



IMMUCELL CORPORATION
(Nasdaq: ICCC)

ImmuCell

Developers of 

First Quarter Fiscal Year 2019
Financial Results

Tuesday, May 14, 2019
9:00 a.m. Eastern

CORPORATE PARTICIPANTS

Michael Brigham – President and CEO, ImmuCell Corporation
Joe Diaz – Managing Partner, Lytham Partners

PRESENTATION

Operator

Good morning, and welcome to the ImmuCell presentation, there will be an opportunity to ask questions. To ask a question, you may press star then one on your telephone keypad. To withdraw your question, please press star then two. 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

Thank you, Carl. Good morning to all of you on the call today. This is Joe Diaz. I'm with Lytham Partners. We're the Investor Relations consultant firm for ImmuCell. I'd like to thank all of you for joining us today, and as a reminder, this call is being recorded today.

I would like to preface this discussion 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 that was issued last night as well as on the company's periodic filings with the SEC, which can be obtained from the SEC or by visiting the company's Investors section via at immucell.com.

With that said, let me turn call over to Michael Brigham, President and Chief Executive Officer of ImmuCell Corporation, after which we'll open the call for your questions. Michael?

Michael Brigham

Thank you all for taking the time to join today's call. I do appreciate that. You all have access to the details of our financial results through the press release and the Form 10-Q that we filed last night, so I will not rehash all the details. I am going to speak to you about a few things that I think are most important about these results and our business strategy going forward.

So first, let's start with the top line. Very strong sales for the first quarter of 2019; in fact, an all-time record. The first quarter is always our best quarter with the seasonality of our sales, and this was the best first quarter ever. So let's look at these numbers in four different ways: for the quarter and for the trailing 12 months, and then within the quarter let's look at the GAAP numbers as in the sales shipped out our door, and then make a non-GAAP adjustment for affecting the backlog.

So with that, the first quarter on a GAAP basis, as you've seen, up \$1.5 million. That's a 53% increase to \$4.4 million. On a non-GAAP basis, again adjusting for the backlog of orders, we're up \$679,000 or 19% to \$4.3 million.

Now going over to the trailing 12 months. So, on a GAAP basis, revenue was up \$2.7 million or 28% to \$12.5 million; and non-GAAP, again, adjusted for the backlog of orders, up \$1.2 million or 11% to \$11.9 million. So a lot of numbers there, a few different ways to look at it. But bottom line, a record quarter for us, which is really exciting to achieve that in this very difficult dairy economy. The milk prices have been sitting at really an all-time low for quite some time now.

I will add here in March and April we see some improvement in that milk price, but I don't want to underestimate the impact the sustained low milk price had on our industry. We've seen many, many farms go out of business or just left the industry, so the market is shrinking. Those that are left, those that are surviving this period of very low milk price are progressive and they're really set up as good customers for First Defense, as we provide a quality product to a progressive dairy farmer keeping those baby calves healthy, and they value our product.

A little more detail on why sales are up, at least my thinking behind why are sales up. First and foremost, I want to say our sales team is just doing a great job. We now have nine people spread across the country in strategically focused areas of large dairy impact, and they're out on farms and they're out with distribution every day just doing a great job.

Second, a lot of this growth is due to Tri-Shield First Defense. It's created a new market opportunity for us. This is the addition of a rotavirus claim to our legacy Dual-Force First Defense, the dual force being the E. coli and corona product; Tri-Shield being the E. coli, corona plus rota. So, what are people doing for their newborn calves?

They're doing one of three things: they're either treating the calf, or they're doing nothing, or they're vaccinating the dam - in other words, the mother cow. So, with this addition of the rota claim, we look like a vaccine, with this broad coverage of the three claims. We're educating, we're promoting this idea of going Beyond Vaccination, and that's going really well. Producers are really eager and willing to listen to an option to sticking a needle in a cow, vaccinating the dam and then hoping that she will produce better colostrum to be fed to the calf. Instead, with Tri-Shield and with Dual-Force we're saying treat that calf and save that needle, save that stress on the mother cow.



