

During the second quarter of 2018, we recorded a non-cash income tax expense of approximately \$563,000 to record a full valuation allowance against our net deferred tax assets. This reserve was required given that we are currently incurring a net loss and project additional net losses in the near term.

However, we believe that we will return to profitability and utilize these assets before they expire. That's what's important to me that we utilize these tax benefits before they expire, even if the accounting rules require us to record a valuation allowance at this time.

As a result of all this, our net loss was \$798,000, or \$0.15 per share, during the three-month period ended June 30, 2018 in comparison to a net loss of \$218,000, or \$0.05 per share, during the three-month period ended June 30, 2017. Our net loss was \$1,019,000 or \$0.19 per share, during the six-month period ended June 30, 2018 in contrast to net income of \$366,000, or \$0.07 per diluted share, during the first six-months of 2017.

As we focus primarily on creating topline growth and bringing our new products to market at this time, it is important to note how much of this net loss is the result of non-cash expenses. As of June 30, 2018, we had \$2.5 million of cash on hand and \$426,000 of available bank debt in addition to our \$500,000 line of credit.

Lastly, let's talk about the development status of our Nisin-based intramammary treatment for subclinical mastitis. As many of you know, our goal is to revolutionize the way mastitis is treated by making the treatment of subclinical infections economically feasible by eliminating the standard requirement to withhold milk and meat during and, for a period of time, after treatment.

No other product can offer this value proposition. Nisin, the active ingredient, is a bacteriocin that is not used in human medicine, and would not contribute to the growing concern that the widespread use of antibiotics encourages the growth of antibiotic-resistant bacteria known as superbugs. We are making consistent progress towards meeting the final requirements for FDA approval.

During the third quarter for 2018, we began production of registration batches and anticipate making the first phase Nisin drug substance CMC Technical Section submission to the FDA at the end of the third quarter or early in the fourth quarter of 2018. A second phase submission, which would include the drug product data, as well as responses to the first phase review, is expected to be filed during the middle of 2019.

Adherence to this anticipated timeline supports obtaining FDA approval by late 2019 or during the first half of 2020, with subsequent market launch. We had about \$125,000 remaining to fund on the Nisin facility as of June 30, 2018 bringing this project in at just under its \$21 million budget. I will not read out other financial numbers on this call that you can access in last night's press release or in our Form 10-Q, I'd rather hear from you.

So, with that said, let's have Andrea open up the lines for your questions.





QUESTIONS AND ANSWERS

Operator

Thank you. We will now begin the question and answer session. To ask a question, you may press star then one on your touchtone phone. If you are using a speakerphone, please pick up your handset before pressing the keys. To withdraw your question, please press star then two. At this time, we will pause momentarily to assemble our roster.

Our first question comes from Kevin Ellich of Craig-Hallum. Please go ahead.

Kevin Ellich

Good morning, Michael. Thanks for taking the questions, sorry for the background noise. Just wanted to ask a couple of questions. First, can you talk about the potential impact of the soft dairy market? Clearly dairy prices are still weak, I don't know if you have any expectations that supply could change down the road, just wanted to see how you think that might impact the business?

Michael Brigham

Yes. It is a rough time. It is a very rough time, but it is also normal [audio disruption] used to these cycles. We are in a low cycle right now. Milk price is down under \$15 per hundred weight. That's not good for our customers, that's not good for us, but it does cycle, it will come around. These first six months results we are pretty pleased with. If we can achieve the level of unit growth that we have during the first half of the year, given the low milk price and the impact that it's had on small producers, some of them going out of business, we're ready for the upswing as that cycle turns.

Kevin Ellich

Great. And then can you talk about Tri-Shield, it sounds like you are getting some traction there, and do you think you're gaining share in that market, and what's your future outlook there?

