



IMMUCELL CORPORATION
(Nasdaq: ICCC)

ImmuCell

Developers of 

**Third Quarter Fiscal Year 2019
Financial Results**

**Monday, November 11, 2019
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CORPORATE PARTICIPANTS

Michael Brigham – President and CEO, ImmuCell Corporation
Bobbi Jo Brockmann - Vice President of Sales and Marketing, ImmuCell Corporation
Joe Diaz – Managing Partner, Lytham Partners

PRESENTATION

Operator

Good day and welcome to the ImmuCell Corporation Third Quarter Fiscal Year 2019 Financial Results Conference Call. All participants will be in a listen-only mode. Should you need assistance, please signal a conference specialist by pressing the "*" key followed by "0." After today's presentation, there will be an opportunity to ask questions. To ask a question, you may press "*" then "1" on your telephone keypad, to withdraw your question, please press "*" then "2." Please note, this event is being recorded.

I would now like to turn the conference over to Mr. Joe Diaz. Please go ahead.

Joe Diaz

Thank you, Sean, and good afternoon and welcome to everyone on today's call. This is Joe Diaz, with Lytham Partners. We are the investor relations consultant firm for ImmuCell. I thank all of you for joining us today. I'd like to preface this discussion today with a caution regarding forward-looking statements. Listeners are reminded that statements made by management during the course of this call include forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those discussed today.

Additional information regarding these risks and uncertainties is available under the cautionary note regarding forward-looking statements of the safe harbor statements in the company's press release that was issued just about 30 minutes ago, as well as in the company's periodic filings with the Securities and Exchange Commission, which can be obtained from the SEC by visiting the Investors section of the company's website at immucell.com.

With that said, let me turn the call over to Michael Brigham, President and CEO of ImmuCell Corporation, after which we will open the call for your questions. Michael?

Michael Brigham

Okay, great. We have a very good roster assembled here. And I thank you all for taking the time to join today's call. I do appreciate that. I'm excited to update you on our results for the third quarter.

And as always, we have spent a fair amount of time preparing our quarterly report on Form 10-Q, it's worth a read. It will be filed with the SEC tomorrow morning. I'm not going to repeat a lot of those important details on this call. I do want to highlight what I see as the two most important financial results and then update on three important milestones to watch going forward.

I'll start with the two important financial disclosures. Let's talk about the sales results. The very strong increase in total sales, sales are up 38% in the third quarter, compared to third quarter of 2018. They were up 25% for the first nine months of the year compared to the same period ended September 30, 2018. This brings sales for the trailing 12-month period to just over \$13 million.

Tri-Shield is creating most of this growth, Tri-Shield has created a new market opportunity for us. It's about quality over quantity in the dairy industry these days and we are encouraging customers to go beyond vaccination.

We are back with distribution and a mass market selling effort to both the dairy and beef producers. It's exciting to see what our sales team can do now that they are spending their time selling and accessing new customers rather than allocating scarce products, so great work by the sales team.

This is a strong achievement for us in this difficult dairy economy. I say difficult dairy economy because it has been hard with low milk prices for years. However, we are seeing some improvement in milk prices presently and some project that this critical measure of a dairy operations and revenue may stay strong into the near future.

For the second financial highlight, I point to page four of our press release. I think it's really important to look at these non-GAAP disclosures in the press release. I think we should be aware of certain non-cash expenses like depreciation, amortization, stock-based compensation and income taxes. I include income taxes because we have accumulated over \$10 million in NOL carry forwards for tax purposes. At times our reported losses could have been income, had it not been for these large non-cash charges.

, Let me turn to the three important business milestones to watch going forward. First, the \$3 million investment in the First Defense production capacity. We are investing about \$3 million to increase our liquid processing capacity by 100% and our freeze dry capacity by 50%. We expect this investment to increase the annual sales value of our production capacity from what is presently about \$18 million to about \$27 million.

