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ImmuCell Corp. (ICCC)

Q4 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

Louis Parks

Analyst, Tyro Capital Management, LLC

George Melas-Kyriazi

Analyst, MKH Management Company LLC

MANAGEMENT DISCUSSION SECTION

Operator: Good morning and welcome to the ImmuCell Corporation Reports' Fourth Quarter Fiscal Year 2020 Financial Results Conference Call. All participants will be in a 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. Good morning and welcome to all out there. As Grant indicated, my name is Joe Diaz. I'm with Lytham Partners. We're the Investor Relations consulting firm for ImmuCell. We thank you for joining us today to discuss the unaudited financial results for the year ended December 31, 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 provided with last night's press release.

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.

Great. Thanks, Joe. I appreciate the opportunity to provide some updates on what is going on at ImmuCell. It's an exciting – very exciting time here. The press release we disclosed last night covers the key financial highlights for the year ended December 31, 2020. We expect to file our Form 10-K providing much more detail around March 30. As you may know we issued a press release covering our preliminary top line sales results on January 7. We have been making these optional filings to give investors a very timely look at what I view as the most critical measure of our operations and financial performance early in the reporting period. There has been no change to our previously disclosed sales results. Product sales were up 12% for the year ended December 31, 2020 in comparison to 2019.

This growth is very important for us and it comes with consistent market share gain as well. Simply put, our sales team continues to disrupt the traditional scour vaccine market by replacing very old vaccine technology with our preformed antibodies. Beyond the top line results that I just discussed and were previously disclosed, the three most important things that I want to talk to you about today are one, the status of our investment to expand our production capacity; two, the road to regulatory approval of Re-Tain and three, our cash flows.

So first, the status of our investment to expand our production capacity. We had a backlog of orders worth about \$1.8 million as of 12/31/2020 compared to no backlog as of 12/31/2019. This strong indication of demand for our product is a good thing and confirms the need for expanded production capacity because we need to get every dose that our customers want into their hands. The leasehold improvements to our new formulation fill an assembly facility were completed during 2020. The final phase of this project, which involves the 100% increase in our liquid processing operations and the 50% increase in our freeze-drying operation is on budget and on schedule for completion during the second quarter of 2021.

This work is being carefully coordinated to minimize disruption to our ongoing operations and product supply. Before this expanded capacity comes online, we do expect to incur a decrease in sales during the first quarter of 2021 in comparison to the first quarter of 2020. This estimate of sales for the first quarter of 2021 amounts to about 92% of the \$4.1 million that we estimate to be our current production capacity per quarter. We sold product equivalent to about 91% of this estimated quarterly capacity during the fourth quarter of 2020.

We are working to fulfill this backlog and return to a growth mode during the second half of 2021, provided that we capture anticipated demand and end the year with available inventory on the shelf ready for peak season sales during the first quarter of 2022, provided that we effectively complete our production capacity expansion investment. Second, the road to regulatory approval of Re-Tain. Product development expenses continue to be our largest operating expense line item, increasing by 18% to \$4.4 million during 2020, including a \$1.5 million – including \$1.5 million of non-cash depreciation expense.

Let's talk about Re-Tain a bit. It's 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 without a milk discard. We recently submitted the last of five significant technical sections required for FDA approval. This one is known as the Chemistry, Manufacturing and Controls or CMC Technical Section.

This kind of submission is subject to a six-month review by the FDA that puts us at a huge fork on the road during the third quarter of 2021. If the FDA has questions for us, we could be required to respond through another submission, which would be subject to an additional six-month review. We do not anticipate that an additional submission would be required after that. Therefore, we are making plans for a mass market launch during the

second quarter of 2022 while also being prepared to flex to an initial limited launch plan during the fourth quarter of 2021, if approval comes through in response to our first submission.

