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, 2024

001-12934
(Commission file number)

ImmuCell Corporation

(Exact name of registrant as specified in its charter)

Delaware	**01-0382980**
(State of incorporation)	**(I.R.S. Employer Identification No.)**
56 Evergreen Drive, Portland, Maine	**04103**
(Address of principal executive offices)	**(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	The Nasdaq Capital Market

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, 2024 was approximately $30,634,000 based on the closing sales price on June 28, 2024 of $4.85 per share.

The number of shares of the registrant's common stock outstanding as of March 21, 2025 was 8,982,623.

Documents incorporated by reference: Portions of the registrant's definitive Proxy Statement to be filed in connection with the 2025 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

ImmuCell Corporation
TABLE OF CONTENTS
December 31, 2024

PART I

ITEM 1	Business…….	1
ITEM 1A	Risk Factors……...	10
ITEM 1B	Unresolved Staff Comments……..	19
ITEM 1C	Cybersecurity…….	19
ITEM 2	Properties…….....	19
ITEM 3	Legal Proceedings……..	21
ITEM 4	Mine Safety Disclosures……	21

PART II

ITEM 5	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities……..	21
ITEM 6	[Reserved]……..	21
ITEM 7	Management's Discussion and Analysis of Financial Condition and Results of Operations……..	21
ITEM 7A	Quantitative and Qualitative Disclosures about Market Risk……...	39
ITEM 8	Financial Statements and Supplementary Data…….	39
ITEM 9	Changes In and Disagreements With Accountants on Accounting and Financial Disclosure……..	39
ITEM 9A	Controls and Procedures……	39
ITEM 9B	Other Information……..	40
ITEM 9C	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections…….…….	40

PART III

ITEM 10	Directors, Executive Officers and Corporate Governance……	40
ITEM 11	Executive Compensation……...	40
ITEM 12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters…….	40
ITEM 13	Certain Relationships and Related Transactions, and Director Independence…….	40
ITEM 14	Principal Accountant Fees and Services……...	41

PART IV

ITEM 15	Exhibits and Financial Statement Schedules...……...……...	41
ITEM 16	Form 10-K Summary…….…….……....	43
	Audited Financial Statements……	F-1 to F-25
	Signatures	

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, goals and strategies for our business; projections of future financial or operational performance; the timing and outcome of pending or anticipated applications for regulatory approvals and pending or anticipated regulatory inspections of our facilities and those of our contract manufacturers; future demand for our products; future adoption of **Re-Tain®** by dairy producers; growth in acceptance of our **First Defense®** product line by dairy and beef producers; the impact of international disputes (including Russia's invasion of Ukraine and unrest 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; future incidence rates of subclinical mastitis and producers' level of interest in treating subclinical mastitis; 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 of our contamination remediation efforts; whether or not we will experience 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 to meet future demand and related technical issues; estimates about our future production capacity, efficiency and yield; the salability of products currently held in inventory pending regulatory approval; future regulatory requirements relating to our products; future expense ratios and margins; the future consequences and effectiveness of our investments in our business; future compliance with, or waivers of, bank debt covenants; anticipated changes in our manufacturing capabilities and efficiencies; our future effectiveness in competing against competitors within both our existing and our anticipated product markets; projections about depreciation expense and its impact on income for book and tax return purposes; and any other statements that are not historical facts. These statements are intended to provide management's current expectation of future events as of the date of this earnings release, are based on management's estimates, projections, beliefs and assumptions as of the date hereof; and are not guarantees of future performance. Such statements involve known and unknown risks and uncertainties that may cause the Company's actual results, financial or operational performance or achievements to be materially different from those expressed or implied by these forward-looking statements, including, but not limited to, those risks and uncertainties relating to: difficulties or delays in development, testing, regulatory approval, production and marketing of our products (including the **First Defense®** product line and **Re-Tain®**), competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand (including the consequences of backlogs), uncertainty associated with the timing and volume of customer orders as we come out of a prolonged backlog, adverse impacts of supply chain disruptions on our operations and customer and supplier relationships, commercial and operational risks relating to our current and planned expansion of production capacity, and other risks and uncertainties detailed from time to time in filings we make with the Securities and Exchange Commission (SEC), including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements involve risks and uncertainties and are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized under **PART II: OTHER INFORMATION, ITEM 1A-RISK FACTORS** and uncertainties otherwise referred to in this 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.

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 on 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. 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 concerns through reduced use of antibiotics in food-producing animals. We have experienced significant growth in sales of our **First Defense**® product line, a product that provides significant **Immediate Immunity™** to newborn dairy and beef livestock.

We believe that our purified Nisin treatment for subclinical mastitis in lactating dairy cows (**Re-Tain**®) could revolutionize the way that farmers treat mastitis, the single most significant cause of economic loss to the dairy industry. Full commercial sales of this product cannot 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. We are now awaiting FDA action on our fourth submission of the fifth and final Technical Section, which we submitted in January of 2025. At the same time, we are initiating Investigational Product use of this product, as discussed in more detail later in this Annual Report.

We are making ongoing efforts to maintain compliance with current Good Manufacturing Practice (cGMP) regulations in all of our manufacturing operations, which requires a sustained investment but further enhances the quality of all of our products and our operating efficiency. We continue to invest in personnel, equipment and facility modifications to increase the efficiency and quality of our operations.

Over the past nine years, 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. 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. During 2024, we issued an aggregate of 1,228,227 shares of common stock, raising gross proceeds of approximately $4.6 million, through our At-The-Market (ATM) Offering. 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 $10.5 million in outstanding debt as of December 31, 2024 compared to approximately $3.2 million as of December 31, 2015. This increase in equity and debt capital has been, and is being, used to increase the production capacity for the **First Defense**® product line and to 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 $45.1 million as of December 31, 2024 from $14.6 million as of December 31, 2015, and our stockholders' equity has increased to $27.5 million as of December 31, 2024 from $10.6 million as of December 31, 2015. This represents a 209%, or $30.5 million, increase in total assets and a 159%, or $16.9 million, increase in stockholders' equity over this nine-year period.

Production Capacity Increase and Product Contamination

During 2019, we began a series of investments to increase our production capacity for the **First Defense®** product line to $30 million or more per year. The facility expansions and new equipment needed to increase production capacity were in place by the end of 2022. Around the end of the third quarter of 2022, as this increased production capacity was coming online, we detected a product contamination event that required us to scrap significant inventory. 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, we 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 $407,000 and $527,000 during 2024 and 2023, respectively. We have been operating without any new contamination events since April of 2024.

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. We believe that the contamination events we suffered between 2022 and 2024 stemmed from us processing more milk (colostrum) from more farms than ever before in order to increase production output and meet increasing customer demand. We believe that we now have significantly 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 backlog of orders and then resume being a reliable supplier of a very effective product to the dairy and beef calf markets. Once achieved, our goal is to continue to expand our penetration of the beef market and less price sensitive dairies with **Tri-Shield®**, while simultaneously launching a lower-cost spray-dried product without USDA claims, targeting more price sensitive large calf ranches and dairies. Overall, our goal is to continue to grow sales and differentiate our brands in both the beef and dairy markets.

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 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 that calves with scours 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 2024 marked the 33rd anniversary of the original USDA approval of this product in 1991. During the fourth quarter of 2024, our cumulative sales of **First Defense®** since inception passed 36 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 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 do not 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™**. 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 colostrum 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. We are working to expand this product category to include a spray-dried, bulk powder format. 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 leader of stakeholder engagement, one director of marketing and six 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 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 are more actively marketing to the beef market and pursuing new international territories. 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.

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 and cold stress during the winter months can increase the incidence of scours. 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 $31.1 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 $81.8 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, but we also believe that these gains have been limited by our short supply of product to the market in recent years. 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	2024
36%	41%	43%	44%	48%	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	2024
11%	13%	13%	14%	14%	15%

We continue our efforts to grow sales of the **First Defense**® product line in North America, where there are approximately 37.3 million dairy and beef cows in the United States and approximately 4.4 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 implementing 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 and covering Iran with Senikco, LLC of Laguna Niguel, California during the fourth quarter of 2016. 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 this 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 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 anti-

microbial 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 pre-slaughter withdrawal period. 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 pre-slaughter withdrawal period. 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 place increased pressure on the industry to treat cows with subclinical infections rather than ignore them and leave them sick.

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 pre-slaughter withdrawal cost, we expect producers to be more motivated to identify and treat cows at the subclinical stage. 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 of 2024, will guide our pricing strategies. In addition, we expect that **Re-Tain**® will be priced at a premium to the traditional antibiotic products currently on the market, which are all sold subject to milk discard and pre-slaughter withdrawal period requirements.

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 $40 million per year is spent on drug treatments. We believe more than this amount is spent on dry cow 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 upon 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 $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 DS facilities to double the production capacity by installing a second DS 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 product produced at our DS facility and filled by our contract DP manufacturer. 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. Note 16, "Segment Information", to the accompanying audited financial statements displays 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 $26.5 million achieved during the year ended December 31, 2024 as soon as possible. Our longer-term goal is to exceed $35 million in product sales by approximately 2027.

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. Between 2000 and 2024, we invested an aggregate of approximately $30.2 million in direct expenditures for the development of this product (excluding depreciation, the capital cost of our DS production facility and overhead expenses). Approximately $2.9 million of this investment was offset by related product licensing revenues and grant income, most of which was earned from 2001 to 2007. More recently, we have initiated a preliminary investigation into potential applications of Nisin for human healthcare, but we do not see a clear commercial path at this time.

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 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.

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. Our Nisin technology includes patented processing and purification methods to achieve pharmaceutical-grade 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 second most important product development initiative (in terms of dollars invested and, we believe, potential market impact) has been focused on other improvements, extensions or additions to our **First Defense®** product line. We anticipate initiating commercial sales of a new spray-dried format of our **First Defense Technology®** in a bulk powder later this year. 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 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 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.

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 75 employees (including 6 part-time employees) in comparison to 79 employees (including 5 part-time employees) approximately a year ago. Approximately 57 full-time equivalent employees are engaged in quality and manufacturing operations, 8.5 full-time equivalent employees in sales and marketing, 2.5 full-time equivalent employees in product development activities (primarily supporting facility maintenance and operation, regulatory filings and commercial scale-up for **Re-Tain®**) and 4 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**
- **Risk Pertaining to Common Stock**
- **Other Risks**

Financial Risks

Gross margin on product sales: One of our goals is to achieve a gross margin as a percentage of total sales of 40% or more (including depreciation expense) after the initial launch of new products. Depreciation expense will be a larger component of costs of goods sold for **Re-Tain®** than it is for the **First Defense®** product line. Gross margins generally improve over time, but this anticipated improvement may not be realized for **Re-Tain®**. Many factors discussed in this Annual Report (including contaminations, process yields, inflation, cost increases, supply-chain disruptions and the rising price of oil and other commodities and supplies) impact our costs of goods sold. There is a risk that we are not able to achieve our gross margin goal, which would adversely affect our operating results and could impact our future operating plans. We missed our gross margin goal during the years ended December 31, 2024 and 2023 with realized gross margins of 30% and 22%, respectively. There is a risk that our plans to maintain or improve our gross margin may not be realized due to cost increases, production yield losses, additional manufacturing contamination events, production equipment failures, price inelasticity 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. Increases in interest rates since 2020 have had only limited effect on our direct cost of borrowing. During the first quarter of 2020, we refinanced our bank debt (with the exception of our line of credit) with fixed rate notes. Our mortgage debt outstanding as of December 31, 2024 was $5.6 million bearing interest at the fixed rate of 3.53% per annum. Our equipment loans outstanding as of December 31, 2024 were $1.9 million bearing interest at the fixed rate of 3.50% per annum. The outstanding balance on the two State of Maine loans as of December 31, 2024 was approximately $592,000 bearing interest at the

fixed rate of 5% per annum. The $3 million in debt that we borrowed during the third quarter of 2023 (which had an outstanding balance of approximately $2.5 million as of December 31, 2024) bears interest at the blended fixed rate of 7.33% per annum illustrating the effect of rising interest rates. Our outstanding debt as of December 31, 2024 aggregating $10.6 million (gross of debt issuance and debt discount costs) 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. The additional debt we incurred to fund our growth objectives has significantly increased our total debt service costs. We are obligated to make principal and interest payments aggregating approximately $2 million and $3.7 million during the years ending December 31, 2025 and 2026, respectively. See Note 9 to the accompanying audited financial statements for more details about our debt. A decline in sales or gross margin, coupled with this debt service burden, could impair our ability to fund our capital and operating needs and objectives.

Debt covenants: Our debt with Maine Community Bank (formerly Gorham Savings Bank) and the Finance Authority of Maine is subject to certain financial covenants. We are required to meet a minimum debt service coverage (DSC) ratio of 1.35. Our actual DSC ratios were 0.73, (1.10), 0.44, 2.68 and 2.03 for the years ended December 31, 2024, 2023, 2022, 2021 and 2020, respectively. During the first quarter of 2023, the DSC ratio covenant for the year ended December 31, 2023 was preemptively waived by our lender. Instead, we were required to meet a minimum DSC ratio requirement of 1.35 for the twelve-month periods ended June 30, 2024, September 30, 2024 and December 31, 2024, and then again annually after that. During the first quarter of 2024, the DSC ratio covenant for the twelve-month period ended June 30, 2024 was preemptively waived by our lenders. During the third quarter of 2024, the DSC ratio covenant for the twelve-month period ended September 30, 2024 was preemptively waived by our lenders. During the fourth quarter of 2024, the DSC ratio covenant for the twelve-month period ended December 31, 2024 was preemptively waived by our lenders. Our next compliance obligation is for the year ending December 31, 2025. There is no assurance that we will be able to achieve the required DSC ratio going forward. If we are unable to do so or reach a favorable agreement with our lenders regarding that requirement (including an amendment to or waiver of such requirement), we would be in violation of that covenant, which could result in unfavorable amendments to the terms of our bank debt (including a possible bank requirement to prepay our debt) or have other adverse impacts on our business and results of operations.

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

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

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

*Risks associated with our funding strategy for **Re-Tain®**:* The inability to maintain adequate cash and liquidity to support the commercialization of **Re-Tain®** is a risk to our business. Achieving FDA approval of our pharmaceutical-grade Nisin produced at commercial-scale is the most critical action remaining in front of us on our path to U.S. regulatory approval of **Re-Tain®**. Having completed the construction and equipping of the DS production facility (as described in more detail in **PART I: ITEM 2** of this 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, although we are reducing these expenses now that production of inventory for our Controlled Launch is complete.

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

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

Product Risks

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

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

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

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

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

3) Producers' current practice generally is to treat only clinical mastitis, which has the visual indicator of abnormal milk. In

order to gain market penetration for **Re-Tain®**, we will need to change that practice and increase awareness of the importance of treating subclinical disease. This will require the producers' ability and willingness to diagnose without visual indicators. Users of **Re-Tain®** could have unsatisfactory treatment outcomes if they lack the equipment needed to measure and monitor somatic cell counts (SCC) of the herd or individual cows (for which data is needed). This risk limits our access to treatment cows because about 40% of farms do not presently have access to this kind of testing at the cow level, and thus are not good candidates for the use of **Re-Tain®**.

4) Lower than anticipated treatment cure rates could be experienced because the product is administered to cows that we would not identify as the best treatment candidates based on SCC data or because the product is administered to cows that are infected with pathogens outside of our label claims.

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

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

7) Our agreement to have DP filled by our current contract manufacturer expired in November of 2024. However, this agreement does provide for ongoing product labeling and packaging through the first quarter of 2026. Based on the anticipated best-case product expiration dating for **Re-Tain®**, we could have inventory available for sale into the first quarter of 2026. We would need to secure a new DP manufacturing agreement, or bring the process in-house, to fill more inventory after that.

*Reliance on sales of the **First Defense®** product line:* We presently 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, March 31, 2022 and December 31, 2024 without the gross margin that we earned on sales of the **First Defense®** product line. Our anticipated return to profitability is contingent upon the gross margin we earn from **First Defense®** and prudent management of product development expenses.

Concentration of sales: Sales of the **First Defense®** product line aggregated 99% of our total product sales during both of the years ended December 31, 2024 and 2023. Our primary customers for the majority of our product sales (86% and 91% during the years ended December 31, 2024 and 2023, respectively), are in the U.S. dairy and beef industries. 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 (77% and 79% during the years ended December 31, 2024 and 2023, respectively), was made to two large distributors. A large portion of our trade accounts receivable (78% and 79% as of December 31, 2024 and 2023, respectively) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us in a manner unfavorable to us.