We signed a lease for about 14,300 square feet to help us complete this investment. We're in the permitting process and we're bidding and setting contracts with builders and contractors to do the work. We'll keep you updated on our progress, but we expect to have that project complete around the middle of 2020.

Second, we're tracking on a \$4 million investment to create our own aseptic filling capability for Re-Tain. This investment is necessary to give us control over the production process from start to finish. We have agreed to a short-term contract with Norbrook, our current aseptic filling CMO. This will allow



us to complete the development work and produce the initial product for product launch inventory. We'll do that with Norbrook, as we complete the investment in the aseptic filling function to bring it in-house.

Third, the runway to the FDA approval of Re-Tain is becoming more clear and present. We received the FDA's review comments to our first phase drug substance submission of the CMC technical section during the third quarter.

We're working on our responses now to the queries raised by the FDA, which will be submitted when we make our second phase drug substance and drug product submission of the CMC technical section. We expect that to be around the third quarter of 2020, we expect that submission of the drug substance and drug product CMC's technical section to be around the third quarter of 2020.

We're also responding to a preapproval inspection of our drug substance facility. As anticipated at this early stage, some deficiencies were noted that needed to be resolved prior to commercial production and sales. We are confident that we can effectively resolve the deficiencies to the FDA's satisfaction by the end of 2019 without significant cost or any delay to the timeline to product approval.

All this could set us up for product approval in 2021. More details regarding the submission schedule and the runway to FDA approval of Re-Tain will be provided in the 10-Q, which is being filed tomorrow morning. In conclusion, I think we've hit the most important topics, I do again encourage you to review our press release and the Form 10-Q for more details, also, please take a look at the updated corporate presentation slide deck.

I will be presenting that at the Craig Hallum Alpha Select Conference in New York City tomorrow and again on Wednesday to other interested investors. I believe it provides a very good summary of our business strategy and our objectives, as well as our current financial results.

The updated version has been posted to our website. You could just see the investor section and click on corporate presentation. I hope you appreciate the streamlined approach to this call that saves more time to your questions, which are important to me.

With that said, let's have the operator, Sean, would you open up the lines for questions.

QUESTION AND ANSWER

Operator

Thank you. We will now begin the question and answer session. To ask a question, you may press "*" then "1" on your touchtone phone. If you are using a speakerphone, please pickup your handset before pressing the keys, to withdraw your question, please press "*" then "2."

Our first question will come from Kevin Ellich with Craig Hallum. Please go ahead.

Kevin Ellich

Good afternoon, Michael. Good updates. I have a number of questions for you, if that's okay. Before we get into the regulatory comments you made on Re-Tain, first thing that jumped out to me with the



financial results, gross margin this quarter extended pretty nicely on a year-over-year basis, even sequentially. Talk about what drove that improvement.

Michael Brigham

Yes, we're moving to a strategy away from focus on a percentage and more focus on total dollars. Given that gross margin close to 50%, just under 50%, it's not like the old days of the bolus-only business at a higher than 50% margin, but we'll take the cash. The goal is total cash, re-grow the top line. We have a lot of fixed costs that just get amortized over more volume. I think you're right to point to that gross margin. I look at it closely that's money, we didn't have three months period of 2018, and nine month period of 2018 that is really going to help us.

Kevin Ellich

Sure, that makes sense. And then going back to your comment that the \$3 million investment to increase capacity from \$18 million to \$27 million, you said that should be done by mid-2020. Are you actually seeing demand in the marketplace for that amount, is that way you guys expanded the capacity?

Michael Brigham

Well, we've spent some time with sales being ahead of production, and we've suffered through product allocation during that period through 2018 and beginning of 2019, we don't want to go back there. Seeing demand, hoping to see demand, we look forward; we see what people are saying about Tri-Shield and want to be ready for it. What that means to the numbers is our current facility, if we just let things status quo, didn't put the \$3 million into growth, we can probably push about \$18 million worth of product out of our current facility, trailing 12 months or 13, so we've got a little bit of room today. We are investing for the future that investment will bring that \$18 million capacity up to about \$27 million.