Michael Brigham

Yes, it's a very exciting product. The initial reaction to this product has been stronger than we anticipated. The challenge is we don't have enough inventory. The production cycle for this product is six months long. The fixes we're making now will be available in doses of inventory to the market in the beginning of 2019. As I mentioned, I think you do the best you can with the circumstances that are put in front of you. Great to have the customer demand. Great to have people really interested in hearing our story about not just using our calf level product, but also about considering using our product instead of a dam-level vaccine.

We'll continue to work with these big customers that we are able to supply. We want to be a reliable supplier to those customers that are getting our product rather than a broad-based approach where we couldn't get it to everyone. So, that initial feedback is good. Those relationships being built are good and we are just working over the next six months to build inventory to initiate a broader-based relaunch of this product coming into 2019.

Kevin Ellich

That sounds good. Then lastly, recently I noticed you guys made some additions to the management team of the company. Could you talk about that and who you hired and also anyone else or any other positions you think you need to fill? Thank you.

Michael Brigham

Yes. Some people said, "Why did you put out a press release about hiring a Senior Director of Quality?" Maybe that's an internal matter, but we felt like it was a bit newsworthy just to show the continual progress of the Nisin plant. It's the step-up from our 25 plus years of USDA operation to becoming an FDA operation as well. Gustavo Scaffa joined us just this week, just a week ago, Monday. He brings a depth of experience from running quality operations at Pfizer and Zoetis Animal Health.

He is working closely with Betsy Williams, who is our VP of Manufacturing Operations. She joined us just over two years ago. And we were just signaling to our investors or communicating to our investors that as this facility comes online we're staffing up and these were the kind of people with the experience they have that can work with our team. We have our entire product development team dedicated to these initial batches and speeding the staff up at the manufacturing operations level. Progress both in making these registration batches and hiring the people that we need to run that operation, again moving from the USDA world to the FDA world.

Kevin Ellich

Sounds good. Thank you.

Michael Brigham

Thanks, Kevin. That's great.

Operator

Again, if you have a question, please press star then one.

Our next question comes from Sam Rebotsky of SER Asset Management. Please go ahead.

Sam Rebotsky

Good morning, Michael. Let's see, the dealing with the Tri-Shield, I believe it is part of the Q. You spoke of being able to sell \$650,000, was that in the fourth quarter of 2018?

Michael Brigham

Yes. We were trying to give some indication, a very forward-looking projection that's going to be a little bit off, a little high, a little low, but directionally accurate. This quarter-million dollar level was where we've been since launch, quarter-million per quarter in sales, but we see that ramping up significantly into the fourth quarter as we turn the corner into 2019. That doubled, it was steady, steady, steady for the first three quarters and then the production ramps up and we anticipate more or less a doubling of that volume of that inventory level available for sale in the fourth quarter and as we turn into 2019.

Sam Rebotsky

I believe you started out talking about the market of \$34 million, which I assume is both Tri-Shield and First Defense, and in the Q, I think you talk about the ability to manufacture or sell \$17 million, which is a combination of Tri-Shield and First Defense and what sales expectation say, do you feel you could do of Tri-Shield, and will Gustavo help you achieve getting the product that you need and guide you in getting the product you need that you could increase your sales?



Michael Brigham

Yes, great. Thanks, Sam. Two thoughts. One, just clarifying what we put out as market projections. We have long felt the market we compete in at the calf level, against two or three big companies, is around \$17 million in total sales, and that's where 90% of our sales today are. Then with Tri-Shield, we get into this dam vaccine market. There is about double that. There is about \$34 million of these dam vaccines sold. A much bigger market that we access with Tri-Shield.

That production capacity being able to take 10 today is \$10 million or trailing 12 months, \$11 million, up to that \$16 [million], \$17 million capacity will be the result of Tri-Shield, but it will be a net. Tri-Shield will get some new customers and just brand-new business, someone that's never tried a calf level product before, maybe someone that's never even tried a dam-level product before or somebody that is using a dam-level product and switches or somebody that uses a calf-level product and switches. It's going to be a net growth factor to some cannibalization of the, what we call Dual-Force, the bivalent First Defense. Again, some new market. I don't really care where it comes from, as long as we're growing and that's our reporting plan going forward is not to focus on how much of each product line, but just the entire First Defense product line, bivalent and trivalent.

