IMMUCELL CORPORATION
Nasdaq: ICCC

Second Quarter Fiscal Year 2017
Financial Results

Monday, August 14, 2017
4:30 p.m. Eastern

CORPORATE PARTICIPANTS

Michael Brigham – President and CEO, ImmuCell Corporation
Adam Lowensteiner – Senior Account Manager, Lytham Partners

PRESENTATION

Operator
Good afternoon and welcome to the ImmuCell Corporation Second Quarter Fiscal Year 2017 Financial Results Conference Call. All participants will be in 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 also note that this event is being recorded.

I would now like to turn the conference over to Mr. Adam Lowensteiner. Please go ahead.

Adam Lowensteiner
Thank you, Andrea and I thank all of you for joining us today to review the unaudited financial results of ImmuCell Corporation for the second quarter of 2017 which ended on June 30th, 2017. My name is Adam Lowensteiner with Lytham Partners. We are the investor relations consulting firm for ImmuCell. With us on the call representing the company today is Michael Brigham, President and CEO.

Before Michael gets started, let me say that statements made by management of ImmuCell during the course of this conference call that are not historical facts are considered to be forward-looking statements that are subject to risks and uncertainties.

The Private Securities Litigation Reform Act of 1995 provides a 'Safe Harbor' for such forward-looking statements. Words, such as, believe, expect, anticipate, intend, estimate, will and other similar words or statements of expectation identify forward-looking statements. Such statements involve risks and uncertainties, including but not limited to those risks and uncertainties detailed from time to time in filings the company submits to the Securities and Exchange Commission.

Investors are cautioned that forward-looking statements made during the course of this conference call are based on management's analysis as of today and actual results could differ materially from the statements made. The company undertakes no obligation to publicly release the results of any revision to these forward-looking statements. A more complete 'Safe Harbor' statement was included in the press release and the Form 10-Q that were both filed by the company today.

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
Thanks, Adam. And I thank all of you on the line for taking the time to join us on today's call. I do not want to spend too much time together reviewing the quarterly numbers because all the financial details are available in both the press release and the Form 10-Q that were filed earlier today. So I will briefly review the top line and bottom line results for the second quarter of 2017 and then move on to some updates about our business.

Sales during the second quarter of 2017 of $1.7 million decreased by $626,000 or 26% in comparison to the second quarter of 2016. The drop in sales during the second quarter of 2017 was not a surprise to us, because sales during the second quarter of last year included nearly $1.3 million of orders that had been on backlog as of March 31, 2016. This disruption in the order shipping pattern makes the two quarters difficult to compare.

A prolonged period of order backlog which began in early 2015 and extended through the middle of 2016 disrupted our normal shipping patterns. The order backlog was reduced to $365,000 as of June 30, 2016 which backlog was subsequently cleared during the third quarter of last year. Since then, we have had sufficient inventory to ship in accordance to the demand of our distributors.

Sales of $5.3 million during the first six months of 2017 were within $68,000 of the sales recorded during the first six months of 2016. The quarterly record setting sales achieved during the first quarter of 2017 offset some of the second quarter decrease that I just mentioned to bring us about level for the first half of this year compared to the first half of last year.

We expect to report positive sales growth for both the six month and twelve month periods ending December 31, 2017, in comparison to the same periods of the prior year. It will be good to have the impact of the backlog removed from our period-to-period comparisons going forward so that we can look at the sales results on more of an apples-to-apples basis.

We reported a net loss of $218,000 or $0.05 per share during the second quarter of 2017 compared to $9,000 or less than $0.01 per share during the second quarter of 2016. We reported net income of $366,000 or $0.07 per diluted share during the six months ended June 30, 2017, compared to $443,000 or $0.11 per diluted share during the six months ended June 30, 2016.

Market conditions in the dairy and beef industries, including milk prices and prices for calves, weakened during 2016 in comparison to 2015. Milk prices have made modest improvements going into 2017 over the annual averages for 2016 and 2015.

Our objective is to bring the most effective technology to market. Our competitors, including Boehringer Ingelheim, Elanco, Merck and Zoetis may be bigger than we are, but they do not offer the kind of products that we do. Getting market share from competitive products at both the calf level for scours and the cow level for mastitis provides a great opportunity for us.