Kevin Ellich

Got it, okay. And then going to your comments about the, actually really good update there, on the FDA CMC technical section in the comment that you got back hoping to have that the second stage plan submission in Q3 of 2020. Was there anything unusual or anything that you really didn't expect that came back to you in those first set of comments?

Michael Brigham

No, I think it's all very manageable, I think both of the responses to the inspection and to the first round submission of the drug substance, both are normal, both are achievable, we can get a full response to them without a delay and without spending a lot more money. And what I look forward at this point is some kind of roadblock, a huge new requirement or a new investment, or something that would delay adds a significant amount of time. I don't see either. I think there's no big money spend, no time delay at all. Which I really think routine, we can handle. There's good feedback from the FDA and we can handle our response to them.

Kevin Ellich

Okay, that's great. And then, again, good catching up for you at World Dairy Expo early October, just wondering if you could comment about how the show went for you and how Bobbi and the team did? Did you see the type of business pick up that we should see here in Q4? Do you think that we'll see a sequential increase similar to what we saw last year?



Michael Brigham

Yes, it was good to see you there, Kevin. I always think that that we can...Madison, Wisconsin first week of October is just one of the most exciting times of the year for us. You were able to see that real time at our booth. We just have great traffic. It's always busy, sales team is just always on their A game, but it comes in a big public display at World Dairy Expo. The customer feedback is great and people just come by to chat, new customers learn about the product, old customers want to say, thank you. It gives me great confidence for the future. We're going into the peak season. First quarter is always our best quarter, sales are a bit seasonal that way and this first quarter we're going into it with inventory, which we can't say about the first quarter of 2019.

Kevin Ellich

Yes, that that was good. You gave away a lot of capes [ph], but...

Michael Brigham

Yes, we had some superheroes...some cast superheroes flying around the expo.

Kevin Ellich

Yes, that's always good, good marketing. Two last ones from me, first product development costs had ticked very, very modestly higher the last couple of quarters. It's about \$1 million a good quarterly run rate going forward when you think about product development costs will that increase with the extended production?

Michael Brigham

Yes, the production will not impact PD, so that production is going to be capitalized as CAPEX. The PD is really driven by depreciation. We're in a situation where that facility is in place for its intended purpose which is to produce Nisin the active ingredient in Re-Tain, but we're not selling any. We've got no revenue, and we've got the expenses. You'll see in the Q in the morning, Kevin, I've just detailed that very precisely what...how much of PD expense is depreciation. Cash versus non-cash, PD, it's a big driver to the PD expense.

Kevin Ellich

Got you. We'll take a look at that. And then lastly, just updated thoughts on the overall dairy market, it seems like we've suffered since the last couple years, but I've been hearing that some pockets and parts of the market, especially in the upper Midwest, are seeing some stabilization. Is that what you'd say?

Michael Brigham

Well, what's encouraging is and we've got a milk tariff as I talk here, I'll get the number of the slide, right in our slide deck because I think one of the most relevant indexes to follow is the price of milk, just to get a feel for where the industry is, it's slide 40 of the slide deck that just got updated and posted this afternoon. But the swing there is from a very, very high back in 2014 of around \$22 to a low of just under \$15, and 2016, 2017, 2018 struggling around that \$15, \$16, \$15 level. And so just recently we're seeing a much...well not I shouldn't say much higher, but a reasonably higher milk price. I've seen some forecasters pushing a projection that that could stick for six months out, 12 months out. Milk prices in the \$16, \$17 range really helps our customer; that \$14 levels did not.

Kevin Ellich

I see the slide now. That's helpful. That's all I had, sorry for taking up so much time.



**Michael Brigham**

No, no. I appreciate the questions, Kevin. Thanks.

Operator

Our next question will come from Sam Rebotsky with SCR Asset Management. Please go ahead.

