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Cryoport, Inc.

Fourth Quarter Calendar 2017 Results Call

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PRESENTATION

Operator:

Greetings, and welcome to the Cryoport Inc. Fourth Quarter Calendar 2017 Results Conference Call. At this time all participants are in a listen-only mode. A question and answer session will follow the formal presentation. 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. I would now like to turn the conference over to your host, Todd Fromer. Please go ahead.

Todd Fromer:

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. Jerrell Shelton, Chief Executive Officer of Cryoport. Jerry, the floor is yours.

Jerrell Shelton:

Thank you, Todd. Good afternoon ladies and gentlemen. We appreciate you joining us today.

With me this afternoon is our Chief Commercial Officer, Dr. Mark Sawicki, and our Chief Financial Officer, Mr. Robert Stefanovich. Later during this call, Dr. Sawicki will provide you with his comments on our commercial activities, and Mr. Stefanovich will explain our financial results for 2017.

Let me start by saying, 2017 was a very good year for our company. We achieved many of our goals and entered the next stage of our growth trajectory. Some of our notable achievements throughout the year included upgrading our internal operating systems, adding strength to our bench of personnel, securing 85 new biopharma clinical trials and, most significantly, announcing that Cryoport had secured long-term commercial logistics agreements to support the world's first two FDA-approved CAR T-cell therapies: Yescarta™ by Gilead's Kite Pharma and Kymriah™ by Novartis. These seminal milestones cemented our position as the global leader in temperature-controlled logistics and established a solid foundation for future revenue growth and profitability.

There's no doubt we are getting attention in the marketplace, and yesterday *Wired* magazine ran an excellent feature article on our company, entitled "Inside the Company Delivering the Next Generation of Cancer Therapies", which highlights our leadership position, some of our clients and our advanced technologies. I would encourage you to visit our website to access a link to this article.

Now, turning to the upgrading of our internal operating systems, we think it is important to invest in advancing our technologies and our people, who arm us with market-leading competencies. Cryoport's end-to-end solutions are powered by the most advanced temperature-controlled technologies in the life sciences industry, including our Cryoportal™ Logistics Management Platform, our SmartPak II™ Condition Monitoring System and our family of Cryoport Express® Shippers. In 2017, we further expanded our solutions offering with the introduction of our Cryoport Express® C3™ shippers. C3™, standing for "Cryoport. Certified. Cool.", supports the front end of some autologous therapies that require temperature-controlled transportation within the 2° to 8° Celsius temperature range.

This is just one example of our commitment to innovation, which is at the core of Cryoport's philosophy, and with this in mind, we continue to invest in building out our company's infrastructure and services to ensure we are positioned to support the expansion of our services in our markets of animal health, reproductive medicine and biopharma.

Of course, our fastest-growing market today is the global regenerative therapy market, which we vigorously support, beginning with the scheduled ramp-up of Novartis' Kymriah™ and Gilead's Yescarta™. Gilead recently stated that they have 28 points-of-care centers certified and that, by mid-year, they will have enough of these qualified centers to treat approximately 5,000 eligible Yescarta™ patients per year.

In order to support our current forecast of demand in all of our markets, construction is underway for two new state-of-the-art Cryoport Global Logistics Centers, one located in the Eastern United States and the other in The Netherlands. Both are scheduled to open during the first half of 2018. They will support current and new clients as well as anticipated therapy approvals in the European Union and the United States. One example of our growing demand in Europe is our recently announced support of the clinical trials for TiGenix's SEPCELL for the treatment of sepsis.

As a result of our continuing investment in research and development, our company remains at the forefront of innovation; we continue to build our reputation in the life sciences for unrivalled technology and service, and our markets are continuing to recognize this, as evidenced by the growing strength of our client list, to which we added a net total of 15 new biopharma clinical trials in the fourth quarter of 2017, bringing us to 214 regenerative medicine programs currently supported. We can proudly say that no other company in the temperature-controlled logistics industry serving the life sciences can offer the quality, expertise, experience, technology, dedicated personnel and/or customer references that Cryoport delivers.

The addition of commercial programs such as Kymriah™ and Yescarta™, along with our new collaboration with McKesson, is testimony to the growing strength of our strategy and the dominant competitive advantage we have achieved. Over the course of 2017, we added strength to our bench of personnel as we substantially upgraded the competencies of our commercial, management, technical, logistics, administrative and service teams. During 2017, we introduced key operating functions vital to our ability to continue to serve our clients with effectiveness and surety.

As we secured 85 new biopharma clinical trials during 2017, we further added to our critical mass of biopharma companies having now integrated our logistics solution into their collection and distribution processes in the race to develop new regenerative therapies. Clearly, these clients consider Cryoport logistics solutions to be an essential component to their cell-based regenerative therapies such as CAR T-cell, CAR B-cell, antibody and allogeneic stem cell therapies.

As I stated earlier, Cryoport now supports a total of 214 clinical trials in the regenerative medicine space, up from 129 trials just a year ago. This increase was driven by new clients as well as existing clients expanding their programs. As we have seen with Novartis and Gilead, these trials represent major embedded revenue growth for our company as our biopharma clients progress through the clinical phases and successful therapy candidates ultimately reach commercialization.

As a result of the anticipated number of accelerated United States Biologic License Applications and European Medicine Agency filings from our current clients, and based on public reports, we are increasing our projected number of combined BLA and EMA filings. Previously, we anticipated supporting two to four additional therapies during 2018; we now think that number is five to seven therapies. With these opportunities, we expect Cryoport's leading position as the logistical backbone of the regenerative medicine industry to strengthen, accelerate and grow as we leverage both near and long-term opportunities.

We have developed credentials in the area of temperature-controlled logistics that are indisputable with our diversified client portfolio consisting of the very cutting edge of regenerative therapy development,

encompassing a wide range of therapeutic areas, including oncology, hematology, cardiovascular, central nervous system, immunology, infectious diseases and more.