Production capacity constraints: We invested $9.9 million from 2019 to December 31, 2024 to increase our annual production capacity (in terms of annual sales dollars) for the **First Defense®** product line from approximately $16.5 million to approximately $30 million or more based on current selling prices and estimated production yields. We are making initial plans to further increase our production capacity. While previous capacity expansion investments have proceeded very close to budget, there is a risk of cost overruns in our ongoing projects and any future production expansions that we may undertake, and a risk that we will not be able to achieve our production capacity growth objectives on a timely basis, resulting in a continuing or increasing shortfall in supply to the market. The inability to meet market demand for our products is a risk to our business. The historically large backlog of orders, as well as any ongoing order backlog, presents a risk that we could lose customers during this period that are not easily regained thereafter, when our production capacity is expected to meet or exceed sales demand. Our long-term capital plan to continue to expand the **First Defense®** product line requires ongoing review of equipment capacity and utilization across the manufacturing value stream at **Building 56** and our leased facilities at **Building 175A** and **175B**, 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 the stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product, which could interrupt sales and adversely affect our operating results. Territories outside of the United States may require additional regulatory oversight that we may not be able to meet with our current facilities, processes and resources. There is a risk that we will become subject to regulatory actions in the future, including actions that result in our inability to ship product. In these cases, the resulting interruption in sales could have a material and adverse effect on our operating results.

*Regulatory requirements for **Re-Tain®**:* Commercial introduction of this product in the United States requires us to obtain FDA approval. Completing the process of obtaining FDA approval of the pending NADA involves risk. The regulatory development process timeline has been extensive (approximately 17 years from when the product rights were returned to us by a former partner in 2007) and has involved multiple commercial production strategies and multiple submissions of the Chemistry, Manufacturing and Controls (CMC) Technical Section. We received an Incomplete Letter from the FDA regarding this CMC Technical Section during the third quarter of 2022 that clarified the required path to product approval. During May of 2024, we received an Incomplete Letter from the FDA in response to our November of 2023 re-submission. To reduce the risk associated with this process, we are working with a qualified contract manufacturer (Norbrook) for alignment of the required validations and DP manufacture and have met with the FDA to clarify filing strategy and requirements. Early during the first quarter of 2024, the FDA conducted another pre-approval inspection of our DS facility. This resulted in the issuance of one deficiency as identified on the FDA's Form 483. Since then, we have cleared the inspectional observation with the FDA. However, our efforts continue to be subject to inspection and approval by the FDA and other factors outside of our control, and there remains a risk that the required FDA approvals of our product and facilities could be further delayed or not obtained. The facility of our contract manufacturer is subject to similar inspectional obligations and is currently working to resolve certain inspectional observations at their facility and is subject to re-inspection by the FDA. International regulatory approvals would be required for sales of **Re-Tain®** outside of the United States, and there is a risk that these approvals would be or become too costly to pursue or be delayed or not obtained.

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

Economic Risks Pertaining to the Dairy and Beef Industries

Immigration: The U.S. government is stepping up deportation efforts, resulting in a rising rate of deportations of criminals that are in our country illegally. Many farms employ hard-working, non-criminal employees who have not yet achieved legal citizenship. Significant deportations of these individuals could have a negative impact on the operations of our customers and of our source farms.

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 and to 87,200,000 as of January 1, 2024. This count dropped to 86,700,000 as of January 1, 2025. The cattle count has not been this low since it was 82,100,000 in 1951. 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. The USDA did not make this data point available as of July 1, 2024. A significant decline in the cattle count could negatively affect the size of our addressable market.

Herd size: Prior to 1957, there were over 20,000,000 cows in the U.S. dairy herd. Prior to 1986, there were over 10,000,000 cows in the U.S. dairy herd. From 1998 through 2021, the size (annual average) of the U.S. dairy herd ranged from the low of 9,011,000 in 2004 to the high of 9,448,000 in 2021. This average declined to 9,402,000 during the year ended December 31, 2022 and then declined to 9,386,000 during the year ended December 31, 2023. This average declined slightly to 9,342,000 during the year ended December

31, 2024. A significant decline in the herd size could negatively affect the size of our addressable market.

Milk cow price: The all-time high value (annual average) for a milk cow was $1,993 during 2015. Since then, this annual average value steadily declined to $1,205 during 2019 before increasing to $1,300 during 2020 and to $1,363 during 2021. This price for 2022 increased significantly to an average of $1,598, which is a 17% increase over 2021. The 2023 average price of $1,763 represents a 10% increase over prior year. This price for 2024 increased to an average of $2,243, which is a 27% increase over 2023. A significant decline in the milk cow price could negatively affect the size of our addressable market.

Milk price: The dairy market, similar to many others, has been unstable for several reasons including as a result of the pandemic. The price paid to producers for milk has been very volatile. This market volatility, and the resulting impact on our primary end users, could negatively impact our ability to maintain and grow sales at a profitable level. The Class III milk price (an industry benchmark that reflects the value of product used to make cheese) is an important indicator because it defines our customers' revenue level. This annual average milk price level (measured in dollars per hundred pounds of milk) reached its highest point (since these prices were first reported in 1980) during 2014 at $22.34 (peaking at $24.60 in September of 2014), which price level has never been repeated. During the year ended December 31, 2020, this average milk price was equal to $18.16, but it was extremely volatile during the year due largely to disruption in demand related to the COVID-19 pandemic. The one-month fluctuation of 73% from a low of $12.14 in May of 2020 to $21.04 in June of 2020 set an all-time record for variability. The average price for 2021 decreased by 6% to $17.08. This price average increased by 29% to $21.96 during the year ended December 31, 2022. The average price decreased by 22% to $17.02 during the year ended December 31, 2023. This average price increased by 11% to $18.89 during the year ended December 31, 2024. The annual fluctuations in this milk price level are demonstrated in the following table:

Average Class III Milk Price During the Years Ended December 31,		(Decrease) Increase
2014	$22.34	
2015	$15.80	(29%)
2016	$14.87	(6%)
2017	$16.17	9%
2018	$14.61	(10%)
2019	$16.96	16%
2020	$18.16	7%
2021	$17.08	(6%)
2022	$21.96	29%
2023	$17.02	(22%)
2024	$18.89	11%

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 by 12% to 1.67 during the year ended December 31, 2023. This ratio increased to 2.49 during the year ended December 31, 2024, representing an increase of 49%. The following table demonstrates the annual volatility and the low values of this ratio recently:

Average Milk-To-Feed Price Ratio During the Years Ended December 31,		(Decrease) Increase
2014	2.54	
2015	2.14	(16%)
2016	2.26	6%
2017	2.42	7%
2018	2.05	(15%)
2019	2.25	10%
2020	2.32	3%
2021	1.74	(25%)
2022	1.91	10%
2023	1.67	(12%)
2024	2.49	49%

Volatility of the dairy market: 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 75 employees (including 6 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. The cost of attracting and retaining the needed additional personnel in this current job market and inflationary environment could adversely affect our margins and profitability.

Reliance on outside party to provide certain services under contract for us: We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Re-Tain®**, who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. One example of this outside reliance is Norbrook, our DP contract manufacturer. Because Norbrook notified us of its intent to terminate its supply agreement with us, we initiated an investment of approximately $4 million during 2022 to construct and equip our own DP formulation and aseptic filling capability for **Re-Tain®** in our existing DS facility. Due to the loss in gross margin during 2023 caused by the slowdown in production output necessary to remediate product contamination events, we have decided to defer spending of approximately $2 million of these funds for the near term. The objective of this investment is to end our reliance on an outside party to perform these services for us. Actual project costs could exceed our current estimates. Completion of this project could be delayed due to a number of factors outside our control, including delays in equipment fabrication, equipment delivery or facility construction. In addition, there is a risk that we fail to achieve regulatory approval of the new facility or that such approval is delayed or requires significant additional expenditures to obtain. We are evaluating alternatives for DP supply going forward, which include the resumption of the investment in our own in-house DP services (when prudent based on our cash reserves) or another contract manufacturing agreement or a further extension with Norbrook. We anticipate a supply interruption under our Controlled Launch of **Re-Tain®** after the DP supply provided from our contract manufacturer is consumed and until new supply from a new contract manufacturing agreement or our own formulation and aseptic filling facility is implemented.

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

Tariffs and Trade Policies: Changes in tariffs or cross-border trade policies could affect our ability to expand sales of our products into foreign markets. The businesses of some of our U.S. dairy and beef customers could be significantly affected by changes in tariffs or trade policies, thus negatively affecting demand for our products. Additionally, tariffs on products and materials that we import could increase our costs of goods sold.

International Conflicts: International conflicts, including ongoing wars in Ukraine and the Middle East, give rise to uncertainties and stress on the global economy, which in turn can affect the demand for our products and our costs of operation.

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. In addition, concerns regarding greenhouse gas emissions and other potential environmental impacts of livestock production have led to some consumers opting to limit or avoid consuming animal products. If such events affect our customers' businesses, they may purchase fewer of our products, and our revenues may be negatively impacted. Climate driven changes could have a material adverse impact on the financial performance of our business and on our customers. In addition, increased frequency of natural disasters and adverse weather conditions may disrupt our manufacturing processes or our supply chain. These disruptions may have a material adverse effect on our business, financial condition, results of operations and/or cash flows.

Bovine diseases: The potential for epidemics of bovine diseases such as Highly Pathogenic Avian Influenza (HPAI), Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) presents a risk to us and our customers. We have seen a severe negative impact of bird flu on the U.S. poultry flock causing a significant increase in the price of eggs. We have seen a cross-over to cows in the dairy industry. Documented cases of BSE in the United States have led to an overall tightening of regulations pertaining to ingredients of animal origin, especially bovine. The **First Defense®** product line is manufactured from concentrated bovine colostrum, which is not considered a BSE risk material. Future regulatory action to increase protection of the human food supply could affect the **First Defense®** product line, although presently we do not anticipate that this will be the case.

Risks Pertaining to Common Stock

Stock market valuation and liquidity: Our common stock trades on The Nasdaq Capital Market (Nasdaq: ICCC). Our average daily trading volume (which was 7,100 shares per day during the 20-day period ended March 21, 2025) is lower, our bid/ask stock price spread can be larger and our share price can be more volatile than what other companies experience. Those factors could result in investors facing difficulty selling their stock for proceeds that they may expect or desire. Our share price as of March 21, 2025 was $4.91. Most companies in the animal health sector have market capitalization values that greatly exceed our market capitalization of approximately $44.1 million as of March 21, 2025. Our product sales during the year ended December 31, 2024 were $26.5 million. This means that our market capitalization as of March 21, 2025 was equal to approximately 1.66 times our sales during the year ended December 31, 2024. Before adequate 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 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;
- 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. 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 or repurchase stock in the future will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, contractual restrictions, restrictions imposed by applicable laws, current and anticipated needs for liquidity and other factors our Board of Directors deems relevant.

Possible dilution: We are accessing the capital markets and issuing additional common stock, from time to time, under an ATM Offering in order to fund our operations, as described elsewhere in this Annual Report. Such issuances have a dilutive effect on our existing stockholders.

Other Risks

Access to raw materials and contract manufacturing services: Our objective is to maintain more than one source of supply for the components used to manufacture and test our products that we obtain from third parties. However, we may experience 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, Maine 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 were dependent on a contract with Norbrook for the DP formulation and aseptic filling for supply of our Nisin DP through 2024. Any facility used to perform these services will be subject to FDA inspection and approval, the outcome and timing of which are not within our control. We anticipate that this FDA approval process would take at least two years. The potential alternative options for these services are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). Any significant damage to or other disruption in the services at any of these third-party facilities or our own facilities (including due to lack of financing, regulatory issues or non-compliance) would adversely affect the production of inventory and result in significant added expenses and potential loss of future sales. We anticipate a supply interruption and adverse effects on our Controlled Launch of **Re-Tain®** beginning during the first quarter of 2026 (subject to confirmation of final product shelf-life disposition by the FDA). These goods represent the initial DP production from our contract manufacturer. The extent of the interruption will be subject to the supply timeline from a new contract manufacturing agreement or from our own formulation and aseptic filling facility for DP.

Failure to protect intellectual property: The protection and enforcement of our intellectual property rights may require the expenditure of significant financial, managerial and operational resources. We rely on trademark, copyright and patent law, trade secret protection, agreements and other methods with our employees and others to protect our proprietary rights. However, we may be unable to adequately protect our intellectual property rights or prevent third parties from infringing or misappropriating our intellectual property rights. We may not be able to obtain registration for all intellectual property we seek to register, and effective intellectual property protection may not be available in every country in which our products are sold. In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. Instead, we have sought (and may seek in the future) to maintain the confidentiality of any relevant proprietary technology through trade secrets, operational safeguards and contractual agreements. Reliance upon trade secrets, 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. 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. See also **PART I, ITEM 1C – CYBERSECURITY** below.

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, implement and monitor systems to protect against cybersecurity threats. Based on the information available to us through the time of this filing on March 28, 2025, 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** above 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 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 are using this space for the following three purposes: 1) much needed additional warehouse space, 2) the relocation of all shipping and receiving services from **Building 56** and 3) space for additional freeze-drying equipment in the future 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 relocated all shipping and receiving operations from **Building 56** to **Building 175B** and began to 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 for the same property through March of 2025 that includes an option to renew for an additional two-year term. During February of 2025, we exercised this option and extended the lease through March 1, 2027. In addition, 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 of 2025. 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 ICCC. As of March 21, 2025, we had 15,000,000 common shares authorized and 8,982,623 common shares outstanding, and there were approximately 572 stockholders of record. We have not paid dividends on our common stock and do not have any present plan or expectation to pay dividends.

ITEM 6 — [RESERVED]

ITEM 7 — MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

We focus on the two most critical stages of dairy productivity, those being the first 30 days of life and the first 30 days of lactation. Our concentrated colostrum and purified Nisin technologies offer unique animal health solutions during these periods when immunity is at its most vulnerable. Both of our product lines present growth opportunities and, in the future, may potentially be applied to other species or potentially the human health sector, alongside the animal health sector that we currently serve. The **First Defense®** production capacity expansion that we initially thought might have been completed in a year to a year and a half ended up taking about three years to complete, but our fourth quarter sales results do demonstrate that we have increased our production capacity to, or above, $30 million per year. The increased capacity is enabling us to address our order backlog that was equal to approximately $4.4 million and $4.7 million, as of December 31, 2024 and March 21, 2025, respectively. 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 the Cautionary Note under **Part I: ITEM 1 — BUSINESS and 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 RESULTES OF OPERATIONS

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

Liquidity and Capital Resources

We are fortunate to be experiencing strong customer demand for the **First Defense®** product line, but the significant investments in facilities, equipment and staffing necessary to double our production capacity have been challenging. Despite delays in the installation of certain equipment, we completed these capacity-expanding investments around the end of 2022. In late 2022, we began experiencing production contamination events that became more frequent during 2023 and continued through April of 2024. With newly implemented controls in place, we now believe that we have successfully remediated the issues underlying these contamination events. Our next challenge is to resume our past production yields and achieve our gross margin goals in excess of 40%. By both remediating the contamination events and optimizing the operation of the new equipment installed to increase production output, we began to improve process yields beginning during the fourth quarter of 2024, as demonstrated by the 37% gross margin we achieved

during the fourth quarter of 2024. We did not find one “smoking gun” as the root cause to the contamination and yield losses. We think the solution is more about optimizing and controlling critical process parameters and multiple production inputs and process steps.

Concurrently, we are reducing product development expenses as we await approval of **Re-Tain®** by the FDA. After an investment of about 25 years and approximately $50 million in the development of this technology, we are committed to seeing this product through to regulatory approval and our previously disclosed limited distribution, controlled launch strategy (Controlled Launch). At the same time, we are also in the very early stages of exploring potential strategic options that could offset some of our product development expenses and enhance a mass-market launch of **Re-Tain®**. In order to help fund these gross margin losses and production capacity expansions, we raised some new debt during 2023 and equity during 2024.

Net cash provided by operating activities was $358,000 during the year ended December 31, 2024 in contrast to net cash (used for) operating activities of ($4.7 million) during the year ended December 31, 2023. This $5 million improvement in net cash provided by operating activities between the years was largely due to a $3.6 million decrease in the net loss and a $2.5 million swing from cash used for inventory during 2023 to cash generated by reductions in inventory during 2024, which sources of cash were net against $1.2 million more cash being used for accounts receivable during 2024 than during 2023. Our inventory balance decreased by $699,000 to $7.1 million as of December 31, 2024 from $7.8 million as of December 31, 2023. Interest expense (excluding amortization of debt issuance and debt discount costs) was $526,000 and $453,000 during the years ended December 31, 2024 and 2023, respectively. Our debt bears interest at fixed rates, which on a blended basis amounts to 4.51% per annum. We anticipate that interest expense (excluding amortization of debt issuance and debt discount costs) will be $452,000 and $322,000 during the years ending December 31, 2025 and 2026, respectively. Our total non-cash depreciation, amortization and stock-based compensation expense was approximately $3.1 million during both of the years ended December 31, 2024 and 2023. We anticipate that depreciation expense (largely pertaining to Re-Tain®), 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. Further, as we fill the order backlog for **First Defense®**, we will require additional capital to fund an anticipated increase in inventory levels.