Sam Rebotsky

Good afternoon, Michael. And considering that the last third quarter had \$700,000 profit, this is pretty good. Our sales are \$10 million. What...how much of this would be the Tri-Shield and the First Defense? And what we could expect the ratio eventually between Tri-Shield and First Defense? And the \$18 [million] to \$20 million is your capacity. Could you sort of relate all the numbers together on that?

Michael Brigham

Sure. Yes. Thanks, Sam. Hi. Generally, what we're seeing is the what we call a dual products line, that's the bivalent product to the original capsule of the relatively new gel tube bivalent has been pretty flat and the majority of our growth is coming off Tri-Shield and that's just fine with us. I think that's strategically our plan. If we can gain as many new bolus or dual force customers as we lose, as we convert some of them to Tri-Shield keep that business flat and just grow with this new opportunity, the trivalent, Tri-Shield. That's the plan going forward. We have a plant that's growing production facility that purifies antibodies out of milk and we put them out there in several different formats. Let the customer choose which way they want to deliver the product, but same antibodies, either bivalent or trivalent, to E. coli, the coronavirus, the rotavirus.

Sam Rebotsky

At this point in time, when we get our order, we could ship it right away. There's no time lag and we're able to ship overseas also? In other words our ability to take advantage of any of the orders, domestic or internationally, all we have to do is we ship it, we have the product available?

Michael Brigham

That's true. Yes, now that's right, Sam. The only detail I'd add is the bolus ships room temp every day, the gel tubes ship mostly on Monday, sometimes on Tuesday just because of the cold chain requirement on that product.

Sam Rebotsky

Okay. Now the lease of the 14,300 square feet building, is that's what you're going to work on and get approval for 2020 and you're going to put more equipments in that building to do the manufacturing also and processing?

Michael Brigham

Yes, so we were leasing as an open warehouse. We've got to equip it to our requirements. This is USDA not FDA, the USDA is going to hold us to a high standard, but it's a bit easier to get a facility site licensed on the USDA side. FDA is just a bigger challenge. What we need to do over the next six, seven months or so to get this done in mid-2020 is build out these rooms essentially what the project is taking all of the final assembly. Whether you put the powder into a capsule or into a gel tube, all that assembly...final assembly and formulation work, take that out of our current facility, put that into the new facility that stays vacated will allow us to do the expansion of the liquid 100% and the freeze dry by 50%. There is no room to do that in the current facility today. Basically we are going to split the operation in two, the all the liquid process which is relatively dirty process of farm buckets of milk and

cheese and all that, bring that up to a powder and take that clean powder over to the new facility for assembly.

Sam Rebotsky

And I presume we expect this to save on costs, expect to the extent that to structure it with both processes done separately?

Michael Brigham

Yes, I mean, the long-term goal for me is just to keep right around that 50% range. I don't want to get too greedy on the top line, I don't want to get too sloppy on the costs, if we can mix all these things, the new investments, the new sales and keep that gross margin as we've reported here in the third quarter, I call that a success.

Sam Rebotsky

Okay. One more and I'll come back in the queue, Michael. The Norbrook, they have another additional problem with the FDA. Now they've resolved all their problems and they could do whatever we need to do when we're ready to submit the syringe to the FDA.

Michael Brigham

Right. Just to be clear there never was any problem with the FDA. And in fact, that's why we work so hard to get this short term agreement with Norbrook as they are an FDA approved facility. With the agreement signed with Norbrook does is just outline the terms which they will work with us for this short term period through December of '21.

Sam Rebotsky

Alright. Sounds exciting. Good luck, Michael.

Michael Brigham

Hey Sam. I appreciate. Thank you.

Operator

As a reminder, if you would like to ask a question, please press "*" then "1". Our next question comes from the line of...

Michael Brigham

Hey, Sean. Let me just jump in one second before the next question. I don't know, if we lost Kevin. That's okay. Just to update a data point on Kevin's question about milk price. If you look at page 36 on the Q in the morning, you're going to see what's publicly available. The milk price posted, but what's important that trend is averaging at \$16 for nine months, but the July to September average is \$17.82. That is a very positive trend for us on the milk price. But thanks, Sean, go right ahead with number three.