I would like to discuss the two largest competitors we face in the calf level market. First, Calf-Guard from Zoetis is the unit volume leader, but this product does not have an E. coli claim and puts calf through vaccination stress and can be inactivated by colostrums, which is why it is recommended to withhold colostrums when administering Calf-Guard. We provide calves immediate immunity that can be administered with colostrums soon after birth as possible and we know that this is best practice for good calf health.
Second, the market share of Bovine Ecolizer from Elanco which is derived from horse blood is relatively small compared to ours and to Calf-Guard's, but we are still aggressively displacing that product by reminding customers about the importance of our coronavirus claim which their product does not have, and by discussing new data from our lab that shows that a dose of First Defense contains multiple times more E. coli antibodies, they are providing calves more protection.

Very importantly, the anticipated addition of a rotavirus claim to our bivalent gel tube product later this year will allow us not only to compete more effectively against these products at the calf level, but also against vaccines that are given to the mother cow to increase the quality of the colostrums that she produces for the newborn. We intend to market this new product under the trademark First Defense Tri-Shield.

Subject to USDA approval, we anticipate launching Tri-Shield during the fourth quarter of 2017. We also anticipate establishing USDA claims for our bivalent gel tube formulation of First Defense Technology which we will continue to sell after Tri-Shield is available to the market.

During in July, we raised net proceeds of just over $1 million by issuing 200,000 shares of common stock at $5.25 per share. Without this incremental equity raise, we have been holding off on non-essential investments pending completion of the construction of our Nisin production facility.

To name just one use of these new funds, we are now going ahead with a plan to increase our team of regional sales and marketing managers from five to six. This will better prepare us for the launch of Tri-Shield.

We like the calf scours market, we believe that the disease costs the dairy and beef industries about $740 million per year. That's a good size market, but the mastitis market is even bigger.

Mastitis costs the dairy industry about $2 billion per year, representing the single largest cause of economic harms for the dairy industry. Presently, mastitis is treated with traditional antibiotic products and treatment is generally reserved for clinical infection when the cow produces non-salable milk.

Subject to FDA approval, we expect to enter into the mastitis market with our Nisin based treatment for subclinical mastitis. Our groundbreaking product innovation is unlike all other antibiotic treatments on the market today.

Our goal is to revolutionize the way mastitis is treated by making the treatment of subclinical infections economically feasible by not requiring a milk discard or a meat withhold during or for a period of time after treatment. No other product can offer this value proposition.

Nisin, the active ingredient, is a bacteriocin that is not used in human medicine and would not contribute to the growing concern that widespread use of antibiotics encourages the growth of antibiotic resistant bacteria or superbugs.

As many of you know, we initiated construction of our $20.2 million pharmaceutical facility to produce Nisin during the third quarter of 2016. As of June 30, 2017, we have invested approximately $10.1 million in this project, leaving just over $10 million to go.

To finance this, we had approximately $4.3 million in cash and investments on hand as of June 30, 2017, and have access of up to $6 million in available bank debt. Our available cash was increased by $1 million subsequent to June 30, 2017, through the equity raise that I mentioned previously.

Construction of the building shell is now substantially complete, and we have made significant progress on the interior fit out. I encourage you to go to the products page of our recently redesigned website at www.immucell.com and click on the purified Nisin for Mastitis page to view progress photos of the construction. The tangible visual progress is really very exciting. We will continue to provide periodic updates there.

We expect spending on this project to be largely complete by September 30, 2017. To maintain the time line for anticipated FDA approval in 2019, we are working to complete the facility construction and the installation and qualification of equipment by the fourth quarter of 2017 which would be followed by a process validation and subsequent regulatory filings. We expect that two submissions of the regulatory package covering the manufacturing objectives will be required, each of which will be subject to a six months review by the FDA.

With that said, let's have the operator open up the lines for your 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 telephone keypad. If you are using a speakerphone, please pick up your handset before pressing the keys, to withdraw your question, please press "*" then "2." At this time, we will pause momentarily to assemble our roster.