For years, we've been competing with what I view as superior technology at the calf level with our bivalent product. Now we're competing against these dam vaccines, which we see the market opportunity on the dam vaccine is about twice the size as these calf-level products. So, Beyond Vaccination is working and that's fueling a lot of our growth.

Sales demand is still outpacing production supply. The shortage of supply has been largely due to our lack of enough vaccine, the vaccine we use in our production process. So throughout 2018, our manufacturing team and our product development team have been doing some great work on scaling up the quantity of the vaccine we produce, again, the vaccine used in our manufacturing process. With the achievements that they've reached here in the first quarter of 2019, I feel confident that's a fix to our shortage.

Now keep in mind this is a long production cycle, so the fixes we're making in the first quarter are not really available in the form of finished doses for sale until about six months later. So what we expect is to have quarterly production output up to approximately \$1.5 million beginning in the second half of 2019. So that's kind of the top line.

Let's take a look at the bottom line. You did see we reported a small profit. I think it's really important to take a look at some non-GAAP measures on this financial metric as well, so I've provided that in the press release. I think it's important that we tack on the depreciation expense, amortization expense, stock option expense, income taxes, these significant expenses that are non-cash that we can, on a non-GAAP basis, add back to our net income.

Moving on to the balance sheet. The equity raise; we completed a very strong equity raise here at the end of the first quarter. Net proceeds were \$8.3 million. This has strengthened our balance sheet, and it enables us to fund two important growth initiatives. So first, about \$3 million of these proceeds will go to increasing First Defense production capacity. We're going to increase our liquid processing capacity by 100% and our freeze-drying capacity by about 50%. We expect this investment to increase our production capacity from what is currently about \$18 million to approximately \$27 million. That's an annual production output figure.

The second use of these proceeds, about \$4 million has been earmarked for Re-Tain because it's increasingly likely that we're going to invest in our own aseptic filling capability. So we are making progress on a short-term contract with our current aseptic filling CMO as we evaluate the best options for the long-term strategy, and as you should anticipate, we will issue a press release when we have this resolved, up or down.

I focused my comments on the results that are most important to me rather than repeating numbers and details that you can access on your own through our press release and our Form 10-Q. I value our time together, and hope you agree that this is a productive approach for the call. This saves more time for your questions, which are important to me.

So with that said, let's have the operator open up the lines for your questions.





QUESTIONS AND ANSWERS

Operator

We will now begin the question and answer session. To ask a question, you may press star then one on your touchtone phone. If you're using a speakerphone, please pick up your handset before pressing the keys. To withdraw your question, please press star then two. At this time we will pause momentarily to assemble the roster.

And our first question today comes from Kevin Ellich with Craig-Hallum. Please go ahead.

Kevin Ellich

Good morning, Michael. How are you doing?

Michael Brigham

Hey Kevin, very well. Thanks for joining the call.

Kevin Ellich

Yes. Congrats on the nice quarter. I guess to start off with, what really did you see in the market that changed this quarter that really drove the strong sales that you saw? Was it just better supply of Tri-Shield, or can you give us a little bit more color as to what's going on behind the scenes?

Michael Brigham

Yes. I was careful to point out some non-GAAP numbers. I do think we need to look at that backlog. We did have a big backlog in the second quarter of 2018, \$901,000, so that product did not ship in the comparative quarter of prior year. So that's one factor, just sort of the math, the timing of production and release of products. So that's one adjustment.

Two is what I really care about is getting the product out the door, and that's our GAAP basis. We got more product produced and more product out the door in first quarter, so yes, number two would be better production supply.

Number three out of four would be, as I mentioned, Tri-Shield. We're just gaining great traction with that product. And the more we produce, the more we sell. We're just selling it as soon as we make it at this point.

And number four would be the beef impact. I think we had better access to the beef market with Tri-Shield. Beef is very seasonal, all the calving is going on here, February, March, April, so that beef seasonality and with the addition of Tri-Shield, and more of it available for sale, definitely helped the first quarter.

