plan, respectively.

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

	2010 Plan	2017 Plan	Weighted Average Exercise Price	Aggregate Intrinsic Value⁽¹⁾
Outstanding as of December 31, 2021	218,500	224,500	\$6.94	\$468,425
Grants	—	210,500	\$7.73	
Terminations/forfeitures ⁽²⁾	(11,000)	(32,500)	\$7.34	
Exercises	(5,000)	—	\$6.13	
Outstanding as of December 31, 2022	202,500	402,500	\$7.19	(\$661,310)
Grants	—	122,000	\$5.16	
Terminations/forfeitures ⁽²⁾	(10,000)	(94,500)	\$7.12	
Exercises	(4,000)	—	\$4.69	
Outstanding as of December 31, 2023	<u>188,500</u>	<u>430,000</u>	\$6.82	(\$1,071,121)
Vested as of December 31, 2023	<u>188,500</u>	<u>92,500</u>	\$6.43	(\$377,712)
Vested and expected to vest as of December 31, 2023	<u>188,500</u>	<u>430,000</u>	\$6.82	(\$1,071,121)
Reserved for future grants	<u>—</u>	<u>202,000</u>		

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

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

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Notes to Audited Financial Statements (continued)

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, 2023	307,000	\$3.80	\$7.71
Non-vested stock options as of December 31, 2023	337,500	\$3.66	\$7.14
Stock options granted during the year ended December 31, 2023	122,000	\$2.80	\$5.16
Stock options that vested during the year ended December 31, 2023	57,000	\$2.23	\$5.59
Stock options that were terminated or forfeited during the year ended December 31, 2023	104,500	\$3.30	\$7.12

During the year ended December 31, 2023, 4,000 stock options were exercised by one employee with \$18,760 in cash. During the year ended December 31, 2022, one former employee and two employees exercised stock options covering 5,000 shares with \$30,670 in cash. The aggregate intrinsic value of options exercised during the years ended December 31, 2023 and 2022 was \$1,040 and \$10,525, respectively. The weighted average remaining life of the options outstanding under the 2010 Plan and the 2017 Plan as of December 31, 2023 was approximately 5 years and 8 months. The weighted average remaining life of the options exercisable under these plans as of December 31, 2023 was approximately 3 years and 6 months. The exercise prices of the options outstanding as of December 31, 2023 ranged from \$4.00 to \$10.04 per share. The 122,000 stock options granted during the year ended December 31, 2023 had exercise prices between \$4.61 and \$5.22 per share. The 210,500 stock options granted during the year ended December 31, 2022 had exercise prices between \$6.52 and \$9.39 per share. The weighted-average grant date fair values of options granted during the year ended December 31, 2023 and 2022 were \$2.80 and \$4.03 per share, respectively. As of December 31, 2023, total unrecognized stock-based compensation related to non-vested stock options aggregated \$619,845, which will be recognized over a weighted average remaining period of approximately 1 year and 8 months. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, for the purpose discussed in Note 2(n), with the following weighted-average assumptions:

	During the Years Ended December 31,	
	2023	2022
Risk-free interest rate ⁽¹⁾	3.59%	3.04%
Dividend yield ⁽²⁾	0%	0%
Expected volatility ⁽²⁾	54%	53%
Expected life ⁽³⁾	6.2 years	5.9 years

⁽¹⁾ The risk-free interest rate is based on U.S. Treasury yields for a maturity approximating the expected option term.

⁽²⁾ The dividend yield and expected volatility are derived from averages of our historical data.

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

Common Stock Rights Plan

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

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

Upon the Distribution Date, the holder of each Right not owned by the Acquiring Person would be entitled to purchase common stock at a discount to the initial purchase price of \$70.00 per share, effectively equal to one half of the market price of a share of

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Notes to Audited Financial Statements (continued)

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

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

During the third quarter of 2011, our Board of Directors voted to authorize an amendment to the Rights Plan to increase the ownership threshold for determining "Acquiring Person" status to 20%. During the second quarter of 2015, our Board of Directors also voted to authorize an amendment to remove a provision that prevented a new group of directors elected following the emergence of an Acquiring Person (an owner of more than 20% of our stock) from controlling the Rights Plan by maintaining exclusive authority over the Rights Plan with pre-existing directors. We did this because such provisions have come to be viewed with disfavor by Delaware courts. Each time that we made such amendments we entered into amendments to the Rights Agreement with the Rights Agent reflecting such extensions, threshold increases or provision changes. No other changes have been made to the terms of the Rights or the Rights Plan.