Thirdly, and last our cash flows. I think we should focus on our cash flows more than on our GAAP net loss at this stage in our development. Page 5 of last night's press release provides a look at the impact of non-cash expenses on our financial results. We reported increases in both EBITDA and what I describe as a measure of cash flows, which I believe is most relevant to tracking our performance. While both are important metrics to consider in understanding our cash flows, the most important measure is the statement of cash flows that will be included with our Form 10-K filing around the end of March. Subject to completion of our audit, we do expect to see year-over-year increase in net cash provided by operating activities of approximately \$1.1 million, which included the benefit of \$938,000 in other income from the forgiveness of our Paycheck Protection Program loan from the Federal Government.

So, in conclusion, I encourage you to review the press release that we filed last night. Also please have a look at our corporate presentation slide deck at February update was just posted to our website last night, I believe it provides a very good summary of our business strategy and objective as well as our current financial results. See the investors section on our website and click on Corporate Presentation or just contact our office and we can send you out a copy.

With that said, I will be happy to take your questions. Let's have the operator open up the lines.

QUESTION AND ANSWER SECTION

Operator: We will now begin the question-and-answer session. [Operator Instructions] Looks like we have a question from Sam Rebotsky with SER Asset Management. Please go ahead.

Sam Rebotsky

Analyst, SER Asset Management

Q

Good morning, Michael. Now tell me you – we were expecting to submit the Re-Tain information in December 31, so presumably we just submitted it. And could you discuss the – why it took us so long to put all the pieces together?

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. Just simply Sam, by the way good morning. Just a very complex submission, so yes month ago, I'm actually not sure exactly how many months we made that projection for year-end, we did not meet it and I'm okay with that to meet the – previously disclosed deadline with less than our best effort, would have been a foolish price. So we took the time we needed to get it right and just understand it is a very, very complex submission involving data and input from other parties, when it was together and when it was right, it was submitted and as I said recently submitted so plus or minus weeks on something like that magnitude, I think, is a bit of a rounding error sooner would have been premature.

Sam Rebotsky

Analyst, SER Asset Management

Q

So, we got all the data that we needed from Norbrook and presumably that we're more comfortable on the submission, did the FDA respond in any way to our submission?

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

No, they won't do that. We wouldn't expect them to do that. No, I'd say it's a statutory review period. While there could be some back and forth during those six months. Nothing that we wouldn't expect their response until that six months review period is up.

Sam Rebotsky

Analyst, SER Asset Management

Q

Okay, okay. And as far as getting the facility ready to manufacture, when do we expect the next quarter that will be short on complete – getting everything to the – will be about 90% submitted? When do we expect that – during the second quarter, do we expect to catch up and so we're fully able to submit our product.

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Right. So it's pretty much an on/off switch, Sam. That 90%, 91%, 92% different periods, different – slightly different percentages, but over 90% of our current capacity is what we do today. And our current capacity is about \$16.5 million per year as far as we push that plan – as far as we push our staff, we keep coming up to that similar number. Then when the new line comes on, it's mostly about more freeze-drying, mostly about more liquid processing. When that comes online, we move from \$16.5 million annual capacity to \$23 million annual capacity. So, it's that \$23 million that we need to be at because that gives us a little bit headspace over the \$15.3 million that was current sales for 2020.

Sam Rebotsky

Analyst, SER Asset Management

Q

So the \$23 million, do we know which quarter we expect to or do have a...?

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Next quarter, 2Q, yeah that come...

Sam Rebotsky

Analyst, SER Asset Management

Q

Right.

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

...all this work gets completed here in 2Q and that's our transition from the backlog, will it get on – fill ongoing demand and then start building some inventory, so that we are not looking at this backlog as we look into the second half of 2021 and most importantly build for peak season sales first quarter of 2022.

Sam Rebotsky

Analyst, SER Asset Management

Q

It sounds good, Michael. It's been a rather struggle, I guess, with the COVID and everything else. Good luck to the whole ImmuCell team.

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

Thanks, Sam. Appreciate that. Yeah.

A

Sam Rebotsky

Analyst, SER Asset Management

Thank you.

