

Cryoport, Inc.
Full Year 2018 Earnings Q&A Call
March 7, 2019

CORPORATE PARTICIPANTS

Todd Fromer, KCSA Strategic Communications, IR

Jerrell Shelton, President & Chief Executive Officer

Robert Stefanovich, Chief Financial Officer

Mark Sawicki, Chief Commercial Officer

CONFERENCE CALL PARTICIPANTS

Andrew D'Silva, B. Riley FBR

Richard Baldry, ROTH Capital

Larry Smith, SmithOnStocks

PRESENTATION

Operator:

Greetings, and welcome to Cryoport, Inc. Full Year 2018 Earnings Q&A Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow Management's introductory remarks. If anyone should require Operator assistance during the conference, please press star, zero on your telephone keypad. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Mr. Todd Fromer. Thank you, Mr. Fromer. You may begin.

Todd Fromer:

Thank you, Jessie. Good evening everyone and good afternoon to everyone on the West Coast.

Before we begin today, I would like to remind everyone that this conference call contains certain forward-looking statements. All statements that address our operating performance, events or developments that we expect or anticipate occurring in the future are forward-looking statements. These forward-looking statements are based on Management's beliefs and assumptions and not on information currently available to our Management team.

Our Management team believes these forward-looking statements are reasonable, as and when made. However, you should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. We do not undertake any obligation to publicly update

or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results, events and developments to differ materially from our historical experiences and our present expectations or projections. These risks and uncertainties include, but are not limited to, those described in item 1A Risk Factors and elsewhere in our annual report on Form 10-K filed with the Securities and Exchange Commission, and those described from time to time in other reports which we file with the Securities and Exchange Commission.

I would now like to turn the call over to Mr. Jerry Shelton, Chief Executive Officer of Cryoport. Jerry, the floor is yours.

Jerrell Shelton:

Good afternoon, ladies and gentlemen. Thank you for joining us today. With me this afternoon is our Chief Commercial Officer, Dr. Mark Sawicki and our Chief Financial Officer Mr. Robert Stefanovich.

As announced, we have changed our format for this call. So, hopefully you've seen from the conference call instructions in today's earnings release explaining that we are using a different format for today's call. Instead of delivering prepared remarks, we have uploaded our 2018 year in review document in the events and presentation page of our Investor Relations website. This document provides a review of our recent financial and operational performance and a general business outlook. Hopefully you've had a chance to read it, by now, but if not, I would encourage you to go to our website and download it.

This conference call will therefore be in the format of a questions-and-answer session, where we will address queries investors and analysts have regarding our Company's results. Our expectation is that the year in review document will serve as a useful resource for those of you interested in acquiring a deeper understanding of our progress. Then this new approach will provide more room for discussion.

Now, I'll turn the call over to the Operator to open the telephone lines for Q&A.

Operator:

Thank you. We will now be conducting the question-and-answer session. If you would like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate that your line is in the question queue. You may press star, two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key. One moment please while we poll for questions.

Thank you. Our first question is from the line of Andrew D'Silva with B. Riley FBR. Please proceed with your question.

Andrew D'Silva:

Good afternoon. Thanks for taking my questions. I read through your year in review. I'd have to admit, I did have another company report at the same time, so I'm going to review it one more time, but I did see that you mentioned that four MAAs and two BLAs were filed last year. I was curious, out of those six, how many of those were Cryoport partners?

Jerrell Shelton:

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Andrew, Mark will answer that question.

Mark Sawicki:

Of the six that were filed, five of them were related to business that we're supporting.

Andrew D'Silva:

Okay, great. Have you seen—this was probably the biggest quarter-over-quarter from a number standpoint, increase in total clinical trials that you've been in, at least in recent history. Could you maybe describe what you view as the catalyst that took place during the quarter? Are you seeing perhaps clients that were previously utilizing other forms of cryogenic shipping and storage shift over to what you're looking at or what you're offering? Then, this is more related to internally within existing customer, for example, with Novartis, who has a numerous trials ongoing and newer subsidiaries as well.

Jerrell Shelton:

Well, that certainly has a lot of components to it, Andrew, it's a long question. So, because of its complexity, I'm going to turn it over to Mark Sawicki.

Mark Sawicki:

Andrew, yes, so couple of things to take into account when you're looking at our trial number for this particular quarter. First and foremost is, yes, we've seen additional growth in our network of trials that are being supported, and this comes from two different sources. One is, us pulling third-parties in that may have been supported by an alternative option, and the second is, expansion of clinical trial portfolios within our existing trial base or client base. But, the second component as we've started also reporting Europe, as an additional number in the number of trials reported out of Europe, because it has hit a critical mass and that number for the quarter was, well a net add of about 40 trials for the overall number. So, it's a combination of both.