And our first question comes from Sam Rebotsky of SER Asset Management. Please go ahead.

Sam Rebotsky
Yes, good afternoon, Michael.

Michael Brigham
How are you, Sam?

Sam Rebotsky
Hi, so we've been working on international sales. What is the structure? Do we expect any significant sales in the third and fourth quarter of the current year, have we hired some new people or what's going on with international sales?

Michael Brigham
Slow moving on that front, Sam, so I would not expect anything significant. We definitely would not be hiring an employee for that. But we're working with some in-country expert, so it's going to be a case-by-case kind of situation. And hope that they will do the regulatory work. They will do the in-country sales work, sales and regulatory. And we would retain our role as manufacturer. But yes, nothing big, nothing, as you said anything significant, third and fourth quarter. It'd be an upside to me, nothing that I'd expect at this point.

Sam Rebotsky
Okay. Now as far as the facility in this third quarter, we have some of the equipment. Do we expect to have all the equipment on the site in the third quarter or where we...?

Michael Brigham
Yes, we do. We do, really. As I mentioned, the construction is largely complete. We're well into install and that's my comment about having almost all the cost or the investment fully incurred by September 30 because that's the first, buying the equipment. So it's transitioning from facility construction to installation and then ultimately, validation and process runs. So by September 30, I think we're going to have almost all of it incurred.

Sam Rebotsky
Do we pay for it on receipt or do we pay for it when it's fully installed and acceptable and we talk criteria?

Michael Brigham
Well, we try and hold on to a piece for full installation. But most of these vendors want a deposit upfront, a progress payment and then a completion payment. That's pretty much true across the board. So, yes, it's all happening between, really, June and September.

Sam Rebotsky

So do we hope to get everything fully installed by December or when do we expect to get it installed and have the equipment run the Mast Out and then submitted to the FDA?

Michael Brigham
Yes. There's some lever on that between the very end of the year and the very beginning of next year, but we're going to be running these tanks in 2017. That process validation step needs to be completed before we're ready to run the batches. We need to make three validation batches that get submitted to the FDA. So that's what gets us into the completing installation in '17 then initiating the validation and the process, test runs and then the submissions, the manufacturing for submission in 2018.

Sam Rebotsky
And as far as the rotavirus, when do we expect the final approval on the rotavirus?

Michael Brigham
We are sticking with that projection for fourth quarter. We think its right. It's a little hard to be certain because it is at the discretion of the USDA. It's a little bit unlike the FDA, where you get a statutory turnaround. With the USDA, it's a little more flexible. The timeline is a little more in their control. But I still think it's reasonable to look for that product to get approved in the fourth quarter.

Sam Rebotsky
Okay, great, Michael. Look, I will now let somebody get into the queue and ask questions. I will come back after.

Michael Brigham
Great. Thanks, Sam.

Operator
Again, if you have a question, please press "*" then "1."

And we have a follow-up question from Sam Rebotsky. Please go ahead.

Sam Rebotsky
Yes, hi, Michael. So as far as...the stock has moved back a little bit even though the volume is not so heavy. Is there any thoughts about telling the story or do you have any awareness where the buying is coming from?

Michael Brigham
Sam, when you say moves back, what are you...?

Sam Rebotsky
Well, it moved up then it was down to 6.46. It's just been trending up. There seems to be more strength in the stock.

Michael Brigham

Okay. Okay. Yes, I took it the wrong way meaning back down but more back up. Yes, traded strong on a price per share basis over the last couple of weeks which is encouraging. I hope we've been able...the second quarter decrease, I think is well explained. It was well anticipated. I hope we don't lose momentum due to that because that would be a disservice to the stock. But yes, I continue to work with Lytham Partners. We get out, we meet investors, we do calls. Just getting the Q filed today. There's a lot more to the story than this backlog-influenced drop in second quarter sales. So I hope people read the press release, read the Q, ask questions, understand what's going on because I think there's some very, very strong, very good progress disclosures in that Q to those who would read it.

Sam Rebotsky
Okay. And at this point, do you go to Kansas City in August or is that...