Operator

Our next question will come from Ben Andrews with Andrews Capital Management. Please go ahead.

Ben Andrews

Hi, Michael.

Michael Brigham

Hey there, Ben.

Ben Andrews

How much Tri-Shield did you make in Q3?

Michael Brigham

We've achieved our goal which we stated was being close to \$1.5 million worth of product per quarter. Looking at where we think sales are going in all it's a \$6 million run rate, production at \$1.2 [million] to \$1.5 million per quarter. That's going to be steady until we see the next level.

Ben Andrews

Have you sold any into Canada yet or no?

Michael Brigham

We have not; we do have approval up there. We're just being very cautious; we do not want to get back on allocation. I know, that's a decision for 2020. But I think we're going to be careful how we get through this first quarter, the peak season in the U.S. and just be careful on that growth step. We don't...again, so we don't get back into an allocation. I want to make sure this U.S. market is 100% taken care of through peak season. And then Canada becomes the next upside force.

Ben Andrews

Okay. And a question on the PD expense, I know you had one earlier. But looking at the Re-Tain piece, there's no actual expenses on a quarterly basis for the Re-Tain piece except the depreciation coming from that facility in that line item?

Michael Brigham

No. Right, thanks for asking that question to make sure I clarify. I was just pointing out that depreciation is a huge component of that PD expense, but almost all of our PD expense right now is going to Re-Tain. We're not producing commercial inventory. We're not building inventory. We're not capitalizing inventory costs, all of the facility plant operating costs are going through PD expenses. There's a lot of cash expense in there too. I'm just highlighting the large component of which...of total PD is not cast depreciation. Does that make sense, Ben?

Ben Andrews

Yes, kind of. Help me understand that line item then when we're in steady state with Re-Tain and with First Defense. Is that line item then pretty much depreciation unless you're coming out with a new version of one of the products or how does that work?

Michael Brigham

Right, I would never want to PD to go to zero, but it does come down to a more manageable level, the operating expenses that I'm referring to, moved from PD expense into cost of goods. And then PD becomes largely just what we continue to do is this line extensions other developments of the same core technologies whether it be a new formulation for First Defense and new claim for First Defense or we'll continue to do process improvement work on Re-Tain. But there's going to be the steady state on non-cash depreciation, and then there's going to be a swing from the operating costs going from PD to cost of goods to inventory.



Ben Andrews

Okay. What I heard you say, correct me if I'm wrong, of the 985 in the quarter, the majority of that expense is either Re-Tain development or Re-Tain depreciation, correct?

Michael Brigham

Yes, that's definitely true. We continue to do things with a very small PD staff, but we continue to do things to support First Defense, but the majority is towards Re-Tain.

Ben Andrews

You're carrying nearly a million a quarter of excess expense you're getting no benefit for at least as of yet?

Michael Brigham

Yes, it's great concept of matching expenses with revenues. Now, we're taking the expenses and not getting the revenues. And then Ben, by the time I see you tomorrow, we'll have the Q filed and we can look at the exact number still right out in the Q. I want people to know how much of that PD is depreciation.

Ben Andrews

Okay, thank you, Michael. Look forward to meeting you and seeing you tomorrow.

Michael Brigham

Yes, me too. Thanks.

Operator

As a reminder, if you would like to ask a question please press "*" then "1".

At this time, there are no further questions in the question queue. This will conclude today's Q&A session and I would like to turn the conference back over to Mr. Joe Diaz for any closing remarks.

CONCLUSION**Joe Diaz**

Thank you, Sean, and thanks to all of you for participating in today's call. We look forward to talking with you again to review the results of the full year of 2019 around the beginning of February 2020. Again, I encourage you to review ImmuCell's SEC filings for the full unaudited third quarter results. Thanks again for your time. Have a great week. We'll talk to you soon.

Operator

The conference has now concluded. Thank you for attending today's presentation and you may now disconnect.