Net cash used for investing activities was ($461,000) during the year ended December 31, 2024 versus ($1.9 million) during the prior year consisting primarily of cash spent to fund the purchase of property, plant and equipment. To conserve cash at this time, we have deferred all large dollar capital expenditure projects.

Net cash provided by financing activities was $2.9 million during the year ended December 31, 2024 versus of $1.8 million during the prior year. During the third quarter of 2023, we received $3 million in new debt proceeds. We had aggregate debt outstanding (net of debt issuance and debt discount costs) of approximately $10.5 million and $12 million as of December 31, 2024 and 2023, respectively. Debt principal repayments (excluding the line of credit) aggregated $1.5 million and $1.2 million during the years ended December 31, 2024 and 2023, respectively. We anticipate that debt principal repayments will aggregate approximately $1.5 million and $3.3 million during the years ending December 31, 2025 and 2026, respectively. During the first quarter of 2024, the availability of our $1 million line of credit, which bears interest at the National Prime Rate per annum, was extended until September 11, 2025. No draw on our line of credit was outstanding as of December 31, 2024 or December 31, 2023. See Note 9 to the accompanying audited financial statements for more information about our bank debt. During the second quarter of 2024, we entered into an At-The-Market (ATM) Agreement with Craig-Hallum Capital Group LLC, under which we may offer and sell up to $11 million of shares of our common stock. As of December 31, 2024, we had sold 1,228,227 shares under this ATM Offering conducted pursuant to the ATM Agreement. Net proceeds through December 31, 2024 (net of approximately $152,000 in upfront legal, accounting and other fees and approximately $140,000 in sales commissions) were approximately $4.4 million. The ATM Agreement gives our board the flexibility to evaluate the potential uses of the proceeds while considering the cost of dilution in real time. This funding has provided a very productive financial bridge for us to fund our operations, while we work to improve our gross margin and reduce product development expenses. While the capital raised is not enough to fund larger capital expenditure investments, such as further increasing **First Defense®** production capacity or building our own facility for the aseptic filling services for **Re-Tain®**, it has allowed us to release funding for certain smaller and necessary capital expenditures.

We project (based on our best estimates) that our existing cash and cash equivalents, together with gross margin anticipated to be earned from ongoing product sales will be sufficient to meet our currently planned working capital and capital expenditure requirements and to finance our ongoing business operations for at least the next 12 months (the period of time required to be addressed for such purposes by accounting disclosure standards). The table below summarizes the changes in selected key accounts (in thousands, except for percentages):

	As of December 31, 2024	As of December 31, 2023	Increase Amount	Increase %
Cash and cash equivalents	$3,758	$979	$2,779	284%
Net working capital	$10,631	$7,272	$3,358	46%
Total assets	$45,100	$43,808	$1,292	3%
Stockholders' equity	$27,518	$24,993	$2,525	10%
Common shares outstanding[(1)]	8,979	7,751	1,228	16%

(1) There were 664,000 and 618,500 shares of common stock reserved for issuance for stock options that were outstanding as of December 31, 2024 and 2023, respectively.

Capital Expenditure Investments

During the three-year period ended December 31, 2016, we invested the aggregate of $4.2 million to construct a 7,100 square foot facility addition at 56 Evergreen Drive (**Building 56**) and related equipment (primarily Freeze-Dryer #2) and cold storage capacity increasing our freeze-drying capacity by 100% and making other improvements to our liquid processing capacity, which increased our annual production capacity (in terms of annual sales dollars) to approximately $16.5 million. 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 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 **Building 56**. After construction of the DS production facility for **Re-Tain®** at 33 Caddie Lane (**Building 33)** was completed, this space was converted for use in the production of the gel tube formats of the **First Defense®** product line. After renovations of our leased facility at 175 Industrial Way (**Building 175A)** were completed during the second quarter of 2020, this space was converted to double our liquid processing capacity.

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

During 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 from approximately $16.5 million to approximately $30 million or more per year (with an option to increase further to approximately $40 million in the future). The additional investment in **First Defense®** should allow us to fulfill the current backlog of **First Defense®** orders and materially reduce the risk of another order backlog. Operating at very close to 100% of available capacity is not efficient or sustainable. Our objective is to be in position to operate without significant contaminations at the capacity level we choose to cover sales with adequate buffer stock, which would allow more time for necessary preventative maintenance. We also need to meet or exceed our production yield assumptions to succeed. Our production process is complex and difficult to scale-up quickly. We remain deeply committed to meeting demand for **First Defense®** and overcoming the current short supply that we have been experiencing.

The primary 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 in order to lessen or eliminate our reliance on third-party DP manufacturing services as well as the build out of warehouse space at **Building 14** for packing and shipping facilities for **Re-Tain®**. We began initial installation of the filling equipment during the first quarter of 2022 and then paused this installation work due to the lack of adequate cash.

The amount and timing of these additional investments in **First Defense®** and **Re-Tain®** that were initiated beginning in 2019 are detailed in the following table (in thousands):

Paid During the	First Defense®	Re-Tain®	Other	Total
Year Ended December 31, 2019	$279	$538	$574	$1,391
Year Ended December 31, 2020	2,938	581	554	4,073
Year Ended December 31, 2021	1,633	976	-	2,609
Year Ended December 31, 2022	3,498	430	47	3,975
Year Ended December 31, 2023	1,097	796	-	1,893
Year Ended December 31, 2024	410	54	2	466
Total Paid through December 31, 2024	9,855	3,375	1,177	14,407
Estimate to Complete[(1)]	4,246	2,000	-	6,246
Total Project Cost	$14,101	$5,375	$1,177	$20,653

[(1)] The investments of approximately $3 million of these funds to increase **First Defense®** production capacity from approximately $30 million to $40 million per year and approximately $2 million to build an in-house aseptic filling facility for **Re-Tain®** have been deferred for the time being, due to cash constraints caused by production slowdowns implemented during 2023 to remediate certain contamination events. These estimated costs to complete are based on historic quotations and have not been updated or adjusted to account for inflation, project scope change and other factors.

The first phase of the additional investments in **First Defense®** beginning in 2019 included significant renovations to a 14,300 square foot leased facility at **Building 175A**, some facility modifications at **Building 56** and the necessary production equipment (including Freeze-Dryer #3) to increase our liquid processing capacity by 100% and our freeze-drying capacity by 50%. This resulted in increasing the annual production capacity of the **First Defense®** product line (in terms of annual sales dollars) from approximately $16.5 million to approximately $23 million. Renovations of **Building 175A** to enable this expansion were completed during the second quarter of 2020. By moving our powder and gel filling and assembly operations from **Building 56** into this new space, we created space at **Building 56** for the installation of the expanded freeze-drying capacity. The new facilities are built to contemporary cGMP standards with efficient material and people flows. A site license approval for this new facility was issued by the USDA during the third quarter of 2020. During the second quarter of 2021, we completed the relocation of our gel formulation equipment from **Building 56** to **Building 175A**, which created the space necessary to double our liquid processing capacity at **Building 56**. We obtained site license approval of the expanded freeze-drying capacity (Freeze-Dryer #3) at **Building 56** from the USDA during the third quarter of 2021, and we obtained site license approval of the expanded liquid processing capacity at **Building 56** from the USDA during the third quarter of 2022. This investment also included equipment and vehicle purchases necessary to expand and improve our colostrum collection capabilities and logistics.

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

The third phase of the additional investments in **First Defense®** involved the construction of an additional 15,400 square feet of space adjacent to and connected to **Building 175A** at 175 Industrial Way (**Building 175B**) and new equipment to further increase our estimated annual **First Defense®** production capacity from approximately $30 million to approximately $40 million with options for further expansion. Given the long lead time required for investments like this, we initiated this project by entering into a lease amendment during the third quarter of 2022 covering a to-be-constructed building shell for approximately $250,000 per year. Construction of the building shell by our landlord was substantially complete as of April 1, 2023, and rent payments commenced as of August 1, 2023. We made this lease commitment because of the unique proximity of the land adjacent to our currently leased space and the high level of demand for properties of this type in the Portland market. We did not want to risk losing this opportunity to others. The anticipated benefits to us from this new lease include: i) space for the potential to install Freeze-Dryers #5, #6, #7 and #8 if justified by market demand in the future, ii) improved space and quality for our powder milling operations by separating our upstream processes (liquid processing) at **Building 56** from our clean downstream processes (milling, formulation, filling and packaging) at **Building 175A** and iii) much needed additional warehouse space. 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. Freeze-Dryer #5 is the key piece of equipment required to allow us to increase our estimated annual production capacity to above $30 million. Based on past experience, we are planning for approximately 18 months of lead time for fabrication, installation, qualification and

implementation of Freeze-Dryer #5. However, due to the loss in gross margin during 2023 caused by the slowdown in production output necessary to remediate the product contamination events discussed below, we have decided to defer most of this investment, for the time being. Instead, we initiated the initial steps on a portion of this project with a reduced budget of approximately $700,000 at **Building 175B** during the third quarter of 2023. This work was completed during the first quarter of 2024, which provided additional warehousing space and allowed us to move all shipping and receiving functions out of **Building 56** to create more space for liquid processing at **Building 56**.

Production Contamination Events

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

As we look back at these production contamination events, we believe that the root cause of the initial contaminations was associated with rapid growth in our purchases from the farms where we acquire our raw material. Having largely remediated that problem, we then experienced additional contaminations that we believe were largely caused by rapidly increasing our production capacity. Our proprietary production process does allow us to create an effective product out of a non-aseptic starting raw material. This requires a careful monitoring, however, of the tradeoff between the benefit of adding more heat for longer periods of time to reduce bacterial load against the alternative benefit of less heat for shorter periods of time to preserve more antibody content. Although using more heat could potentially reduce bacterial load, our yield is higher when we use less heat. We know that putting our Work-in-Process inventory through freeze/thaw cycles is not beneficial to yield and increases the risk of contamination. One effective improvement we have implemented, where appropriate, is to lengthen the time of a heat treatment step instead of running two shorter heat treatment steps separated by a freeze/thaw. As we continue to optimize these critical process parameters, we believe we can significantly reduce the risk of further contaminations and improve our gross margin.

Although these types of losses are expected to happen from time to time in the production of a biological product such as ours, we believe that the sudden and large contamination events were related in several different ways to our efforts to increase production output. We also believe we have mitigated the risk of large-scale reoccurrence of such losses by implementing various new quality control steps and manufacturing process and facility improvements. To meet our goals, we must run without significant equipment failures or contamination losses, and we must continue to improve our production yields.

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

	Approximate Cost of Work-in-Process Scrap	Approximate Retail Value of Finished Goods[(1)]
Year Ended December 31, 2022	$589	$2,193
Year Ended December 31, 2023	$527	$2,487
Year Ended December 31, 2024	$407	$1,766

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

We still have more work to do to catch up to product demand for **First Defense®**. We continue to optimize our investments to increase production capacity and to implement the corrective actions being taken in response to these contamination events. Although we produced far less than we needed during 2023 and 2024, we believe that our remediation efforts are allowing us to steadily ramp back up to full production capacity. Our current goal is to exceed $30 million in annual production output, while also allowing for essential preventative maintenance. We believe that the $7.8 million in sales recorded during the fourth quarter of 2024 suggests that during the quarter we achieved, even exceeded, this goal.

The lessons 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 in-process and 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 complete in-process quality control test results for the current stage are reviewed. Although this adds time to the overall production cycle, we believe that it has helped us reduce the chance of further contaminations. Notwithstanding the challenges that contamination events have posed for us, we are excited to have reached both our estimated full capacity of at least $30 million per year for **First Defense®** (with an option to increase our estimated full capacity to approximately $40 million per year in the future with the additional capital investments, as discussed above) while, at the same time, advancing to the final stages of a very significant FDA product development initiative with **Re-Tain®**.

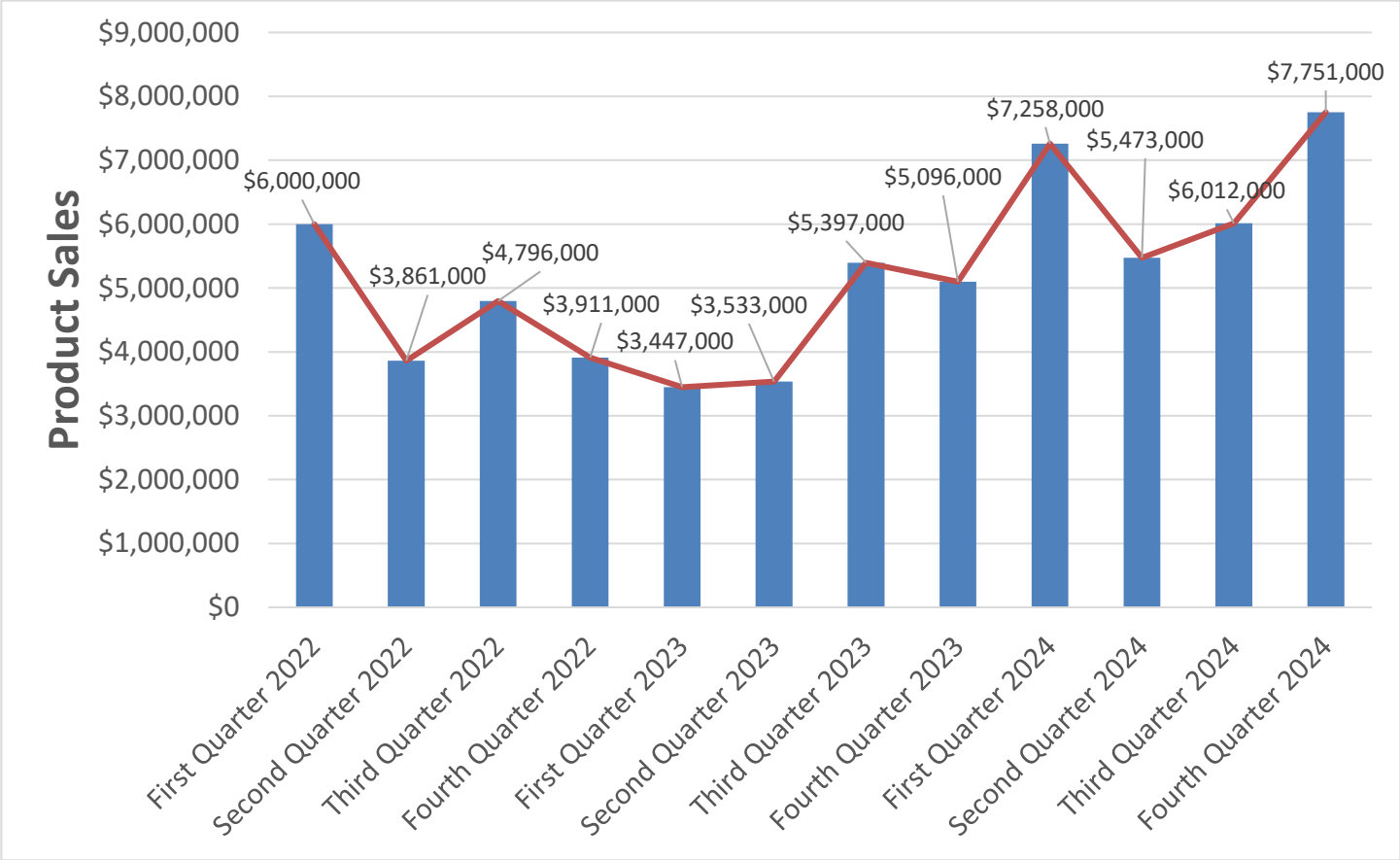
We pursued an insurance claim under our business interruption policy to offset at least some portion of the losses that we incurred from the contamination events discussed above. Although not a total recovery of our financial losses, we did settle our insurance claim during the first quarter of 2025 and received an insurance payout of approximately $427,000, which is in addition to the $250,000 that we previously received during the third quarter of 2023 under this claim.

Results of Operations

a) Product Sales

Our near-term goal is to increase and stabilize supply of **First Defense®**, regain lost business and continue our growth curve. This goal not only aims to meet end-user demand but also to replenish our distributors with the necessary buffer stock. The significant increase in sales recognized during the fourth quarter of 2024 results from our higher production output, but also from the comparison to 2023 when our sales were limited due to a production slowdown necessary to remediate certain contamination events. We do not anticipate being able to repeat this high level of year-over-year sales growth when we compare 2025 to 2024. We do not solely benchmark our sales expectations off trailing twelve-month sales results. Instead, we look at the sales of competitive products to assess the size of the addressable market and plan for growth when projecting our future production capacity needs.