Q

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

Yeah. Thanks for tracking so closely. Appreciate it, Sam. Good.

A

Operator: Our next question will come from George Melas with MKH Management. Please go ahead.

George Melas-Kyriazi

Analyst, MKH Management Company LLC

Good morning, Michael.

Q

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

Hey, there. George, good morning.

A

George Melas-Kyriazi

Analyst, MKH Management Company LLC

Good morning. It looks like orders in the quarter were quite strong because I think you started the quarter with a backlog of just \$100,000 and you ended with \$1.8 million. So it looks like you have orders in the quarter of, I think, more than \$5 billion, is that correct and how does that compare with the prior years?

Q

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

George, I'm not following that math. The backlog at the end of the year 12/31/2020 was \$1.8 million that compares to zero as of 12/31/2019. So, as we come in to the first quarter of 2021, we had that \$1.8 million of orders yet on unmet as we continue to work through that in the first quarter here. But, maybe, I didn't get the question, does that answer, make sense?

A

George Melas-Kyriazi

Analyst, MKH Management Company LLC

[ph] Right, right (00:15:08). So let me see if I can ask – see if my question makes sense. It seems like the orders in the fourth quarter, you had orders that you fulfilled in the first quarter – in the fourth quarter plus the orders of \$1.8 million that you were not able to fulfill. So, it seems like the orders in the fourth quarter were quite strong. Is that correct?

Q

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Oh! For sure. Fourth quarter things just started to really roll. I mean the orders were – yeah, that was – there was a huge amount of demand in the fourth quarter that because we had a larger backlog, we worked that down to a lower level there at 9/30 – September 30, 2020 and it just built up strong.

George Melas-Kyriazi

Analyst, MKH Management Company LLC

Q

And is that partly related to the strength of the dairy industry or what do you attribute that to because it seems like orders sort of exploded in the fourth quarter?

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Right. I see where we're going. Yes. Well, obviously, a lot of factors. The dairy industry has been very volatile through this COVID pandemic, but towards the end of the year became very strong. It suffered in the early part of the March, April, May, with very low milk prices, rebounded as has the whole food service system sort of adjusted from schools and restaurants to the more take-out. And then the whole adjustment here was, I've got a good chart on milk price I could share with you. It just was very, very low there March, April, May and then rebounded to a very high price.

So, the industry ended strong so that times out to the strong fourth quarter. So that probably is related. I like to think that what's really going on is the sales team is just as I mentioned in my in my talk there just they're having great success with this new effort to replace dam vaccines. I mean, the addition of our rotavirus claim on top of the E. coli and corona makes our product very attractive and we're having great success, it's a great conversation to have in the barn about hey you're immunizing your cow. Why? What if you left that cow alone, didn't stick a needle in her, didn't subject yourself to this variable vaccine response. Let ImmuCell do the work for you. We'll give you preformed antibodies measured out in a dose and you can give it just to that newborn calf. So I think it's a combination of great work by the sales team and a strong market that sort of rebounded from the early COVID pandemic lows.

George Melas-Kyriazi

Analyst, MKH Management Company LLC

Q

Okay. Okay. I think that provides some good explanation because I mean, I think that the order numbers, you do some simple math, they seem to be very strong, so I think that goes really well for the expansion of capacity that you are – that will come online very soon.

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. It's very needed. I think that's a very, very good investment and just needed as soon as possible.

George Melas-Kyriazi

Analyst, MKH Management Company LLC

Q

And just Michael, the sales team right now is it still nine people or is it – how is that [indiscernible] (00:18:22)?

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. We're level – we had a couple of open positions during the year, but we're level at nine. So we are full staff, and that's the seven regional marketing managers – sales and marketing managers and the director of marketing and then Bobbi Jo Brockmann, the VP of Sales.

George Melas-Kyriazi

Analyst, MKH Management Company LLC

Q

Great. Okay. Thank you very much.

