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ImmuCell Corp. (ICCC)

Q3 2020 Earnings Call

CORPORATE PARTICIPANTS

Joe Diaz
Managing Partner, Lytham Partners, LLC

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

OTHER PARTICIPANTS

Sam Rebotsky
Analyst, SER Asset Management

MANAGEMENT DISCUSSION SECTION

Operator: Good morning and welcome to the ImmuCell Corporation Reports Third Quarter Fiscal Year 2020 Financial Results Conference Call. All participants will be in listen-only mode. [Operator Instructions] After today's presentation, there will be an opportunity to ask questions. [Operator Instructions] Please note this event is being recorded.

I would now like to turn the conference over to Joe Diaz with Lytham Partners. Please go ahead.

Joe Diaz
Managing Partner, Lytham Partners, LLC

Thank you, Grant, and good morning to everybody on today's call. As the operator indicated, my name is Joe Diaz. I'm with Lytham Partners. We're the Investor Relations consulting firm for ImmuCell. I thank all of you for joining us today to discuss the unaudited financial results for the third quarter which ended September 30, 2020.

I would 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 or the Safe Harbor statement in the company's press release and its Form 10-Q, which can be obtained from the SEC or 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 F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

Thanks, Joe. Appreciate the opportunity to provide some updates on what is going on at ImmuCell. Thank you all for taking the time to join today's call. Just last night we filed our Form 10-Q for the three-month and nine-month periods ended September 30, 2020, and issued a press release summarizing some of the key results. I'm not going to rehash a lot of the detail that you can pick up from the Q and the press release, but I would like to highlight a few of what I see as the more important disclosures.

First, as you may know on October 6, we issued a press release covering our preliminary top line sales results only. We are doing that to give investors a very timely look at what I view as a most critical measure of our operations and financial performance early in the reporting period. There has been no change to those preliminary numbers. Product sales were up 25% during the third quarter. That follows on a 9% increase during the second quarter of 2020 and an 11% increase during the first quarter of 2020.

Product sales are up 15% during the nine-month period ended September 30, 2020. And they were up 17% during the trailing 12-month period ended September 30, 2020. All the increases that I have just described are in comparison to the same period a year earlier. This growth is really exciting for us and it comes with consistent market share gain as well.

Our sales team has been focused on disrupting the traditional scour vaccine market by replacing very old vaccine technology with our preformed antibodies. Our production team is working hard to catch up with that demand. We had a backlog of orders worth about $945,000 as of June 30. We reduced that to about $130,000 as of September 30. As market demand for First Defense continues to strengthen, meeting that demand is a good problem or challenge for us to have. The plan to increase our production capacity first to $23 million per year then later to about $30 million per year is discussed in detail as Project C in the 10-Q under the Liquidity and Capital Resources section of the MD&A.

The heavy lifting on this project being the renovations to our new formulation, fill and packaging facility at 175 Industrial Way is complete and it is fully cGMP compliant with good material, equipment and people flows and nice cleanable surfaces and rooms. We are now implementing the work to increase our liquid processing capacity by 100% and our freeze drying capacity by 50%. This work is being carefully coordinated to minimize disruption to our ongoing operations and product supply. We expect to fully realize the benefits of this expanded production capacity beginning in the second quarter of 2021.

Let's move to gross margin. You can find a detailed analysis of gross margin in the 10-Q under the Results of Operations section of the MD&A. We achieved a 46% gross margin during the third quarter. That is a three-point improvement over the second quarter. We are working hard on several fronts to try to improve this important measure. The two leading causes for the increasing costs of goods sold are the product sales mix shifting to gel tubes and biology.

First, gel tubes are more expensive to make than a legacy capsule product format. The gel paste format produces a higher gross margin on a dollar basis than the capsule and we are selling a lot of those tubes. Second, as we increase colostrum collection to support increased production, we need to work with new cows that have not seen our proprietary vaccines yet. The biological yield should increase as these cows come through our program the second time. Spreading our fixed and relatively fixed costs over higher production volumes should improve margins going forward.

Next, I am very happy to report that we received some really good news from the federal government. Our Paycheck Protection Program loan of almost $938,000 has been fully forgiven. This income will be recognized during the fourth quarter. We have disclosed this in the subsequent events footnote number 20 as well as in the press release.

As we all know the COVID-19 pandemic continues its unprecedented disruption of the global economy and lives around the world and it challenges our employees and our operations at ImmuCell in many different ways, we have not lost significant time in production due to the pandemic but everything is different. Our dedicated production team has been flexible and creative pushing First Defense production and facility expansions forward.

The government funding has allowed us to move forward with our expansion plans without significant interruption and operate our business without furloughs or layoffs; in fact, we have been hiring. This funding has helped us continue production at such an intense pace as safely as possible during this unprecedented time.