In 2017, we experienced strong revenue growth with the momentum continuing in 2018. biopharma revenue increased 63%, bringing it to 76% of our total revenue for the fourth quarter of 2017. Even as we continue to grow our market share in the pre-clinical and clinical market for regenerative therapies, we expect our most significant revenue growth to come from temperature-controlled logistics support agreements for FDA- and EMA-approved commercial products.

As I mentioned earlier, we announced that we signed long-term commercial logistics agreements supporting Gilead/Kite's Yescarta™ and Novartis' Kymriah™. Cryoport agreements to support these first-to-market, high-profile ground-breaking immunotherapies further entrenches our market leading position and reputation in the biopharma market. As Kymriah™ and Yescarta™ are ramped up to full commercialization, they are expected to save many lives and drive significant revenue growth for Cryoport, who will provide the crucial logistics services to enable these miracles to happen.

The signing of these latest contracts portends the start of a new wave of regenerative therapies that are in development and expected to be commercialized over the next several years. To give you an idea of the promise of these new regenerative therapies, according to The Alliance for Regenerative Medicine, $7.5 billion was raised for the development of regenerative therapies in 2017, compared with $4.2 billion in 2016, an 80% increase year over year.

We announced last week a strategic collaboration with McKesson Specialty Health to support the delivery of cell and gene therapies to patients at points of care. Both companies recognize the complex support ecosystem that is emerging as regenerative therapies reach commercialization, and we think our collaboration underscores Cryoport's leadership position and growing reach.

This new relationship will allow us to further extend and amplify our cold-chain logistics expertise with McKesson's end-to-end patient access and support services focused on assisting patients entering treatment through accelerated patient onboarding, prior authorizations and educational support programs.

Now, turning to animal health and reproductive medicine, our technologically advanced logistics solutions and first-in-class reputation around the world also drove significant revenue growth in these two important markets during 2017.

In 2017, our animal health clients continued to include established names such as Zoetis, VetStem and Boehringer Ingelheim. We concluded 2017 with a $1.1 million revenue for a 34% revenue growth in our animal health market.

In reproductive medicine, we enjoy excellent relationships with more than 400 fertility clinics worldwide and concluded 2017 with $1.7 million of revenue for an 11% annualized growth. Many factors are at work in the reproductive medicine market, including technological advances in combating infertility as well as managing fertility. Consequently, an increasing number of cases are driving an increasing demand for our solutions, especially in the United States. You may have noticed that we recently branded our IVF services as Cryostork℠, and, as a matter of priority, we are directing our sales and marketing efforts to our Cryostork℠ solutions to meet the largely unmet need for premium quality cryogenic logistics solutions in this growing market.

Both animal health and reproductive medicine are consistently growing markets and sources of revenue that we plan to expand throughout 2018.

Now, Dr. Mark Sawicki, our Chief Commercial Officer, will provide further details on the particulars of our market. Mark.

Mark Sawicki:

Thank you, Jerry. It's a pleasure to have the occasion to speak with you all today. Jerry has provided a succinct overview of our three focus markets: biopharma, animal health and reproductive medicine. My objective for this call is to apprise you on Cryoport's current view of the developments within these markets and how they apply to our business, as well as an update on our engagement and support strategies in making Cryoport indispensable to our clients and partners in support of their developmental goals and objectives.

Due to the fact that biopharma companies now encompass more than 76% of our overall revenues I will be focusing my comments primarily on our activities within the regenerative therapy space including more detail surrounding the business impact of recent announcements and how they fit into our market strategy to drive revenues in the current fiscal year.

To start with, I would like to provide a short overview of the animal health space. As mentioned previously, Cryoport supports two key healthcare needs within the space, one in the transport of key vaccines and reproductive materials for foodstock and the other in the movement of stem cell and clinical trial materials for companion animal treatments. The market is anticipated to grow at a 5.4% compound annual growth rate over the next seven years, driven primarily by vaccines and companion animal therapies, both of which are core to our business. Our efforts in this space have resulted in an increase in revenue from the animal health market of 62% in the fourth quarter compared to the same quarter last year. This can be attributed to Cryoport improving its awareness and positioning within the space and the initiation of a new client relationship within the vaccine space.

Within the reproductive medicine, Cryoport has recently launched its Cryostork℠ service offering in support of increasing demand within the global IVF services market, which is currently estimated at $2.2 billion and growing at a 10.5% compound annual growth rate. Cryoport's Cryostork℠ offering was launched with one of its goals to capture additional market share within the projected $100 million frozen embryo transfer market. Cryostork℠ is a unique service offering providing intended parents the most reliable solution for moving their reproductive materials by incorporating our SmartPak II™ Condition Monitoring system and the Cryoportal™ Logistics Management Platform in support of their shipments.

Turning our attention to the biopharma space, Cryoport has been focused over the last three years on capturing a first mover advantage supporting regenerative medicine related to clinical trial cold-chain distribution within the cellular therapy space with the goal of maintaining these relationships throughout the clinical phases and into commercialization.

This strategy has led to the support of 214 clinical programs including 26 Phase 3 programs and two commercial therapies, Novartis' Kymriah™, and Kite Pharma/Gilead's Yescarta™. Moreover, we anticipate the potential of additional five to seven Cryoport-supported new BLA/EMA filings in the next 12 months, increasing from our previous estimate of two to four filings.

This increase can be explained by an increase in the number of accelerated filers within regenerative therapy leveraging the Regenerative Medicine Advanced Therapy or RMAT designation established by the 21st Century Cures Act. In fact, in September, the FDA disclosed that it already had 550 active investigational new drug applications or INDs related to regenerative therapies, including 76 active INDs related to CAR T-cell therapies. As of February 20, it has been reported that a total of 14 RMAT designations have been granted.