Sales during the three-month period ended December 31, 2024 were $7.8 million, representing a 52%, or $2.7 million, increase over sales of $5.1 million during the fourth quarter of 2023. Sales during the year ended December 31, 2024 were $26.5 million, representing a 52%, or $9 million, increase over sales of $17.5 million during the year ended December 31, 2023. By increasing production capacity and mitigating contamination events, we were able to significantly increase sales during the most recent periods compared to the year prior. Quarter to quarter sales since the beginning of 2022 are displayed in the following table:



We captured a 52% increase in sales revenue during the fourth quarter of 2024 compared to the fourth quarter of 2023. Domestic sales during the three-month period ended December 31, 2024 increased by 35%, and international sales increased by 308%, in comparison to the three-month period ended December 31, 2023. International sales aggregated 17% and 6% of total sales during the three-month periods ended December 31, 2024 and 2023, respectively. The quarterly sales results are summarized in the following table (in thousands, except for percentages):

	During the Three-Month Periods Ended December 31,		Increase	
	2024	2023	Amount	%
Total Product Sales	$7,751	$5,096	$2,655	52%

We captured a 52% increase in sales revenue during the year ended December 31, 2024 compared to the year ended December 31, 2023. Domestic sales during the year ended December 31, 2024 increased by 44%, and international sales increased by 136%, in comparison to the year ended December 31, 2023. International sales aggregated 14% and 9% of total sales during the years ended December 31, 2024 and 2023, respectively. The sales results for the years are summarized in the following table (in thousands, except for percentages):

	During the Years Ended December 31,		Increase	
	2024	2023	Amount	%
Total Product Sales	$26,493	$17,472	$9,021	52%

Sales of the **First Defense®** product line made up 99% of our total sales during both of the three-month periods ended December 31, 2024 and 2023 and during both of the years ended December 31, 2024 and 2023. Our sales are generally seasonal with highest demand expected during the first quarter of each year. The compound annual growth rate (CAGR) of our total product sales was 52%, 14% and 16% during the year, five-year and six-year periods ended December 31, 2024, respectively.

We obtained USDA approval of **Tri-Shield First Defense®** (the trivalent format of our product delivered via a gel tube, which provides broader protection to calves) near the end of 2017. Around the time of this new product format launch, total product sales during the years ended December 31, 2017 and 2018 were $10.4 million and $11 million, respectively. **Tri-Shield®** requires two

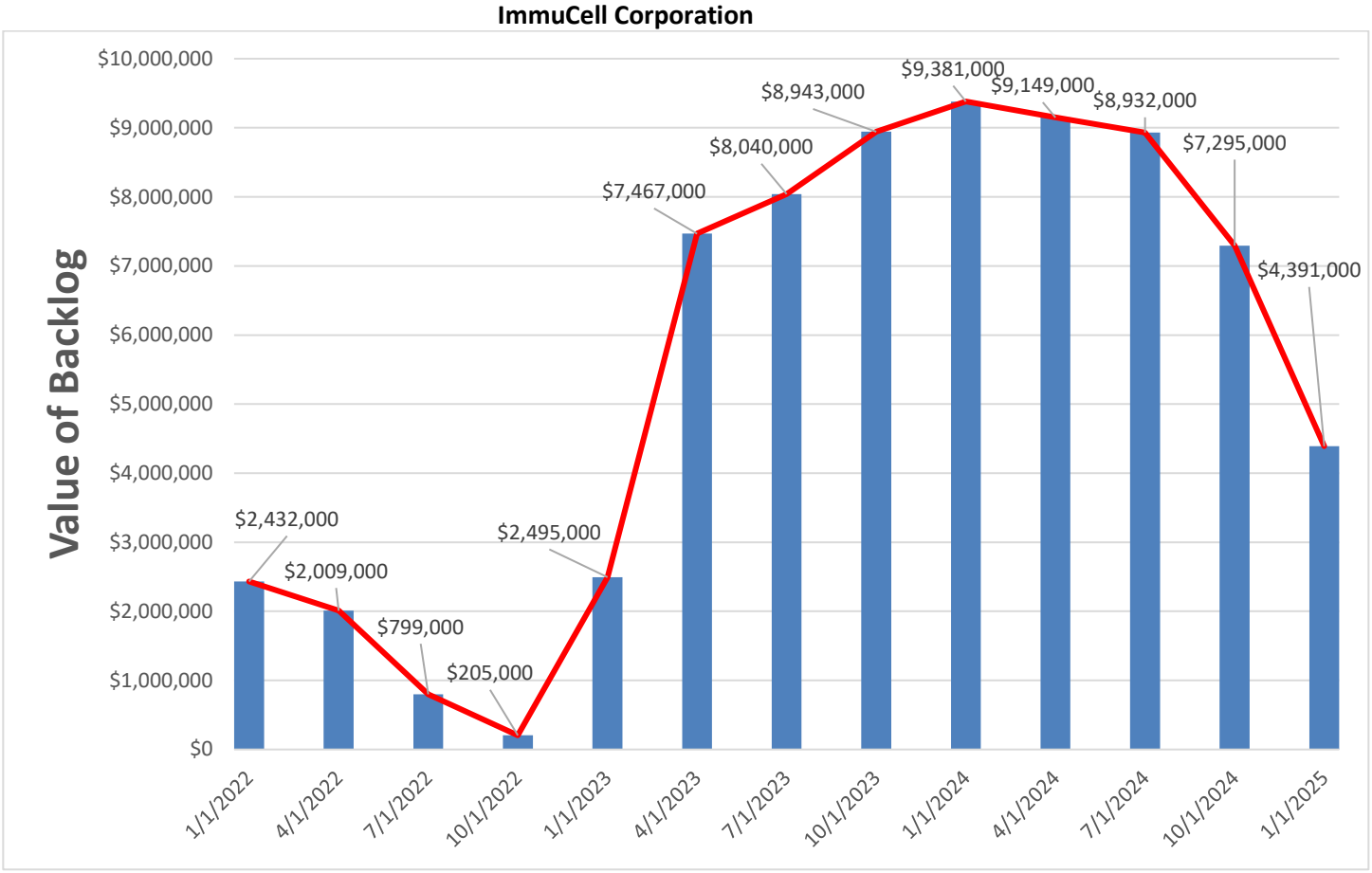
separate liquid production processes for each dose manufactured and sold (in contrast to the bivalent product formats that require just one) making it more expensive to produce. This new product format has become the highest revenue contributor, as demonstrated in the table below (in thousands, except for percentages):

	During the Three-Month Periods Ended December 31,				During the Years Ended December 31,			
	2024	% of Total	2023	% of Total	2024	% of Total	2023	% of Total
Tri-Shield®	$4,227	55%	$3,768	74%	$15,762	59%	$10,316	59%
Other	3,524	45	1,328	26	10,731	41	7,156	41
Total Product Sales	$7,751	100%	$5,096	100%	$26,493	100%	$17,472	100%

We likely lost some business beginning in late 2022 and through the first half of 2024 as a result of the backlog. During the first half of 2023, the impact of tight supplies hit even harder, leaving our customers without product during their busiest calving season. The 2023 production shortage caused largely by the contamination events discussed above may prove to be more detrimental to our growth curve than any prior production shortage because it depleted distributor inventories and impacted more customers for a longer period of time. Our inability to timely meet the needs of our customers could result in the loss of some customers who seek alternative scours management products during this period of short supply, and some of these customers may not resume purchasing our product when we have eliminated the backlog. While we worked to allocate product directly to certain large customers during this period of short supply, we likely lost some customers that could not procure 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 has resumed more normal sales growth initiatives now, in anticipation of increasing product supply. We will work to regain end-user customers that we may have lost while we were short on product and will aggressively compete for new business. As we emerge from an extended period of time on backlog, we anticipate higher than normal sales fluctuations quarter to quarter. What is most important to us at this time is that we achieve sales growth over the longer periods of time, even if we experience some quarter-to-quarter fluctuations.

The production slowdown during the first ten months of 2023 helped cause an increase in the amount of our order backlog. Valuation of the backlog is a non-GAAP estimate that is based on purchase orders on hand at the time that could not be met because of a lack of available inventory. We are reporting this figure because it reflects the orders on our books presently that we cannot ship. Quantification of the backlog during the current periods has become far less comparable to prior periods. At times, customers have placed orders for more than a month’s worth of their demand, perhaps in reaction to our ongoing backlog situation, whereas in the past they ordered more closely in line with their current demand. We are concerned that this backlog amount may not be highly relevant at this time as it includes very old orders, redundancy in demand and orders that may be cancelled given the time that has passed since they were originally placed.

The backlog was reduced from approximately $2.4 million as of December 31, 2021 to approximately $205,000 as of September 30, 2022. In part because of a first contamination event experienced around the end of the third quarter of 2022, our backlog increased to approximately $2.5 million as of December 31, 2022. In part because of a second contamination event experienced during the first quarter of 2023, the backlog continued to increase to approximately $7.5 million as of March 31, 2023, to approximately $8 million as of June 30, 2023, to approximately $8.9 million as of September 30, 2023 and to approximately $9.4 million as of December 31, 2023. We were able to reduce this backlog modestly to approximately $9.1 million as of March 31, 2024 and then reduce it further to approximately $8.9 million as of June 30, 2024. We were able to reduce this backlog further to approximately $7.3 million as of September 30, 2024 and then further to $4.4 million as of December 31, 2024. The backlog of orders was worth approximately $4.7 million as of March 21, 2025. As sales demand increased while our production output was reduced, the value of our order backlog has fluctuated as demonstrated in the following table:



We also sell our own **CMT**, which is used to detect somatic cell counts in milk. Sales of **CMT** aggregated approximately 1% of our total product sales during the periods reported. Sales of **CMT** decreased by 30%, or $17,000, to $39,000 during the three-month period ended December 31, 2024, in comparison to the three-month period ended December 31, 2023. Sales of **CMT** increased by 1%, or $1,000, to $179,000 during the year ended December 31, 2024 in comparison to the year ended December 31, 2023.

Effective January 1, 2022, we increased our selling price of the **First Defense®** product line by approximately 5% and **CMT** by approximately 7%. Effective January 1, 2023, we increased our selling price of the **First Defense®** product line by approximately 4% (a range of 2% to 8%) and **CMT** by approximately 5%. Effective November 15, 2023, we increased our selling price of the **First Defense®** product line by approximately 8%. Also, effective November 15, 2023, we increased our selling price for **CMT** by approximately 12%. Effective January 1, 2025, we increased our selling price of the **First Defense®** product line by approximately 6% (a range of 5% to 7.5%). At the same time, we also increased our selling price for **CMT** by approximately 7%.

b) Gross Margin

The change in our gross margin (product sales less costs of goods sold) and our gross margin as a percentage of product sales during the three-month periods and years ended December 31, 2024 and 2023 are summarized in the following tables (in thousands, except for percentages):

	During the Three-Month Periods Ended December 31,		Increase	
	2024	2023	Amount	%
Gross margin	$2,832	$1,258	$1,574	125%
Percent of product sales	37%	25%	12%	48%

	During the Years Ended December 31,		Increase	
	2024	2023	Amount	%
Gross margin	$7,941	$3,869	$4,072	105%
Percent of product sales	30%	22%	8%	35%

The gross margin during recent periods was significantly less than what we anticipate going forward. The 2023 reduction in production output was largely the result of our decision to slow down our production rate while remediating the production contamination events discussed above. During 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. As we build back sales, we are increasing the amount of gross margin earned compared to prior periods and improving the gross margin as a percentage of sales compared to 2023. The gross margin as a percentage of product sales was 30%, 22%, 41%, 45%, 45%, 49%, 47% and 50% during the years ended December 31, 2024, 2023, 2022, 2021, 2020, 2019, 2018 and 2017, respectively. The 22% gross margin percentage during the year ended December 31, 2023 (including even lower gross margin percentages during the three-month period ended March 31, 2023 and the six-month period ended June 30, 2023) was our lowest ever. Achieving process yield improvements (in addition to running without significant equipment failures or product contaminations) will be essential to increasing our gross margin in future periods. Some of the critical process parameters that we are investigating include optimizing: 1) the time and temperature for pasteurization steps, 2) a critical filtration step and 3) the antibody content of incoming Work-in-Process inventory. As we fully integrate and utilize our increased capacity and evaluate our product costs and selling price, we believe we could increase our gross margin by approximately 3 to 8 percentage points over the 37% gross margin reported for the three-month period ended December 31, 2024. Our immediate goal is to resume a 40% gross margin. This goal has been reduced from prior projections given the lower rates experienced during 2023.

While our biological and process yields continue to be variable, we have seen a favorable improvement to our finished goods yield recently. 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 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. Additionally, the biological yields from our raw material are always variable, which affects 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, one of the key commercial benefits 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.

Additionally, the significant global supply-chain disruptions that almost all industries are experiencing presently are a challenge to us. The costs of our critical supplies, components, raw materials, utilities and services increased significantly during 2021 and that trend has continued since then. We have little choice but to pay the higher prices and try to take on more months of supply than we would have held previously if we could get our orders fulfilled timely. We believe that gross margin trends going forward should be viewed over longer periods of time than just one quarter.

The following table displays the relationship between sales and gross margin during recent periods (in thousands except for percentages):

	Product Sales	Gross Margin Dollars	Gross Margin Percentage
Year Ended December 31, 2021	$19,243	$8,656	45%
Year Ended December 31, 2023	$17,472	$3,869	22%
Year Ended December 31, 2022	18,568	7,649	41%
Decrease during 2023 under 2022	($1,096)	($3,780)[1]	(19%)
Three-Month Period Ended March 31, 2023	$3,447	$301	9%
Three-Month Period Ended June 30, 2023	3,533	1,044	30%
Three-Month Period Ended September 30, 2023	5,396	1,267	23%
Three-Month Period Ended December 31, 2023	5,096	1,257	25%
Year Ended December 31, 2023	$17,472	$3,869	22%
Three-Month Period Ended March 31, 2024	$7,258	$2,295	32%
Three-Month Period Ended June 30, 2024	5,473	1,230	22%
Three-Month Period Ended September 30, 2024	6,011	1,584	26%
Three-Month Period Ended December 31, 2024	7,751	2,832	37%
Year Ended December 31, 2024	$26,493	$7,941	30%

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

As demonstrated in the table below, Work-in-Process inventory as a percentage of total inventory has ranged from 57% to 81%, and the dollar value of Work-in-Process inventory has increased significantly since December 31, 2021. The hyper-immunized colostrum we purchase for use in the production of **First Defense®** is the largest component of Work-in-Process inventory. As we began to increase our production capacity, we also increased the supplier base that we work with in order to increase the availability of this critical ingredient. As certain contamination events discussed above slowed the implementation of our increased capacity, we accumulated more colostrum than originally planned. While this is a good safety measure to have in place to ensure that we do not run short of colostrum, we do expect to reduce this use of cash as we move forward with our increased production rate. Also, we are developing what could potentially be a spray-dried alternative format of **First Defense Technology®** that would not require the liquid processing and freeze-drying production steps used to produce **First Defense®** in a capsule or gel tube. If successful, this effort could expand our product portfolio with a bulk product designed to meet the needs of large dairy and calf-ranch customers at a lower cost. This would help us turn some of this inventory to cash sooner. In a frozen state, this colostrum has a 30-month useable shelf life. The increase in Work-in-Process inventory is demonstrated in the following table (in thousands, except for percentages):