Michael Brigham
Sam, that's a great question. I struggle with that. The answer is no, not this year. I do want to keep connections with those people. They're a great group of animal health companies that are all centered out there. There's a little conflict in my schedule this year. And honestly, it did not become a priority because we chose our site for the Nisin plant here in Portland. And a lot of our work out there was considering a potential site out that way. So with that decision behind us with the facility in Portland, I am directing that time at the end of August in a different direction. But I'll be back. It's a great group of people who we want to stay connected with.

Sam Rebotsky
Well, you're making good progress, it's the ability of finally funding everything and hopefully, you get to completion, the rotavirus soon, so you could start selling more and you have the ability to sell more of the First Defense overseas with your expansion. And hopefully, you could get some more sales there and move on. Good luck, Michael.

Michael Brigham
Thank you, Sam. I appreciate it. That's exactly where we're at, with our sales teams charged and ready to go for it.

Operator
And our next question comes from Doris Rossiter of Shattemac. Please go ahead.

Doris Rossiter
Mike and Adam, congratulations on all the progress you are making. It sounds exciting. I'm just wondering, Mike, if you could talk a little bit more about what the commercial rollout of Mast Out will look like. Is there any kind of qualitative things you can tell us? Will you be going to conferences to present it? I'm just wondering how you get word out about it? And what type of timeline you would be expecting for the launch?

Michael Brigham
Yes. So of course, it depends on this final stage of the regulatory development. But our timeline was getting that first submission in 18 to 6 months review. We do anticipate needing

to make a second submission, that's just almost always the case. I just don't anticipate there will be a unique exception to that rule. So a few months in between then a second submission and then there's about 90 days on the back end which is much more administrative. But very quickly, that gets us out to the second half of 2019. So timing, that's how we see the approval timeline layout.

So, sales and marketing strategy. One baby step, it's a really small step, but it's an important step with the hiring of the new rep which we anticipate we're going to do here shortly, just grow the team a little bit based on just First Defense volume. But that team's going to need to grow to launch a product as big as Mast Out. But that would come out later in 2019. And I would also, Doris, reference you, if I may, over to the Q, where, having just got that filed a few minutes ago, you probably hadn't had a chance to read it yet. But I'd point you to Page 28, where we actually tried to lay this timeline and the sales dollar launch plan out in pretty good detail, the best view we could have to what would happen in 2019 and the first few years' right after that.

Doris Rossiter
Okay. I'll take a look. So you'd actually expect to start seeing sales then in later 2019?

Michael Brigham
We do. We need to stick to that very, very challenging timeline of getting that first submission in. Once that first submission is in, then the clock does become much more predictable. Getting that first submission in the earlier part of 2018 gives us time to make two submissions and turnaround in between first and second and get to an approval by the second half of 2019, yes.

Doris Rossiter
Okay. I'm just wondering then once, let's forget about the regulatory part of it, you're past all that and now you're in launch mode. Do you have any kind of feel for what the cadence of the roll-out will be? Is it going to be like a slow build? Or is going to be a big pop at the beginning and then a slowdown? Do you have any sort of feel for the cadence of the sales growth for Mast Out?

Michael Brigham
Yes. We're going to work with the same distributors that already know us with First Defense. We're going to leverage our pretty small force. It will be a sales force; it'll be a little bit bigger at that point to really get the word out there in advance of 2019 but more aggressively with the approval. In the section of the Q on the MD&A on Page 28, we did answer the question to the extent we can predict it and estimate it. I know I'm going to be wrong, I just don't know if I'm a little high or a little low. But looking at first year's sales in the $5 [million] to $6 million range.

Doris Rossiter
$5 [million] to $6 [million]. Okay, so that will be a first full year?

Michael Brigham

First full 12 months, exactly.

Doris Rossiter
Okay so that would possibly be a 2020-type number.

Michael Brigham
Yes. Maybe it's fourth quarter '19, first 3 quarters, like that. We need a rolling 12 months to get that product out there and hit that kind of level in first year sales. But we think it's possible, but we haven't done it yet.

Doris Rossiter
Okay. And then if you were just to focus on the US market, your current clientele. Do you have an idea of what the total potential is over time, the sales of Mast Out?

