facility to produce Nisin, the active ingredient in Mast Out.

As a result, we now for the first time have a roadmap to complete the development of Mast Out and bring the product to market. Of the five technical sections required for approval of a new animal drug application, also known as an NADA by the FDA three-year complete. We expect to complete the fourth technical section by mid-2017. The fifth and last technical section requires us to build a commercial scale production plant.

Our preliminary budget for this project is approximately $17.5 million. We aim to complete the construction and installation work by the end of 2017. Sales of this product are subject to FDA approval. We have disclosed a timeline of events that could lead us to achieving this approval during 2019. This is an important milestone in the history of ImmuCell. We look forward with great anticipation.

So to summarize, we continue to execute on the two core components of our business strategy, first, we are expanding the market penetration for First Defense, our best-in-class treatment for calf scours, and second, we are advancing the development of Mast Out, our novel treatment for sub-clinical mastitis in lactating dairy cows.

In April, we announced the hiring of Elizabeth Williams as our Vice President of our manufacturing operations. Betsy is already making a significant contribution towards helping us achieve our business objectives. To introduce Betsy I have asked her to share a few comments with you directly. Betsy?

Elizabeth Williams
Thanks Michael. I am delighted to join ImmuCell at such an important time in the history of the company. In the very short time that I've been here, I'm certainly impressed with the dedication and commitment of the full team, and excited to know that we are on the verge of a critical milestone in terms of enabling for future, further growth of our Company.

A little bit on my background, I have spent most of my career in the animal health industry, the majority of it with Pfizer Animal Health and most recently with Zoetis. I held numerous leadership roles at different plants and regional locations, and in these roles I've had responsibility for expanding facilities and operations for new product start-ups, implementing new capabilities and technologies in manufacturing and also responsible for validation, new product regulatory filings and preparing for preapproval inspection by the global authorities. This would include USDA and FDA. So this well aligns with my role here at ImmuCell.

As an update, cascading on from what Michael has indicated, the Mast Out facility design is well underway. We anticipate breaking ground this year and expect to complete building construction and equipment installation by the end of 2017. We also expect that the validation of the equipment and the process will be completed at the end of 2018. In parallel with design and construction of facilities, we are advancing the preparation of the regulatory strategy and the dossier or the filing for the manufacturing process, all this to achieve a timely approval by the FDA.

As Michael has noted, we've already received Technical Section Complete Letters from the FDA for three of the five sections. The CMC or the Chemistry Manufacturing and Control technical section is quite extensive involving drug substance, drug product and certainly defines the critical path for product approval.

Our timeline well positions us for NADA approval by the FDA in 2019. As relates to First Defense, our team remains laser focused on increasing capacity to meet this expanded sales demand. We're looking at all aspects of the manufacturing value stream, start to finish to improve the yield and the output and to optimize the recently added capacity in both liquid processing and in the freeze-drying areas, all this to address and fill the order backlog. So I'm very excited to be here, and look forward to making meaningful contributions to the growth of the Company and to enhance the value to our stockholders.

With that let me turn the call back over to Michael.

Michael Brigham
Thank you, Betsy. So to conclude, I'd like to again comment that we have provided extensive additional details in our press release and our quarterly report on Form 10-Q. I encourage interested investors to review these filings.

And with that I'd like to move to the Q&A. So let's open up the call for your questions. Operator, could you help us with that?

QUESTION AND ANSWER

Operator
Yes sir. We will now being the question and answer session. To ask a question, you may press "*" then "1" on a touchtone phone. If you are using a speakerphone, please pick up your handset before pressing the keys. If at anytime your question has been addressed and you'd like to withdraw your question, please press "*" then "2." Again that is "*" then "1" to ask a question. At this time we will just pause momentarily to assemble our roster. Again, if you would like to participate in today's Q&A please press "*" then "1" on your touchtone phone. Again that is "*" then "1." We will just pause momentarily.

The first question we have will come from Steve Roberts of NorthPointe Capital. Please go ahead.

Steve Roberts
Hi guys. I'm just wondering looking ahead here to the second quarter, with the backlog and the increased capacity, should we expect sales to increase over the first quarter or I mean typically your first quarter is one of the stronger quarters, so...

Michael Brigham
Yes, it is seasonal Steve. So first quarter is always our top quarter, the other three quarters tend to be pretty similar and the guidance that we've set out is one to identify the amount of backlog so you know orders, in-house ready to go and simply to say there, we do expect the growth trend for First Defense to continue and we do expect the recently profitability trend to continue.

