

Michael Brigham

And you're right. Like I said, these Tri-Shield customers, really a lot of these are customers that didn't ever try the bolus, but they're creative and they're aggressive and they're progressive and they like this Beyond Vaccination. So they're opinion leaders. They're big farms and they're new relationships to us through earnings through Tri-Shield. So yes, we would like to go back and say, "Hey, you tried something new a year ago. We got something new now." That's how we would start that launch of the new product.

Scott Billeadeau

Great. And then just a final question here quick. You've been working on this for quite a while. Has there been as you look around to the industry, anything coming down the pipe, anyone new coming with this type of or anything you see that's coming behind Nisin with similar, or what the competitor is going to do? Again, you're going to kind of blaze a new market here, because no one can really attack this market anyhow because of being able to keep the milk. But any thoughts there at all?

Michael Brigham

Well, as small as we are, small things are very material to us. Match that with our style, our strategy as full disclosure. We just really get into quite a bit of detail. So we are telling a lot more about what we're doing than the big guy would. When you look at Zoetis or Elanco or Merck, they would never be providing disclosure of the detail that we do.

So the answer is they could have something that just not talking about that we don't know about that similar or down this path, but we don't see it. And we think we're way ahead with the FDA process. And as long as it's been for us, it's going to be long for anybody to bring something novel, something new through the FDA. So to the best of our knowledge, we're ahead and we're unique and that's definitely what keeps us going.

Scott Billeadeau

Great, thanks. I appreciate it.

Michael Brigham

All right, Scott. Thanks.

Operator

Once again, if you would like to ask a question, please press star then one.

And our next question comes from Sam Rebotsky with SER Asset Management. Please go ahead with your question.

Sam Rebotsky

Yes. Good morning, Michael. Thanks for taking my call. And this is a milestone when you submit the Nisin. Do we think we're going to submit it just before Christmas, or we're just closer to—how are we looking at, because Christmas is very busy at the FDA, people on vacation and holiday, so we have any thoughts there?

Michael Brigham

Yes, every day. Hi, Sam, thanks for the question. Every day. It's a tradeoff just getting the best possible package versus the soonest possible package. So we're just tweaking that final decision. And when the date is right, when the batches are right and we can wait a long time and have a perfect submission. And we, on the other end, we could have submitted prior to now and have flawed submission.

So there's quite a team on this just sort of navigating that last decision. And that's why I mentioned it is material. It is a big milestone. And when that goes in, I'd think it warrants a press release to tell you and others that, yes, that's where we made the decision. We're in and the clock has started, whether they're on holiday or not, that 180-day clock will be the same from the start of the submission.

Sam Rebotsky

Well that's good, Michael. It's better to get it right and then to screw it up. Now as far as the Tri-Shield by doubling your sales in the fourth quarter. You've been able to produce more product. So how do we look at it going through 2019? I know you are working to help you get more product. Do we think we could consistently improve to maybe \$600,000, \$700,000, \$800,000, \$900,000 a quarter? A million a quarter [ph]? What is our visibility there on the Tri-Shield?

Michael Brigham

Yes. This doubling, if you would ask this question back at launch, I would definitely would have anticipated to have happened, at least, in the third quarter, if not second. So, we've put out that projection as an indication of we are starting to ramp up. We are seeing that build, and we're not stopping there.

So those numbers you mentioned, we have to get into that direction. It's been the first. It was very consistent for four straight quarters and then this double here in the fifth quarter being the fourth. But the launch was fourth quarter of 2017. Those first, second third, those four quarters were very consistent and then it double [ph] and then we just continued to fall that scale as we go into 2019.

So we want to put that out that it's no longer flat, it's a double. But we're not done, we're going to keep going. So just the other factor to keep in mind and I know you know this, Sam, but it's about a six-month production cycle.

So this fourth quarter doubling is really cow work that was done back end of second quarter, beginning of third quarter, because it takes that long from a produced vaccine to the work with the cow to collection and processing and USDA release. So we're battling with that five, six-month production lag for everything we're doing today, we won't see the results for five or six months.

Sam Rebotsky

Okay, that's good. And now as far as improving on the First Defense production, do we have that sort of improved, so that's on target to have [ph] enough product on the First Defense?

Michael Brigham

Having been through the backlog that we were recently in the middle, I'm almost never willing to say we have enough, because we want to be able to respond to any changes in the market that competitive product dropping out or just good work by our sales team and growing sales. But we don't have too much. I don't want too much, but we are in a much better place.

So we have sufficient but we're still building. That would be my answer. We have sufficient inventory,



especially consumer going into the peak season first quarter, but it's not enough. We're still building. So we have enough to meet sales, but we're going to build those levels going through even the first-half of '19. We're just continuing to rebuild that stock. So, way better position, but still building.

Sam Rebotsky

Okay. One final comment. I'm very happy to hear that in your interview with *The Wall Street* transcript, you've indicated, once you get approval for the Nisin, you would look to give the Nisin product to the cows the mast out [ph] prophylactic. I know that's far away you have to get approval first. But are you seeing any rationale for the prophylactic? Do you see any interest in doing that right now or from the farmers, etc.?

Michael Brigham

We'll be honest, Sam. I don't remember that specific question or that specific quote in *The Wall Street* transcript. So I need to go back and take a look at that. I think, the only topic in that area, I hope is related, is the claim on this product, which we're going to be very careful about, this is a script product and the claim is going to be treatment of subclinical infection.

But we have commented that, that may be the label. But what a product, any product, not just ours, any product that can treat a subclinical infection is essentially in practice in the real world preventing a clinical infection. So many of the subclinical infections progress to clinical, you won't see that on your label. But the reality is, you prevented some clinical infections. And that's definitely a position our product will be in, treat that subclinical, but avoid the clinical. But again, the label is very clear. The label very clear is going to say the treatment of subclinical.

Now with that interest, post-approval, because we want to keep our strategy, our sites, our regulatory plan very narrow, very direct. By post-approval, we will look at coming back and perhaps running a clinical study to expand that claim and see if we can develop that data for the treatment of clinical infections; same pathogens, just a different disease stage.

Sam Rebotsky

Well, that sounds exciting, Michael. Good luck on the submission.

Michael Brigham

Great. Thank you, Sam. I appreciate it.

CONCLUSION

Operator

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

Michael Brigham

Cole, I think we may have lost Joe, and that's okay. We're going to wrap up quick and just say thank you to everybody for participating in today's call. And we do look forward to talking with you again to review the full-year 2018 results around the middle of February, and have a great balance of the week everybody. Thank you.



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