At various times over the years, our Board of Directors, which has the authority to amend the Rights Plan, has voted to authorize amendments to the Rights Plan to extend the expiration date of the Rights Plan. Our Board of Directors decided to seek an advisory vote by stockholders at the Annual Meeting of Stockholders held in June 2022, as to whether to extend the Rights Plan by one year to September 19, 2023. Of the votes actually cast on this proposal, 65% voted in favor, 32% voted against and 3% abstained. On the basis of this vote, our Board of Directors voted to extend the Rights Plan by one year to September 19, 2023. Our Board of Directors decided to seek another advisory vote by stockholders at the Annual Meeting of Stockholders held in June 2023, as to whether to extend the Rights Plan by another year to September 19, 2024. Of the votes actually cast on this proposal, 65.10% voted in favor, 34.60% voted against and 0.30% abstained. On the basis of this vote, our Board of Directors voted to extend the Rights Plan by one year to September 19, 2024. Recognizing that there might be a substantial number of broker non-votes, our Board of Directors disclosed that it would be guided by the votes actually cast on these proposals in deciding whether to extend the expiration date of such plan by one year.

Authorized Common Stock

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

14. REVENUE

We primarily offer the **First Defense**[®] product line to dairy and beef producers to prevent scours in newborn calves. Generally, our products are promoted to veterinarians as well as dairy and beef producers by our sales team and then sold through distributors. Our primary market is North America. We do sell into select international regions and may expand this international reach in the future. There were no material changes between the allocation and timing of revenue recognition during the years ended December 31, 2023 or 2022. We do not have any contract assets for which we have satisfied the performance obligations, but do not yet have the right to bill for, or contract liabilities such as customer advances. All trade receivables on our balance sheet are from contracts with customers. We incur no material costs to obtain contracts.

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

	During the Years Ended December 31,			
	2023	%	2022	%
United States	\$15,949,382	91%	\$17,020,797	92%
Other	1,522,287	9%	1,547,165	8%
Total Product Sales	\$17,471,669	100%	\$18,567,962	100%

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

	During the Years Ended December 31,			
	2023	%	2022	%
First Defense [®] product line	\$17,293,933	99%	\$18,411,949	99%
Other animal health	177,736	1%	156,013	1%
Total Product Sales	\$17,471,669	100%	\$18,567,962	100%

15. OTHER EXPENSES, NET

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

	During the Years Ended December 31,	
	2023	2022
Interest expense ⁽¹⁾	\$475,598	\$348,536
Loss (gain) on disposal of property, plant and equipment	8,099	(7,334)
Interest income	(96,570)	(153,100)
Insurance recovery ⁽²⁾	(365,127)	—
Income-other	(107)	(912)
Other expenses, net	\$21,893	\$187,190

⁽¹⁾ Interest expense includes amortization of debt issuance and debt discount costs of \$22,619 and \$7,658 during the years ended December 31, 2023 or 2022, respectively.

⁽²⁾ The insurance recovery income resulted from insurance benefit proceeds paid to us under our business interruption policy related to the product contamination losses and a recovery from a vendor's policy related to an equipment malfunction.

16. INCOME TAXES

Our income tax expense aggregated \$4,627 and \$7,672 (amounting to less than 1% of our loss before income taxes) during the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had federal net operating loss carryforwards of \$17,759,519 of which \$16,047,612 do not expire and of which \$1,711,907 expire in 2034 through 2037 (if not utilized before then) and state net operating loss carryforwards of \$4,681,644 that expire in 2037 through 2038 (if not utilized before then). Additionally, we had federal general business tax credit carryforwards of \$726,474 that expire in 2027 through 2042 (if not utilized before then) and state tax credit carryforwards of \$775,473 that expire in 2024 through 2042 (if not utilized before then).

The provision for income taxes is determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the estimated future tax effects of temporary differences between book and tax treatment of assets and liabilities and carryforwards to the extent they are realizable. During the second quarter of 2018, we assessed our historical and near-term future profitability and recorded \$563,252 in non-cash income tax expense to create a full valuation allowance against our net deferred tax assets (which consist largely of net operating loss carryforwards and federal and state credits) based on applicable accounting standards and practices. At that time, we had incurred a net loss for six consecutive quarters, had not been profitable on a year-to-date basis since the nine-month period ended September 30, 2017 and projected additional net losses for some period going forward before returning to profitability. Should future profitability be realized at an adequate level, we would be able to release this valuation allowance (resulting in a non-cash income tax benefit) and realize these deferred tax assets before they expire. We will continue to assess the need for the valuation allowance at each quarter and, in the event that actual results differ from these estimates, or we adjust these estimates in future periods, we may need to adjust our valuation allowance. Currently, we adjust the valuation allowance at the end of each quarter to reduce the value of our deferred tax assets to zero.