Steve Roberts
So do you think Q2 will be more than Q1 or no?

Michael Brigham
That's never happened. Q1 is just a seasonality, the winter scours season, the beef calving season. The first quarter is always our best, so…I think that would be unusual. I would just expect continued growth and I would continue to expect the first quarter to be the best, the highest.

Steve Roberts
And then for the share count, what's the fully diluted share count going forward?

Michael Brigham
So, outstanding 4.179 million, fully diluted with that equity rates closing on February 3, so fully diluted in the first quarter, given the fact that we have…excuse me one second.

Steve Roberts
What I'm trying to model Q2, I'm looking for what the share counts going to be going forward.

Michael Brigham
Okay, yes so. 4.178 million, 844 is outstanding and then we do have a foot note in the EPS calculations just for the dilutive options, let me just give you that number, because first quarter will be pretty similar to second quarter. And sorry, bear with me…EPS calc…Steve I'm going to have to follow up with you. I don't want to waste your time or the time of others. We don't have a whole lot of options, but I can give you that exact number, I put my finger right on it. So start with 4.178 million and similar dilution from the outstanding options [multiple speakers].

Steve Roberts
Okay. Thank you.

Operator
Next we have Sam Rebotsky of SER Asset Management.

Sam Rebotsky
Good afternoon Michael and congratulations Betsy on joining ImmuCell.

Michael Brigham
Thank you, Sam.

Sam Rebotsky
The backlog would you…are we prepared to ship in other words are we in full production now with the new equipment to produce as much as we…there's a demand for our product.

Michael Brigham
Yes, the scale up is complete, but it is going to ship out over time. It doesn't just come on overnight. So it came online end of the first quarter and as I mentioned we'll have that benefit fully realized as we go forward to the second, third and going forward basically the ability to produce twice as much product. But it just doesn't hit the switch on April 1.

Sam Rebotsky
The backlog, what is the appropriate backlog that we would like to carry, in other words and ship out the product as fast as we can with the backlog.

Michael Brigham
The long term objective is zero, I don't want any backlog. But we are in a catch-up mode and the production and then the build on the product that has a six-month production cycle, that's where we're at right now, but the goal is zero. The whole point of the investment was by doubling capacities to be ahead of orders, ahead of sales demand and have zero backlog.

Sam Rebotsky
So, in which quarter do we think we would get there?

Michael Brigham
I'm not ready to pinpoint that. It is going to depend on just performance over the next three quarters. We were a little bit general in our disclosure saying fully realized going forward over these next three quarters. So it is a fill and a build and a fill and ship, but I'm going have hard numbers for you quarter-by-quarter, I don't have a hard projection on that.

Sam Rebotsky
Okay. And the export sales went down; is there a reason for export sales to go down?

Michael Brigham
There really isn't…..backlog is difficult, albeit our VP of Sales and Marketing, Bobbi Brockmann spends a lot of time trying to allocate those backlogged orders as best we can and sometimes one market gets the shipment a little earlier than the other market. So I think that's all that's going on there is just allocation between markets of a scarce product.

Sam Rebotsky
Okay, now with Betsy on board and First Defense we're looking for approval in 2017 and Mast Out in 2019, is there…and I'm not sure if you're prepared to say it's the first half, the first quarter, is there something that Betsy could do to help ImmuCell speed up this dates to

reduce it, so that we could…with the Mast Out, I know the FDA has indicated that antibiotics is supposed to be reduced as…eliminated as of December 31, 2016. So to take advantage of that if we can sort of do something sooner or get something done quicker, is there anything we could do?

Michael Brigham
Well two things, when you say 2017, I believe you're talking about USDA approval of the Rotavirus claim. I think that's pretty well locked in. I'm glad to have Betsy help us with the production aspects of that…..completing that initiative, but that timeline is pretty set. Which month in '17 I don't know, but there just is a process we go through with the USDA that takes us out into '17. Now with '19 they are talking about Mast Out, and I think that is realistic. We put it out there as our best estimate; Betsy is going to help us achieve that. But just having Betsy here is not going to move an FDA timeline by a significant amount. I would consider that a huge success just to not let it push forward. So '19 is our best and if we have an update to that, we would provide it as soon as we have some confidence in it. But there's just a lot of new activities that fall on Betsy's plate just to achieve that approval. All the construction, all the installation, all the validation and the final submissions of the CMC, as she mentioned to get to that '19 approval.

Sam Rebotsky
Okay, good luck.

Michael Brigham
Hey Sam, while I have the floor here, just wanted to come back to Steve's question, in the first quarter that fully diluted option was just over 100,000. So it's the $4.178 million plus a little more than 100,000 of dilution from stock options to get to the fully diluted shares outstanding.

Sam Rebotsky
Thank you.

Michael Brigham
Thanks Sam.

Operator
Again as a reminder if you like to participate in today's Q&A please press "*" then "1." on a touchtone phone. Again that is "*" then "1". Next we have David Starkey of Morgan Stanley.

David Starkey
Hi guys. I just had a question related to the potential of the sales growth, given that your added capacity if you're potentially doubling capacity over the next say six or nine months as the plant comes on, would you be able, all things being equal to be able to do 6 million in sales in the first quarter of next year…..in that range?

Michael Brigham
Yes, it's clearly mathematically, very clearly a double. How that plays out by a quarter, not sure. So capacity, we want to be ahead of demand, so we'll have a capacity if we did about 10 million in the trailing 12, we would have capacity to double that. Each quarter could double, but the demand is different than the capacity. We want production capacity ahead of demand after we satisfy the backlog.

David Starkey
Right, your sales this quarter…last year you said that competitor was not able to head the product off to market. So, this latest completed quarter that competitor had a product on the market the whole quarter and you were still only down a couple of percent, right?

Michael Brigham
Exactly, exactly. They did come back and we see them in the market, so the first quarter '15 did benefit from their absence, but I would argue first quarter '16 didn't suffer greatly from their return, it went down due to the orders that we couldn't ship not due to loss to the competitor.

David Starkey
Right. And how many competitors are there in that particular product do you see?

Michael Brigham
Yes, I would answer it in two parts. One, if you have time, we just put an updated investor deck on our website.

David Starkey
Yes, I'm looking at it.

Michael Brigham
It matches and it's detailed there, but I'll read you the highlights from one important side that speaks to your question. The competitors are three products by three companies, the biggest one is the Calf-Guard product by Zoetis and Elanco has a product called Bovine Ecolizer. That's the one that had interrupted supply. And the third one is not a major competitor, but when we look at the total category of oral scours preventatives, we had Boehringer Ingelheim's Bar-Guard-99 and that's on slide 14 on that slide deck.

David Starkey
Okay alright, I will check that out. The other question I have was related to MASTiK [ph] and coming up here in a couple of years. So what kind of market potential do you see on that?

Michael Brigham
Yes, I mean we really see this as a big one. I mean, we're very proud of First Defense and it's been paying the bills and taking us a long way to be able to double sales from 5 million just five years ago to 10 million now. But, I'll also make reference back to that same slide deck, because there is a convenient way to answer your question. These numbers are all fully

publicly disclosed in our quarterly filing and that's why we put the new slide deck, the revised updated slide deck on the website in conjunction just after filing the cue and getting the press release out. But, I'm now on Slide 24 and you can see our detailed assumptions of how we created this model with a well-known consulting firm in the animal health space. That takes us from a 5 million kind of product in year one to a sales potential of 36 million out there in five years.

David Starkey
So, that would be like 20-24 or something along that…36 million?

Michael Brigham
Yes. Its 19 getting launched, we were talking about 19, 20, 21, 22, 23ish into 24 for the 30 kind of million level.

David Starkey
Is that plant going to be able to produce all that or you're going to have to have two or three plants.

Michael Brigham
I think as we get into the higher end, the later years, we're going to need some capacity expansion. So, we're sort of staging this investment to get us launched, get us well into the launch. And then verify and validate those sales and take a look at this projection model and see how it stands up against the actual. If it's proven in the market, I can see us needing to make further investment out there in the year four, five.

David Starkey
Right, okay, I see that slide right now. Okay, and then I guess in terms of fundraising everything, are you okay for now in the next couple of years? We got kind of hit by the last offering here last year, caused a pull-back in the stock.

Michael Brigham
Right. So, when we look at Mast Out, we look at that 17.5 million this is the math I do. We have 11 million today that includes the equity raised. We do have a debt facility for another 4.5 million, that's 15.5. We are looking at $17.5 million investment, the other two coming from First Defense cash flows, continued profitability. So, that's what I meant when I said this equity raise, this debt facility for the first time gives us a clear roadmap to bring this product to market.

David Starkey
Right. Do you have land picked out and everything?

Michael Brigham
We do. We bought it actually in December. It's adjacent to our facility, essentially right out the back door. So, that's the land we own and we are working to get a shovel in the ground.

David Starkey
Okay, great. Well, I look forward to seeing the process as we go forward here. Thank you.

Michael Brigham
Great, thank you.

Operator
Next we have Jane Lindenman, Investor.

Jane Lindenman
Good afternoon Michael, how are you?

Michael Brigham
Hi there Jane, doing great. Thank you. How are you?

Jane Lindenman
I came across a story back in March, and I was wondering if you could comment on it. This Elanco came out with this, got approval for this investor, which also which treats mastitis, and I was wondering how it would compete with us. I know we had the [indiscernible] for Mast Out, but how would it compete with us. Is it something that's concerning to you being that we are still quite a ways away from approval? So, if you could address that a little bit, I would appreciate it.

Michael Brigham
Yes. It's an interesting product, very new. It's an immune stimulant, so it boosts the cow's immune system. It has a clinical claim. We are seeking a sub-clinical claim. It's given a dry-off, and we intend…our product will be delivered during lactation. So, a little bit in our space, but not directly and I think those are the key differences, sub-clinical versus clinical, dry versus lactating and immune boosting as opposed to our Nisin is a mastitis treatment. So, I think our positive view of the changing landscape in the market is that there could be some synergy there if cows have better immune response. That could be good for the cow, good for the owner and good for other products that can treat the disease benefiting from the immune boost.

Jane Lindenman
Could you see possibly using both products side by side?

Michael Brigham
Right. You made the point better more clearly than I did. Being that they're boosting the immune system, we're treating the disease, they are dry-off, and we come after in lactation. You clearly could do both, without a conflict.

Jane Lindenman
So, I guess the thing that would be most concerning to me is that since they're already approved and we're still into the future, would they capture enough market shares to hurt us before we can get going.

Michael Brigham
Well, they're going to work real hard to develop this dry period treatment, the dry period immune boost. But, I don't think they are going to eliminate sub-clinical mastitis. So, I lean more towards another competitor when I look at our market prospects and I look at Zoetis and I look at what they did towards the end of last year getting a sub-clinical claim on their Spectramast product in addition to their clinical claim, they got a sub-clinical claim, and they are doing some great work educating the market how important it is to no longer ignore sub-clinical mastitis and treat it now that they have a sub-clinical claim with their product. Yet, they're arguing that the benefit of treating sub-clinical is so good or the cost of ignoring sub-clinical is so high that it's worth discarding the milk and of course our position would be that is all true and also do not discard the milk, don't incur that cost.

Jane Lindenman
So, our biggest advantage would be not having to discard the milk, and that would kind of compete with all these other products.

Michael Brigham
Yes. That definitely has always been…this achieving… as you know, we got that zero milk discard claim from the FDA, I do believe the product development would have ceased without that claim. You have a me-too product and you're competing against the big guys without a competitive advantage. So, the zero milk is still and always has been a key. We want to have real good robust efficacy in comparison to the competition. But then the advantage, the differentiating feature is zero milk.

Jane Lindenman
Okay. Is there, will we be able to use our current sales force to sell this product when we get online with it?

Michael Brigham
Oh, they're eager to go. They love selling First Defense; sales people always like something new. Absolutely, same distribution, all the same First Defense relationships stay in place, you'll just get even stronger because you've got a little something extra to sell on the same ride along on the same distributor visit.

Operator
Alright. Well, I thank you very much for giving you all that detail, we appreciate it and good luck to you guys.

Michael Brigham
Thanks Jane. Thank you.

Operator
Again as a reminder, if you would like to ask a question please press "*" then "1" on a touchtone phone. Again, that is "*" then "1". Again we will just pause momentarily to assemble our roster. Well, at this time it appears that we have no further questions. We'll go ahead and conclude the question-and-answer session. I will now like to turn the conference call back over to Mr. Joe Diaz for any closure remarks. Sir?

CONCLUSION

Joe Diaz
Thank you. We want to thank all of you for taking the time to participate on today's call. We will look forward to talking with you again in August with our second quarter financial results, and as a note, we hope to see many of you at our annual meeting of stockholders on June 15. If you have any questions regarding that please feel free to give me a call, Joe Diaz at Lytham Partners. And I can be reached at 602-889-9660, again 602-889-9660. We appreciate your time today and hope you have a great rest of the day. Thank you.

Operator
We thank you Mr. Diaz and to the rest of the management team for your time also today. The conference call is