Kevin Ellich

Sure. That's helpful. And then I think I caught your comments about Norbrook, and are the plans to still do the aseptic filling, and what's the timeline on Re-Tain with the FDA?

Michael Brigham

Yes. So, I do feel, and have said, we're making progress in Norbrook, but it really doesn't mean that much to you or to me or anybody else until I get a signed agreement. That signed agreement will be the subject of a press release. We will announce that as soon as we have it. So making progress there, but I've got to get it finished.

And then, ultimately, that really drives the timeline, so I think we've said the quicker we can get going with the CMO, I think that's the fastest way to get FDA approval and initial launch. But we are understanding that that will not be a long-term solution; Norbrook would like us to exit as they focus their business on proprietary products. What we're looking for is a short-term bridge to our own aseptic filling, and the success of those two events will trigger the answer to your question; win FDA approval sooner, 2021, with a CMO; later, 2021, 2022 without that CMO.

That's priority number one around here is getting an agreement and defining that path as well as the timing of that investment. To bring that long-term it's going to come in-house, and that's an important use of proceeds from that equity raise is to enable us to do that. But again, fastest and quickest approval and launch with a CMO is the best recourse. So, a work-in-progress, but making progress.

Kevin Ellich

That's good to hear. And then of the \$3 million of proceeds that are going to be used to increase production capacity, how long will that take before you do have that increased supply?

Michael Brigham

Yes. The good news is we raised some money and we're starting the project now, so we'll have it in place when we need it, which is the second half of next year. Parts of that will come online as this project gets started now and into the end of this year and the beginning of next year. But ultimately, some of this equipment has 12- to 15-month lead times on it, so I don't expect to have it complete until the second half of 2020, and that's good. As I mentioned, the current capacity at about \$18 million, moving it up to \$27 million by the end of next year, will work well for us.

Kevin Ellich

Got it. And just two last ones for me. Well, in the Q, I saw, it looks like company C in your concentration section, it's now less than 10% of revenue. I guess that it's less than 10%, down from 11% from a year ago. I'm wondering what's the dynamic there; I see customer A shot up to 43%, so a big increase.

Michael Brigham

Right. So, the way I look at significant customers is A and B are our two big distributors. Yes, they're unnamed in the Q, but I have no issue naming them. It's going to be the same for all animal health manufacturers. Most of our sales go through Animal Health International and MWI. I group those two together, and they are consistently our largest two distributors. Again, they are consistently almost everybody's largest two distributors. They're just big and getting bigger, very effective, good people to work with. C, D and E, the next level, is smaller and a bit random. They're more regional and they'll jump up and down, but always a little smaller than the top two.

Kevin Ellich

Got it. That's helpful. I appreciate the time. Thank you, Mike. Wait—



Michael Brigham

Thank you. Yes?

Kevin Ellich

Gross margin really saw a nice improvement both sequentially and on a year-over-year basis. Is that just leverage and the significant acceleration in revenue growth or anything else going on with the gross margin improvement?

Michael Brigham

We have two things going on. All of the gel formulas, so we have a Dual-Force bivalent in a gel and the Tri-Shield trivalent in a gel. The gel formulas are more expensive to make and we're selling more and more of them, so that's sort of working against the gross margin percentage. But at the same time, we have a lot of fixed costs. A good chunk of our labor is fixed and a good chunk of our overhead is fixed, so as the volume increases, we're seeing that benefit. So the two kind of net out. Just the throughput really helps us. I think the bottom line is that percentage is important, but what we're looking at is accepting a little bit lower percentage of sales so that we can grow the total dollar, and that's how we pay the bills.

Kevin Ellich

Got it, okay. Thanks, again.

Michael Brigham

Thanks, Kevin.

Operator

And our next question comes from Irwin Gomberg with Irwin Investments. Please go ahead.