As of	Frozen Colostrum	Other	Work-in-Process Inventory	% of Total Inventory
December 31, 2021	$1,032	$870	$1,902	62%
December 31, 2022	$2,418	$1,051	$3,469	57%
December 31, 2023	$3,811	$2,004	$5,815	74%
December 31, 2024	$3,591	$2,156	$5,747	81%

c) Product Development Expenses and Strategy

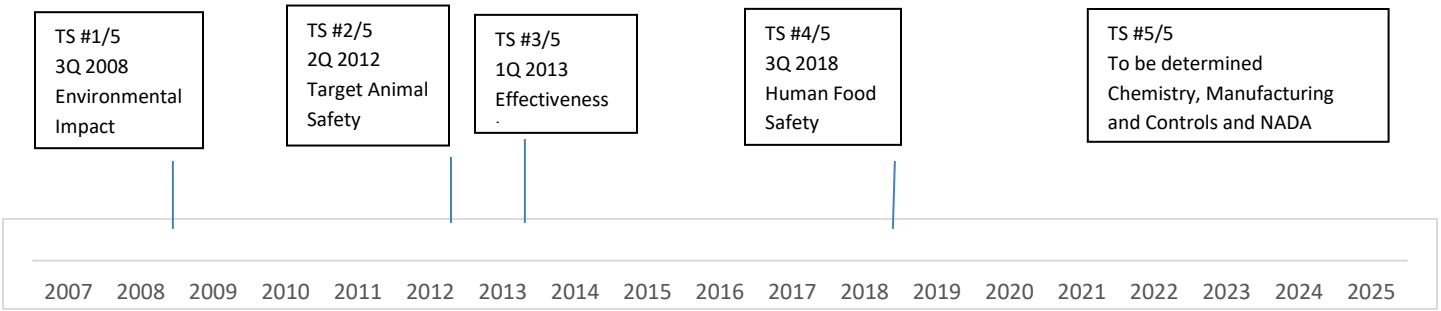
Overview: The majority of our product development expenses pertain to the development of **Re-Tain®**. During the three-month period ended December 31, 2024, product development expenses decreased by 23%, or $247,000, to $819,000 in comparison to $1.1 million during the three-month period ended December 31, 2023. Product development expenses aggregated 11% and 21% of product sales during the three-month periods ended December 31, 2024 and 2023, respectively. Product development expenses included non-cash depreciation and stock-based compensation expenses of $371,000 and $369,000 during the three-month periods ended December 31, 2024 and 2023, respectively. Approximately $341,000 of these non-cash expenses were comprised of depreciation expenses pertaining largely to our DS facility and equipment for **Re-Tain®** during both of the three-month periods ended December 31, 2024 and 2023. During the year ended December 31, 2024, product development expenses decreased by 11%, or $496,000, to $3.9 million in comparison to $4.4 million during the year ended December 31, 2023. Product development expenses aggregated 15% and 25% of product sales during the years ended December 31, 2024 and 2023, respectively. Product development expenses included non-cash depreciation and stock-based compensation expenses of approximately $1.5 million during both of the years ended December 31, 2024 and 2023. Approximately $1.4 million of these non-cash expenses consisted of depreciation expenses pertaining largely to our DS facility and equipment for **Re-Tain®** during both of the years ended December 31, 2024 and 2023. 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. Product development expenses (excluding depreciation expense of $1.4 million) were $3 million during the year ended December 31, 2023, when we were in production mode. Beginning during the second half of 2024, we implemented an aggressive idle of product development expenses pertaining to **Re-Tain®** after the production of inventory intended for our Controlled Launch was completed. It was our goal to reduce product development expenses (excluding depreciation) to approximately $2.5 million during the year ended December 31, 2024. The actual expense incurred was $2,532,000, representing a 16%, or $477,000, reduction from the 2023 expense (excluding depreciation). Product development expenses (excluding depreciation) were $1.6 million during the six-month period ended June 30, 2024. This means that we reduced product development expenses (excluding depreciation) by approximately 43%, or approximately $689,000, during the second half of 2024 in comparison to the first half of 2024. It is our further objective to reduce product development expenses (excluding depreciation) to approximately $2.1 million during the year ending December 31, 2025, which would be an 18%, or approximately $462,000, decrease from the 2024 level. This aggressive idle strategy (as opposed to a complete shut down) allows us to continue our pursuit of FDA approval while reducing our cash spend and ensuring no adverse impact to critical equipment. We have a plan to bring the DS plant back to full production mode in approximately two to three months, subject to available funding.

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 **Building 33** (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
$4.3 million @ April 1, 2024	June 30, 2025	64,000	41,000	23,000
Total		$552,000	$353,000	$199,000

Re-Tain® *Development objective:* Our product, **Re-Tain®**, could be the first mastitis product to be marketed without FDA-required milk discard or pre-slaughter withdrawal period label restrictions. 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 pre-slaughter withdrawal period. While milk prices vary, the cost of the milk discard associated with traditional antibiotics ranges from approximately $53.00 (for 4 days of milk at 70 pounds per day at the Class III milk price average of $18.89 per hundredweight during 2024) to approximately $145.00 (for 11 days of milk at 70 pounds per day at the Class III milk price average of $18.89 per hundredweight during 2024) 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 active ingredient, Nisin A, is an antibacterial peptide that was designated as Generally Regarded as Safe (GRAS) over 40 years ago for use in many foods to prevent the growth of pathogens. Nisin degrades in the gastrointestinal tract to amino acids, which further supports its safety. The Nisin we produce is more than 96% pure, which is purer than any nisin used in food preservation applications. Our product has been subject to the FDA's phased review process since 2004. We received our first major Technical Section Complete Letter from the FDA during the third quarter of 2008, and we received our fourth major Technical Section Complete Letter from the FDA during the third quarter of 2018. The remaining fifth major Technical Section (CMC) is related to commercial manufacturing. We made our first submission of the CMC Technical Section during the first quarter of 2019, and our most recent fourth submission of this Technical Section was made as part of our Non-Administrative NADA submission during January of 2025. As part of this process, we have produced over 50,000 treatments (150,000 doses) worth of product that are now quickly approaching their expiration dating. More specifically, approximately 16,000 treatments would expire between April to May of 2025 if the FDA approves only 18-months of shelf life (or between October to November of 2025 if 24-months of shelf life is approved), and approximately 34,000 treatments would expire between July to August of 2025 if the FDA approves only 18-months of shelf life (or between January to February of 2026 if 24-months of shelf life is approved). We may not be able to utilize all available inventory prior to its expiration dating. The following chart displays the approximate timeline associated with the issuance of the five major Technical Section Complete Letters:



***** TS=Technical Section

Re-Tain® *Development status*: Approval by the FDA of our 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 first quarter of 2013, we received the Effectiveness Technical Section Complete Letter from the FDA. The anticipated product label (which remains subject to FDA approval) carries claims for the treatment of subclinical mastitis associated with *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, and coagulase-negative staphylococci in lactating dairy cattle.

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

4) Human Food Safety: During the third quarter of 2018, we received the Human Food Safety Technical Section Complete Letter from the FDA confirming, among other things, a zero milk discard period and a zero pre-slaughter withdrawal 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.

At this point (almost 6.5 years ago), the remaining hurdle to market launch was focused on the commercial manufacture of the Drug Substance. Details of this effort are described in the next eight paragraphs.

5) Chemistry, Manufacturing and Controls (CMC): The CMC Technical Section is complex and comprehensive. Having previously achieved the four different Technical Section Complete Letters from the FDA discussed above, approval of the CMC Technical Section is the fifth and final significant step required before **Re-Tain®** product sales can be initiated in the United States. Implementing DS production, which is a required component of the CMC Technical Section, has been the lengthiest 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 pilot-scale at **Building 56**. This small-scale facility was used to: i) expand our process knowledge and controls, ii) establish operating ranges for critical process parameters, iii) conduct product stability studies, iv) optimize process yields and v) determine the cost of production. We believe these efforts have reduced the risks associated with our investment in the commercial-scale DS production facility. Having raised equity during 2016 and 2017, we were able to move away from these earlier partnering strategies and assume control over the commercial-scale manufacturing process in our own facility. During the fourth quarter of 2015, we acquired land near our existing Portland facility for the construction of a new commercial-scale DS production facility. We commenced construction of this facility during the third quarter of 2016 and completed construction during the fourth quarter of 2017. Equipment installation and qualification was initiated during the third quarter of 2017 and completed during the third quarter of 2018. Total construction and equipment costs aggregated approximately $20.8 million. With construction of the facility complete, we continue to work with outside parties to investigate improvements to our DS production yields as well as potential efficacy enhancements.

Under the FDA's phased submission process, we made a first-phased DS submission (without the DP submission) during the first quarter of 2019 that included data from the DS Registration Batches produced at commercial scale in our new DS manufacturing facility. This first-phased submission was followed by a second-phased submission covering both DS and DP, during the first quarter of 2021. The second-phased DS and DP submission responded to comments raised by the FDA regarding the first-phased DS submission and included detailed information about the manufacturing process and controls for DP. One of the key components of the second-phased DS and DP submission was also demonstrating stability of the product through expiry. During the third quarter of

2021, the FDA issued a Technical Section Incomplete Letter (Incomplete Letter) with regard to this second-phased DS and DP submission. This response was not unexpected as it is common for the FDA to issue queries and comments, especially related to an aseptic DP submission. We made a second DS and DP submission of the CMC Technical Section during the first quarter of 2022. During the third quarter of 2022, we received an Incomplete Letter from the FDA with regards to this second DS and DP submission of the CMC Technical Section. The Incomplete Letter required that internal and external laboratories re-develop and qualify several analytical tests and associated controls.

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

In early January of 2025, we made a Non-Administrative NADA submission that included our fourth submission of the CMC Technical Section, together with the minor technical sections covering All Other Information and Product Labeling. We implemented this filing strategy to eliminate the need for an Administrative NADA submission covering All Other Information and Product Labeling at the end of the application process, which would then be subject to an additional 60-day review at that time. By statute, this CMC Technical Section submission would be subject to a review period of up to 180 days, but because these latest responses to the CMC Incomplete Letter are not complex, we are hopeful for a shorter review period. We expect the FDA to complete its review only after it clears the inspectional observations at the DP facility of our contract manufacturer. This now appears to be the critical path constraint.

Although the FDA could have refused our Non-Administrative NADA submission because of the open inspection, it did not do so and has used this filing to schedule the on-site re-inspection at Norbrook to be completed by early April. If the inspectional observations are cleared and our contract manufacturer resumes “No Action Indicated” or “Voluntary Action Indicated” status, we anticipate that the path to NADA approval could be expedited. Reflecting the innovative nature of our product and considering the short expiry dating of the inventory on hand, we may now be able to move forward with Investigational Product use with inventory on hand that has a relatively short shelf life. This would allow us to begin to test market acceptance of this novel product.

While mindful of being prudent with how much cash we invested in inventory that would have short expiry dating if market launch were delayed, we did build DS inventory during 2022 and 2023 to support potential initial commercial sales of **Re-Tain®**. Upon FDA approval, we intend to implement our Controlled Launch with relatively short product expiration dating, subject to confirmation of final product shelf-life disposition by the FDA. We presently have no agreement in place to aseptically fill additional DP inventory. We do not anticipate the Controlled Launch to be a significant source of new sales, nor do we anticipate the initial sales to generate gross margin in excess of the associated product development expenses. During the second half of 2024, we began to reduce operating costs at our DS production facility until initial market acceptance (and perhaps the interest of a marketing partner) justifies a new agreement for aseptic filling and the production of additional inventory. We do anticipate a pause in the supply of product to market after the initial 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, if not, then by an alternative contractor that has not been identified yet). While we do not expect **Re-Tain®** to make a significant contribution to our sales growth in the early years after market launch, we do see value in achieving regulatory approval and testing market acceptance of the product.

Our DS manufacturing facility and our potential future DP manufacturing facility (or that of a DP contract manufacturer for us) would be 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. During the first quarter of 2024, we successfully responded to this inspectional observation and achieved “Voluntary Action Indicated” status. The remaining critical path milestone is for Norbrook to successfully complete closure of deficiencies at their DP facility, which is

currently underway.

We had concluded that the fastest route to FDA approval and market launch is with the services of Norbrook, reducing our risk by benefiting from their demonstrated expertise in aseptic filling. From 2010 to the present, we have worked with Norbrook under several amended contract manufacturing agreements covering the DP formulation, aseptic filling and final packaging services. Norbrook filled DP for our Controlled Launch before the filling contract expired during the fourth quarter of 2024. This contract continues through March of 2026 with regards to labeling and packaging services.

Our potential alternative third-party options for the formulation and aseptic filling services that are presently being performed by Norbrook are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). During the first quarter of 2022, we initiated an investment in the installation of equipment to produce DP at our own facility at **Building 33**. Given the loss in gross margin during the first ten months of 2023 caused by the slowdown in production output that was necessary to remediate the production contamination events discussed above and after weighing feedback from the FDA during their 2022 inspection, we decided to defer the completion of our potential DP manufacturing facility for the time being. If we decide to resume our in-house strategy, we would anticipate FDA approval of this facility (which is a requirement for commercial manufacturing) would take at least two years after we resume spending on this project, allowing for two six-month review cycles, subject to the timing of our installation and validation work. This would be a post-approval submission.

If we decide to complete our potential future DP manufacturing facility, we anticipate it would have enough formulation and aseptic filling capacity to exceed the expected production capacity of our DS facility, which is approximately $10 million in annual sales. This production capacity estimate is based on our assumptions as to product pricing and does not yet reflect inventory build strategies in advance of product approval or ongoing yield improvement initiatives. Establishing our own DP formulation and aseptic filling capability would provide us with the longer-term advantage of controlling the manufacturing process for **Re-Tain®** in one facility, thereby potentially reducing our manufacturing costs and eliminating international cold chain shipping logistics and costs. The DP formulation and aseptic filling operation, if completed, will be located in existing facility space that we had intended to utilize to double our DS production capacity if warranted by sales volumes following market launch. As a result, if we decide to complete this DP facility (rather than utilizing a third party for these services), we would need to explore alternative strategies (in parallel with ongoing DS yield improvement initiatives) to expand our DS production capacity. This integrated manufacturing capability for **Re-Tain®** would substantially reduce our dependence on third parties. Upon completion of our formulation and aseptic filling facility, the only significant third-party input for **Re-Tain®** would be the DP syringes. It is anticipated that Hubert De Backer of Belgium (HDB) will supply these syringes in accordance with purchase orders that we submit. HDB is a syringe supplier for many of the largest participants in the human and veterinary medical industries, and with whom Norbrook presently works. Based on HDB's performance history and reputation in the industry, we are confident that HDB will be a dependable supplier of syringes in the quantity and of the quality needed for **Re-Tain®**.

Other product development initiatives: Our next most important product development initiative has been focused on other improvements, line extensions or additions to our **First Defense®** product line. The bolus format of **First Defense®** and **Tri-Shield First Defense®** have been listed with the Organic Materials Research Institute (OMRI) since 2013 and 2019, respectively. This means they can be used on organic farms. During the third quarter of 2024, the gel tube format of **First Defense®** also became OMRI listed. As discussed above, we are developing a potential spray-dried, bulk powder format of our **First Defense Technology®**. During the third quarter of 2024, we entered into a research agreement with the Mayo Clinic, a non-profit, educational, research and healthcare institution, to explore potential applications of Nisin in certain human surgical situations. This data may be published in the future, but we do not see a clear commercial path forward at this time. Subject to the availability of resources, we intend to begin new development projects that are aligned with our core competencies and market focus. We also remain interested in acquiring, on suitable terms, other new products and technologies that fit with our sales focus on the dairy and beef industries, subject to the availability of the needed funding.

d) Sales and Marketing Expenses and Selling Strategy

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

During the three-month period ended December 31, 2024, sales and marketing expenses increased by 25%, or $165,000, to $836,000 in comparison to $672,000 during the three-month period ended December 31, 2023, amounting to 11% and 13% of product sales during the three-month periods ended December 31, 2024 and 2023, respectively. Sales and marketing expenses included non-cash depreciation and stock-based compensation expenses of $27,000 and $61,000 during the three-month periods ended December 31, 2024 and 2023, respectively. During the year ended December 31, 2024, sales and marketing expenses increased by 12%, or $378,000, to $3.5 million in comparison to $3.1 million during the year ended December 31, 2023, amounting to 13% and 18% of

product sales during the years ended December 31, 2024 and 2023, respectively. Sales and marketing expenses included non-cash depreciation and stock-based compensation expenses of $158,000 and $182,000 during the years ended December 31, 2024 and 2023, respectively. Our current budgetary guideline is to keep sales and marketing expenses under 20% of total sales. We continue to leverage the efforts of our small sales force by using animal health distributors.

The **First Defense**® product line serves dairy and beef producers by protecting their calf crop from scours, the leading cause of pre-weaning mortality and morbidity. When calves are healthy during this crucial development period, they mature into more productive milking cows and more efficient beef generators. Our primary competition in this category is vaccines that are also regulated for effectiveness and safety by the USDA. However, animal responses to vaccines 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 years ended December 31, 2024 and 2023, we treated more calves than our next largest calf-level competitive product, which is a vaccine administered to the newborn at birth. Compared to the dam-level competitive products (which are vaccines given to the cow pre-calving), we are second in sales dollars to the market leader. Despite these successes, there remains significant opportunity to displace more competition within North America. There is also opportunity to grow our sales by expanding into international markets. We are being strategic in how we invest in international market development in order not to divert our limited resources away from achieving domestic growth, which is often more efficient to obtain.

We believe that **Re-Tain**® could revolutionize the way that mastitis is managed by making earlier treatment of subclinical infections (while these cows are still producing saleable milk) economically feasible without an FDA-required milk discard or pre-slaughter withdrawal period 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 pre-slaughter withdrawal period 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 "superbugs". Sustainability objectives require that less antibiotics be used in food producing animals, yet a new FDA-approved drug to treat mastitis has not been developed in years. Our product improves sustainability by utilizing a bacteriocin as an alternative to traditional antibiotics that are used in human medicine. In the big picture, we are introducing an entirely new class of antimicrobial as an animal drug, a bacteriocin, that does not promote resistance against antibiotics used in human medicine making it more socially responsible. The industry could keep treating this very significant disease with traditional antibiotics, but it takes innovation to bring a bacteriocin like Nisin to market. **Re-Tain**® would, when introduced, offer a needed alternative to these traditional antibiotics, while at the same time improving milk quality and the quantity of milk produced by treated cows. We believe our product fits very well with where the industry is going to be in the coming years.