Michael Brigham
Again, it's a projection. It's what I say about all projections, it's going to be wrong. I just don't know if it's a little high or a little low. But that same section there, your questions...I must have, in a way, anticipated, because I think we've got better detail on this in this Q than perhaps previously. But trying to get out to $36 million in year five, but understanding that incremental investment will be required to hit that full level of sales because that's above the capacity of this current plant. So we don't want to make that investment before we have proven that, that first and even second year worth of sales and market acceptance. But we have laid out, what we think the market potential is and how we can achieve it with today's facility and then the investment that will be required to increase capacity subject to that proven market acceptance.

Doris Rossiter
Okay, so will the current plant, the shell anyway, is built for the next five years; it's just you will need to add some more lines in there. Is that correct?

Michael Brigham
Right, it's two phases. So the current shell is constructed with one production line with space for the second, once we exceed twice of the capacity that we launch with then we will be looking at a completely different building and would not even be on the same site, there is not even square footage for it, there is not even land for it.

Doris Rossiter
Okay, but the current building would serve you out to that year five?

Michael Brigham
No, we wouldn't quite get there. I will read my section from that page 28. If annual sales exceed approximately $25 million, we would have to evaluate all Nisin supply options factoring in and experience and yield improvements at that point, building an additional Nisin production facility to meet our needs. It might be the most cost effective way to go. So that would be a decision we would make out of that point with sales under our belt.

Doris Rossiter
Okay. Mike, this is a lot of detail. Thank you so much, I appreciate it.

Michael Brigham
Yes, it is a great question. I feel good, the last paragraph on page 28 is exactly where your question is going. I think you will find the answer there, but we have touched on it here, too.

Doris Rossiter
Okay. Yes, I will read it, in fact, I just found it now. So you're right, it's already on the internet and available for consumption so...

Michael Brigham
These are facts, these are projections, these are these market estimates have been available previously. I just think we are at the point now and you've proven me right here. We need to put in one concise place and that's where it is. I think it pulls all the capacity, the launch, the timing altogether in one relatively long paragraph, but it's packed with the answer to your question.

Doris Rossiter
Thank you, Mike, I appreciate that.

Michael Brigham
Great, Doris.

Operator
Again, if you have a question, please press "*" then "1."

Our next question comes from Tom Fox, a private investor.

Tom Fox
Hi, thank you for taking my question. My question was actually about the FDA approval process. It seems to me like there is a step involved where you guys need to show the FDA in their laboratory, how to detect Nisin in the milk. I have just read this based off of what I have seen on the website. Yes, I was wondering if there is any update on that or if you guys have achieved that by now.

Michael Brigham
No, to be honest the timeline is driven by the manufacturing technical section that we have just been discussing. Inside of that is another technical section. So the manufacturing is called chemistry, manufacturing and controls. Here we are referring to the human food safety. The most important piece of human food safety is the zero milk discard. So we were granted that claim, I believe that was 2012, I will just check that real quick. And when they granted that, they said...I am sorry, Q2 2011. So back in 2011, we got the zero milk discard claim out of human food safety and since then we have been working on this method as you described it very well to detect Nisin in milk. So that's at its later stage right now, that process, that

submission is very active. We think we can get it done by the end of the first quarter of 2018. If not, soon thereafter, it is in that time frame of the work being done now and then a six month submission. So very quickly, we will have six month FDA review period in there, we are out into first quarter of 2018. But we've always seen that technical section as not being critical path because the manufacturing one will run longer. But nonetheless, your point's well taken, we will be very happy when we just check that box and get that method that you just described, detecting Nisin in milk validated and transferred over to the FDA lab.

Tom Fox
Okay, thank you for taking my question and congratulations on your continued progress.

Michael Brigham
Okay, Tom. Good to meet you. I appreciate it.

Operator
This concludes our question and answer session. I would like to turn the conference back over to Mr. Adam Lowensteiner for any closing remarks.

CONCLUSION

Adam Lowensteiner
Thanks, Andrea. I like to thank everyone for participating in today's call. We look forward to talking with you again at the conclusion of the third quarter around November 9th. Have a great week. Thank you.

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