As management, we continue to see Cryoport's solution becoming more and more entrenched within our clients' clinical and commercial processes as the complexity of supporting these products increases. To that end, Cryoport recently launched its C3™ product offering. This provides our clients the opportunity to leverage our SmartPak II™ Condition Monitoring system and the Cryoportal™ Logistics Management Platform in support of their inbound 2° to 8° Celsius shipments. Receptivity has been very positive with multiple companies adopting the platform in support of their clinical pipelines.

Finally, as indicated in a recent press release issued by our newest collaborator, McKesson, Cryoport has been actively engaging potential partners that understand Cryoport's solutions and differentiators within the regenerative medicine space and the value of integrating our service offerings into a unified product platform. This relationship, as well as others we are actively developing, provides our clients with the opportunity to integrate and standardize their support needs not only for temperature-controlled logistics support, but also engage Cryoport and McKesson to provide end-to-end solutions for complex products which require high-touch patient access and adherence support as well as temperature-controlled product logistics.

Now, I will turn the call back to Jerry.

Jerry?

Jerrell Shelton:

Thank you, Mark. Now, Robert Stefanovich, our CFO, will give you a detailed financial report for our Fiscal Year 2017. Robert?

Robert Stefanovich:

Thank you, Jerry. Good afternoon everyone. I will review the twelve months and fourth quarter results of our fiscal year 2017, provide some additional comments, then turn the call back to Jerry.

Net revenue for the year ended December 31, 2017, was $12.0 million, an increase of 55.7% or $4.3 million as compared to $7.7 million reported for 2016. As Jerry and Mark mentioned, the biopharma market continues to be the leading driver behind our revenue growth.

Revenue in the biopharma market increased by 71.9% over the prior year to $9.1 million for 2017, driven by an overall increase in the number of clients utilizing the company's solutions, complemented by growth and frequency from our current client base. We added 83 new biopharma clients during the year, further expanding our platform for future revenue growth. As I have mentioned before, we have a strong client relationship and client retention, given that our solutions are considered critical to our clients' clinical programs and commercial launches.

Revenue in the reproductive medicine market increased by 11.4% to $1.7 million for 2017 compared to the prior year. This increase was primarily driven by revenue growth in the U.S. market of 43.8%, fueled by our new Cryostork℠™ offering and marketing campaign, and partially offset by a decline in international markets of 32.5%, which continues to be impacted by the restriction of medical and reproductive tourism and changing regulation in certain countries.

Our revenue for the animal health market was $1.1 million for 2017, representing a 34.3% increase over 2016, reflecting the addition of new clients and growth from our current client base.

Gross margin for 2017 was 49.9% or $6 million compared to 40.4% or $3.1 million for 2016. This is an improvement of 9.5 percentage points and reflects our continuing efforts to drive margin growth towards our target of 60% as we grow the business and benefit from economies of scale.

Operating expenses increased by $2 million or 16.8% to $13.9 million for 2017 as compared to $11.9 million for the prior year. This increase is primarily due to an increase in the number of employees and related salaries and associated employee costs, as well as recruiting fees and noncash stock-based compensation expense.

As Jerry mentioned earlier, we brought additional expertise into the Company to support our expected growth and secure our leadership position. This ranges from key hires in our business development team, business operations, program and product management as well as engineering. With the increase in clinical trials we are supporting, two therapies already commercially launched and additional BLA filings expected in 2018, it is critical that we have the organizational talent and expertise in place to fully support our clients and leverage our unique position.

In addition, we continually strive to improve and expand the features of our Cryoport Express® Solutions. Our developments are directed towards facilitating the safe, reliable and efficient logistics of life science commodities through innovative and technology-based solutions. During the year ended December 31, 2017, we made significant progress in developing the next generation of our Cryoportal™ Logistics Management platform and upgraded the firmware and software of our SmartPak II™ Condition Monitoring System that tracks the key aspects that could affect the quality and/or timing of delivery of the commodities shipped to its intended destination. We also continued to design and validate additional new primary and secondary packaging solutions and accessories in response to requests from our clients and to maintain our leadership position in temperature-controlled logistics.

Net loss attributable to common stockholders for 2017 was $7.9 million or $0.34 per share compared to a net loss of $13.2 million or $0.93 per share.

Adjusted EBITDA for the year ended December 31, 2017, was a negative $3.7 million, a reduction of 30.6% compared to a negative $5.3 million for 2016.

Now, moving to our quarterly results, for the quarter net revenues increased by $1.1 million or 49.0% to $3.3 million for the three months ended December 31, 2017, as compared to $2.2 million for the prior year fourth quarter. This growth was driven by our success in the biopharma market where revenues increased by 62.7% over the prior year quarter to $2.5 million from $1.5 million. This reflects an increase of 15 new clients during the quarter as well as revenue growth within our existing client base.

Revenue in the reproductive medicine market decreased by 2.5% over the prior year quarter to $453,000 for the three months ended December 31, 2017. This decrease was primarily due to a decrease of 27.6% internationally and was partially offset by revenue growth in the U.S. market of 14.8%.

Our revenue in the animal health increased by 62.1% to $353,000 for the quarter compared to the same period in the prior year, primarily due to a cell bank move for a new multinational client and growth from existing clients.

Gross margin for the three months ended December 31, 2017, was 51.6% or $1.7 million compared to 42.2% or $940,000 for the prior year quarter. This increase in gross margin by over 9 percentage points is primarily due to the economies of scale from the increase of business volume coupled by pricing adjustments.

Operating expenses increased by $1 million for the three months ended December 31, 2017, or 35.4% as compared to the prior year. As I mentioned in my remarks for the full fiscal year, this increase is primarily due to an increase in the number of employees and related salaries and associated costs as well as recruiting fees and noncash stock-based compensation expense.

We reported no interest expense for the quarter ended December 31, 2017, compared to interest expense in the prior year quarter of $18,000 resulting from promissory notes that were paid off in 2017.

Net loss attributed to common stockholders for the three months ended December 31, 2017, was $2.3 million or $0.09 per share compared to $4.3 million or $0.25 per share for the last fiscal quarter.

Adjusted EBITDA for the fourth quarter ended December 31, 2017, was a negative $1.1 million, which was relatively flat against a negative $1.1 million for the same three-month period in the prior year.

We ended our year with a strong cash position and are debt-free, reporting $15.0 million in cash and cash equivalents as of December 31, 2017, compared to $4.5 million as of December 31, 2016, having repaid outstanding indebtedness of $0.7 million in April of 2017. The increase in cash and cash equivalents includes net proceeds of $11.4 million received from an underwritten public offering on March 31, 2017, and net proceeds of $5.2 million for the exercise of warrants and stock options during the 12-month period ended December 31, 2017. Subsequent to year end, we also completed a warrant tender offer resulting in gross proceeds of $4.7 million, further bolstering our cash balance and allowing us to execute on our plans for 2018.

We will file our Form 10-K with the SEC for the 3-month and 12-month periods ended December 31, 2017, this Thursday March 8.

Now, I'd like to turn the call back to Jerry.

Jerrell Shelton:

Thank you, Robert.

Operator, we would now like to open the phone lines for questions.

Operator:

At this time we will be conducting a 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 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 the handset before pressing the star key. One moment, please, while we poll for questions.

Our first question is with Len Yaffe with Stoc Doc Partners. Please proceed with your question.

Len Yaffe:

(Inaudible) for you. One is, in the *Wired* magazine article, I was just wondering if you could comment, they have a quote where they say that there were shipments awaiting clients that included Novartis, Gilead, which you've discussed, Juno, Celgene, J&J and Bluebird. So I was just wondering if you could discuss if there are any special relationships with any of those latter four companies, such as those that you have with Novartis and Gilead, and then my question for Rob is, I notice that the gross profit margin declined sequentially about 240 basis points despite a slight uptick in revenues, and I was just wondering if you

could discuss that and what we should expect for gross profit margin, based on either the percent of business that comes from biopharma or any other factors that you choose to mention. Thank you.

Jerrell Shelton:

Len, thank you for those questions. You have two questions there, and I'm going to direct the first one to Mark Sawicki to answer, and after that then Robert Stefanovich can answer your gross margin question. So, Mark?

Mark Sawicki:

Yes. Thanks Jerry. Hi Len, how are you doing?

Len Yaffe:

Fine, thank you.

Mark Sawicki:

Yes, I mean it's absolutely safe to say that we do have relationships with all of those entities that have been mentioned in that article. I can't stipulate as to the extent of those relationships at this point in time, but obviously we're key to over 214 clinical programs right now, and most of the volume that we see going out the door from a biopharma standpoint is related to clinical trial support. I think, as you noticed, we have a net of 19 new clinical programs for the quarter out of actually 23 new program starts, so we have four that dropped and 23 that added for the quarter.

Robert Stefanovich:

Hi Len, this is Robert. Just to answer your question related to the gross margin, and you are correct. We showed significant growth quarter over the fourth quarter last year and year-over-year, and we still continue to believe that our 60% gross margin is very attainable. In terms of the revenue mix, compared to the third quarter, biopharma was slightly down as total revenue, with 76% in Q4 compared to 78% in Q3, but that's really not the driver for the margin. You'll see differences just in terms of overall mix between the revenue, the component of freight within our revenue, that may change margins slightly; again over all we expect it to increase. I will add that we are moving forward with another logistics center here in the U.S. on the eastern side, that we'll be opening later this year, and we're also converting our European logistics center to a company-operated logistics center to have closer quality control and direct influence on the logistics operations center in Europe in anticipation of the expected growth in Europe. Those things will impact gross margin, as we see revenues ramp, but you will see some variation in gross margin quarter-over-quarter, but again the trend over all is towards the 60% gross margin.

Len Yaffe:

Great. Thanks so much.

Operator:

Our next question is with Brian Marckx with Zacks Investment Research. Please proceed with your question.

Brian Marckx:

Hi guys. Congrats again on another great quarter and another great year. It's pretty impressive.

My first question is sort of a high-level expense question, I guess, and don't take this as criticism because it's not the way that I mean it, I'm just trying to get a little bit better idea of all the moving parts. SG&A in Q4 was a little bit higher than I expected, and I know you guys are adding infrastructure, as you talked about, and you added some head count, and I'm not going to ask about specifics in terms of guidance, but just as a kind of a broader view, I guess, going into 2018, you're adding these pieces which obviously you're adding them for the right reasons because you've got a ramp in demand and growth and business and all the good stuff. But going into 2018, can you give us just a little bit of kind of help in terms of what you guys think, relative to these new costs that are coming on line, and are they coverable from a revenue and margin standpoint, relative to 2017? I guess in a long way I'm asking, should we expect to see operating income improve in 2018 versus 2017?

Jerrell Shelton:

Brian, I'm going to let Robert answer in more detail, but I want to give you some general guidelines to judge us by. Your question's a good question, and certainly if you're not in the Company one might have that question. But we're preparing for the future. We have to prepare for the future. Remember, we forecasted the number of BLAs and EMAs is going up from two to four; it's going up to five to seven, up from that two to four. That's a big burden of responsibility for Cryoport to be prepared for. Remember we're rolling out Yescarta™ and Novartis. We can't forecast everything that's needed for Yescarta™ and Novartis very far in advance; we have to be ready to adjust, and there are tweaks as we roll these two revolutionary therapies out to the market. In addition to that, we're shifting our company to more commercialized products. Our model for clinical is robust, but it's a different model than the model for commercial products. In commercial products, one has to I say be bullet-proof; you really have to beef up your systems, your quality systems, your repetitiveness, and it's a different sort of delivery. We're very grateful for that opportunity to serve those commercial clients. All of this says we have to build in advance of the demand. The demand is not only strong now but we see it getting stronger, and so we do have to invest.

I often say to people who ask the question about profitability, we could be profitable today. I could cut costs today. I'd kill the company, but I could cut costs today and be profitable right now. So the question is, do we want to have a reward for our long-term shareholders and continue to build value, or do we want profitability immediately for the short term and hurt our company? My answer is always to build for the future. This market is very very exciting and that's my long-winded answer to you in terms of the general things and the general guidance for the company. Now I'll turn it to Robert to answer with more specificity about the near term.

Robert Stefanovich:

Brian, and as you know, at this point we don't give guidance to the street; however, your observation's correct, and it is all about operational execution. We're in a very, very unique position in the market space as it's unfolding as therapies are being launched and companies are getting ready to launch the therapies. The expectations our clients have are clearly that we provide leadership and our expertise. With that we have to build our operational team. It's really more with precision, in terms of finding the right individuals to complement the expertise that we already have, as well as looking at the logistics operation centers that we're setting up; those are very kind of natural moves that you would make in our position, in opening an Eastern facility to support commercial launches as well as our client base there, and to take full ownership now of our European logistics operation center. Early on it made sense to work with third parties, it was more cost-efficient. Now, it's really about quality control and assurance and having that

direct line of communication. If you look at the organization that we're building, it's really all driven by the visibility that we have, demand by our clients and the prospects that we're working with, and then that's really what we're embarking on for 2018. As I mentioned earlier, we have a strong cash balance, the strongest cash balance the Company ever had, and we have the means to execute on delivering a very strong 2018.

Brian Marckx:

Yes, you guys have done, in my opinion, just an absolutely fantastic job and it's been fun watching the Company mature over the years, and it sounds like you guys are kind of getting to the inflection point but I'm not—and again, my question has nothing to do with criticism, I'm just trying to understand things a little bit more. But Jerry, in your prepared comments, and you referenced it in the answer to my first question was, and I think you said that you think that in 2018 most of your revenue growth is going to come from commercialized products, so number one is that correct? And if that is correct, is this the first year that that would be the case?

Jerrell Shelton:

I'm going to turn that question to Mark Sawicki. He's very close to it and it's very precious to his mission.

Mark Sawicki:

I wouldn't attribute most of the revenue growth strictly to commercial. There's a variety of other sources that are coming in. As Robert had mentioned, and Jerry did on the call, we're expecting five to seven additional commercialization events. There's a lot of preparation that goes into those from a developmental standpoint, revenue generation standpoints, that will contribute. But we're also going to see significant contribution on additional clinical onboards, so we almost doubled our new clinical onboarding count last year. We anticipate additional significant additions in this fiscal year. That's why we put together such a strong sales team to support that clinical onboarding. We're also having very very strong efforts on both the animal health and the IVF space. In animal health, we've got some significant activity that we think is going to accelerate the growth in that space, and we were up 34% last year, we think that we're going to see significant growth this year as well, as well as start to see some acceleration in the growth for the reproductive medicine space as well.

Brian Marckx:

Terms of the five to seven BLAs, how many of those, if any, are under expedited or fast track pathways or review?

Mark Sawicki:

I'd have to go back and check definitively, but suffice to say the vast majority would have an RMAT accelerated designation.

Brian Marckx:

Okay. I don't want to take up too much time, so I'll try to be quick. The animal health number was obviously really good, you talked about it a little bit. It sounds like there was a new client or a new product in Germany, is that level of revenue, again not asking for guidance, but is that sticky I guess, with that customer, that this new relationship?

Mark Sawicki:

It's too early for me to be able to tell you more about that at this point in time. Let me just talk in more generality. We do believe that we're going to see acceleration from a revenue standpoint in that space this year. I can't really tell you what the distribution of that's going to be, at this point, I don't want to—I'm not prepared to talk about that publicly. So.

Jerrell Shelton:

Maybe just to add a little bit of color to it just on animal health, if you look at the growth for the year of 34.3%, if you exclude the new client revenue that was really mostly generated in Q4, we still showed a growth of 30.6%, so it was really the Q4 numbers that were mostly impacted by onboarding this new multinational client. These were initially large moves, but that also opens the door to additional business with that client.

Brian Marckx:

Okay. That's all I had. Thanks guys. Appreciate it.

Jerrell Shelton:

Thank you.

Operator:

Our next question is with Jason Seidl with Cowen and Company. Please proceed with your question.

Jason Seidl:

Thanks, Operator. It's Jason Seidl from Cowen. Gentlemen, I appreciate the time. Couple quick questions here. In the past you've given us some guidance with sort of the ELAs and BLAs in terms of the revenue opportunities. The three new ones that you've added here, could you give us sort of a little bit more guidance in terms of the revenue opportunity, the three new ones?

Jerrell Shelton:

Jason, we really can't go any farther than the guidance that we've given in the past, and that's $2 million to $20 million once they're ramped up. That's about as far as we can go in terms of giving you an indication. We just can't be more specific at this time.

Jason Seidl:

Okay. Fair enough. The McKesson collaboration, that seems fairly exciting. They're a huge name. Seems like it enables you to go sort of up- and downstream. Could you talk a little bit more about that, and what that's going to let you do, not this year but maybe say over the next three years?

Jerrell Shelton:

We're very pleased with the McKesson agreement. I'm going to turn that to Mark, because he helped engineer that to large extent.

Mark Sawicki:

We've really been focused on building a network, and a network that helps us provide broader and deeper coverage throughout the regenerative therapy space. In fact, we just had a two-day workshop last week where we had over 120 folks come in, from clients, prospective clients, to partners. Not only McKesson supported that event but it was also co-sponsored by GE, Fisher Bio, and b2match from a support standpoint. There's a core strategy for us which is to be able to leverage our competencies in support of organizations such as McKesson moving forward because we believe that we can provide a tremendous amount of value to those organizations, but it also provides a lot more value to our core client base, both through clinical development as well as commercial launch.

Jason Seidl:

Okay. Appreciate the color. Final question is going to be more on the operational cash flow side. Obviously I agree with your statement, Jerry, you want to invest for the future, you just don't want to just say, "Hey, we're profitable," in one quarter and kill all the potential growth, which is why people are interested in your company. Could you talk a little bit about your projected operational free cash flow status for the fiscal year 2018? I know you've given some loose guidance in the past.

Jerrell Shelton:

Well, again, we don't give guidance. But I'm going to turn that to Robert Stefanovich to talk about that, and it'll be in broad terms.

Robert Stefanovich:

In general, you look at free cash flow, s we talked before, we're building out our organizational infrastructure for our new spectrogram (phon) ramp in revenue. We certainly have some additional cap ex requirement as we set up our logistics centers, we build out our fleet, but it should be clear that we are driving toward the ultimate goal of ours is still an operating or adjusted operating margin of 30%, and that is our target. This is not something that we're going to reach in the very short term, but it continues to be our target.

Jason Seidl:

Okay. Gentlemen, thank you for the time as always.

Jerrell Shelton:

Thank you, Jason, thank you.

Operator:

Our next question is with Richard Baldry with Roth Capital. Please proceed with your question.

Richard Baldry:

Thanks. Is there a way to generally look at the number of say Phase 3 trials on a trailing basis, whether that's 12 months, 18 months, 24 months, and then sort of think about what that should mean for BLA, EMA filings? Internally, do you think about it that way as sort of a success rate and a duration to kind of get to that, with the internal data that we sort of can't see from just the top line number per quarter?

Jerrell Shelton:

What we do is we look at the clinicaltrial.gov stats. The biologics are new to the market, of course, but we have to look at the stats. Those stats start back with Phase 1 and go through commercialization. Phase 1 is low, it's about 11%; Phase 2 15% to 17%; Phase 3, getting out of Phase 3 is about 50% or so; and then, once the BLA or the EMA is filed, it's about 85%, give or take. We use those stats in our forecasting. Each month or each quarter when you see the number of clinical trials that we cover, those are net numbers. It means that Phase 1 is a very dynamic phase, because you've got only 11% get out of Phase 1, and Phase 2, again, very dynamic, only 17% get out of Phase 2, and so on. They're moving numbers, they're net numbers, and we're gaining on those net numbers in the market. That's the way we look at it.

Richard Baldry:

When I look at the sales and marketing growth, how tied is that to building capacity for sort of year out versus reflecting the current wind in current periods?

Jerrell Shelton:

It's very reflective of building out. Remember, in 2017, we went through a great year of transition, which I talked about in my comments, where we actually upgraded every department in the company and especially the Business Development group to the Commercial group, with competencies and capabilities we haven't had in the past. So you have to recruit those people, bring them in, train them, and get them up to speed, so that is a costly exercise. So we're always building for the future. Always.

Richard Baldry:

Longer term, as these things move into commercialization, what do you think the likelihood is that you'll have certain logistic centers in certain areas but that you could be asked by certain biopharma vendors to co-locate at where their labs are, and how would that change sort of the investment needed for a logistic center?

Jerrell Shelton:

Well actually, it wouldn't change our investment needs very much at all, and we do prefer, and like, embedded centers. We have an embedded center at Zoetis, and frankly we would have had in one of these two commercializations except there wasn't enough room and we located proximally. But we have several candidates. Part of our solution is to have embedded centers, and we welcome that. But in terms of changing the capital investment, it doesn't, because we still have our people there, we still use our software, we still have the capital expenditure, going forward.

Richard Baldry:

All right. Thanks for your help.

Jerrell Shelton:

Thank you. Thanks for the question.

Operator:

Our next question is with Paul Knight for Janney Montgomery Scott. Please proceed with your question.

Paul Knight:

Hey Jerry, can you hear me?

Jerrell Shelton:

I can, Paul. Thank you very much.

Paul Knight:

Great. Congratulations on the numbers. The roll-out of Yescarta™ and Kymriah™ unit volumes, any way to say, are they tracking as expected, not as expected? How does the unit shipments roll out for those particular therapies, any change in your thinking or pace?

Jerrell Shelton:

Paul, that's a great question, and it's somewhat of a moving target. I'm going to turn it to Mark for a more specific answer, but it'll still be very general.

Mark Sawicki:

Hey Paul, how are you?

Paul Knight:

Good-o.

Mark Sawicki:

What I can say to you is that we're seeing acceleration. So both Kite/Gilead and Novartis have put out their latest projections. I think you can use those as a basis to kind of extrapolate, because I can't go further than that, but what I can say is we are seeing acceleration. I'll kind of leave it there at the moment.

Jerrell Shelton:

Paul, you did hear in my comments that Yescarta™ thinks that by mid year they'll have enough points of care open to support 5,000 qualified Yescarta™ patients per year, so that's some indication, but we really can't go too much further than that because it does move around quite a bit, as these are new, novel, and we run into different things that we have to figure out and make sure that the quality is there and so forth. That's about as far as we can go, Paul, in terms of answering that.

Paul Knight:

Okay; and then, reproductive medicine was down a little bit in the fourth quarter. Was it a comp issue? Anything going on in reproductive medicine we should be thinking about?

Jerrell Shelton:

Again, I'm going to turn that back to Mark.

Mark Sawicki:

Well, there's nothing—it's just seasonal variation. Nothing of a critical trend. In fact, we've retooled that business because we think there's a lot of built-in growth there, and they're putting a significant emphasis on it, so I wouldn't put much in stock in the temporary variation.

Robert Stefanovich:

We grew sequentially as well as (inaudible) year over year.

Paul Knight:

Then lastly, you've raised the number of BLA/EMA filings that you're involved with, I guess. Is the nature of these five to seven any different than the two to four that you had put out there previously in terms of—is approval possibility increasing? Is the unit size or patient population increasing? Do you have color on that in terms of, yes, you've raised the number of filings, but anything within the nature of those five to seven, any different than the prior batch that you've been involved with?

Jerrell Shelton:

Again, Paul, I'm going to turn that question to Mark for an answer.

Mark Sawicki:

Paul, what we're seeing is more environmental in nature. If you take a look at the data that's coming in from the FDA, there's a definitive acceleration in the number of RMAT filings, and so in fact, if anything, I think what we're seeing is these numbers are moving a little bit more quickly than we anticipated, which is obviously good for us and good for the industry as a whole. The FDA is taking a very progressive stance here. I think that we're going to see—assuming that they demonstrate clinical benefit, which most of these programs are, we're going to have a significant number of acceptances, I think, in the short term.

Obviously, volumes are very, very heavily dependent on the indication. You're going to have some very small indications, which are ultra-orphan, and there's also programs that are publicly acknowledged that are allogeneic in nature, which may have patient unit volumes of 40-, 60-, 80,000 patients a year. I think if you go through the RMATs you'll get a good understanding of what that demographic potential looks like.

Paul Knight:

Okay. Thank you very much. Lastly, Jerry, your facility roll-out, you're opening the two facilities, Europe and the United States. How quickly do you want to open up new bricks and mortar?

Jerrell Shelton:

These two facilities will open in the first half of this year, and then beyond that, it will be opportunistic. I certainly will be looking at our Singapore site and evaluating that. It's an important site for Asia-Pac, and then the remainder of those will be somewhat driven by the demand coming from new introductions.

Paul Knight:

Okay. Thank you very much.

Operator:

Our next question is with Paul Higgins, Private Investor. Please proceed with your question.

Paul Higgins:

Thanks for taking my call. I have two questions. I'm not a scientist, so I'll try to put this in layman terms if I could. It seems to me that the—what I guess you'd call the hard core biopharma is kind of the tip of the iceberg versus the 2 to 8 kind of business, and I wondered if you guys could guesstimate, or if you've worked out your metrics this way, what percentage of the 2 to 8 business of your biopharma revenues, overall revenues, is that today, and where would you expect the 2 to 8 business be a year or so from now?

Secondly, when you see Juno and Kite getting taken out for over $20 billion and the space is obviously a lot bigger, not saying what percentage of the business or the market cap that Cryoport would get, but what do we think the opportunity is in market cap terms for businesses that are servicing the Junos and Kites of the world? Is it 1% of that market cap, or is it 5%? I'm just trying to get an idea because it seems to me, if somebody has all the pizza delivery business for Domino's and Papa John's, somebody out there should be able to guesstimate what that portion of that business is worth.

Jerrell Shelton:

Paul, those are good questions, and in terms of taking your last question first, we ponder that quite a bit ourselves. Of course we don't give guidance, we can't give guidance at this point of our development. It's really—it wouldn't be prudent of me to give you a percentage of what the revenue of our clients, because we don't really even know what that revenue is going to be. We're in the very very early stages here with simply Kymriah™ and Yescarta™, and then these other five to seven coming out, it's very early, so it's impossible for us to be able to—we'd like to answer that question, believe me, we'd like to answer it for ourselves, but I certainly can't give you any guidance on that. You'll have to come to those conclusions from some of the public reports that our clients do put out, but it's just very difficult for us to go any further on that question.

I'm going to let Mark address the 2 to 8 in a moment, but our 2 to 8 solution is for a very specific part of the 2 to 8 market, it is not for the general 2 to 8 market. That 2 to 8 solution called C3™, Cryoport Certified Cool, was tailored to, as I said in my comments, to address the front end of autologous solutions. Now, there are other clients out there, potential clients, that would like to have a more robust, and a more expensive I might add, 2 to 8 solution, which ours is. But it was for a very specific reason. Mark, do you want to add to that?

Mark Sawicki:

Yes, I'll just give you a little bit of a comment. Similar to what we've talked about there, we're trying to build this overall platform ecosystem. Where we're bringing in partners like McKesson, we're also obviously trying to broaden our offering portfolio to support these types of programs from end to end. The 2 to 8 space to support that is a natural progression and an extension basis for us in the regenerative medicine space. Obviously there's further applications beyond that, in particular moving into biologics and other high-value pharmaceutical distribution which would include things like clinical sample moves and others along those lines. But we're not trying to compete with a 2 to 8 dollar-box that gets shipped out with ice in it. That's not what we're interested in. We're interested in the high-value shipments that require extensive monitoring and convey a significant commodity value in that particular box itself. Hopefully that answers your question.

Paul Higgins:

Yes. I think, thank you very much for clarifying that. Is it a fair thing to say that the specialized 2 to 8 business is a greater opportunity than what we're seeing today?

Mark Sawicki:

I would say it does have a broader context beyond regenerative therapy than strictly cryogenic distribution.

Paul Higgins:

Because of the tracking and whatnot?

Mark Sawicki:

It does have a broader context. I'm sorry?

Paul Higgins:

Because of the tracking and the platform that Cryoport has?

Mark Sawicki:

It's just the market. Obviously we've had a focus on cryo over the years, the 2 to 8 space that we're going after is an extension of our current cryo platform, but it does have high-value application beyond just strictly cryo distribution.

Paul Higgins:

Okay. Thank you very much.

Mark Sawicki:

You're welcome.

Operator:

Our next question is with Nathan Kosick, Private Investor. Please proceed with your question.

Nathan Kosick:

Hi, guys. I had a couple questions. I wanted to start maybe sub-linking to that last question and looking at in the previous earning calls in the past you had talked about trying to get integrated with large pharma clients. I wanted to kind of see if you guys had any update on that, I guess both in the cryo and possibly the 2C to 8C if you're targeting more the like cell bank shippings and stuff like that versus like bulk large storage APIs and stuff like that. Thank you.

Mark Sawicki:

The short answer is yes. We absolutely are supporting a lot more cell bank movements, for example, in support of biologics manufacturing.

Nathan Kosick:

Okay great, and is that the long-term like target niche, like you were saying on the—for almost targeting the CAR T market for the 2C to 8C, or are you looking at possible as a logistics provider with the bulk for storage?

Mark Sawicki:

We already do a lot of work with the storage providers. So that obviously is a target of ours, as is a broader service offering supporting cell bank moves and other aspects along those lines.

Nathan Kosick:

Okay, cool. Then, with the current like fleet expansion and both the European conversion and East Coast center, do you expect your cash on hand to be sufficient for this, or are you looking for possibly like debt markets or possible secondary offerings to deal with this construction and further buildout?

Jerrell Shelton:

Well we'll approach the financing as we go along. We have enough cash now to fulfill our plan for this year, so debt's not on the table, and we'll look at things as we move along, but we have nothing planned at this time.

Nathan Kosick:

Okay, great.

And then, my last question is sort of with the other ones with—you were saying on a previous call that allogeneic treatments can be an order of magnitude obviously because of the shipment volume? Would the two to 20 need—would be—need be revised as a estimate for these at commercial scale, correct?

Jerrell Shelton:

Well, your question is a little bit fuzzy, because allogeneic treatments will come to market at some point, and we certainly are supporting some allogeneic trials right now. Allogeneic is generally off the shelf, and so you could have higher volumes there for sure, but that's not a 2 to 8 product.

Nathan Kosick:

Oh, no, not for 2 to 8, just in general.

Jerrell Shelton:

Yes.

Mark Sawicki:

Let me—so, allogeneic in general does have a higher volume. But it can also be standardized in a packaging configuration that is more streamlined, and so your cost per transfer would be lower. So, I still think that our expected commercial—our revenue per commercial product is in range.

Nathan Kosick:

Okay great. Yes, that's a great point about the cost per shipment. Then with that, you guys are—for allogeneic ones, are you trying to—because of those streamline transportation, trying to do on-site logistics versus possibly other site buildouts?

Jerrell Shelton:

Well, if the opportunity comes up, we would certainly consider that, but we aren't making decisions right now on embedded solutions versus off-site logistic support. That's on a client-by-client basis, and when it comes up we'll be reporting it. It's always a consideration, but it's customer—it's client-specific.

Nathan Kosick:

Okay great. Hey, thank you so much for answering all the questions, and thanks for the great quarter.

Jerrell Shelton:

Thank you.

Operator:

Our next question is with Richard Baldry with Roth Capital. Please proceed with your question.

Richard Baldry:

Thanks. Just a quick follow-up. Sort of curious. Do you track what, from the outside, I would call like a utilization of your existing facility in Southern Cal? I'm trying to get at what sort of a capacity that you have available and how that would change with the two new facilities. Is it basically simple triples up your capacity or, because you're only utilizing at a moderate level, you're really (inaudible) 5X, 6X, 8X (inaudible) utilization higher and at the new facilities? Thanks.

Jerrell Shelton:

Well, Rich, our facility here in Irvine runs one shift now, so we definitely could run two shifts. Three shifts doesn't make sense for our business, but two could make sense. The two new facilities have to do with supporting the onslaught of commercial activity that we are in the midst of now, as well as what we see coming. It also has to do with growing demand in the clinical trial area. I gave you one example of our growth in Europe, being TiGenix, in the clinical trial that we've announced there, but there are others as well. Looking at where we are today doesn't portend the future for us at all.

Richard Baldry:

Thanks.

Operator:

Ladies and gentlemen, we have reached the end of our question and answer session, and I would like to turn the call back over to Jerry Shelton for closing remarks.

Jerrell Shelton:

Thank you very much, Operator. I would like to thank all of you for your questions, and especially our long-term shareholders for their ongoing support of Cryoport as we enter this very exciting chapter of our growth. Much of the groundwork that we've laid over these past several years has allowed us to build a strong company powered by excellent business, technical and support teams of dedicated employees, extensive infrastructure and the world's most advanced temperature-controlled logistics technology. Our reputation as the gold standard of temperature-controlled logistics is growing on a global basis and we're unrivalled in what we do.

While we are positioned to grow in all of our markets, we are now in a very exciting position to participate in the growth of the regenerative medicine market as a trusted partner to the world's most innovative biopharma companies. We've secured important agreements with major names like Zoetis, Novartis, Gilead, FedEx, UPS, DHL, McKesson and many others. They choose to partner with us for one simple reason, and that is that no other company does what we do or has technologies or competencies that come close to ours. We are sensitive to our markets and the role we play in providing leading-edge logistics for our clients. We are client-centric in our actions and mindful of the special relationships we have with them.

We not only have the most advanced suite of temperature-controlled logistics solutions in the market, we also have a proven track record of supporting the industry's most well-regarded names in the regenerative medicine, animal health, contract manufacturing and reproductive medicine space. For any newcomer to the market, it would be incredibly difficult to overcome our advanced state and to gain meaningful market share. We have made the barriers to entry into our market for potential competitors high and, across the board, almost impossible to overcome. Our demonstrable track record grows daily and our reputation for reliability and safety is unreproachable.

On your behalf, my colleagues and I are proud (inaudible) to save lives, and to achieve the interest of all of our stakeholders.

With that, I will conclude the conference call. We look forward to updating you again on our next quarterly earnings call. Thank you very much for joining us today.

Operator:

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