As with all new products, the market determines 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 into the first quarter of 2026 or so, as we seek to transform the way that mastitis is treated in the dairy industry over the long term. Our goal is to help early adopters select treatment candidates, develop easy to use protocols, optimize treatment results and realize a positive return on their investment. We intend to limit initial distribution of **Re-Tain®** to a level that enables our sales team to select the optimal dairy farms at which to introduce **Re-Tain®** and to limit the initial number of participating farms so that the desired levels of support and guidance relating to effective usage of **Re-Tain®** can be provided with our available resources. We recognize that it will be important to manage expectations from the producer to the milk processor because it is possible that processors may express reservations with regards to the zero milk discard claim. Our Controlled Launch strategy reduces the amount of inventory that we would need to build at risk before regulatory approval is achieved. This strategic choice means that we have elected not to pursue an alternative strategy that might have maximized short-term, initial sales quickly through a mass market approach where we provide product to distribution and let them sell it to as many farms as possible. While we are dedicated to increasing our sales revenue, we considered available product supply and the damage a mass market strategy could cause to the long-term value of the product. We have seen products sold by much larger companies that were substantially damaged by such failed market launch strategies. We 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 potential problems that would deter its adoption and usage. Our overarching objective is to minimize the risk of early-stage unsatisfactory outcomes that could harm the longer-term prospects and market acceptance of **Re-Tain®**.

e) Administrative Expenses

During the three-month period ended December 31, 2024, administrative expenses increased by 6%, or $31,000, to $555,000 in comparison to $523,000 during the three-month period ended December 31, 2023. Administrative expenses amounted to 7% and 10% of product sales during the three-month periods ended December 31, 2024 and 2023, respectively. Administrative expenses included non-cash depreciation and stock-based compensation expenses of $51,000 and $50,000 during the three-month periods ended December 31, 2024 and 2023, respectively. During the year ended December 31, 2024, administrative expenses increased by 4%, or $82,000, to $2.2 million in comparison to $2.1 million during the year ended December 31, 2023. Administrative expenses amounted to 8% and 12% of product sales during the years ended December 31, 2024 and 2023, respectively. Administrative expenses included non-cash depreciation and stock-based compensation expenses of $198,000 and $210,000 during the years ended December 31, 2024 and 2023, respectively. We strive to be efficient with these expenses while funding all the legal, audit and other costs associated with being a publicly-held company with a team of four employees. 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. Recently, 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 though travel restrictions have been eliminated. At the same time, we continue to provide full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as in Current Reports on Form 8-K when legally required or deemed appropriate by management. We believe these efforts have helped us access the capital markets to fund our growth objectives. Considering our objective to hire a Chief Financial Officer during the first half of 2025 as well as inflation and all the necessary support services that fit into this category, we believe that approximately $2.7 million per year is an efficient budget goal to fund the administrative expenses of a publicly-held company.

f) Net Operating Income (Loss)

During the three-month period ended December 31, 2024, our net operating income was $621,000 in contrast to a net operating loss of $1 million during the three-month period ended December 31, 2023. The $1.6 million swing from net operating loss to net operating income was largely caused by a $1.6 million increase in gross margin. During the year ended December 31, 2024, our net operating loss of $1.6 million was significantly less than our net operating loss of $5.7 million during the year ended December 31, 2023. The $4.1 million decrease in our net operating loss during the year ended December 31, 2024 compared to the year ended December 31, 2023 was largely caused by the $4.1 million increase in gross margin.

g) Other Expenses, net

During the three-month period ended December 31, 2024, other expenses, net, aggregated $101,000 in comparison $135,000 during the three-month period ended December 31, 2023. Interest expense decreased to $136,000 during the three-month period ended December 31, 2024 from $152,000 during the three-month period ended December 31, 2023. Non-cash amortization of debt issuance and debt discount costs (which is included as a component of interest expense) was $11,000 and $10,000 during the three-month periods ended December 31, 2024 and 2023, respectively. Interest income was $36,000 and $17,000 during the three-month periods ended December 31, 2024 and 2023, respectively.

During the year ended December 31, 2024, other expenses, net, aggregated $506,000 in comparison to $22,000 during the year ended December 31, 2023. During the year ended December 31, 2023, we benefited from $365,000 of insurance recoveries, compared to no such benefit during the year ended December 31, 2024. Interest expense increased to $569,000 during the year ended December 31, 2024 from $476,000 during the year ended December 31, 2023 due to the additional debt taken out during the third quarter of

2023. Non-cash amortization of debt issuance and debt discount costs (which is included as a component of interest expense) was $43,000 and $23,000 during the years ended December 31, 2024 and 2023, respectively. We anticipate that our interest expense (excluding non-cash amortization of debt issuance and debt discount costs) will be approximately $452,000 and $322,000 during the years ending December 31, 2025 and 2026, respectively. Interest income was $78,000 and $97,000 during the years ended December 31, 2024 and 2023, respectively. We incurred a $15,000 loss on disposal of property, plant and equipment during the year ended December 31, 2024 compared to an $8,000 loss during the year ended December 31, 2023.

h) Income (Loss) Before Income Taxes

During the three-month period ended December 31, 2024, our income before income taxes was $521,000 in contrast to a loss before income taxes of $1.1 million during the three-month period ended December 31, 2023. The $1.7 million reduction in our loss before income taxes during the three-month period ended December 31, 2024 compared to the three-month period ended December 31, 2023 was largely the result of a $1.6 million improvement in gross margin and a $247,000 decrease in product development expenses that were offset, in part, by a $165,000 increase in sales and marketing expenses. During the year ended December 31, 2024, our loss before income taxes was $2.1 million in comparison to a loss before income taxes of $5.8 million during the year ended December 31, 2023. The $3.6 million decrease in our net loss during the year ended December 31, 2024 compared to the year ended December 31, 2023 was largely the result of the $4.1 million increase in gross margin that was reduced by an increase of $485,000 in other expenses.

i) Income Taxes and Net Income (Loss)

During the three-month periods ended December 31, 2024 and 2023, we recorded income tax expense of $6,000 and $1,000, respectively, which is comprised of minimum state tax liabilities. Our net income of $515,000, or $0.06 per diluted share, during the three-month period ended December 31, 2024 was in contrast to net (loss) of ($1.1 million), or ($0.15) per basic share, during the three-month period ended December 31, 2023. During the years ended December 31, 2024 and 2023, we recorded income tax expense of $10,000 and $5,000, respectively, which is comprised of minimum state tax liabilities. Our net (loss) of ($2.2 million), or ($0.26) per basic share, during the year ended December 31, 2024 was in comparison to net (loss) of ($5.8 million), or ($0.75) per basic share, during the year ended December 31, 2023.

We have substantial net operating loss carryforwards that will largely offset future income tax liabilities. As of December 31, 2024, our federal net operating loss carryforward was $17.6 million. As of December 31, 2024, our state net operating loss carryforward was $5.2 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 and the discussion under **Liquidity and Capital Resources** above 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, 2024 have been taken into consideration in preparing the financial statements. The preparation of financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates. Significant estimates include our valuation of inventory, deferred tax assets and costs of goods sold. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have chosen to highlight certain policies that we consider critical to the operations of our business and understanding of our financial statements. These critical accounting estimates have been consistently applied.

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

tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We generally have experienced an immaterial amount of product returns.

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

ITEM 7A — QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable

ITEM 8 — FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements, together with the notes thereto and the report of the independent registered public accounting firm thereon, are set forth on Pages F-1 through F-25 at the end of this 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, 2024 and 2023	F-3
Statements of Operations during the years ended December 31, 2024 and 2023	F-4
Statements of Stockholders' Equity during the years ended December 31, 2023 and 2024	F-5
Statements of Cash Flows during the years ended December 31, 2024 and 2023	F-6 to F-7
Notes to Audited Financial Statements	F-8 to F-25

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

None

ITEM 9A — CONTROLS AND PROCEDURES

Disclosure Controls and Procedures: Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management, with the participation of the individual who serves as our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of December 31, 2024. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date.

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. 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.

Changes in Internal Controls over Financial Reporting: Our principal executive and principal financial officer and our Director of Finance and Administration periodically evaluate any change in internal control over financial reporting which has occurred during the prior fiscal quarter. We have concluded that there was no change in our internal control over financial reporting that occurred

during the quarter ended December 31, 2024 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

Executive Officers of the Company

Our executive officers as of March 21, 2025 were as follows:

MICHAEL F. BRIGHAM (Age: 64, Officer since 1991, Director since 1999) 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. 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 January 2018) 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.

Information with respect to our directors is incorporated herein by reference to the section of our 2025 Proxy Statement titled “Election of the Board of Directors”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2024. 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.

ITEM 11 — EXECUTIVE COMPENSATION

Information regarding compensation paid to our executive officers is incorporated herein by reference to the section of our 2025 Proxy Statement titled “Executive Officer Compensation”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2024.

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

Information regarding ownership of our common stock by certain owners and management is incorporated herein by reference to the section of our 2025 Proxy Statement titled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2024.

ITEM 13 — CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information regarding certain relationships and related transactions and director independence is incorporated herein by

reference to the section of our 2025 Proxy Statement titled “Certain Relationships and Related Transactions and Director Independence”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2024.

ITEM 14 — PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information regarding our principal accounting fees and services is incorporated by reference to the section of our 2025 Proxy Statement titled “Principal Accounting Fees and Services”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2024.

PART IV

ITEM 15 — EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1.1	At the Market Agreement between the Company and Craig-Hallum Capital Group LLC dated as of April 8, 2024 (incorporated by reference to Exhibit 1.1 of the Company’s Current Report on Form 8-K filed on April 9, 2024).
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 and restated September 20, 2024 (incorporated by reference to Exhibit 3.2 of the Company’s Current Report on Form 8-K filed on September 24, 2024).
4.1	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+	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).
10.3+	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).
10.4+	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).
10.5+	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).
10.6+	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).
10.7+	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).
10.8+	Fourth Amended and Restated Incentive Compensation Agreement between the Company and Bobbi Jo Brockmann dated as of March 27, 2024 (incorporated by reference to Exhibit 10.11 to the Company’s Annual Report on Form 10-K for the year ended December 31, 2023).
10.9+	Employment and Separation Agreement between the Company and Elizabeth L. Williams dated as of December 6, 2024 (incorporated by reference to Exhibit 10.1 of the Company’s Current Report on Form 8-K filed December 9, 2024).
10.10+*	Incentive Compensation Agreement between the Company and Michael F. Brigham dated as of March

27, 2025.

10.11+* Amended and Restated Incentive Compensation and Severance Agreement between the Company and Bobbi Jo Brockmann dated as of March 27, 2025.

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 Amending Agreement between the Company and Norbrook Laboratories dated as of November 29, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed December 2, 2024).

10.15 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).

10.16 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).

10.17 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).

10.18 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).

10.19 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).

10.20 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).

10.21 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).

10.22 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).

10.23 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).

10.24 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).

10.25 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).

10.26 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).

10.27 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).

10.28 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).

10.29 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).

10.30 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).

10.31 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).
10.32	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).
10.33	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).
10.34	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).
10.35	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).
10.36	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).
10.37	Consent and First Amendment to Economic Recovery Loan Program Loan Agreement, by and between ImmuCell Corporation and the Finance Authority of Maine dated as of April 8, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on April 9, 2024).
10.38	Fourth Amendment of Indenture of Lease for Premises Located in Portland, Maine between the Company and TVP, LLC dated as of June 11, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on June 14, 2024).
10.39	Fifth Amendment of Indenture of Lease for Premises Located in Portland, Maine between the Company and TVP, LLC dated as of September 20, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on September 24, 2024).
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).
19*	Insider Trading Policy of the Company adopted as of December 11, 2024.
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 (incorporated by reference to Exhibit 97.1 of the Company's Annual Report on Form 10-K for the year ended December 31, 2023).
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, 2024 and 2023, and the related statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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, 2024, the Company's inventory was $7,112,623. 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
March 28, 2025

ImmuCell Corporation

BALANCE SHEETS

	As of December 31,	
	2024	**2023**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$3,758,232	$978,741
Trade accounts receivable	3,771,133	2,185,383
Inventory	7,112,623	7,811,841
Prepaid expenses and other current assets	400,762	493,885
Total current assets	15,042,750	11,469,850
Property, plant and equipment, net	25,349,019	27,575,683
Operating lease right-of-use asset	4,560,679	4,571,149
Goodwill	95,557	95,557
Intangible assets, net	19,104	38,208
Other assets	33,368	57,655
TOTAL ASSETS	$45,100,477	$43,808,102
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of debt obligations	$1,497,619	$1,428,807
Current portion of operating lease liability	432,072	644,276
Accounts payable and accrued expenses	2,482,522	2,124,337
Total current liabilities	4,412,213	4,197,420
LONG-TERM LIABILITIES:		
Debt obligations, net of current portion	9,040,975	10,540,496
Operating lease liability, net of current portion	4,129,102	4,077,109
Total long-term liabilities	13,170,077	14,617,605
TOTAL LIABILITIES	17,582,290	18,815,025
CONTINGENT LIABILITIES AND COMMITMENTS (See Note 10)		
STOCKHOLDERS' EQUITY:		
Common stock, $0.10 par value per share, with 15,000,000 shares authorized and 9,042,392 and 7,814,165 shares issued and 8,979,091 and 7,750,864 shares outstanding as of December 31, 2024 and 2023, respectively	904,240	781,417
Additional paid-in capital	40,916,155	36,357,239
Accumulated deficit	(14,163,726)	(12,007,097)
Treasury stock, at cost, 63,301 shares as of both December 31, 2024 and 2023	(138,482)	(138,482)
Total stockholders' equity	27,518,187	24,993,077
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$45,100,477	$43,808,102

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

ImmuCell Corporation

STATEMENTS OF OPERATIONS

	During the Years Ended December 31,	
	2024	**2023**
Product sales	$26,493,169	$17,471,669
Costs of goods sold	18,552,125	13,602,385
Gross margin	7,941,044	3,869,284
Product development expenses	3,898,582	4,394,852
Sales and marketing expenses	3,466,072	3,088,215
Administrative expenses	2,216,549	2,134,295
Operating expenses	9,581,203	9,617,362
NET OPERATING LOSS	(1,640,159)	(5,748,078)
Other expenses, net	506,414	21,893
LOSS BEFORE INCOME TAXES	(2,146,573)	(5,769,971)
Income tax expense	10,056	4,627
NET LOSS	($2,156,629)	($5,774,598)
Basic weighted average common shares outstanding	8,167,244	7,747,686
Basic net loss per share	($0.26)	($0.75)
Diluted weighted average common shares outstanding	8,167,244	7,747,686
Diluted net loss per share	($0.26)	($0.75)

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

ImmuCell Corporation

STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock				Treasury Stock		
	Shares	Amount	Additional paid-in capital	Accumulated Deficit	Shares	Amount	Total Stockholders' Equity
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
Net loss	—	—	—	(2,156,629)	—	—	(2,156,629)
At-the-Market Offering of common stock, net of $291,834 of offering costs	1,228,227	122,823	4,233,365	—	—	—	4,356,188
Stock-based compensation	—	—	325,551	—	—	—	325,551
BALANCE,							
December 31, 2024	9,042,392	$904,240	$40,916,155	($14,163,726)	63,301	($138,482)	$27,518,187

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

ImmuCell Corporation

STATEMENTS OF CASH FLOWS

	During the Years Ended December 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	($2,156,629)	($5,774,598)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation	2,668,077	2,697,897
Amortization of intangible assets	19,104	19,104
Amortization of debt issuance costs and debt discounts	42,666	22,619
Stock-based compensation	325,551	368,866
Loss on disposal of property, plant and equipment	15,391	8,099
Non-cash rent (benefit) expense	(149,741)	95,724
Changes in:		
Trade accounts receivable	(1,585,750)	(426,783)
Inventory	699,218	(1,773,302)
Prepaid expenses and other current assets	93,123	(87,830)
Other assets	24,287	18,973
Accounts payable and accrued expenses	362,606	156,995
Net cash provided by (used for) operating activities	357,903	(4,674,236)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(465,725)	(1,892,513)
Proceeds from sale of property, plant and equipment	4,500	2,474
Net cash used for investing activities	(461,225)	(1,890,039)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from debt issuance	—	3,000,000
Proceeds from line of credit	—	2,000,000
Proceeds from At-The-Market Offering	4,648,022	—
Debt principal repayments	(1,468,338)	(1,185,774)
Line of credit repayments	—	(2,000,000)
Payments of debt issuance costs	(5,037)	(35,425)
Payments of debt discounts	—	(46,107)
Payments of equity issuance fees	(291,834)	—
Proceeds from exercise of stock options	—	18,760
Net cash provided by financing activities	2,882,813	1,751,454
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,779,491	(4,812,821)
BEGINNING CASH AND CASH EQUIVALENTS	978,741	5,791,562
ENDING CASH AND CASH EQUIVALENTS	$3,758,232	$978,741

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,	
	2024	**2023**
CASH PAID FOR:		
Income taxes	$7,293	$6,466
Interest	$528,907	$444,954
NON-CASH ACTIVITIES:		
Change in capital expenditures included in accounts payable and accrued expenses	$4,421	$50,086
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	$103,115	$2,472,203

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. We focus on the two most critical stages of dairy productivity, those being the first 30 days of life and the first 30 days of lactation. Our concentrated colostrum and purified Nisin technologies offer unique animal health solutions during these periods when immunity is at its most vulnerable. As disclosed in Note 16, "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 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 contamination events from time to time in our production process, beginning in the third quarter of 2022, as disclosed previously. We implemented a production slowdown during 2023 to remediate this problem, which led to the recognition of lower sales and gross margin. The last identified contamination event occurred during the first half of April of 2024, and we have been operating without further contamination events since then and through the time of this filing on March 28, 2025.