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Okay. Good. George. Thank you.

Operator: [Operator Instructions] There being no further question – Oh! Looks like we have a question from [ph] Scott Cossa (00:19:00) who is a private investor. Please go ahead.

Q

First of all, congratulations. Great work especially in terms of what's been going on over the last year. It seems as though you've penetrated the market quite substantially and obviously no one has a crystal ball, but to what extent do you think that you have further penetration developable in the market?

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah, thanks, [ph] Scott (00:19:41). A part of my answer I'm going to refer you to our slide deck because I think that the numbers and the details there I referred to growing market share as well as growing sales. The slides around 14, 15, 16 really define what I see as the market, [ph] I saw at the end (00:19:56), there's some pie charts there and we're showing this continual and consistent growth in market share and we define the market in two ways. One, the direct competition of products that are given to the newborn calf and then this larger market that I just started to discuss there a little bit with the prior question of including those dam vaccines, those vaccines given to the mother cow, but so about \$22 million on that calf level about \$42 million when you include the mother cow. So that's our opportunity and that's our – that's the market that we keep competing in and those percentages, we have a pie chart there, just our share is red, getting up to 41% of that calf level and up to 13% of that when you combine in the dam vaccine market. So, well – that leaves \$87 million available.

[indiscernible] (00:21:01)

Q

Right. Great. Thank you. And that would be more a country-wide domestic market, correct?

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah, you're absolutely right. Yeah, this is only – those numbers and those charts are just US. So we are up into Canada, we're having some good sales results up there. We're into a few other territories in a small way and the longer-term plan coming out of backlog and having this capacity in place would be to continue to grow in other

international markets, but that really wouldn't help us right now. In 2020, that would have just added to our backlog.

Q

No. Absolutely, it's a good problem to have.

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. Nice problem to have. That's a good way to put it. Thank you, [ph] Scott (00:21:47). Yeah.

Q

Thank you so very much.

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Great. Thanks.

Operator: Our next question will come from Louis Parks with Tyro Capital Management. Please go ahead.

Louis Parks

Analyst, Tyro Capital Management, LLC

Q

Hi, Michael. Happy New Year and thanks for the update. My question actually piggybacks on what you were just discussing. I was going to ask you to expand a little bit upon the international sales strategy.

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

A

Yeah. So, as I said north – we're really in North America right now. We do get into South Korea. We do get into Japan. And we've started that advance work, the regulatory work. We want to work with some in-country experts that would help us through the regulatory. There's different systems in each territory much like a USDA plus or minus. So it's a product that does require in-country regulatory approval. And then we just talked about nine sales reps there. We're not going to have reps in these different territories. So, we're going to rely on a partner that's going to be – we'll be the manufacturer. They'll be the distributor. They'll help us with the regulatory. So, that work is underway. Bobbi is sort of leading that charge. But we did want to stagger it. As I just mentioned we just didn't want to disappoint new territory, new customers and just increase this backlog burden. So, yeah, it's the regulatory work. It's the partner work. And as we get into 2022 and after, I think, there's scours around the world and there's lots of new opportunities that we'll start to address.

Louis Parks

Analyst, Tyro Capital Management, LLC

Q

Thank you.

Operator: [Operator Instructions] There being no further questions. This will conclude our question-and-answer session. I'd like to turn the conference back over to Joe Diaz for any closing remarks.

Michael F. Brigham

President, Chief Executive Officer & Director, ImmuCell Corp.

Hey, Grant, we may have lost Joe there, but I've got the script and I know he was just going to have us close. So, Joe, are you coming back or...

Joe Diaz

Managing Partner, Lytham Partners, LLC

I'm on, I'm on. Again as I was going to say, I'd like to thank everybody for participating on the call today. And we're certainly looking-forward to talking with everyone again to review the results of the current first quarter here at 2021, sometime around the second week of May. So have a great week. Stay safe and well. Thanks to everyone, and Michael, thanks to you.

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

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