Irwin Gomberg

Yes, congratulations on a record quarter. Can Re-Tain cure clinical mastitis? Is that possible?

Michael Brigham

The answer is yes, it's possible. Our label claim is going to be subclinical mastitis, and I think post-approval we don't want to put any confusion into the regulatory submission with a new look or a new twist, but post-approval, I think we'd come back and look at clinical and run that study and hope to get that claim. But right out of the chute, the label claim is going to be subclinical. In a sense, what you're doing is preventing some clinical by not letting that cow get clinically infected, so we have sort of that approach of prevention to clinical. And then we come back and I think some people will use the product, it's not going to hurt the clinically infected cow, but we'd come back post-approval and seek that claim.

Irwin Gomberg

Right. Can you talk a little about your foreign markets, when do you plan to try and go into those foreign markets?

Michael Brigham

Yes. Irwin, are you talking to with First Defense here?



Irwin Gomberg

Yes.

Michael Brigham

Yes. So, right now we are just really North America. We do get a little bit of product into Japan and South Korea, but Canada and U.S. is our market today. Part of the thinking behind this capacity expansion is right now getting some foreign international territories really wouldn't help us. It would just put us in a tighter supply situation. So we're trying to time the two out. As we increase this capacity expansion, we are now currently starting the regulatory work to look at these new territories, get into these new territories, but be ready to supply them with the increased production capacity.

So I think the short answer to your question is it's not going to happen in 2019. We're making progress on those regulatory efforts in 2020 to hit some markets in 2021 and 2022. I think that would work really good to match up production and supply with a new demand.

Irwin Gomberg

Right. Well, thank you.

Michael Brigham

Thanks, Irwin.

Irwin Gomberg

Sure.

Operator

Once again, if you'd like to ask a question, please press star then one. And our next question comes from Tom Fox, private investor. Please go ahead.

Tom Fox

Hello, and thank you for taking my question. It's about the third-party manufacturer. As I understand it, this is the first time a drug like this has been manufactured on this scale. It says on your Form 10-Q that Norbrook Laboratories covers the product formulation, aseptic filling and packaging services. Does this mean they had to learn how to do all this and manufacture it for you? Or did you learn how to do this in your scaled down pilot facility and they are just the ones responsible for carrying out the process? In general, how dependent are you on them to manufacture this drug on a commercial scale? Thank you.

Michael Brigham

Right. It's a great question. I think the best way to answer is just to maybe step back and I'll clarify the difference between drug substance and drug product. So what ImmuCell does uniquely is make the drug substance, and that is the \$21 million investment we made in the facility. That's where we've made the registration batches for the FDA submission. The first submission of that drug substance has been made to the FDA, and it does not include the drug product. So the drug product is then simply taking the drug substance and filling it into a syringe. I say simply, it's not that simple. It has to be done aseptically, and Norbrook is a world-class leader in this. There are others. We have been with Norbrook for many years. They do it for many products, so they can plug our product into their existing line with an existing FDA approval and really simplify and accelerate the approval process.



So what we're looking at is that idea of we need them on drug product, but we want to over time get control of that process and not be dependent on any CMO and be able to do that aseptic filling on our own. So it's a two-step process, agreeing to this short-term like approval and launch, agreement with the current CMO, and then longer term in making that investment to not be reliant, as you suggested, on a CMO.

Tom Fox

Okay. Thank you.

Michael Brigham

Thanks, Tom.

CONCLUSION**Operator**

And 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 Brigham

Joe, I don't know if we lost you there. But Joe was just going to wrap, and I'll join him in thanking you for participating in today's call. We look forward to talking to you again to review the results for the second quarter of 2019 around the middle of August. So again, I encourage you all to review our SEC filings for the full unaudited first quarter details, unless, Joe, you wanted to add anything?

Joe Diaz

Other than have a great week. Thank you for being on the call.

Michael Brigham

Great, Joe. Thank you.

Operator

The conference is now concluded. Thank you for attending today's presentation. You may now disconnect your lines at this time, and have a nice day.