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.

(c) Trade Accounts Receivable

Accounts receivable are carried at the original invoice amount less an estimate made for credit losses, when applicable. Management determines the allowance for credit losses 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, 2024 or 2023 because the time past due was not significant, and there was no accrual for such interest charges as of December 31, 2024 or 2023. As of December 31, 2024 and 2023, we determined that no allowance for credit losses was necessary. Accounts receivable are written off when deemed uncollectible. No accounts receivable were written off during the years ended December 31, 2024 or 2023. Recoveries of accounts receivable previously written off are recorded as income when received. No such recoveries were recorded during the years ended December 31, 2024 or 2023. See Note 3.

(d) Inventory

Inventory includes raw materials, work-in-process and finished goods and is recorded at the lower of cost, on the first-in, first-out method, or net realizable value (determined as the estimated selling price in the normal course of business, less reasonably predictable costs of completion, disposal and transportation). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. At each balance sheet date, we evaluate our ending inventories for excess quantities and obsolescence. Inventories that we consider excess or obsolete are written down to estimated net realizable value. Once inventory is written down and a new cost basis is established, it is not written back up. We believe that supplies and raw materials for the production of our products are available from more than one vendor or farm. Our policy is to maintain more than one source of supply for the components used in our products when feasible. See Note 4.

(e) Property, Plant and Equipment, net

We depreciate property, plant and equipment on the straight-line method by charges to operations and costs of goods sold in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The facility we have constructed at 33 Caddie Lane to produce the Nisin Drug Substance (DS) for **Re-Tain®** (**Building 33**) is being depreciated over 39 years from when a Certificate of Occupancy was issued during the fourth quarter of 2017. We began depreciating the equipment for our Nisin DS facility when it was placed in service during the third quarter of 2018. Approximately 86% of these assets are being depreciated over 10 years. We began depreciating the leasehold improvements to our new **First Defense®** production facility at 175 Industrial Way (**Building 175A**) over the remainder of the 10-year lease term beginning when a Certificate of Occupancy was issued during the second quarter of 2020. During August of 2022, this lease term was extended to January of 2043 in connection with a new lease covering additional space at 175 Industrial Way (**Building 175B**). As a result, the net book value of these leasehold improvements as of August 31, 2022 is now being depreciated over the remainder of the extended lease term. Significant repairs to property, plant and equipment that benefit more than a current period are capitalized and depreciated over their useful lives. Insignificant repairs are expensed when incurred. See Notes 2(h) and 6 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 11 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 the fair value of the net assets (including tax attributes) are recorded as goodwill under the acquisition method of accounting. We assess the impairment of intangible assets that have indefinite lives (when applicable) and goodwill (at the reporting unit level) on an annual basis (as of December 31st) and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We would record an impairment charge if such an assessment were to indicate that the fair value of such assets was less than the carrying value. Judgment is required in determining whether an event has occurred that may impair the value of goodwill or identifiable intangible assets. Factors that could indicate that an impairment may exist include

significant under-performance relative to plan or long-term projections, significant changes in business strategy and significant negative industry or economic trends. Although we believe intangible assets and goodwill are properly stated in the accompanying financial statements, changes in strategy or market conditions could significantly impact these judgments and require an adjustment to the recorded balance in the future. No goodwill impairments were recorded during the years ended December 31, 2024 or 2023. See Notes 2(h) and 7 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, 2024 or 2023.

(i) Fair Value Measurements

In determining fair value measurements, we follow the provisions of Codification Topic 820, *Fair Value Measurements and Disclosures*. Codification Topic 820 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. The topic provides a consistent definition of fair value which focuses on an exit price, which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The topic also prioritizes, within the measurement of fair value, the use of market-based information over entity-specific information and establishes a three-level hierarchy for fair value measurements based on the nature of inputs used in the valuation of an asset or liability as of the measurement date. As of December 31, 2024 and 2023, the carrying amounts of cash and cash equivalents, accounts receivable, inventory, prepaid expenses and other current assets, other assets, accounts payable and accrued expenses approximate fair value because of their short-term nature. The amount outstanding under our bank debt facilities is measured at carrying value in our accompanying balance sheets. Our bank debt facilities are valued using Level 2 inputs. The three-level hierarchy is as follows:

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

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

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

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

We assess the levels of the investments at each measurement date, and transfers between levels are recognized on the actual date of the event or change in circumstances that caused the transfer in accordance with our accounting policy regarding the recognition of transfers between levels of the fair value hierarchy. During the years ended December 31, 2024 and 2023, there were no transfers between levels. As of December 31, 2024 and 2023, our Level 1 assets measured at fair value by quoted prices in active markets consisted of cash and money market accounts. There were no assets or liabilities measured at fair value on a nonrecurring basis as of December 31, 2024 or 2023. The carrying values of our cash and money market accounts as of December 31, 2024 and 2023 approximated their fair market values. Due to inflation and the changing interest rate environment, the carrying values of our fixed rate bank debt as of December 31, 2024 and 2023 differed from their fair market values. These values are reflected in the following tables:

	As of December 31, 2024			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and money market accounts	$3,758,232	$—	$—	$3,758,232
Liabilities:				
Bank debt	$—	$9,465,500	$—	$9,465,500

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

(j) Concentration of Risk

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

	During the Years Ended December 31,	
	2024	**2023**
Company A	47%	47%
Company B	30%	32%
Total	77%	79%

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, 2024	**As of December 31, 2023**
Company A	57%	43%
Company B	21%	36%
Total	78%	79%

(k) Revenue Recognition

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

a purchase or sales order are discrete and stand-alone. We recognize revenue when we satisfy a performance obligation in a contract by transferring control over a product to a customer when product ships to a customer. Amounts due are typically paid approximately 30 days from the time control is transferred. Shipping and handling costs associated with outbound freight are accounted for as a fulfillment cost in costs of goods sold. We do not bill for or collect sales tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We generally have experienced an immaterial amount of product returns. See Note 13 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 2021. We have evaluated the positions taken on our filed tax returns and have concluded that no uncertain tax positions existed as of December 31, 2024 or 2023. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 15.

(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 $325,551 and $368,866 during the years ended December 31, 2024 and 2023, respectively. See Note 12.

(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 664,000 and 618,500 during the years ended December 31, 2024 and 2023, respectively.

	During the Years Ended December 31,	
	2024	**2023**
Net loss attributable to stockholders	($2,156,629)	($5,774,598)
Weighted average common shares outstanding - Basic	8,167,244	7,747,686
Dilutive impact of share-based compensation awards	—	—
Weighted average common shares outstanding - Diluted	8,167,244	7,747,686
Net loss per share:		
Basic	($0.26)	($0.75)
Diluted	($0.26)	($0.75)

(p) Use of Estimates

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

(q) New Accounting Pronouncement Adopted

In November of 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant expenses. The amendments require disclosure of significant segment expenses that are regularly provided to our chief operating decision-maker and included within segment profit and loss. The adoption of ASU 2023-07 did not have a material impact on our financial statements.

(r) New Accounting Pronouncements Not Yet Adopted

In November of 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*, to provide disaggregated disclosures of specific expense categories underlying all relevant income statement expense line items on an annual and interim basis. The disclosure requirements will be applied on a prospective basis, with the option to apply it retrospectively. The effective date for the standard is for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. We are evaluating ASU 2024-03 to determine its impact on our financial statements.

In December of 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which includes amendments that 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 assess the impact on our financial statement disclosures and to determine the transition method in which the new guidance will be adopted.

3. TRADE ACCOUNTS RECEIVABLE

Trade accounts receivable amounted to $3,771,133 and $2,185,383 as of December 31, 2024 and 2023, respectively. No allowance for credit losses or product returns was recorded as of December 31, 2024 or 2023. We consider a broad range of information to estimate credit losses. Historically, we have experienced a very low level of credit loss expense, and most of our trade receivables are collected by the due date or within a few days of the due date. We anticipate no future events or conditions that would impact our ability to collect our accounts receivable. Because of the generally short duration from the balance sheet date to the date of collection, our collection rate is not expected to be significantly impacted by events occurring after the balance sheet date. The trade accounts receivable balances included $52,097 and $42,507 due from a related party as of December 31, 2024 and 2023, respectively. See Note 17.

4. INVENTORY

Inventory consisted of the following:

	As of December 31, 2024	As of December 31, 2023
Raw materials	$1,356,228	$1,594,028
Work-in-process	5,746,865	5,815,194
Finished goods	9,530	402,619
Total	$7,112,623	$7,811,841

These inventory figures are net of write-offs of scrapped inventory in the amounts of $406,565 and $527,133 during the years ended December 31, 2024 and 2023, respectively, that resulted principally from contamination events and other production process losses**.**

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of December 31, 2024	As of December 31, 2023
Prepaid expenses	$360,207	$454,152
Other receivables	40,555	39,733
Total	$400,762	$493,885

6. PROPERTY, PLANT AND EQUIPMENT, net

Property, plant and equipment consisted of the following:

	Estimated Useful Lives (in years)	As of December 31, 2024	As of December 31, 2023
Laboratory and manufacturing equipment	3-10	$21,234,259	$20,953,601
Buildings and improvements	10-39	20,889,395	20,784,565
Office furniture and equipment	3-10	1,056,145	1,036,374
Construction in progress	n/a	2,693,904	2,768,224
Land	n/a	516,867	516,867
Property, plant and equipment, gross		46,390,570	46,059,631
Accumulated depreciation		(21,041,551)	(18,483,948)
Property, plant and equipment, net		$25,349,019	$27,575,683

As of December 31, 2024 and 2023, construction in progress consisted principally of payments toward the **First Defense®** production capacity expansion project and equipment needed to bring the formulation and aseptic filling for **Re-Tain®** in-house. The costs associated with property, plant and equipment disposals were $130,365 and $100,142 during the years ended December 31, 2024 and 2023, respectively. Depreciation expense was $2,668,077 and $2,697,897 during the years ended December 31, 2024 and 2023, respectively.

7. 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, 2024 and 2023. The net value of these intangibles was $19,104 and $38,208 as of December 31, 2024 and 2023, respectively. Intangible asset amortization expense is estimated to be $19,104 during the year ending December 31, 2025.

Intangible assets as of December 31, 2024 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	$184,100	($165,690)	$18,410
Customer relationships	1,300	(1,170)	130
Non-compete agreements	5,640	(5,076)	564
Total	$191,040	($171,936)	$19,104

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

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

8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of December 31, 2024	As of December 31, 2023
Accounts payable – trade	$934,883	$874,558
Accounts payable – capital	8,754	13,175
Accrued payroll	1,195,703	942,999
Accrued professional fees	102,815	97,800
Accrued other	234,552	192,754
Income tax payable	5,815	3,051
Total	$2,482,522	$2,124,337

9. BANK DEBT

Loans #1 and #2: During the first quarter of 2020, we closed on a debt financing with Maine Community Bank (formerly known as Gorham Savings Bank) (MCB) 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 $3,687,608 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, MCB 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, 2024 or 2023.

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

Loan #4: During the fourth quarter of 2020, we closed on a $1,500,000 note with MCB that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). Proceeds of $624,167 were used to prepay a portion of the outstanding principal on our mortgage note (Loan #1), which reduced the outstanding balance to 80% of the most recent appraised value of the property securing the debt, which allowed MCB to release the $1,400,000 that had been held in escrow. The remaining proceeds were available for general working capital purposes.

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

Loan #6: During the third quarter of 2023, we closed on a $2,000,000 term loan bearing interest at a fixed rate of 7% per annum from MCB. The Finance Authority of Maine (FAME) provided $1,000,000 of loan insurance to MCB. This loan is repayable under a 7-year amortization schedule with a balloon payment of $1,285,047 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 $649,259 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 and into the first nine months of 2024, the debt service covenant (DSC) requirements for the twelve-month periods ended December 31, 2023, June 30, 2024, September 30, 2024 and December 31, 2024 were waived pre-emptively by our lenders. We are required to meet a minimum DSC ratio of 1.35 for the year ending December 31, 2025 and annually thereafter. In connection with these credit facilities, we incurred aggregate debt issuance and debt discount costs of $173,305. 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 MCB and FAME. Failure to make timely payments of principal and interest, or otherwise to comply with the terms of the agreements of Loans #3 and #5, would entitle the MTI to accelerate the maturity of such debt and demand repayment in full. These loans may be prepaid without penalty at any time.

Debt proceeds received and principal repayments made (excluding our $1,000,000 line of credit) are reflected by loan during the periods as described in the tables below:

	During the Year Ended December 31, 2024		During the Year Ended December 31, 2023	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	$—	$230,763	$—	$223,222
Loan #2	—	512,139	—	494,455
Loan #3	—	96,104	—	91,446
Loan #4	—	213,227	—	205,884
Loan #5	—	66,470	—	32,017
Loan #6	—	235,393	2,000,000	93,054
Loan #7	—	114,242	1,000,000	45,696
Total	$—	$1,468,338	$3,000,000	$1,185,774

Principal payments (net of debt issuance and debt discount costs) due under bank loans outstanding as of December 31, 2024 (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,						
	2025	**2026**	**2027**	**2028**	**2029**	**Thereafter**	**Total**
Loan #1	$239,864	$248,604	$257,649	$266,537	$276,720	$4,321,768	$5,611,142
Loan #2	530,738	549,881	140,423	—	—	—	1,221,042
Loan #3	101,001	106,146	83,143	—	—	—	290,290
Loan #4	220,998	228,965	240,438	—	—	—	690,401
Loan #5	69,856	73,415	77,156	81,086	—	—	301,513
Loan #6	253,003	1,418,550	—	—	—	—	1,671,553
Loan #7	124,364	715,698	—	—	—	—	840,062
Subtotal	1,539,824	3,341,259	798,809	347,623	276,720	4,321,768	10,626,003
Debt issuance cost	(21,314)	(13,580)	(5,420)	(3,513)	(3,513)	(7,834)	(55,174)
Debt discount cost	(20,891)	(11,344)	—	—	—	—	(32,235)
Total	$1,497,619	$3,316,335	$793,389	$344,110	$273,207	$4,313,934	$10,538,594

10. 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, 2024 or 2023. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

The development, manufacturing and marketing of animal health care products entails an inherent risk that liability claims will be asserted against us during the normal course of business. We are aware of no such claims against us as of the time of this filing on March 28, 2025. 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, 2024 or 2023.

We plan to purchase certain key parts (syringes) and services (formulation, aseptic filling and final packaging) pertaining to **Re-Tain®** Drug Product (DP), our Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows, exclusively from contractors. The contract for formulation, aseptic filling and final packaging of DP terminated on November 30, 2024. This contract was extended through March of 2026 for the purpose of final packaging of existing DP inventory, but this contract extension does not anticipate the production of new DP inventory. During 2019, we initiated an investment in the necessary equipment to perform the DP formulation and aseptic filling services in-house, but this investment has been paused at the present time.

Effective March 28, 2022, we entered into an Amended and Restated Separation and Deferred Compensation Agreement (the "Deferred Compensation Agreement") with Mr. Brigham (our President and CEO) that superseded and replaced in its entirety a March 2020 severance agreement between the Company and Mr. Brigham. Upon separation from the Company for any reason, Mr. Brigham's Deferred Compensation Agreement allows Mr. Brigham to be paid, among other amounts, all earned and unused paid time off. Accordingly, an expense of $222,379 for earned and unpaid sick time was accrued during the first quarter of 2022 and a related accrual of $230,162 was included in accounts payable and accrued expenses as of December 31, 2024 and 2023. Additionally, Mr. Brigham was paid $300,000 in deferred compensation during the first quarter of 2025 (which was accrued over the three-year period

ending in December 2024). This deferred compensation payment vested as to $300,000, $200,000 and $100,000 on January 1, 2025, 2024 and 2023, respectively. Deferred compensation of $300,000 and $200,000 was included in accounts payable and accrued expenses on the accompanying balance sheets as of December 31, 2024 and 2023, respectively. In addition, upon termination of Mr. Brigham's employment (a) by the Company other than for cause, (b) due to death or disability or (c) by Mr. Brigham for good reason, in each case as described and defined in the Deferred Compensation Agreement, the Company agrees to pay Mr. Brigham 100% of his then current annual base salary and a lump sum payment equal to the employer portion of the costs of continued health benefits for Mr. Brigham and his covered dependents for a twelve-month period following termination, and certain equity incentive awards granted to Mr. Brigham would continue to vest following such termination in accordance with the terms of the Deferred Compensation Agreement.