Andrew D'Silva:

Okay. I see. So, in the years past or quarters past, it was just the U.S. trials that you were including that number?

Mark Sawicki:

Correct. We hit a critical mass in Europe. So, we felt it was appropriate to start reporting on that as well.

Jerrell Shelton:

Andrew, actually you'll see in the year-end overview, there's a different color for the European trials on the chart on Page 5.

Andrew D'Silva:

I see, I saw that, I just haven't fully digested everything just yet, but I will review it one more time, absolutely. This is just obviously a current event with Scott Gottlieb resigning effective, I guess, next month. I was just curious how you see that and if you view it potentially impacting anything that you're doing or benefiting it, and I know, last quarter you were out pursing the ISO 276, just curious how that all kind of ties together?

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Jerrell Shelton:

I didn't get the full question. Did you get it?

Mark Sawicki:

Yes. So, the Gottlieb announcement, from our perspective, it's far too early to really honestly get any understanding of whether or not it'll have an impact on the regenerative medicine space. I think everybody is seeing the quotes that he put out before he resigned back in January where he anticipated up to 20 filings a year within 2021-2022 timeframe. Our expectation and hope is that, obviously that's absolutely correct. But, it's far too early to understand whether or not his resignation will have any impact on that overall strategy.

Andrew D'Silva:

Okay, perfect. Last two-part question, actually. Just related to the off-the-shelf market and your potential M&A strategy, so this is a question I get from investors a lot just related to how you play in the off-the-shelf space? When you're thinking about M&A, is it related to repository activity, or are you thinking about things from a different aspect?

Jerrell Shelton:

Andrew, we have talked about this a number of times in the past and we're very measured on what we do, what we entertain in the M&A area, and we'll look at things in the space that we're in right now in terms of increasing our depth or we'll look at adjacencies to expand our footprint. What I mean by where we are today, we'll look at software companies, we'll look at components of manufacturing that could provide strategic advantage.

We'll also look at adjacencies and we talked about some of those in the past, like storage and like, again, software and other services that we think fit with our Company. So, we definitely are looking at them, but we have yet to pull the trigger.

Andrew D'Silva:

Great, and the off-the-shelf side of business?

Jerrell Shelton:

You're talking about the allogeneic?

Andrew D'Silva:

Yes.

Jerrell Shelton:

Let me turn that to Mark, because that is a developing part of our business, and I'll turn that to Mark, it's a great part of our business and we are looking forward to that development. So, Mark, (inaudible).

Mark Sawicki:

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Yes, our allogeneic portfolio is very strong. We're extremely active with most of the big players in the space that are dealing with allogeneic late phase clinical pipeline and we're well situated to support any eventual launch activity on any of those therapies on a global basis.

Andrew D'Silva:

Okay, perfect. Great. Well, that's all I have. Thank you very much and look forward to talking to you guys offline.

Jerrell Shelton:

Thank you, Andrew.

Mark Sawicki:

Thanks.

Operator:

Thank you. As a reminder, ladies and gentlemen, to ask a question at this time, please press star, one on your telephone keypad.

Our next question is from the line of Richard Baldry with Roth Capital. Please proceed with your question.

Richard Baldry:

Thanks. When I look at the past couple years of data either including commercial or not, it appears there is a stronger seasonality starting the year in Q1 periods than ending the year in Q4s. It's a small amount of data. Do you think that's a real seasonal pattern or is it too small a sample, there's reasons to not necessarily believe that when we think about seasonality in revenue for 2019 versus maybe '18 and '17's cadence?

Jerrell Shelton:

Rich, we think it's too early to call that. We do deal with lab products and we can be affected by releases, we can be affected by weather, we can be affected by a number of things. But it's too early for us to call seasonality with any kind of clarity.

Richard Baldry:

We saw an approval in Japan of its first regenerative therapy through its systems. Do you feel like there is a need to put another dedicated facility in the APAC area, similar what you've done recently in Europe, or is it too early for that, how do we think about your infrastructure expansion plans in 2019 and beyond?

Jerrell Shelton:

Rich, there is no question that APAC is developing and we certainly have our audit (phon), we support a number of trials in APAC, today. So, we are evaluating that and there will be more to come on it, but I have no further comment on that at this point.

Richard Baldry:

All right. Thank you.

Operator:

Thank you. Our next question is from the line of Larry Smith with SmithOnStocks. Please proceed with your question.