Let's move to product development expenses which continued to be our largest operating expense line item. I think it is important to look at the impact of non-cash expenses. On this line item, depreciation, amortization and stock-based compensation comprised about 38% of our product development expenses during the nine-month period ended September 30, 2020. Most of the depreciation charges result from the Nisin Drug Substance facility we constructed and the related production equipment for Re-Tain.

I'd like to talk a little bit about Re-Tain. It has been a long and expensive road but we are nearing completion of the work required to achieve FDA approval of this novel subclinical mastitis treatment for lactating dairy cows. We have disclosed our best thinking and specific details about the final path to market launch of Re-Tain in the 10-Q under the Results of Operations section of the MD&A. It all comes down to achieving approval of the manufacturing technical section, which is known as the Chemistry, Manufacturing and Controls or CMC Technical Section. This is the last of five technical sections required for product approval.

We are on track to make our first submission of the Drug Substance and Drug Product CMC Technical Section before year-end. This kind of submission is subject to a six-month review by the FDA. That puts us at a huge fork in the road near the end of the second quarter of 2021.

If the FDA has questions for us, we could be required to respond through another submission, which will be subject to another six-month review. We do not anticipate that an additional submission after that would be required. Therefore, we are making plans for market launch during the first quarter of 2022, while also developing a flex launch plan that we could enact sooner if approval comes through during the third quarter of 2021. The path to market will clarify as we progress the next submissions.

Lastly, I do focus more on cash flows and our GAAP net loss at this stage in our development. Page 4 of last night's press release provides a look at the impact of all non-cash expenses on our financial statements. This is an important metric to consider in understanding our cash flows, but the most important measure is the statement of cash flows in the 10-Q.

So, in conclusion, I encourage you to review the Form 10-Q and the press release that we filed last night. Also, please have a look at our Corporate Presentation slide deck. A November update was just posted to our website last night. I believe it provides a very good summary of our business strategy and our objectives as well as our current financial results. So just see the Investors section of our website and click on Corporate Presentation.

With that said, I would be happy to take your questions. Let's have the operator open up the lines. Thank you. Grant?

QUESTION AND ANSWER SECTION

Operator: We will now begin the question-and-answer session. [Operator Instructions] At this time, we will pause momentarily to assemble our roster. [Operator Instructions] Our first question today will come from Sam Rebotsky with SER Asset Management. Please go ahead.

Sam Rebotsky
Analyst, SER Asset Management

Q

Good morning and congratulations, Michael.

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah.

Sam Rebotsky
Analyst, SER Asset Management

Q

I'm excited to see the submission to the FDA before this December. We've presumably tested many, many times. Is there any need to submit earlier than December 31 or how do we look at the time of submission?

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. There's a need, but it won't go till it's ready. I mean the sooner the better. But there's still a little bit of work to do. A lot of that has to do with stability. So, a lot of this is just time passage. You've got to submit with a certain amount of stability on this product. But I think what Betsy Williams, our VP of Manufacturing Operations, has done with the team to set this up, a whole science team, Joe Crabb, John Zinckgraf, others, many others, they're all pushing this as hard as possible. And, yeah, I think our position was just hold that line and get it in this year, but get it in right.

Sam Rebotsky
Analyst, SER Asset Management

Q

And – okay. That's – it's a long time coming and exciting to hear that. And as far as the money from the federal government, that's good too. That'll improve the balance sheet also. Was that pretty much boilerplate or did you have to spend any time explaining the process that you followed or how did that go?

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. Sam, I would not – I guess maybe boilerplate. But I don't – I think we did have to spend a lot of time explaining. I mean, I guess, what I'm trying to say is our application was pretty straightforward, but I never take anything for granted. It was so important for us to achieve that forgiveness. As much as I was confident we would get it, it's not done until it's done. And our application was simpler than many. And maybe that's why we're sort of at the front tier of the forgiveness pipeline here with other companies not been forgiven yet because we were just 100% payroll.

So we didn't even have to get into rent and mortgage interest and overheads and supplies and different qualified expenses. We just said, look, this is Paycheck Protection Program, we're 100% payroll. I think that may have helped us. I think that may have facilitated the application going through.

Sam Rebotsky
Analyst, SER Asset Management

Q

Okay. And as far as [ph] Tri-Shield and First Defense (00:14:21), are we able to increase the sales in the current quarter from the September quarter? We have finished – basically completed the backlog and are we able to increase the sales based on demand?

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. I mean so that product, it continues to see great demand. I mean we're really happy to see what's going on there. The dairy industry is having some good – reasonably good economic measures like milk prices very strong right now. So that's good for our customer. What's good for our customer is good for us. Ultimately, we'd report those results early just like we did this quarter. So, say, January 5, 6, 7, somewhere in there, we'll get a top line number together in a preliminary press release obviously way in advance of the year-end audit and the full P&L, but I'd like to continue that practice. I think it's my best way to answer your question on the most timely basis possible.