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

In addition to the commitments discussed above, we had committed $67,000 to increase our production capacity for the **First Defense®** product line, $1,629,000 to the purchase of inventory and $686,000 to information technology services and other obligations as of December 31, 2024.

11. 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, June 11, 2024 and September 20, 2024, we amended this lease further to provide for certain tenant improvements on the leased premises to be paid for by our landlord. These improvements will provide heat to an unfinished space, provide additional warehouse space, and create a new primary shipping and receiving facility. As a result of these three amendments and in consideration for the landlord agreeing to pay for the cost of those certain tenant improvements, we agreed to make additional rent payments of $20,000 per month from November of 2023 through June of 2025 and a one-time additional rent payment of $248,743 in July of 2025. Because of these modifications to the lease payments, the ROU asset and lease liability associated with the space at **Building 175B** were remeasured as of the modification dates. Our leases include variable non-lease components. Such payments primarily include common area maintenance charges. As of December 31, 2024, the balance of the operating lease ROU asset was $4,560,679 and the operating lease liability was $4,561,174. As of December 31, 2023, the balance of the operating lease ROU asset was $4,571,149 and the operating lease liability was $4,721,385. The calculated amount of the ROU asset and lease liability is impacted by the length of the lease term and the discount rate used for the present value of the minimum lease payments. We elected not to separate lease and non-lease components for all classes of underlying assets, and instead to account for them as a single lease component. Variable lease cost primarily represents variable payments such as real estate taxes and common area maintenance. The following tables describe our lease costs and other lease information:

	During the Years Ended December 31,	
	2024	**2023**
Lease Cost		
Operating lease cost	$427,519	$348,929
Variable lease cost	66,523	36,774
Total lease cost	$494,042	$385,703
Operating Lease		
Cash paid for operating lease liabilities	$577,260	$248,595
Weighted average remaining lease term (in years)	18.1	19.1
Weighted average discount rate	6.6%	7.11%

Future lease payments required under non-cancelable operating leases in effect as of December 31, 2024 were as follows:

	Amount
During the years ending December 31	
2025	$711,623
2026	349,744
2027	356,732
2028	363,870
2029	371,144
Thereafter	5,578,344
Total lease payments (undiscounted cash flows)	7,731,457
Less: imputed interest (discount effect of cash flows)	(3,170,283)
Total operating liabilities	$4,561,174

12. STOCKHOLDERS' EQUITY

Common Stock Issuances

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

On April 9, 2024, our shelf registration on Form S-3 relating to the offer, issuance and sale by the Company of up to $20,000,000 of securities was declared effective by the Securities and Exchange Commission. Also on April 9, 2024, we entered into an At-The-Market (ATM) Agreement with Craig-Hallum Capital Group LLC, pursuant to which we may offer and sell up to $11,000,000 of shares of our common stock. Legal, accounting and other fees in the amount of $152,272 associated with the completion of the shelf registration and the ATM Agreement were initially capitalized and then were offset against the initial proceeds received during the second quarter of 2024. As of December 31, 2024, we have sold 1,228,227 shares under the ATM Offering conducted pursuant to the ATM Agreement. Net proceeds through December 31, 2024 from shares sold pursuant to the ATM Agreement (net of the upfront legal, accounting and other fees), less sales commissions of $139,562, were $4,356,188.

Stock Option Plans

In June of 2010, our stockholders approved the 2010 Stock Option and Incentive Plan (the "2010 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at no less than fair market value on the date of grant. At that time, 300,000 shares of common stock were reserved for issuance under the 2010 Plan and subsequently no additional shares have been reserved for the 2010 Plan. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case-by-case basis. All options granted under the 2010 Plan expire no later than 10 years from the date of grant. The 2010 Plan expired in June of 2020, after which date no further options can be granted under the 2010 Plan. However, options outstanding under the 2010 Plan at that time can be exercised in accordance with their terms. There were 183,500 and 188,500 options outstanding under the 2010 Plan as of December 31, 2024 and 2023, respectively.

In June of 2017, our stockholders approved the 2017 Stock Option and Incentive Plan (the "2017 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at no less than fair market value on the date of grant. At that time, 300,000 shares of common stock were reserved for issuance under the 2017 Plan. An amendment to the 2017 Plan increasing the number of shares reserved for issuance under the 2017 Plan from 300,000 shares to 650,000 shares was approved by a vote of stockholders at the Annual Meeting of Stockholders in June of 2022. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case-by-case basis. All options granted under the 2017 Plan expire no later than 10 years from the date of grant. The 2017 Plan expires in March of 2027, after which date no further options can be granted under the 2017 Plan. However, options outstanding under the 2017 Plan at that time can be exercised in accordance with their terms. As of December 31, 2024 and 2023, there were 480,500 and 430,000 options outstanding under the 2017 Plan, respectively.

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

	2010 Plan	2017 Plan	Weighted Average Exercise Price	Aggregate Intrinsic Value[1]
Outstanding as of December 31, 2022	202,500	402,500	$7.19	($661,310)
Grants	—	122,000	$5.16	
Terminations/forfeitures[2]	(10,000)	(94,500)	$7.12	
Exercises	(4,000)	—	$4.69	
Outstanding as of December 31, 2023	188,500	430,000	$6.82	($1,071,121)
Grants	—	86,000	$3.91	
Terminations/forfeitures[2]	(5,000)	(35,500)	$6.55	
Exercises	—	—	$—	
Outstanding as of December 31, 2024	183,500	480,500	$6.46	($870,558)
Vested as of December 31, 2024	183,500	136,500	$6.97	($582,340)
Vested and expected to vest as of December 31, 2024	183,500	480,500	$6.46	($870,558)
Reserved for future grants	—	151,500		

[1] Intrinsic value is the difference between the fair market value of the underlying common stock as of the date indicated and as of the date of the option grant (which is equal to the option exercise price).
[2] Terminations and forfeitures are recognized when they occur.

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

	Number of Shares	Weighted Average Fair Value at Grant Date	Weighted Average Exercise Price
Non-vested stock options as of December 31, 2023	337,500	$3.66	$7.14
Non-vested stock options as of December 31, 2024	344,000	$3.12	$6.25
Stock options granted during the year ended December 31, 2024	86,000	$1.84	$3.91
Stock options that vested during the year ended December 31, 2024	54,000	$4.31	$9.73
Stock options that were terminated or forfeited during the year ended December 31, 2024	40,500	$3.33	$6.55

No stock options were exercised during the year ended December 31, 2024. During the year ended December 31, 2023, 4,000 stock options were exercised by one employee with $18,760 in cash. The aggregate intrinsic value of options exercised during the year ended December 31, 2023 was $1,040. The weighted average remaining life of the options outstanding under the 2010 Plan and the 2017 Plan as of December 31, 2024 was approximately 4 years and 10 months. The weighted average remaining life of the options exercisable under these plans as of December 31, 2024 was approximately 2 years and 8 months. The exercise price of the options outstanding under these plans as of December 31, 2024, ranged from $3.60 to $10.04 per share. The 86,000 stock options granted during the year ended December 31, 2024 had an average exercise price of $3.91 per share. The 122,000 stock options granted during the year ended December 31, 2023 had an average exercise price of $5.16 per share. The weighted-average grant date fair values of options granted during the years ended December 31, 2024 and 2023 were $1.84 and $2.80 per share, respectively. As of December 31, 2024, total unrecognized stock-based compensation related to non-vested stock options aggregated $365,124 which will be

recognized over a weighted average remaining period of approximately 1 year and 3 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,	
	2024	**2023**
Risk-free interest rate[(1)]	3.77%	3.59%
Dividend yield[(2)]	0%	0%
Expected volatility[(2)]	52%	54%
Expected life[(3)]	4.6 years	6.2 years

[(1)] The risk-free interest rate is based on U.S. Treasury yields for a maturity approximating the expected option term.
[(2)] The dividend yield and expected volatility are derived from averages of our historical data.
[(3)] The expected life is calculated utilizing the simplified method, which uses the mid-point between the vesting period and the contractual term as the expected life.

Common Stock Rights Plan

In September of 1995, our Board of Directors adopted a Common Stock Rights Plan (the "Rights Plan") and declared a dividend of one common share purchase right (a "Right") for each of the then outstanding shares of the common stock of the Company. Each Right entitled 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 were set forth in a Rights Agreement between the Company and Equiniti Trust Company, LLC, as Rights Agent. At various times over the years, our Board of Directors, which has the authority to amend the Rights Plan, voted to authorize amendments to the Rights Plan to extend the expiration date of the Rights Plan. During 2024, our Board of Directors determined not to further extend the Rights Plan because these plans are generally considered not to be stockholder friendly. With no further extension, the Rights Plan expired as of September 19, 2024. No shares were issued under Rights Plan while it was in effect.

13. 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, 2024 or 2023. We do not have any contract assets for which we have satisfied the performance obligations, but do not yet have the right to bill for, or contract liabilities such as customer advances. All trade receivables on our balance sheets are from contracts with customers. We incur no material costs to obtain contracts.

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

	During the Years Ended December 31,			
	2024	**%**	**2023**	**%**
United States	$22,893,721	86%	$15,949,382	91%
Other	3,599,448	14%	1,522,287	9%
Total Product Sales	$26,493,169	100%	$17,471,669	100%

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

	During the Years Ended December 31,			
	2024	**%**	**2023**	**%**
First Defense® product line	$26,314,250	99%	$17,293,933	99%
Other animal health	178,919	1%	177,736	1%
Total Product Sales	$26,493,169	100%	$17,471,669	100%

14. OTHER EXPENSES, NET

Other expenses net, consisted of the following:

	During the Years Ended December 31,	
	2024	**2023**
Interest expense[(1)]	$568,725	$475,598
Loss on disposal of property, plant and equipment	15,391	8,099
Interest income	(77,702)	(96,570)
Insurance recoveries[(2)]	—	(365,127)
Income - other	—	(107)
Other expenses (income), net	$506,414	$21,893

[(1)] Interest expense includes amortization of debt issuance and debt discount costs of $42,666 and $22,619 during the years ended December 31, 2024 and 2023, respectively.
[(2)] The income from insurance recoveries resulted from claim benefits paid to us under our business interruption policy related to product contamination losses (in the amount of $250,000) and a recovery from a vendor's policy related to an equipment malfunction (in the amount of $115,127).

15. INCOME TAXES

Our income tax expense aggregated $10,056 and $4,627 (amounting to less than 1% of our loss before income taxes) during the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had federal net operating loss carryforwards of $17,647,250 of which $15,935,343 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 $5,194,515 that expire in 2037 through 2038 (if not utilized before then). Additionally, we had federal general business tax credit carryforwards of $842,565 that expire in 2027 through 2042 (if not utilized before then) and state tax credit carryforwards of $777,459 that expire in 2025 through 2042 (if not utilized before then).

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

Net operating loss carryforwards, credits, and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service. Section 382 of the Internal Revenue Code contains provisions that could place annual limitations on the future utilization of net operating loss carryforwards and credits in the event of a change in ownership of the Company, as defined.

We file income tax returns in the U.S. federal jurisdiction and several state jurisdictions. We currently have no tax examinations in progress. We also have not paid additional taxes, interest or penalties as a result of tax examinations nor do we have any unrecognized tax benefits for any of the periods in the accompanying audited financial statements.

The income tax provision consisted of the following:

	During the Years Ended December 31,	
	2024	**2023**
Current		
Federal	$—	$—
State	10,056	4,627
Current subtotal	10,056	4,627
Deferred		
Federal	(500,927)	(1,179,474)
State	(59,032)	(145,802)
Deferred subtotal, gross	(559,959)	(1,325,276)
Valuation allowance	559,959	1,325,276
Deferred subtotal, net	—	—
Income tax expense	$10,056	$4,627

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, 2024 and 2023 respectively, as follows:

	During the Years Ended December 31,			
	2024		**2023**	
	$	%	$	%
Computed expected income tax expense rate	($450,780)	(21.00%)	($1,211,694)	(21.00%)
State income taxes, net of federal expense	(36,681)	(1.71)	(117,149)	(2.03)
Share-based compensation	49,030	2.28	56,214	0.97
Tax credits	(116,091)	(5.41)	(53,241)	(0.92)
Valuation allowance	559,959	26.09	1,325,276	0.09
Other	4,619	0.22	5,221	22.97
Income tax expense/rate	$10,056	0.47%	$4,627	0.08%

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

	As of December 31,	
	2024	**2023**
Property, plant and equipment	($1,833,727)	($2,121,940)
Federal general business tax credits	842,565	726,474
Federal net operating loss carryforwards	3,705,923	3,729,500
State tax credits and net operating loss carryforwards	900,569	886,428
§174 R & D expenditures	727,410	592,915
Deferred compensation	82,370	50,722
Prepaid expenses and other	24,718	37,124
UNICAP	22,443	32,607
Incentive compensation	121,718	100,200
Valuation allowance	(4,593,989)	(4,034,030)
Deferred tax assets, net	$—	$—

16. SEGMENT INFORMATION

Our business operations (being the development, 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 focused on 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 focused on 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 (Center for Veterinary Biologics, U.S. Department of Agriculture for **First Defense®** or Center for Veterinary Medicine, U.S. Food and Drug Administration 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, 2024			
	Scours	**Mastitis**	**Other**	**Total**
Product sales	$26,314,251	$178,918	$—	$26,493,169
Costs of goods sold	18,382,949	169,176	—	18,552,125
Gross margin	7,931,302	9,742	—	7,941,044
Product development expenses	243,578	3,493,298	161,706	3,898,582
Sales and marketing expenses	2,909,799	556,273	—	3,466,072
Administrative expenses	—	—	2,216,549	2,216,549
Operating expenses	3,153,377	4,049,571	2,378,255	9,581,203
NET OPERATING INCOME (LOSS)	$4,777,925	($4,039,829)	($2,378,255)	($1,640,159)

	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)

	Scours	**Mastitis**	**Other**	**Total**
Total Assets as of December 31, 2024	$24,644,294	$16,523,048	$3,933,135	$45,100,477
Total Assets as of December 31, 2023	$24,735,413	$17,827,839	$1,244,850	$43,808,102
Depreciation and amortization expense during the year ended December 31, 2024	$1,373,815	$1,277,218	$78,814	$2,729,847
Depreciation and amortization expense during the year ended December 31, 2023	$1,365,988	$1,287,600	$86,032	$2,739,620
Capital Expenditures during the year ended December 31, 2024	$409,696	$53,721	$2,308	$465,725
Capital Expenditures during the year ended December 31, 2023	$1,096,819	$795,694	$—	$1,892,513

17. 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 $567,114 and $231,405 of products from us during the years ended December 31, 2024 and 2023, respectively, all on terms consistent with those offered to other distributors of similar status. Our accounts receivable (subject to standard and customary payment terms) due from this affiliated company aggregated $52,097 and $42,507 as of December 31, 2024 and 2023, respectively.

18. 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 $203,756 and $178,150 into the Plan for the years ended December 31, 2024 and 2023, respectively.

19. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of this filing on March 28, 2025. First, in January of 2025, we settled a long outstanding insurance claim related to previously disclosed contamination events in our production process incurred from late 2022 through April of 2024. As a result of the settlement, we received $426,587 during January of 2025, which is in addition to the $250,000 that was previously received on this claim and recognized for financial statement purposes during the third quarter of 2023. Second, net proceeds from January 1, 2025 through March 21, 2025 from 3,532 shares sold pursuant to our ATM Agreement (less sales commissions of $584) were $18,849. As of the time of this filing on March 28, 2025, there were no additional 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: March 28, 2025

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.

Signature	Title	Date
/s/ Gloria J. Basse Gloria J. Basse	Director	March 24, 2025
/s/ Michael F. Brigham Michael F. Brigham	President, Chief Executive Officer, Principal Financial Officer and Director	March 24, 2025
/s/ Bobbi Jo Brockmann Bobbi Jo Brockmann	Vice President of Sales and Marketing and Director	March 24, 2025
/s/ Bryan K. Gathagan Bryan K. Gathagan	Director	March 24, 2025
/s/ Steven T. Rosgen Steven T. Rosgen	Director	March 24, 2025
/s/ David S. Tomsche David S. Tomsche, DVM	Director	March 24, 2025
/s/ Elizabeth S. Toothaker Elizabeth S. Toothaker	Controller	March 24, 2025
/s/ Paul R. Wainman Paul R. Wainman	Director	March 24, 2025