As to Gustavo, I think really the answer is no. We cannot afford to have him distracted by the USDA business. He is really focused on the FDA side, working through the remaining objectives with the CMC in getting the plant and the batches made and all the quality documentation. He'll be focused on Nisin and really, indirectly, we're all one team. Indirectly there's benefit to having his thinking on the team, but his day-to-day focus is Nisin and the FDA operation.

Sam Rebotsky

One further thing. In order to get above the 650,000 a quarter, we need to improve the ability to produce. Is it based on getting all the parts to manufacture? We had the product for the First Defense, which I believe we solved, so in other words, are we able to get much larger production now, if we could have larger sales? We could produce, if we get the sales?

Michael Brigham

Yes. These production challenges, gross margin challenges, available supply challenges, really were twofold. One was, as I referred to in the gross margin decrease, a loss in yield from the milk. That really impacted the bivalent, the Dual-Force, the first quarter backlog. We simply weren't getting enough doses out of each batch. That problem has been fixed. That problem would also affect the Tri-Shield because they are both sourced from the milk, different cows, but same production challenge, biological yield from our milk. I feel like with the second quarter here, we've shown a fix to that problem.

The trailing or nagging problem on Tri-Shield is really that as number one, and then number two, lack of supply of the vaccine. That's the problem we're addressing now. As we address that problem, the vaccine we use in our donor cows that's being fixed now, and then lags out, so you see that ramp in the fourth quarter, but it will ramp higher going into 2019. So that fix is underway and we're seeing that six-month lag and that fix being evidenced fourth quarter going into 2019.

Sam Rebotsky

Sounds good Michael, good luck. You've made a lot of accomplishments, and hopefully we could get more of First Defense and Tri-Shield to sell. The market seems to want it.



Michael Brigham

We all appreciate that, Sam. I think you are right, and that is definitely, I don't want to say objective number one, because we have two number one objectives, Nisin and continual growth on the First Defense side.

Sam Rebotsky

Thank you.

Operator

Again, if you have a question, please press star then one.

Our next question comes from Irwin Gomberg [ph] of Irwin Investments. Please go ahead.

Irwin Gomberg

Good morning. What kind of R&D expenses do you expect from the last half?

Michael Brigham

Yes. The run rate on the first six months is going to stay in that neighborhood. These expenses are pretty recurring, as far as what's necessary to run that plant. Regular product development expenses, but the big new expenses are running that plant at the time where it's going through a product development expense because we don't have sales, you know it's not yet going into gross margins. I would love to be able to drop that expense quicker, but it's not going to happen in the second half of 2018.

Irwin Gomberg

Your inventory, once Tri-Shield starts ramping, what kind of inventory do you expect to eventually show, compared to what you have now?

Michael Brigham

Yes. In most of these, being a six-month production cycle, we tend to go longer than a lot of other companies would like to do. We look out six months on some critical supplies. That inventory count has to build up. We have to get to the point where we can avoid another backlog by just pulling product off the shelf. Really, the answer is about six-months' supply and most of the critical, at least the early stage like processed milk and processed milk's about six months. We can be a little more flexible at the other end, as far as what gets diverted into, say a capsule versus a tube, shorter supply there, but we want to avoid what happened in the first quarter, we don't want to repeat that.

Irwin Gomberg

Thank you very much.

Michael Brigham

Thanks for your question. Yes, sure.

CONCLUSION

Operator

This concludes our question-and-answer session. I would like to turn the conference back over to Mr. Joe Diaz, for any closing remarks.

Joe Diaz

Thank you, Andrea. Again, thanks to all of you for participating on today's call. We look forward to talking with you again at the conclusion of the third quarter, sometime around mid-November. We wish you a great day, and a great balance of the week. Thanks again.

Operator

The conference is now concluded. Thank you for attending today's presentation. You may now disconnect.