Larry Smith:

Thank you. I do a calculation to try to relate your revenues to those of Kymriah and Yescarta. So, what I simply do is take the revenues that you report from commercial products and divide by the revenues reported by Gilead and Novartis.

So, if I do that, I get that your revenues were 0.61% of Yescarta and Kymriah sales in the first quarter, 0.53% in the second quarter, 0.56% in the third quarter and 0.74% in the fourth quarter. If my numbers are correct, that's a very significant increase in the percentage that you receive of CAR-T revenues, and I'm curious as to whether that can be explained or whether it's just kind of random, where those numbers (inaudible)?

Mark Sawicki:

Yes, I'd be happy to answer that. So, one of the things that we're always working to do is diversify our revenue streams within our existing relationships, and as these therapies launch on a more global basis, there's a lot of other ancillary or other support activities from our program management standpoint, consulting, validation work and other things that tie into supporting the launch activities in the ongoing ramps of these particular projects. So, it's by design. You know, our goal always is to try to obviously increase the depth and the reach of what we're doing for these accounts. So, that's evidence of that effort.

Larry Smith:

If my numbers are correct that there is a big increase in the percentage in 4Q over 3Q, should I use that to project revenues forward into the 2019 quarters? I used 0.74% of revenues as opposed to something like 0.56% of Kymriah and Yescarta revenues?

Jerrell Shelton:

We'll direct that question to Robert Stefanovich, Larry.

Robert Stefanovich:

Yes, in terms of the revenues, as Mark already mentioned in his response, we are broadening the revenue with both Novartis and with Kite, as well as broadening the revenue stream within the commercial launch support. I mean, when we look at tying it directly to revenue, you can work with that percentage.

I'd probably use an average of the last two, three months going forward. But then as you go into the latter part of next year, you should see that percentage increase further just based on the additional activities that we provide related to consulting services, engineering services and other services that we provide to both Kite and Novartis.

Larry Smith:

Okay. Let me ask you a hypothetical question. As you're moving from CAR-T to (inaudible) and gene therapy products where the number of patients may be somewhat less, my calculation and my estimate is that you net about three—that Kymriah and Yescarta are selling in a net price of about \$325,000 per patient.

What I'm curious is, if you were to supply logistics to a gene therapy company which doesn't have the same patient population as of the CAR-Ts, where you might only be dealing with much less number of patients, but where the net price might be a \$1 million or \$2 million or \$3 million, would the amount of revenues that you derive from such a gene therapy company be proportional to revenues or proportional to number of patients treated?

Jerrell Shelton:

So, revenue or patients, it'd be more related to patients and dosages, Larry. It depends on the indication and it depends on the protocol for the therapy. So, both of those things would relate to the patient as opposed to the revenue.

Larry Smith:

Okay. If I could ask one final question. In the case of allogeneic therapies, CAR-T therapies are—which are way down the line, of course. It seems to me that you will probably need an on-site cold facility, if the allogeneic cells kept on site, and if so, is that a meaningful new part of your business, or how would you put that in perspective if my assumption is correct?

Jerrell Shelton:

Well, Larry, your assumption is partially correct. There is a variety of models developing right now for both autologous and allogeneic, and there will be shipments of allogeneic in bulk as well as being stored onsite. So, we are in touch with our clients and we are in touch with the market and we are developing various models. As I always say, in this business, you have to be sort of in the athletic stance, be ready to move in any direction because the clarity is not yet there. I mean, this is an evolving market and we're an evolving company serving that evolving market. So, it's not clear exactly how the impact of allogeneic—but we are ready to serve either market. We think the allogeneic market will be very, very good for us and we do have several models that we are ready to deploy when required.

Larry Smith:

Okay. Thank you.

Jerrell Shelton:

Do you have anything to add, Mark?

Mark Sawicki:

Yes, let me just add one other element on that. One of the keys that we do is, we work very, very closely with our client base, almost on a strategic basis to help define what that product life cycle looks like. So we sit down with these folks as they go through that commercial readiness process and we play a fairly large role in that strategy. Regardless, like Jerry said of whatever overall strategy they have from a market access standpoint, we have the ability to have a significant role in helping design that.

Larry Smith:

Okay. Great quarter. Terrific execution. Congratulations, and thanks for taking my questions.

Jerrell Shelton:

Thank you, Larry.

Operator:

Thank you. There are no further questions at this time. So, I'd like to turn the floor back over to Management for closing comments.

Jerrell Shelton:

Well, thank you all for joining us today. It was a very simulating brief discussion. I hope you like our new format and that it helps you see the exciting future we see ahead of us at Cryoport. So, until the next call, we bid you farewell.

Operator:

Thank you. This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation.