



















going on now into the beginning of the year then its final submission with what's called the pre-license serials and an estimated review time and that's why we have always said 2017 because it's hard to pick a month or even a quarter. But, we think it's pretty reasonable, based on where we are and where we will be when we make the submission to look for the middle of 2017 for allowing enough time for the USDA to review that submission and put it all together into a product license approval.

**Sam Rebotsky**

So, you are saying it would be submitted for approval by the middle of 2017 or expect a response by the middle of 2017?

**Michael Brigham**

We are looking for the response we are going to finish up that manufacturing towards the beginning of the year, the truth is, we would like to see three to four-month review, they could take nine months and that would put us into later 2017. But, what we are pleased with and what's positive is we are not looking for review of our efficacy data. We are just looking for review of our pre-license serials and so that's why we stuck out that projection for middle of 2017, I think it's reasonable and we are doing everything possible to stick to it, then again, mid-2017 for the USDA approval.

**Sam Rebotsky**

Okay. That's sounds good, Michael. I'm going to step out and I will rejoin the queue after, let somebody else have a chance.

**Michael Brigham**

Thank you, Sam.

**Operator**

Once again, if you would like to ask a question please press "\*" and then "1", to withdraw yourself from the question queue, you may press "\*" and "2", again that is "\*" and then "1" to ask a question. And ladies and gentlemen, at this time I'm showing no additional questions I would like to turn the conference call back over to management for any closing remarks.

**Michael Brigham**

Sam, I do know by the screen I'm looking at people are still listening. I appreciate the people on the call, if you want to come back in with another question I'm happy to take that now or we can wrap here it's up to Sam or any other interested participants?

**Operator**

And sir, we do have a follow-up question from Sam Rebotsky. Please go ahead with your follow up.

**Sam Rebotsky**

Okay. Thank you. Now, as far as we are going to start the construction pretty soon for the Mast Out and we are going to spend the money most of it in 2017 and it's exciting that, you

know, that it's, that it could happen. But, are you comfortable with the timeline in 2019, it seems far away. Is there anyway where we could get this done sooner or does it depend on the construction of the facility?

**Michael Brigham**

I can let Betsy touch on that as well. But, Sam I would say that's a very aggressive timeline and we are monitoring it extremely closely. Every week matters, but I can't anticipate significant improvements to that 2019.

**Betsy Williams**

Yes. So construction is well underway we are, pudding's in place and really aiming to get a winter-tight building by December and then fit out in the first part, the first half of 2017, but yes the timing is aggressive, but we believe achievable that we're, we have done things to de-risk that timeline through meetings with FDA and also engaging our commercial partner Norbrook, , after construction what's the critical path is having full scale commercial batches, resulting stability and then filing. And we have got several phases of that filing. So, everything is well in order for our timeline. But, yes, every day, every week counts and we are tracking it, with the highest level of scrutiny as we go forward.

**Sam Rebotsky**

Yes, and I looked through your 10-Q and I think there is \$2 million plus for the building construction. How much is allocated for the equipment at this point?

**Betsy Williams**

It's roughly \$9 million.

**Sam Rebotsky**

Okay.

**Michael Brigham**

The budget...kind of, kind of half and half on that 20 million budget, allocating exactly between what is infrastructure on the building and pieces of equipment is roughly half and half on the 20. But, I would caution also, that she's got the right team working with her, this crew is busy and engaged and incentivized but no matter what they do, we still need to allow, we are allowing and our timeline to 2019 two submissions and that gets back to your first question directing that over to Mast Out two six-month reviews at this manufacturing technical section. So, just an FDA review time, we have got a full year in there - two separate six-month reviews.

**Sam Rebotsky**

Right. Well, it sounds good. And it's been a long road, hopefully that it gets there sooner and that the rotavirus comes in, so you could increase your revenue and compete because you expect you have the ability to make more of First Defense. So, good luck guys.



**Michael Brigham**

Thanks Sam. I appreciate you staying in touch and thank you.

**Operator**

Once again if you would like to ask a question, please press "\*" and "1". And sir once again I'm showing no additional questions.

**Michael Brigham**

Alright. Thank you, Jamie.

**Adam Lowensteiner**

Yes, go ahead.

**CONCLUSION****Michael Brigham**

Thank you, Jamie. I would like to thank you for participating in today's call everybody. We look forward to talking with you again at the conclusion of the current quarter, which will be our yearend and everybody have a great evening. Thank you.

**Operator**

And with that ladies and gentlemen, we will conclude today's conference call. We do thank you for attending today's presentation, you may now disconnect your lines.