Sam Rebotsky
Analyst, SER Asset Management

Q

Well, that's wonderful. And are we prepared yet to do any further shipping, selling of [ph] First Defense and Tri-Shield (00:15:43) overseas, and when do you think that would happen?

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. I appreciate your interest there. You've definitely kept us focused on that goal, but we've been a little careful. I mean I want to get some distance from this backlog before we open up new markets. So, Bobbi Brockmann, our VP of Sales and Marketing, has done a great job of qualifying certain new markets and new international markets.

But they're going to be stays a little bit. They're going to be pause a little bit later into 2021 and into 2022. I want to make sure we've got North America totally covered, totally out of backlog, with some buffer stock before we create that extra demand through new international markets beyond Japan and South Korea where we are today.

Sam Rebotsky
Analyst, SER Asset Management

Q

Well, congratulations, and let's hope the COVID keeps getting better, that we improve everything and everybody should have, if not this year, next year a Happy Thanksgiving and Happy Holidays. Okay.

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Sad to look at it that way, Sam, but I think you're right. I'm [indiscernible] (00:17:05) put this year. Stay home. Stay safe. Let's get through this all together.

Sam Rebotsky
Analyst, SER Asset Management

Q

Yes. Good luck, everybody, all ImmuCell shareholders, employees, and everybody. Thank you.

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Thank you, Sam. Very nice.

Operator: [Operator Instructions] Our next question will come from [ph] Frank Casper (00:17:41) who is a private investor. Please go ahead.

Q

Yeah, Mike. Great growth on sales. Could you...

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Thanks, [ph] Frank (00:17:55). Good to hear your voice.

Q

Yes. It's been a while.

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah.

Q

Could you – can you maybe give some idea as to – once a farmer knows that his cow or how does he know that his cow has subclinical mastitis, and how does it progress from [indiscernible] (00:18:27), through what chain of events?

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Well, to the first part, it's largely monitoring somatic cell counts in the milk. So we're watching the cows' behavior, temperature and the quality of the milk or the level of somatic cell counts in the milk. I don't know if I quite understood the second part, [ph] Frank (00:18:54). How does it progress to us?

Q

Yeah. In other words, what – now that he knows and I'll – let me ask. Does he – does the farmer know specifically which cow or are they doing a bulk test on the somatic cell count?

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Well, so they'd be doing both. So they'd have an idea of their herd health level and then they have specific cow ID. So I guess I'm catching up to your question. Yeah. We would want them to be watching and actually selecting the highest somatic cell count cows. These are cows that are otherwise healthy. They're eating. They're moving with the herd. They're not often a sick cow pen. They're being milked but they're becoming sick. They're not producing as much milk. They're not as producing the highest quality milk. So, we want to find those cows, select them for treatment to, one, before they get sicker and, two, so that we can improve their quality of milk, their quantity of milk production as soon as they pick them off those herd checks.

Q

Once known, what does the – how does the farmer get your product into his hands? It just goes by it or is there some kind of veterinarian [indiscernible] (00:20:31)?

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. It's very much – we're not recreating that part of the practice. So, it's much what they're doing today is – it's our delivery, our tube, our syringe looks very much like the common antibiotics that are on the market today. So, they know how to go to the fridge, grab that tube, it's a simple infusion into the [indiscernible] (00:20:56) opening. They would just be infusing the nice and the retained product instead of one of those traditional antibiotic products. But otherwise, very similar mode of delivery, the infusion, and they're very familiar with that and pretty simple to do.

Q

Just one more thing. Yeah. Your – presently, your – you have two major suppliers listed in the 10-Q that you sell to. How do you envision them playing into this launch?

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

A huge role down the road initially, maybe a pretty small role as we get started. But ultimately is just like First Defense, all of our First Defense goes right through distribution. And you're right. MWI and Animal Health International are the two biggest for us and they're the two biggest for, I think, for all Animal Health manufacturers. They just have a network throughout the country. So, it's really just the same people, the same network, the same warehouses as First Defense moves through, so we'll retain.

Q

And that's all that I have, Mike, and again congratulate everyone and I have been following ImmuCell for quite some time.

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah.

Q

You've got a great...

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah.

Q

...workforce there. Thank you.

Michael F. Brigham
President, Chief Executive Officer & Director, ImmuCell Corp.

A

I agree. I agree [ph] totally, Frank (00:22:44). Thank you so much for that.

Operator: [Operator Instructions] All right. Well, there being no further questions at this time, this will conclude our question-and-answer session. I'd like to turn the conference back over to Joe Diaz for any closing remarks.

Joe Diaz
Managing Partner, Lytham Partners, LLC

Thank you, Grant. 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 fourth quarter of 2020 sometime in February of 2021. Have a great weekend. Please stay safe and well.

Thank you.

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