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

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 audited financial statements.

The income tax provision consisted of the following:

	During the Years Ended December 31,	
	2023	2022
Current		
Federal	\$—	\$—
State	4,627	7,672
Current subtotal	4,627	7,672
Deferred		
Federal	(1,179,474)	(576,780)
State	(145,802)	(88,533)
Deferred subtotal, gross	(1,325,276)	(665,313)
Valuation allowance	1,325,276	665,313
Deferred subtotal, net	—	—
Income tax expense	<u>\$4,627</u>	<u>\$7,672</u>

The actual income tax expense differs from the expected tax computed by applying the U.S. federal corporate tax rate of 21% to the loss before income taxes during the years ended December 31, 2023 and 2022 respectively, as follows:

	During the Years Ended December 31,			
	2023		2022	
	\$	%	\$	%
Computed expected income tax expense rate	(\$1,211,694)	(21.00%)	(\$522,088)	(21.00%)
State income taxes, net of federal expense	(117,149)	(2.03)	(47,643)	(1.92)
Share-based compensation	56,214	0.97	36,652	1.48
Tax credits	(53,241)	(0.92)	(131,361)	(5.28)
Valuation allowance	1,325,276	0.09	665,313	26.76
Other	5,221	22.97	6,799	0.27
Income tax expense/rate	<u>\$4,627</u>	<u>0.08%</u>	<u>\$7,672</u>	<u>0.31%</u>

The significant components of our deferred tax assets, net, consisted of the following:

	As of December 31,	
	2023	2022
Property, plant and equipment	(\$2,121,940)	(\$2,530,472)
Federal general business tax credits	726,474	673,233
Federal net operating loss carryforwards	3,729,500	3,258,395
State tax credits and net operating loss carryforwards	886,428	817,617
§174 R & D expenditures	592,915	341,683
Deferred compensation	50,722	23,370
Prepaid expenses and other	37,124	15,587
UNICAP	32,607	32,787
Incentive compensation	100,200	76,554
Valuation allowance	(4,034,030)	(2,708,754)
Deferred tax assets, net	<u>\$—</u>	<u>\$—</u>

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

17. SEGMENT INFORMATION

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

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

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

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

ImmuCell Corporation
Notes to Audited Financial Statements (continued)

18. RELATED PARTY TRANSACTIONS

David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone Inc., a domestic distributor of our products (the **First Defense**[®] product line and **CMT**). His affiliated company purchased \$231,405 and \$587,677 of products from us during the years ended December 2023 and 2022, respectively, all on terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from this affiliated company aggregated \$42,507 and \$46,426 as of December 31, 2023 and 2022, 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 \$178,150 and \$159,058 into the Plan for the years ended December 31, 2023 and 2022, respectively.

20. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of filing on the date we have issued this Annual Report on Form 10-K. As of the time of filing, there were no material, reportable subsequent events.

Signatures

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: April 1, 2024

By: /s/ Michael F. Brigham

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

POWER OF ATTORNEY

We, the undersigned directors and employees of ImmuCell Corporation, hereby severally constitute and appoint Michael F. Brigham our true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for us and in our stead, in any and all capacities, to sign any and all amendments to this report and all documents relating thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or advisable to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Gloria J. Basse</u> Gloria J. Basse	Director	March 29, 2024
<u>/s/ Michael F. Brigham</u> Michael F. Brigham	President, Chief Executive Officer Principal Financial Officer and Director	March 29, 2024
<u>/s/ Bobbi Jo Brockmann</u> Bobbi Jo Brockmann	Vice President of Sales and Marketing and Director	March 29, 2024
<u>/s/ Bryan K. Gathagan</u> Bryan K. Gathagan	Director	March 29, 2024
<u>/s/ Steven T. Rosgen</u> Steven T. Rosgen	Director	March 29, 2024
<u>/s/ David S. Tomsche</u> David S. Tomsche, DVM	Director	March 29, 2024
<u>/s/ Elizabeth S. Toothaker</u> Elizabeth S. Toothaker	Controller	March 29, 2024
<u>/s/ Paul R. Wainman</u> Paul R. Wainman	Director	March 29, 2024